INTERNATIONAL SEARCH REPORT

Inte Ional Application No
PCT/US 97/22052

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 689 806 A (MEADOX MEDICALS, INC.) 3 January 1996 see the whole document	1,17
A	EP 0 667 131 A (STRECKER) 16 August 1995 see column 10, line 44 - column 11, line 5; figure 3	1
A	WO 96 10967 A (AEROQUIP CORPORATION) 18 April 1996 see page 7, line 22 - line 30; figures 7,8	1
A	EP 0 716 834 A (FUJI SYSTEMS) 19 June 1996	
A	US 5 192 289 A (JESSEN) 9 March 1993	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 May 1998	08/06/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

Form PCT/ISA/210 (second sheet) (July 1992)

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 689806 A	03-01-1996	US 5522881 A	04-06-1996
		AU 685579 B	22-01-1998
		AU 1504995 A	11-01-1996
		CA 2146057 A	29-12-1995
		FI 953185 A	29-12-1995
		JP 8038520 A	13-02-1996
EP 667131 A	16-08-1995	DE 4401227 A	27-07-1995
		US 5628784 A	13-05-1997
WO 9610967 A	18-04-1996	US 5562727 A	08-10-1996
		AU 687650 B	26-02-1998
		AU 3891195 A	02-05-1996
		CA 2201320 A	18-04-1996
		EP 0785758 A	30-07-1997
		JP 10500050 T	06-01-1998
EP 716834 A	19-06-1996	JP 2726401 B	11-03-1998
		JP 8206227 A	13-08-1996
		US 5669930 A	23-09-1997
US 5192289 A	09-03-1993	US 5425739 A	20-06-1995

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2001

Application or Docket Number
09/771826
BSI - 010US4

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	53	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	53 minus 20=	* 33
INDEPENDENT CLAIMS	11 minus 3 =	* 8
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	370.00	OR	BASIC FEE	740.00
X$ 9=		OR	X$18=	594
X42=		OR	X84=	672
+140=		OR	+280=	0
TOTAL		OR	TOTAL	2006

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 37	Minus	** 53	= —
Independent	* 3	Minus	*** 11	= —
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

6/26/06

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 37	Minus	** 53	= 0
Independent	* 3	Minus	*** 11	= 0
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 8/01)
Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
☆U.S. GPO:2001-482-124/39187

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 10/10/2006

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-25,27-33,39,41,43-49 and 54-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-25,31-33,39,41,43-49 and 54-57* is/are rejected.

7)☒ Claim(s) *27-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-26-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6-26-06 have been fully considered but they are not persuasive.

2. Regarding the rejection under 35 USC 112 of claims 56 and 57, Applicant contends support is provided at p9 lines 15-19, p 10 lines 1-7, p23 lines 20-23, and p44 lines 19-23. Examiner acknowledges the cited passages to recite the **end** hoops being perpendicular to the longitudinal axis, but this does not provide support for the limitation "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member". The specification only provides support for "substantially perpendicular".

3. With regard to Cragg, Fontaine, Furui, and Wolff Examiner maintains the arguments presented in the last office action dated 12-27-05 on pages 2-4.

4. Applicant presents new arguments pertaining to the interpretation of the terms "substantially perpendicular" and "juxtaposed" primarily based upon recent decision of the U.S. Court of Appeals for the Federal Circuit (In re Johnson and Phillips). Examiner notes the decisions are based upon different circumstances, but generally teach general definitions may give way to the definition imparted by the specification. In the current application, Examiner does not see how the current specification provides a distinct definition of "substantially perpendicular" and "juxtaposed" and therefore applying the teaching of In re Johnson and Phillips would not be appropriate. Furthermore, substantially is disclosed in MPEP 2173.05(b) to be "a broad term". Regarding

"juxtaposed", Applicant has not provided support in the specification to require a level of proximity between "juxtaposed apices".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 56-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" which is not disclosed in the specification. The specification only provides support for the phrase "substantially perpendicular".

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 20,22-24,31-33,41,54,55 are rejected under 35 U.S.C. 102(e) as being anticipated by Cragg US PN 5,405,377.

Cragg discloses in figures 1-4 and line 40 of col. 2 through line 4 of col. 3 a stent 10 comprising a plurality of hoops 11 formed from a continuous Nitinol wire comprising pairs of elongate elements forming apices abutting apices of adjacent hoops, which are connected by thermoplastic suture material 12. All hoops are axially aligned and of equal diameter.

3. Claims 20,22-24,31,54-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Fontaine US PN 5,370,683.

Fontaine discloses in figures 6, 9, 10, and 14 a stent comprised of a continuous wire formed into a plurality of interconnected (by welding lines 11-13 of col. 6) hoops at abutting apices or vertices (5,5' and 7,7') formed by pairs of elongate elements within each hoop. All hoops are axially aligned and of equal diameter.

4. Claims 20,22-25,39,43,44,47,54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff US PN 5,104,404.

Wolff discloses in figures 1 and 6 a stent comprised of a plurality of hoops 12 interconnected at apices formed by pairs of elongate elements within each hoop. Securing means 14 connects the apices of adjacent hoops. All hoops are axially

aligned and of equal or different diameter (figure 6). Figure 1 shows the longitudinal ends of the stent being square to the long axis of the stent. As shown in Figure 1, each end portion of the stent, left 12 or right 12, may have a tubular coating of radiopaque material over element 14 (see lines 63-65 of col. 3).

5. Claims 20,22-24,31,39,54 are rejected under 35 U.S.C. 102(b) as being anticipated by Furui JP 4-25755.

Furui discloses in figure 1 a stent comprised of a plurality of hoops interconnected at apices formed by pairs of elongate elements within each hoop. Securing means connect the apices of adjacent hoops. All hoops are axially aligned, of equal or different diameter, and in a plane perpendicular to the longitudinal axis.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 45,46,48,49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff US PN 5,104,404 as applied to claims 54,43,44,47 above, and further in view of Piplani et al. US PN 5,824,039.

Wolff discloses the use of radiopaque markers in the form of tubes but does not expressly disclose the use of gold or platinum as the material or that the marker may be a wire. Piplani teaches a stented vascular graft having gold and platinum markers as well as markers in the form of wires (see lines 22-26 of col. 5 and lines 14-17 of col. 7) in order to provide visibility under fluoroscopy during implantation of the device.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the stent disclosed by Wolff to include gold or platinum as the material or to provide the marker in the form of a wire as taught by Piplani et al. in order to provide sufficient visibility under fluoroscopy during implantation of the device.

Allowable Subject Matter

8. Claims 27-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Matthews (Howie)
Examiner
Art Unit 3738

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

SHEET 1 of 6

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
WM		US-3,304,557	02/21/1967	S. Polansky	
		US-3,657,744	04/25/1972	Ersek	
		US-3,805,301	04/23/1974	Liebig	
		US-4,130,904	12/26/1978	Whalen	
		US-4,202,349	05/13/1980	Jones	
		US-4,494,531	01/22/1985	Gianturco	
		US-4,530,113	07/23/1985	Matterson	
		US-4,545,082	10/08/1985	Hood	
		US-4,787,899	11/29/1988	Lazarus	
		US-4,795,463	01/03/1989	Gerow	
		US-5,163,958	11/17/1992	Pinchuk	
		US-5,192,310	03/09/1993	Herweck, et al.	
		US-5,306,294	04/26/1994	Winston et al.	
		US-5,330,500	07/19/1994	Song	
		US-5,342,387	08/30/1994	Summers	
		US,5,354,308	10/11/1994	Simon et al.	
		US-5,383,892	01/24/1995	Cardon	
		US-5,395,390	03/07/1995	Simon et al.	
		US-5,429,144	07/04/1995	Wilk	
		US-5,443,497	08/22/1995	Venbrux	
		US-5,522,880	06/04/1996	Barone et al.	
		US-5,540,712	07/30/1996	Kleshinski et al.	
		US-5,562,724	10/08/1996	Vorwerk et al.	
		US-5,562,727	10/08/1996	Turk et al.	
		US-5,571,170	11/05/1996	Palmaz et al.	
		US-5,609,605	03/11/1997	Marshall et al.	
		US-5,628,783	05/13/1997	Quiachon et al.	
		US-5,632,772	05/27/1997	Alcime	
		US-5,639,278	06/17/1997	Dereume et al.	
		US-5,662,675	09/02/1997	Polanskyj Stockert et al.	
		US-5,676,697	10/14/1997	MacDonald	
		US-5,683,448	11/04/1997	Cragg	

Examiner Signature	/William Matthews/	Date Considered	09/28/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6]Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 2 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
WM		US-5,697,970	12/16/1997	Schmitt	
		US-5,725,572	03/10/1998	Lam	
		US-5,741,332	04/21/1998	Schmitt	
		US-5,800,456	09/01/1998	Maeda et al.	
		US-5,824,042	10/20/1998	Lombardi	
		US-5,871,536	02/16/1999	Lazarus	
		US-5,876,432	03/02/1999	Lau et al.	
		US-6,090,137	07/18/2000	Schmitt	
		US-6,102,938	08/15/2000	Evans et al.	
		US-6,123,722	09/26/2000	Fogarty, et al.	
		US-6,129,756	10/10/2000	Kugler et al.	
		US-6,156,063	12/05/2000	Douglas	
		US-6,159,239	12/12/2000	Greenhalgh	
		US-6,162,246	12/19/2000	Barone	
		US-6,176,875	01/23/2001	Lenker, et al.	
		US-6,197,049	03/06/2001	Shaolian	
		US-6,200,339	03/13/2001	Leschinsky et al.	
		US-6,210,435	04/03/2001	Piplani et al.	
		US-6,221,099	04/24/2001	Andersen, et al.	
		US-6,221,102	04/24/2001	Baker et al.	
		US-6,235,050	05/22/2001	Quiachon, et al.	
		US-6,251,133	06/26/2001	Richter et al.	
		US-6,251,134	06/26/2001	Alt et al.	
		US-6,261,316	07/17/2001	Shaolian et al.	
		US-6,270,523	08/07/2001	Herweck, et al.	
		US-6,273,909	08/14/2001	Kugler et al.	
		US-6,280,467	08/28/2001	Leonhardt	
		US-6,283,991	09/04/2001	Cox, et al.	
		US-6,287,335	09/11/2001	Drasler et al.	
		US-6,312,462	11/06/2001	McDermott et al.	
		US-6,325,819	12/04/2001	Pavcnik et al.	
		US-6,325,826	12/04/2001	Vardi et al.	
		US-6,331,190	12/18/2001	Shokoohi et al.	
		US-6,334,869	01/01/2002	Leonhardt et al.	

Examiner Signature	/William Matthews/	Date Considered	09/28/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1] Applicant's unique citation designation number (optional).

[2] See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3] Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 3 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
WM		US-6,344,056	02/05/2002	Dehdashtian	
		US-6,348,066	02/19/2002	Pinchuk et al.	
		US-6,361,557	03/26/2002	Gittings, et al.	
		US-6,395,019	05/28/2002	Chobotov	
		US-6,395,022	05/28/2002	Piplani et al.	
		US-6,398,803	06/04/2002	Layne, et al.	
		US-6,398,807	06/04/2002	Chouinard et al.	
		US-6,409,750	06/25/2002	Hyodoh et al.	
		US-6,409,756	06/25/2002	Murphy	
		US-6,416,542	07/09/2002	Marcade et al.	
		US-6,428,565	08/06/2002	Wisselink	
		US-6,440,166	08/27/2002	Kolluri	
		US-6,454,795	09/24/2002	Chuter	
		US-6,464,721	10/15/2002	Marcade et al.	
		US-6,485,524	11/26/2002	Strecker	
		US-6,517,572	02/11/2003	Kugler et al.	
		US-6,524,336	02/25/2003	Papazolgou, et al.	
		US-6,540,777	04/01/2003	Stenzel	
		US-6,547,820	04/15/2003	Staudenmeier	
		US-6,551,350	04/22/2003	Thornton et al.	
		US-6,565,596	05/20/2003	White et al.	
		US-6,576,007	06/10/2003	Dehdashtian et al.	
		US-6,576,009	06/10/2003	Ryan et al.	
		US-6,582,458	06/24/2003	White et al.	
		US-6,592,614	07/15/2003	Lenker, et al.	
		US-6,645,242	11/11/2003	Quinn	
		US-6,652,567	11/25/2003	Deaton	
		US-6,682,541	01/27/2004	Gifford, III, et al.	

Examiner Signature	/William Matthews/	Date Considered	09/28/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1] Applicant's unique citation designation number (optional).

[2] See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

[4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 4 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
WM		EP 0 464 755	01/08/1992	Nissho Corp.		
		GB 1205743	09/16/1970	Colin C. Didcott		☐
		GB 2269104	02/02/1994	Taha R. Lazim		
		FR 1602513	01/29/1971	National Research Development Corp.(GB)		
		JP 3133446 (w/English Abstract)	06-06-1991	Cook Inc.		
		JP 5305092	11/19/1993	Cook Inc.		
		JP H05-76554	03/30/1993	Endovascular Technologies, Inc.		
		JP 6023031	02/01/1994	Endovascular Technologies, Inc.		
		WO 83/03752	11-10-1983	Hans Wallstén		
		WO 92/06734	04/30/1992	Ho Young Song		
		WO 95/01761	01/19/1995	Dr. T. J. Fogarty		
		WO 97/09008	03/13/1997	Medtronic, Inc.		
		WO 98/27895	07/02/1998	Prograft Medical, Inc.		

Examiner Signature	/William Matthews/	Date Considered	09/28/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).
[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).
[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[6]Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 5 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
WM		CA 2,086,333	04/25/1991	Schneider (USA) Inc.		☐
WM		CA 2,158,373	10/27/1994	Pharmacyclics, Inc.		☐
WM		CA 2 144 305 C	02/02/1995	Cook Incorporated		☐

Examiner Signature	/William Matthews/	Date Considered	09/28/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).
[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).
[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[6]Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (08-03) (AW 10/2003)

Approved for use through 7/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 6 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
WM		Notice of Opposition by Scimed Life Sciences, Inc. to European Patent No. 0 676 937 B	☐
WM		Opposition by William Cook Aps to European Patent No. 0 676 937 B	☐
WM		Verlag, "Interventional Radiology," pp. 692-699 (1990)	☐
WM		Yoshioka et al., "Self-Expanding Endovascular Graft: An Experimental Study in Dogs," AJR 15: pp. 673-676 (1988)	☐
WM		U.S. App. 08/051,728	☐
WM		Official Action in Canadian Application No. 2,182,982, issued by the Canadian Intellectual Property Office on March 30, 2006	☐
			☐
			☐
			☐

Examiner Signature	/William Matthews/	Date Considered	09/28/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

The collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
updated prior search	9/28/2006	WHM

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 01/23/2007

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER
MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Interview Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) *William H. Matthews (Howie)*. (3) *Stanley Weinberg*.

(2) *Joshua Cohen*. (4)_____.

Date of Interview: *10 January 2007*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *54 and 56*.

Identification of prior art discussed: *Fontaine*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussed possible amendments to claims 54 and 56, location of support in specification for "perpendicular hoops" (p44 line 23 and abstract) and "substantially perpendicular. Also discussed relevance of Fontaine to claim 56 should "substantially" be added before "perpendicular" in order to overcome the 112 rejection*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

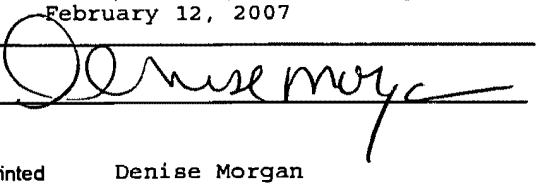
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
BSI-010US4

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on February 12, 2007

Signature 

Typed or printed name Denise Morgan

Application Number	Filed
09/977,826	10/15/2001

First Named Inventor
George Goicoechea

Art Unit	Examiner
3738	William H. Matthews

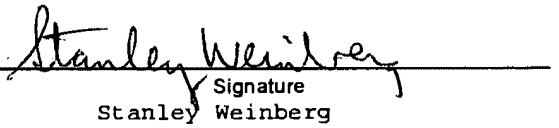
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record. Registration number 25,276
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____



Signature

Stanley Weinberg

Typed or printed name

610-407-0700

Telephone number

02/12/2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Reasons For Review

The issues raised for purposes of this Pre-Appeal Request For Review are limited to the rejections of independent claims 54 and 56.

Claim 54

Claim 54 has been alternatively rejected as anticipated by Cragg (U.S. Patent No. 5,405,377); Fontaine (U.S. Patent No. 5,370,683); Wolff (U.S. Patent No. 5,104,404); and Furui (JP 4-25755) under various subsections of 35 U.S.C. § 102.

The following recitation is relevant to the rejections of claim 54 based on Cragg and Fontaine:

> each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Page 2, ¶3 of the Office Action (incorporating by reference pp. 2-3, ¶¶3, 4 of the December 27, 2005 Office Action) states that Applicants' specification does not define the scope of "substantially perpendicular" or define that term to mean "perpendicular." Then, instead of relying on Applicants' disclosure to construe the term "substantially perpendicular," the Office Action relies solely on a general dictionary to define "substantial" as "being largely but not wholly that which is specified" and, in ¶3 of the incorporated Office Action, expands upon that definition and concludes that

> the broadest reasonable interpretation [of "substantially perpendicular"] may include at least 90, 80, 70 or 60 degrees from the longitudinal axis.

When read in view of the claim rejections, this is not a reasonable interpretation of the term "substantially perpendicular" in claim 54 because it is based solely upon a general dictionary and ignores the meaning of that term in the important context of Applicants' disclosure.

In re Johnston, 435 F.3d 1381, 1384 (Fed. Cir. 2006) (an appeal from the BPAI) states that "dictionary definitions must give way to the meaning imparted by the specification." (emphasis added). Applicants have previously brought *Johnston* to the Examiner's attention. In response, para. 4, p.2 of the Office Action incorrectly interprets *Johnston* as allowing the Examiner discretion to use a general dictionary definition in the first instance, stating that a general dictionary definition may give way to the specification. But when the general dictionary definition relied upon in the Office Action "gives way" to Applicants' disclosure as required by *Johnston*, claim 54 as properly construed is allowable over the cited prior art.

Dictionary definitions must give way because "the specification. . .is the single best guide to the meaning of a disputed term. . . . The specification is, thus, the primary basis for construing the claims." *Phillips v. AWH Industries*, 415 F.3d 1303, 1315 (Fed. Cir. 2005), *cert. denied*, 164 L.Ed.2d 49 (2006) (citations and internal quotations omitted). *Accord, MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, No. 2006-1062, *Slip op. at p. 8* (Fed. Cir. 1/24/07). Applicants have previously provided a copy of *Phillips* to the Examiner. Because dictionary definitions "do not necessarily reflect the inventor's goal of distinctly setting forth his invention as a person of ordinary skill in that particular art would understand it," "[a] claim should not rise or fall based upon the preferences of a particular dictionary editor." *Phillips*, 415 F.3d at 1322.

> [T]he 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.

Phillips, 415 F.3d at 1313 (citations omitted) (emphasis added).

Applicants, persons of ordinary skill in the art, have described their invention in the specification, figures, and claims in a way that would be understood by one of ordinary skill in the art. Claim 54 must be interpreted in a way that is consistent with the specification and figures rather than based solely on a general dictionary definition. Therefore, claim 54 must be evaluated based upon Applicants' entire disclosure and certainly should not be evaluated based on a dictionary definition that contradicts Applicants' specification and figures.

It is significant in this matter that Cragg and Fontaine disclose helical configurations. See Cragg, col. 1, lines 57, 64; col. 2, line 44. Fontaine describes some hoops as wrapped in a spiral (col. 4, lines 13-15) and having a spiral shape (col. 7, lines 55-59).

Applicants expressly distinguished their configuration as claimed in claim 54 from the helical configuration of EP-A-0556850 (the European patent corresponding to the cited U.S. Cragg reference) as an alternative to Cragg's helical configuration:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent.

(p. 9, lines 13-19) (emphasis added).

Applicants' Figs. 1A, 1B, 2A, 2B, 3, 4A, 5-7, and 15-20 illustrate the "substantially perpendicular" embodiment in which the hoops do not form a helical configuration. The specification explains how the hoops of this embodiment are substantially perpendicular to the longitudinal axis of the stent. See, e.g., page 9, lines 13-19 ("the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent); page 23, lines 20-23 ("the circumference of each hoop is substantially perpendicular to the longitudinal axis of the mandrel"). Furthermore, Applicants' specification as quoted above, distinguishes helical configurations from a "substantially perpendicular" configuration. Applicants' specification thus excludes helical configurations from the meaning of "substantially perpendicular." Therefore, the recitation in claim 54 that "hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent" is not anticipated by references disclosing helical stents.

In summary, the Office Action is legally deficient because it relies solely upon a general dictionary definition without regard to Applicants' specification and figures. It is also legally deficient because it uses that general dictionary definition to erroneously construe claim 54 to encompass a configuration (a helical configuration) that Applicants' specification excluded from the claim.

The following recitation is relevant to the rejections of claim 54 based upon Furui and Wolff:

> means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

Neither the current Office Action nor the incorporated Office Action contends that Applicants' disclosure fails to define the term "juxtaposed" as used in claim 54. Nevertheless, the Furui rejection of claim 54 (para. 7, p.4 of the incorporated Office Action) uses a general dictionary to define "juxtaposed" as "side by side" and "synonymous with adjacent and does not imply contact." The current Office Action then apparently gives controlling weight to this general dictionary definition of "juxtaposed." This reliance on the general dictionary definition gives primacy to the general dictionary definition and relegates Applicants' disclosure to secondary status. This analysis directly contradicts *MBO Laboratories*, *Johnston*, and *Phillips*. The general dictionary definition must give way to Applicants' specification and figures.

Applicants' specification, together with the embodiments depicted in the figures, explains and illustrates the meaning of "juxtaposed." For example, page 10, lines 18-20 explains that an apex of the sinuous wire in one hoop is secured "to a

juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors." Page 20, lines 1-4 explains that Figs. 4(b)-4(f) illustrate means for securing juxtaposed apices. Other passages in the specification, depicted in referenced figures, illustrate the meaning of "juxtaposed." See, e.g., page 25, lines 4, 7, 10 and Fig. 4(a); page 25, lines 14 and 17, referring to Figs. 4(b) and 4(c), respectively; page 26, lines 8, 16, describing features shown at least in Figs. 1B, 2A, 3; page 29, line 20 describing juxtaposed apices shown at least in Fig. 1B. The juxtaposed nature of Applicants' apices is also shown in Figs. 1A, 2B, 3, and 5-7.

The term "juxtaposed" must be construed with reference to Applicants' specification, and the general dictionary definition of "juxtaposed" must give way to Applicants' specification and figures when construing claim 54. Based on Applicants' specification, one skilled in the art would interpret "juxtaposed" to mean apices positioned in such a way that each hoop formed by the apices is supported by its neighbors. Page 10, lines 18-20.

Furui (translation provided September 29, 2005) does not show juxtaposed apices as defined by Applicants' specification and figures. Instead, Furui discloses a stent structure in which separate wires (item 6 in the translation) are interposed between the valleys of one wave-shaped ring and the peaks of the other wave-shaped ring to connect the valleys to the peaks. (Page 3, third-to-last paragraph of translation.) This structure is intended to prevent the stent from closing up when placed in a bent part of a blood vessel. (Page 4, second-to-last paragraph of translation.)

The Wolff rejection of claim 54 apparently relies on the same general dictionary definition of "juxtaposed." In contrast to a meaning of the term "juxtaposed" properly based on Applicants' disclosure, Wolff shows a hinge 14 that is interposed between ends of stent segments 12 to maintain spacing between adjacent segments (col. 1, lines 45-52). These hinge 14 components act as a bridge separating the spaced stent segments. (Column 3, lines 55-62.)

Claim 56

Claim 56, rejected under § 112, first paragraph, recites, in part:

> the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Para. 6, p. 3 of the present Office Action states

> Claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" which is not disclosed in the specification. The

> specification only provides support for the phrase "substantially perpendicular." (emphasis in original)

Para. 2, p. 2 of the present Office Action also states that the specification

> does not provide support for the limitation "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." The specification only provides support for "substantially perpendicular." (emphasis in original)

It is respectfully submitted that Applicants' specification clearly supports an embodiment in which each hoop is perpendicular.

For example, page 68, lines 7-8 (Abstract) refers to "an endoluminal stent having perpendicular hoop members." (emphasis added) Also, page 44, lines 19-23 describes axially aligned stent segments

> each of the requests [sic] comprising one or more adjacent hoops, perpendicular to a common axis. . . . (emphasis added)

The specification therefore has support for "perpendicular" without the term "substantially."

As indicated above, page 68, lines 7-8 refers to "an endoluminal stent having perpendicular hoop members." This phrase refers to "hoop members," rather than a single hoop member. Also, page 44, lines 19-23 states that "each" of the stent segments comprises one or more adjacent hoops that are perpendicular to a common axis. Finally, the figures illustrate embodiments in which all hoops are oriented in this manner. The application therefore has support for "each" hoop having vertices that lie in a common plane perpendicular to the longitudinal axis.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections of claims 54 and 56 are legally deficient and should be withdrawn. A Notice of Allowance is therefore respectfully requested.

Alternatively, it is submitted that the rejection should be re-evaluated and a new Office Action should be issued that is consistent with recent legal requirements of the U.S. Court of Appeals for the Federal Circuit.

AF

PTO/SB/31 (04-05)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional)
BSI-010US4

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on February 12, 2007

Signature Denise Morgan

Typed or printed name Denise Morgan

In re Application of

George Goicoechea

Application Number	Filed
09/977,826	10/15/2001

For

ENDOLUMINAL STENT

Art Unit	Examiner
3738	Willaim H. Matthews

Applicant hereby **appeals** to the Board of Patent Appeals and Interferences from the last decision of the Examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 500.00

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ ____

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 18-0350 . I have enclosed a duplicate copy of this sheet.

☒ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. Registration Number: 25,276

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34.____.

Stanley Weinberg
Signature

Stanley Weinberg
Typed or printed name

610-407-0700
Telephone Number

2/12/2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 2 forms are submitted.

PTO/SB/22 (10-04) (12-04)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2005** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818))*	Docket Number (Optional) BSI-010US4
Application Number 09/977,826	Filed 10/15/2001
For ENDOLUMINAL STENT	
Art Unit 3738	Examiner William H. Matthews

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☒ One month	(37 CFR 1.17(a)(1))	$120	$60	$120.00
☐ Two months	(37 CFR 1.17(a)(2))	$450	$225	$_____
☐ Three months	(37 CFR 1.17(a)(3))	$1020	$510	$_____
☐ Four months	(37 CFR 1.17(a)(4))	$1590	$795	$_____
☐ Five months	(37 CFR 1.17(a)(5))	$2160	$1080	$_____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 18-0350. I have enclosed a duplicate copy of this sheet.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number: 25,276.

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

Stanley Weinberg
Signature

2-12-07
Date

Stanley Weinberg
Typed or Printed Name

610-407-0700
Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

02/15/2007 GWORDOF1 00000022 09977826

02 FC:1251 120.00 OP

PTO/SB/17 (12-04v2) (AW 1/2005)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/04.
Fees pursuant to the Consolidated Appropriations Act. 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 620.00

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoechea
Examiner Name	Willaim H. Matthews
Art Unit	3738
Attorney Docket No.	BSI-010US4

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify):_____

☒ Deposit Account Deposit Account Number: **18-0350** Deposit Account Name: **RatnerPrestia**

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	____
Design	200	100	100	50	130	65	____
Plant	200	100	300	150	160	80	____
Reissue	300	150	500	250	600	300	____
Provisional	200	100	0	0	0	0	____

2. EXCESS CLAIM FEES

Fee Description	Small Entity Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)	Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	- 20 or HP =	_____	x	_____	=	_____	_____	_____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x	_____	=	_____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/ 50 =	_____	(round up to a whole number) x	_____	=	_____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	____
Other (e.g., late filing surcharge): Notice of Appeal Fee and 1 month extension of time	620.00

SUBMITTED BY Complete *(if applicable)*

Signature	Stanley Weinberg	Registration No. Attorney/Agent)	25,276	Telephone	610-407-0700
Name (Print/Type)	Stanley Weinberg			Date	2/12/2007

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/21 (09-04) (AW 10/2004)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

ENCLOSURES *(Check all that apply)*

- ☒ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/Declaration(s)
- ☒ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below): 1 pg. Pre-Appeal Brief Request for Review; 5 pg. Reasons for Review; Credit Card Payment Form; post card receipt

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm Name	RatnerPrestia		
Signature	Stanley Weinberg		
Printed Name	Stanley Weinberg		
Date	2/12/2007	*Registration No.*	25,276

CERTIFICATE OF TRANSMISSION / MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Denise Morgan		
Typed or Printed Name	Denise Morgan	*Date*	2/12/2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, ALEXANDRIA, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 04/11/2007

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/977,826	GOICOECHEA ET AL.	
	William Matthews	Art Unit 3738	

Document Code - AP.PRE.DEC

Notice of Panel Decision from Pre-Appeal Brief Review

This is in response to the Pre-Appeal Brief Request for Review filed 2/14/07.

1. ☐ **Improper Request** – The Request is improper and a conference will not be held for the following reason(s):

☐ The Notice of Appeal has not been filed concurrent with the Pre-Appeal Brief Request.
☐ The request does not include reasons why a review is appropriate.
☐ A proposed amendment is included with the Pre-Appeal Brief request.
☐ Other:

The time period for filing a response continues to run from the receipt date of the Notice of Appeal or from the mail date of the last Office communication, if no Notice of Appeal has been received.

2. ☒ **Proceed to Board of Patent Appeals and Interferences** – A Pre-Appeal Brief conference has been held. The application remains under appeal because there is at least one actual issue for appeal. Applicant is required to submit an appeal brief in accordance with 37 CFR 41.37. The time period for filing an appeal brief will be reset to be one month from mailing this decision, or the balance of the two-month time period running from the receipt of the notice of appeal, whichever is greater. Further, the time period for filing of the appeal brief is extendible under 37 CFR 1.136 based upon the mail date of this decision or the receipt date of the notice of appeal, as applicable.

☒ The panel has determined the status of the claim(s) is as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 27-30.
Claim(s) rejected: 20, 22-25, 31-33, 39, 41, 43-49, and 54-57.
Claim(s) withdrawn from consideration: _____.

3. ☐ **Allowable application** – A conference has been held. The rejection is withdrawn and a Notice of Allowance will be mailed. Prosecution on the merits remains closed. No further action is required by applicant at this time.

4. ☐ **Reopen Prosecution** – A conference has been held. The rejection is withdrawn and a new Office action will be mailed. No further action is required by applicant at this time.

All participants:

(1) Corrine M. McDermott. (3) William Matthews.

(2) Janet Baxter. (4)_____.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 05/04/2007

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) *William H. Matthews (Howie)*. (3)_____.

(2) *Stanley Weinberg*. (4)_____.

Date of Interview: *24 April 2007*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *none*.

Identification of prior art discussed: *none*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussed the reasons for panel decision*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

WILLIAM H. MATTHEWS
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/SB/21 (09-04) (AW 10/2004)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

ENCLOSURES *(Check all that apply)*

- ☒ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/Declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below): 2 pg. PTO/SB/08a-08b; 10 references; 3 Japan Patent Office Communications; PTO-2038; post card receipt

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm Name	RatnerPrestia		
Signature	Stanley Weinberg		
Printed Name	Stanley Weinberg		
Date	7/12/07	*Registration No.*	25,276

CERTIFICATE OF TRANSMISSION / MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Denise Morgan		
Typed or Printed Name	Denise Morgan	*Date*	7/12/07

PTO/SB/17 (12-04v2) (AW 1/2005)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/04.
Pursuant to the Consolidated Appropriations Act. 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2007

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 180

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Examiner Name	William H. Matthews
Art Unit	3738
Attorney Docket No.	BSI-010US4

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify):_____

☒ Deposit Account Deposit Account Number: **18-0350** Deposit Account Name: **RatnerPrestia**

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	____
Design	200	100	100	50	130	65	____
Plant	200	100	300	150	160	80	____
Reissue	300	150	500	250	600	300	____
Provisional	200	100	0	0	0	0	____

2. EXCESS CLAIM FEES

Fee Description	Small Entity Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee ($)		Fee Paid ($)	Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	- 20 or HP =	_____	x _____	=	_____	____	____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x _____	=	_____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____	- 100 =	_____	/ 50 =	_____ (round up to a whole number)	x _____	= ____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	____
Other (e.g., late filing surcharge): Submission of IDS	180

SUBMITTED BY

Complete *(if applicable)*

Signature	Stanley Weinberg	Registration No. Attorney/Agent)	25,276	Telephone	610-407-0700
Name (Print/Type)	Stanley Weinberg			Date	7/12/07

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoecha
Filed:	October 15, 2001
Title:	Endoluminal Stent
TC/A.U.:	3738
Examiner:	William H. Matthews

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the documents listed on the PTO/SB/08a and PTO/SB/08b forms submitted herewith. Copies of the documents listed on the PTO/SB/08a and PTO/SB/08b forms are enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

Based on a communication from the Japanese Patent Office in Japan Application No. 2004-335171 dated April 24, 2007, English language EP 0 565 251 A1 (a copy of which is enclosed with this submission) is believed to correspond to JP H06-7454; English language WO 91/17789 (a copy of which is enclosed with this submission) is believed to correspond to JP H05-509008; and English language EP 0 357 003 A2 (a copy of which is enclosed with this submission) is believed to correspond to JP H02-68052.

Based on a communication from the Japanese Patent Office in Japan Application No. 2006-104574 dated May 15, 2007, English language WO 90/15582 (a copy of which is enclosed with this submission) is believed to correspond to JP H04-500328.

Based on a communication from the Japanese Patent Office in Japan Application No. 2006-104577 dated May 15, 2007, English language EP 0 346 564 A1 (a copy of which is enclosed with this submission) is believed to correspond to JP H02-167178.

STATEMENT UNDER 37 C.F.R. § 1.97(e)

The undersigned hereby states that

☒ each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement.

☐ no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(e) more than three months prior to the filing of the Information Statement.

The required fee set forth in 37 C.F.R. § 1.17(p) is provided herewith.

Respectfully submitted,

Stanley Weinberg

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicants

JLC/SW/dhm

Enclosures: PTO/SB/08a and PTO/SB/08b
(10) References
(3) Japan Patent Office Communications
Transmittal Form
Credit Card Payment Form
Fee Transmittal

Dated: July 12, 2007

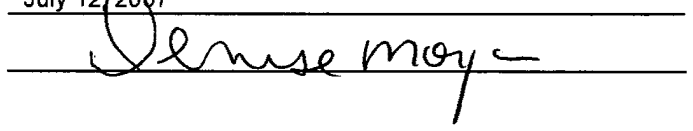
☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith..

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

July 12, 2007



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 2

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		JP H02-167178	06/27/1990	Medtronic, Inc.		☐
		EP 0 346 564 A1	12/20/1989	Medtronic, Inc.		☐
		JP H04-500328	01/23/1992	Hugh Trout		☐
		WO 90/15582	12/27/1990	Hugh Trout		☐
		JP H06-7454	01/18/1994	Cook Incorporated		☐
		EP 0 565 251 A1	10/13/1993	Cook Incorporated		☐
		JP H05-509008	12/16/1993	Richard Stack		
		WO 91/17789	11/28/1991	Richard Stack		
		JP H02-68052	03/07/1990	Corvita Corporation		
		EP 0 357 003 A2	03/07/1990	Corvita Corporation		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6]Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 2 of 2

Complete If Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Notice of Reasons for Rejection of Japan Patent Application No. 2004-335171 dated April 24, 2007	☐
		Notice of Reasons for Rejection of Japan Patent Application No. 2006-104574 dated May 15, 2007	☐
		Notice of Reasons for Rejection of Japan Patent Application No. 2006-104577 dated May 15, 2007	☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

The collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

⑲日本国特許庁(JP)　⑪特許出願公開

⑫公開特許公報(A)　平2−167178

⑤Int.Cl.[5]　識別記号　庁内整理番号　⑬公開　平成2年(1990)6月27日
A 61 M 29/00　6859−4C

審査請求　未請求　請求項の数 10　(全9頁)

⑤④発明の名称　圧縮形ステント及びその付与装置

⑳特　願　平1−62324
㉒出　願　平1(1989)3月16日
優先権主張　㉜1988年6月17日㉝米国(US)㉛208,252

⑦②発明者　クレツグ　ダヴリユ.　アメリカ合衆国　ミネソタ州　55330　エルク　リバー
ダンス　ツイン　レークス　ロード　19276
⑦②発明者　ロドニー　ダヴリユ.　アメリカ合衆国　ミネソタ州　55369　マープル　グローブ
ウルフ　イーグル　レーク　ドライブ　ダヴリユ.468
⑦②発明者　ブライス　レタ　エム.デイー.　フランス国　ローエン　76000　ル　ド　レナード　134
⑦①出願人　メドトロニツク　インコーポレーテツド　アメリカ合衆国　ミネソタ州　55432　ミネアポリス　エヌ.イー.セントラル　アベニユー　7000
⑦④代理人　弁理士　小林　十四雄　外1名

最終頁に続く

明　細　書

1．発明の名称

圧縮形ステント及びその付与装置

2．特許請求の範囲

(1)　ワイヤで形成された全体的に筒状型式の血管ステントにおいて、

(a)本質的に真直な中央セグメントを各々が有する多数本の等寸・等形のワイヤであって、端末セグメントが上記中央セグメントに対し斜めに曲げられ、上記ワイヤ各々の端末セグメントは本質的に他の端末セグメントに対し平行とし、

(b)上記曲げた端末セグメントを平行に方向づけした各ワイヤの互いに隣接するワイヤ同志が重なり相接するようにして上記ワイヤが筒状を形成するように方向づけ及び等間隔とし、

その結果、各隣接対ワイヤの上記中央セグメント同志のなす角が鋭角となり、総ての端末セグメントにおいてワイヤ同志が固着されており、

(c)上記ワイヤはスプリング金属で生体適応性物質で形成され、上記ワイヤは上記ワイヤセグメント内にエネルギーを貯えるように曲げて上記ステントの直径が細く出来るようにし、且つこのステントを経皮的に生体内に設置し得るべく圧縮した時にこのステントを受け入れる大きさの外側カテーテル内に挿入出来るようにした

ことを特徴とする圧縮可能の血管ステント。

(2)　上記外側カテーテル内に滑り嵌合出来るような寸法の内側カテーテルを更に具備し、上記内側カテーテルが上記外側カテーテル内に嵌合され、上記ステントが圧縮されて該外側カテーテル内に嵌着された時に上記内側カテーテルの壁が上記ステントの端末に当たるような寸法にされていることを特徴とする前記請求項1記載のステントの付与装置。

(3)　上記内側カテーテル、外側カテーテルの端末であって上記ステント付近に放射線不透過のマーカを貼付したことを特徴とする前記請求項2記載の付与装置。

(4) 上記内側カテーテルと上記ステントとを同軸に貫通して案内ワイヤを通し、該内側カテーテルとステントとの寸法は該案内ワイヤが中心を滑り通り得る寸法にし、循環系に上記カテーテルを挿通する助けとすることを特徴とする前記請求項2記載の付与装置。

(5) 上記外側カテーテルを滑り挿通せしめる寸法の案内カテーテルに該外側カテーテルを同軸的に挿通し、上記内・外カテーテルの循環系への案内手段となすことを特徴とする前記請求項4記載の付与装置。

(6) 上記内側カテーテルが第1Y－コネクタ止血バルブにより上記外側カテーテルに対し係止・封止され、上記案内ワイヤが近位端において外部に露出されており上記内側カテーテルに対し上記案内ワイヤを抜き差し調節出来るようにしたことを特徴とする前記請求項4記載の付与装置。

(7) 上記内側カテーテルが第1Y－コネクタ止血バルブにより上記外側カテーテルに対し係止・封止可能であり、上記外側カテーテルが第2Y－コネクタ止血バルブにより上記管内カテーテルに対し係止・封止可能であり、上記案内ワイヤが近位端において露出され、上記内側カテーテルに対する上記案内ワイヤの抜き差し調節が出来るようにしたことを特徴とする前記請求項4記載の付与装置。

(8) 上記ワイヤが溶接により共に固定されていることを特徴とする前記請求項1記載のステント組立体。

(9) 総体的に筒状の道具であって、第1端からの軸方向のボア及び同軸セグメントに連接した第2端からの軸方向のフレア付開口とを有し、該道具は上記外側カテーテル内に上記ステントを装填する手段を設ける寸法にしたことを特徴とするステント付与道具。

(10) 上記ワイヤが放射線不透過材料で作られることを特徴とする前記第1項記載のステント。

3．発明の詳細な説明

＜産業上の利用分野＞

本発明は、血管内ステントに係り、経皮的、透視式脈管形成術（ＰＣＴＡ）法あるいは経皮的脈管形成術（ＰＴＡ）法いずれかによるバルーン式脈管形成術の後に動物あるいは人類の末梢血管あるいは冠状動脈内に適用して血管の通過性を維持しておく血管内ステントに係る。

本ステントは1本1本のワイヤを一緒に溶接し、外側カテーテル内に入れるようにその筒型の直径を小さくするようその軸方向に沿って圧縮しこの圧縮状態を保ち得るステントであって、又バルーン式脈管形成後に内側カテーテル及び案内ワイヤを用いてステントを脈管形成領域に永久的に挿入配置、そして固定して急性の脈管再閉塞及び術後の再狭窄を防止するものである。本ステントの構造はその寸法及びその装置の材質は動脈の内部に所与のラジアル方向の力を与えて血管を閉塞しようとする力に抗してその形状を保持するように選ばれる。この閉塞力は血管内膜切開片、その垂れ下がり、けいれんによる急性再閉塞ばかりでなく血小板による再狭窄に基因する力も含まれる。これらはステント自体の上に新たに成長する血管内膜により防止乃至は発症を遅らせ得る。ステントの長さは種々変えられたり1ヶ所に1本以上のステントを用いて血管の曲がりに対処したりその他特殊な血管の性質に対処する事が出来る。内側及び外側カテーテルの端末にある放射線不透過性マーカ物質により外部からの監視により所望のところにステントを置くことの出来るようにしたり、或いはステント自体を放射線不透過に作ることも出来る。

＜従来の技術＞

米国特許第4，553，545号明細書及び図面にはワイヤコイルをその長さ方向の回りに回転し、巻回数を減らして直径を太くするような血管内に挿入した後拡張できる装置が示されている。米国特許第4，503，569号明細書及び図面には螺旋巻きコイルが115°Ｆ乃至125°Ｆの範囲に転移温度を有する形状記憶ニチノル（ＮＩＴＩＮＯＬ）合金で作られたものが示されている。血管内に置いた後このコイルが加熱されてもとの大

きさ及び形状を取戻すように加熱される。これら従来例に示された解決策では装置に熱か機械力かを加え、ステントをその場で拡張する結果人体を傷つけることになる。

米国特許第4，580，568号明細書及び図面に示すものにおいてはステントが細かいジグザグ模様にした0.45mm（0.018インチ）のステンレススチール・ワイヤより作られている。このステントを血管系内にステントを配置するのに用いるシース内にこのステントを取付けるため圧縮してその寸法を減少する。ステントをその通路内に置いて保持するためこのシース内を通す平らな端末をもったカテーテルが用いられるがこのシースが引き抜かれている間にステントを原型まで拡張し通路を拡張できるようにする。仕様書によればこのステントが原型に復するためのエネルギー分のみが曲げられたステント内に貯えられていたことになる。

この装置及びその付与装置は多数の制約及び問題点に悩まされていた。

一連のワイヤをジグザグ模様に折り曲げるようステントを格好付けるにはステントの両端でワイヤを極端に曲げて格好を付けなければならない。このワイヤはワイヤ径の数倍の割合でのみ曲げ得る。正確な倍数は材料の性質によって変わる。

この公知例の特許では、0.04572センチメートル（0.018インチ）径のワイヤを用いており、その曲げ程度は、0.2センチメートル以下である。この曲げ率はおよそ1から4.37となる。ワイヤが曲げられてジグザグ模様となるので隣の脚との間にある程度の角度があり、これが脚間の最小スペースを限定することになる。ステントが短い時はステントを圧縮するに大きい力を必要とする。と言うのはエネルギーが曲がりのみに貯えられるからである。ステントがその直径に比し比較的短い時にはワイヤを曲げてステントを圧縮するに要するに力は大きい。これまた、曲がり部分のみがエネルギーの貯わえられる場所だからである。ステントがその直径に比し比較的長く作られた時には血管を開いて保持しておくに必要な力は減る。

クレームには完全拡張で長さ5.5cm×径4cm及び長さ3.0cm×径2.5cmのステントを特に取り上げている。この比較的大きい長さ及び直径は力が管器官に広く兼用できることになるが非常に大きい末梢動脈・静脈のみにしか適用できないことは明らかである。もう1つの作用はステントが圧縮し得る絶対的の最小寸法にある。前述したように端末における隣接ワイヤ間の角度関係はその隣接ワイヤ間の最低間隔を限界し、これはステントの最小寸法を冠状動脈及びこれと同等な寸法の血管には兼用できない寸法に限定してしまう。

更に加えて、ワイヤの直径と材料組成はその長さにわたり連続であるから、これらのパラメータは変わらずジグザグの曲がり部と直線部との間に異なった特性を与える。材料の曲がり部分のみが貯えられるエネルギーに関与するので、曲がり部対直線部との特性はすべての要求、特に生体適応性材料使用の必要性が加わった時は当然に兼用できることにはならない。更に1本のワイヤでジグザグ模様を緻密に完成させるにはスリーブを2つの末端におき、ワイヤを一緒に接続するがこれはこの点において異質性を生ずる。

＜課題を解決するための手段＞

本発明においては従来のこれらの本来的の制約を回避するのに全く従来と異なる解決手段を採り、個々の部分を一緒に溶接し、材料の曲げ部の必要性を完全に排除した。

この手段は上述に列挙した制限・制約すべてを解決する。

本発明によるステントは他の解決手段としてワイヤの本数を少なくして用いない限り必要とする脈管寸法までは縮径出来ないような特に小直径の冠状動脈でも用い得る。

もし本数の少ないワイヤが用いられたとすると、血管壁にかかる力も血管壁を覆う力も甚だしく限定されることになる。

このステントの付与装置は人体の外部から狭窄領域に対するステントの位置決め手段はもたない。案内ワイヤも用いられず、ステントがカテーテルの近位端から挿入されて用いられる。

＜発明の概要＞

本発明は病変した冠状動脈あるいはその他太い脈管の経皮的透視式脈管形成術（ＰＣＴＡ）あるいは経皮的脈管形成術（ＰＴＡ）がどちらかであるバルーン式脈管形成術に関連して用い、術後の脈管の急性の再閉塞とか再狭窄を防止する予防ステントを特徴とする。

本ステントは手術の延長として、バルーン式形成手術後直ちに施す。本ステントは末端が開放しているチューブ形状でありこれはワイヤの組がその端末で最終的に軸に対し斜め方向になるように一緒に溶接され、次いでこれが筒状に成型され端末ワイヤが一緒に溶接される。この構成を採ることにより、ワイヤは一端から反対端へと斜めに接続される。このワイヤは曲げて密にまとめ得るようなスプリング材であって小直径チューブに変形でき、直線セグメントにエネルギーを貯えるが圧縮力が除去されるとワイヤが斜めのワイヤから自己拡張して元の筒状体直径への力を発する。この回復力は動脈を拡張した位置に保持しておき且つ動脈を閉止しようとする他のすべての力に抵抗するに適当である。この選ばれたステント構造は動脈を支持するこの構造体の若干割合部分が新血管内膜層の組織成長を与え、プラーク（平滑斑）あるいはその他の繊維成長を防止し又再狭窄を遅らせたりもする。本ステントはステントを取り囲み圧縮する外側カテーテルを用いて経皮的に挿入され、その圧縮されたステントと同等の直径を有し同等の寸法を有する内側カテーテルを用いて該ステントを外す。内側カテーテルを通る案内ワイヤが患部へステントを置く助けをし、一方、外側カテーテル上のオプショナルな案内カテーテルが動脈内への内・外カテーテルの挿入の助けをする。この案内ワイヤは従来のバルーン式形成術に用いた案内ワイヤと同じものでよい。

ステント自体の位置はフレオロスコープあるいは同様の装置を用いてカテーテル端上の放射線不透過性マーカを監視し決定しステントを適正な場所に置くことができるようにする。ステント自体はプラチナあるいはプラチナイリジウムのような放射線不透過性材料より作ることもでき、同じフレオロスコープ技術を用いてステントを狭窄部位に容易に配置できるようにする。本ステントは開通状態を確保しこの部位における急性の再閉塞及び再狭窄を防止する。

＜実施例＞

第１図は、本装置を構成する個々のワイヤ10がまだ曲げられず成形もされない状態を示す。第２図においては溶接部12がワイヤ10の末端を１本おきに接続している状態を示す。ここに使われたワイヤは生体適応金属のいずれかである。この生体適応金属は３１６ＬＳＳのような３００シリーズステンレススチール、プラチナ及びプラチナイリジウム合金、ＭＰ３５Ｎのようなコバルトークロミウム合金及び非合金チタン等を含む。溶接部は冠状動脈に適用するためには代表的な長さ１ないし２ミリメートルの範囲にある。例えばＮｄ／ＹＡＧレーザが約５ワットの出力で用いられこの溶接を達成するが、抵抗溶接のような溶接工程を用いる事もできる。

第３図においてはワイヤ10の曲がり部14は各溶接部12において“Ｖ”形態をとる。これら１２本のワイヤ10は第３図に示すように一緒に溶接され、第４図においては、筒状ステント100の形態に成形されるがこの筒体形状はワイヤ端末を一緒に溶接することで達成される。曲がり部14はワイヤ10が第３図に示すように一緒に溶接された後に成形されてもあるいは溶接前に成形されてもよいが、何れの場合でもワイヤは曲がり部により離間され筒状体全表面積の若干パーセント、例えば10～25％程度だけが金属より成る。この金属部面積が小さいことについての利点は後で説明する。

ステント100を形成するこの方法はワイヤ端末が単に溶接されるのみであるから所要とする特性をもった所望するワイヤを利用できる。例えば変型としてワイヤ10を所望とする角度に曲げて、この曲げられたワイヤを筒状に成形保持させ、単純なジグ及び固定具を用いて全構成体を溶接で閉じ合わせてもよい。

この手法で変更できるものはワイヤ寸法、利用

金属、ワイヤ長さ、溶接長、曲げ角度及び筒体直径である。冠状動脈に対しては直径約1/10mm（0.004インチ）程度のワイヤで長さ4～15mm、ステント直径で2～5mmのものが用い得る。このような冠状動脈ステントに用いられるワイヤの本数はステントの直径により8～16本にわたり変更できる。このように冠状動脈に適用するに必要な特に小寸法のものなど、どんな所要とする冠状動脈の要求にも応えられるように容易に製造調製できる。これら範囲のワイヤ寸法及びステント寸法は上述したように筒状体全表面積に対する金属外部表面積を代表的に10～25%となし得る。

より太い末梢動脈については直径0.15mm（0.006インチ）ないし0.4mm（0.016インチ）、長さ10ないし25mmのワイヤであって、ステント径が5～15mmのものが利用できる。ここに用いられたワイヤの本数はステントの直径により8～16本と変更される。

第4図にはステント100の側面図を示す。この図は個々のワイヤで形成した筒状体を示す。第5図はワイヤが一緒に溶接された端末におけるワイヤ10の1対間の間隔が均一であることを示し、第6図はステントの半分長のところの個々のワイヤ間が均一の間隔であることを示す。

第4、5、6図においては、ステント100はワイヤ10が最大限度に離れてエネルギーを貯えず、完全な不拘束状態にある。第7図においては、ステント100は外側カテーテル16内に包囲圧縮され、ステント100の長手軸方向に案内ワイヤ18が通されている。このステント100の大きさはこれが圧縮された時にワイヤ18をステントに容易に通すことのできる寸法である。内側カテーテル20の大きさは外側カテーテル16内に嵌合する大きさであるが内側カテーテルが外側カテーテル内を容易に滑ることのできる材質のものである。内・外側カテーテル20、16の両方の端末には放射線不透過性マーカ22があり、これは装置本体外部のX線励起及びフレオロスコープ監視装置の利用により、これらカテーテルの位置を測定可能とする。特別な案内カテーテル21が外部カテーテル16を包囲する。

これら以上の部材すべてが動脈28内に挿入されるがこれについては後述する。動脈28は狭窄部位30を有し、これが動脈を一循する。第8図においてステント100が外側カテーテル16から外され、これが狭窄部位30を支える。狭窄部位30でのステント100の取り外しを達成する装置及び手順については後述する。

第9図においては、内・外カテーテル20、16、案内ワイヤ18及び案内カテーテル21が示されている。標準Y－コネクタ止血弁24、26は夫々のバルブ調節キャップ25、27と一緒になって出血を制御する。止血弁24は中央孔を有しこれは内側カテーテル20が滑り挿通出来るような寸法である。止血弁26も中央孔を有しこれは外側カテーテル16が滑り挿通出来るような寸法である。

ハブ23は中央孔を有しこの寸法は案内ワイヤ18が滑り挿通出来る大きさである。この構成はキャップ25、27が締まっている位置からゆるめられ図示していないOリングを夫々自由にして隣接部品が滑り得るようにした時に内・外カテーテル20、16が互いに滑り動けるようにする。調節ができた後はキャップ25、27が再び締められ、隣接部品に対し、Oリングを締め付けその相対的動きを止め、血液の流出を封止する。案内カテーテル21は外側カテーテル16を取り囲み、近位端ハブ26Aにより止血バルブ26に固定される。

動脈28に対してバルーン式形成手術を施すには第7図に示すようにしてなされ、狭窄部位30にわたり血管内腔を伸張、変形あるいは拡張する。案内ワイヤ18及び案内カテーテル21はバルーン式形成術に用いたものと同じものであり、外側カテーテル16を案内するためその場に残される。バルーン式形成施術の後、内・外カテーテル20、16及びステント100は、第7、9図に示すように組み立てられ、動脈28内に置かれるが、外側カテーテルの末端にステントが予め装着されており、このステントを圧接して内側カテーテルがあり、そして外側カテーテルは第9図に示すように案内カテーテル21内に包囲されている。このようなステント100を装填する方法は後述する。これらの部品は

全部予め消毒され、バルーン式形成施術に用いられたと同じ経路を通り同じやり方で血管内に挿入されていくが、患部をX線照射して患部付近をフレオロスコープで観察し放射線不透過のマーカ22の位置を監視する。ステント100が放射線不透過性材料の1つで作られた場合にはこれも又位置監視される。

案内ワイヤ18は内側カテーテル20の内部に挿通され、内・外カテーテルはステント100の患部への挿入及び位置決めの間、第9図について前述したようにバルブキャップ25,27を締めることにより、近位端において共に係止せられる。内側カテーテル20は第7図に示すようにステント100の近位端を押圧するので、これはステント100の狭窄部位30内への挿入位置決定中、固定されたカテーテル16及び20に関してステントが同じ相対位置に保持されることを保証するものである。内・外カテーテル20,16の端末からステント100へ至る距離は分かっているので、ステントの遠位端の位置は決定できる。前述したようにステント100自体が放射線不透過性にされれば、フレオロスコープでその位置は容易に決定できる。案内ワイヤ18はカテーテル16及び20よりも可撓性大きく、カテーテルを動脈内に持っていくのに用いられる。案内カテーテル21が予め動脈にぴったりと隣接しておかれ、残りの組立体の案内カテーテルを通って滑り込まされ、この手順が完了する。患者の体に接しておかれるフレオロスコープがステント100が第7図に示すように狭窄部位に置かれた時を指示する。次にバルブキャップ25がゆるめられ、ハブ23及びバルブ24により位置保持されている内側カテーテル20が近位方向に動かされステントが第8図に示すように外されるまで外側カテーテル16を内側カテーテルより引き抜く。外側カテーテル16が引き抜かれるこの経過において、内側カテーテル20はステント100をその場所に保持する。ステント100が外側カテーテル16から外された時このステントは図示してあるように自分で拡張し、狭窄部位30の領域に対しこれを支え且つ固定する。ステント100が外された後は全組立体が引き抜かれステントのみが血管中に残る。この簡単な手続はバルーン式形成術のような一般のカテーテル法のみを必要としてステント100を狭窄部位に配置することができる。

ステント100の設置はバルーン式形成術の追補的手順であって同じカテーテル法中としてなされ、このカテーテル法に要する時間が若干長くなるに過ぎない。この手順の結果によるこの若干の時間延長は人体が十分耐え得るものである。ステント100が拡張されるとこれは全方向外方に向いたラジアル力を発揮するようにして狭窄部位の血管内壁を支える。

この力は2つの重要な作用をなす。1つの作用はけいれん等による血管内方への力に抗して血管を開いた状態に保持し、前もってなされたバルーン式形成術によって生じた血管内膜フラップあるいは切片を本質的に添着し血管の通りをよくする。この力は前述したパラメータの選択により調節できる。この力の第2の作用は血管28の内壁内にワイヤを強固に固定することである。この第2作用はステント100のワイヤ10の上に組織の発芽あるいは新しい内膜の早期再生を助け、再狭窄が減多に生じないようにする。前述したように金属表面積の割合が小さいことはこの早期再生ができるようにし、かつ血栓による急性の閉塞の防止にも役立つ。

前述したように、ワイヤ10によって生ずるスプリング力は所与の手順によって調節できる。このスプリング力は動脈28を完全に開いて保持するに十分な力でなければならないし、また血管収縮力、けいれん及び狭窄部位30に生じてくる新たなプラークの逐次発生に対抗できなければならない。また、と言ってこの力は血管壁の損傷を避けるため上記要求以上の力であってはならない。

ステント100の直径は、外側カテーテル16内に嵌着させるために圧縮される時はその寸法が2～6分の1まで縮径される。この寸法調節の範囲及びスプリング定数の変化範囲は拡張力の調節を所望とする大きさに変えられるようにする。

前述したように、ステント100の代表的寸法は

外側カテーテル16内に嵌め込むために圧縮した時の最小外径寸法2～4㎜、太い動脈血管内で外した時の5～15㎜から、外側カテーテル16内に嵌めこむために圧縮した時の1～1½㎜、冠状動脈内に外した時の2～5㎜の範囲である。

ステント100の長さは場合によって甚だ差があり、狭窄部位の長さに適合できる程度のものであるが、狭窄部分の長さより常に長くなければならない。プラークあるいは病変部位の前後の血管の曲がりくねりとか曲がり角がある場合、ステント100の適用に融通性をもたせるため、ステントの長さを狭窄部の長さより短くし曲がった血管部分あるいは外側カテーテル16において1つ以上のステントをたてに並べ、カテーテルの曲がりがステントの端末同志の間の点で得られるようにすることができる。

ステント100を外側カテーテル16に装着するに総体的に筒状をした特殊な道具32が用いられる。この道具32の断面を第10図に示すがこれは筒状体の一端から内方へ延びるフレア付開口34及び外側端からの円形ボア36とを有し、これら2つの部分の間のフラット部38を有する。外側カテーテル16が道具32の中にボア36の底まで押入され、そして内側カテーテル20がボア36に入る一寸手前にもってこられると共に一方案内ワイヤ18はこのボア及びフレア付き開口両方共貫通して本道具を完全に貫通する。外側カテーテル16、内側カテーテル及び案内ワイヤ18は前述した方法でバルブキャップ25,27を用いてこの関係で固定せられる。

次に、ステント100はフレア付開口を通して押し込まれるがこの開口34はステントがフラット38を越えてボア36に至るのを案内し、ボア36ではステント100がスプリング力で開く。これを第11図に示しこれでステント装填作業が完了する。道具32は次にカテーテル16の周りから取り除かれる。

＜発明の効果＞

ステントは組立容易であり、ワイヤは溶接により接合されるのであるからワイヤ寸法及び材質は所望とするラジアル力及び対象血管寸法のみに基づき選ぶことができる。溶接はワイヤ接点におけるワイヤ間間隔が0であるからどんなワイヤでも溶接できる。冠状動脈に必要とする特に細いステントでもこの技術を用いれば容易に作ることができる。

内・外カテーテルの端末にあるマーカとしての放射線不透過材料の利用は、ステント自体に放射線不透過材料を用いたのと同様にフレオロスコープを用いるだけでステントを正確に位置づけることができる。ステントを外側カテーテル内部に積極的に係止するため円形断面を有する内側カテーテルの利用はステントが容易に外れ易くすることになる。と言うのは、圧縮されたステントの拡張しようとする力が外側カテーテルの内壁を押しつけ支えるようにしているからである。この装置はどんな要求にも容易に応え得るパラメータをもった簡単な構造である。

Y－コネクタ止血バルブ24及び26の利用はステント100の位置における動脈の形状寸法を測定することが必要な時に放射線不透過の薬剤を含ませた液体を注入もできるようにする。必要ならばステント100を設置した後に案内ワイヤを除去してこのスペースを液体注入に利用できる。

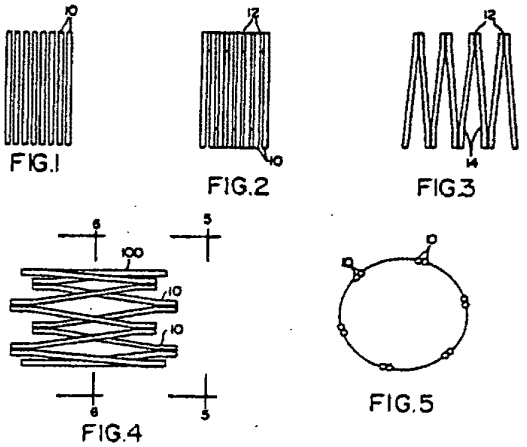
本発明は図示された実施例について説明されたが、この説明は発明を限定する意味で説明しようとするものではない。図示された実施例の種々変型並びに本発明の他の実施例は本明細書を参考にすれば当業者にとって明白であろう。従って請求範囲は以上のような変型あるいは他の実施例をすべてその範囲に含まれるものとして記載されている。

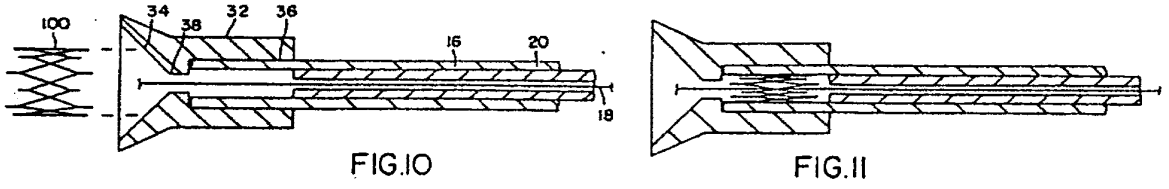
4．図面の簡単な説明

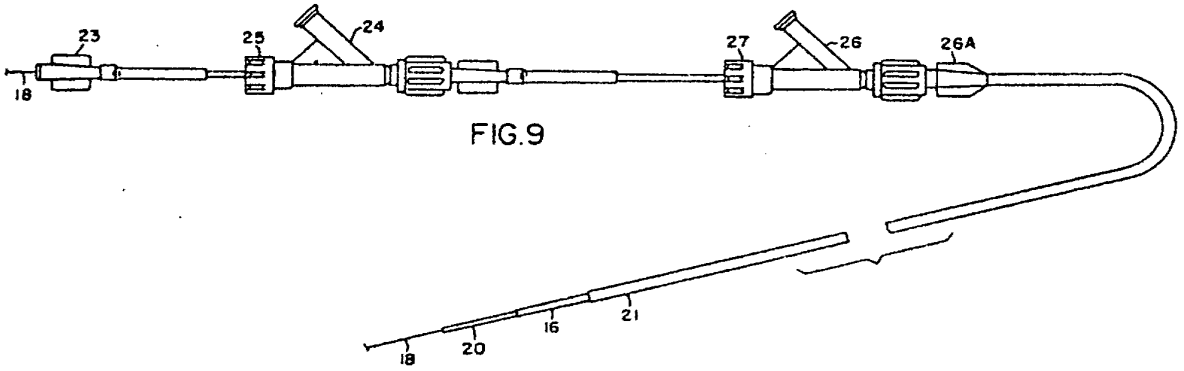
第1図はアタッチメントに整列された個々のワイヤの前面図、第2図は個々のワイヤが一緒に溶接された場合の前面図、第3図は溶接されたワイヤの曲がり部が筒状に成形されない前の前面図、第4図はステントの側面図、第5図は第4図5－5線で切った略図、第6図は第4図6－6線で切った略図、第7図はステントが動脈内に置かれる前の状態を示し、内側カテーテル、外側カテーテ

ル、案内ワイヤ及び装着されたステントと共に動脈の縦方向断面を示した図、第８図はステントを外側カテーテルを引き抜くことによりステントを外し動脈中に置いた後の状態を示す図、第９図はＹ－コネクタ止血バルブ及び案内カテーテルと一緒に組込んだ内・外カテーテル及び案内ワイヤを示す図、第１０図はステントを外側カテーテルの適正位置に装填する道具の断面図、第１１図は外側カテーテル内にステントが装填された状態の第１０図の断面を示す図である。

10…ステントワイヤ，　12…溶接部
14…曲げ部，　16…外側カテーテル，
18…案内ワイヤ，　20…内側カテーテル，
21…案内カテーテル，　28…動脈，
30…狭窄部，　32…ステント装着道具，
100…ステント







第1頁の続き

⑫発　明　者　アラン　クリビエ　エ　フランス国　マローム　76150　ル　アラン　2
ム．デイー．

Citation 2'

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 346 564 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 89102879.7

(51) Int. Cl.4: A61F 2/66

(22) Date of filing: 20.02.89

(30) Priority: 17.06.88 US 208252

(43) Date of publication of application:
20.12.89 Bulletin 89/51

(84) Designated Contracting States:
CH DE FR GB LI NL

(71) Applicant: MEDTRONIC, INC.
7000 Central Avenue N.E.
Minneapolis Minnesota 55432(US)

(72) Inventor: Dance, Creg W.
19276 Twin Lakes Road
Elk River Minn. 55330(US)
Inventor: Letac, Brice
134 Rue Du Renard
F-76000 Rouen(FR)
Inventor: Wolff, Rodney G.
468 W. Eagle Lake Drive
Maple Grove Minn. 55369(US)
Inventor: Cribier, Alain
2 Rue Alain
F-76150 Maromme(FR)

(74) Representative: Kopacz, William James
83 avenue Foch (3 étage)
F-75116 Paris(FR)

(54) Compressive stent and delivery system.

(57) A cylindrical shaped stent (100) to prevent arterial acute closure and subsequent restenosis is inserted immediately after a balloon angioplasty procedure as an extension of this procedure. The cylinder is formed of longitudinal wires of biocompatible metal. The wires (10) are welded together in pairs at alternate ends with each pair of wires bent into a V-section. The wires (10) are all formed into a cylinder welded closed to form the stent. The stent is compressed and loaded into an outer catheter by a special tool. The stent is positioned and released for self expansion in situ by an inner catheter. A guide wire through both assists in threading the catheters through blood vessels. This guide wire can be the same one used in the prior balloon angioplasty if desired. An optional guide catheter encloses and directs the outer catheter to a point adjacent to the site. The stent (100) itself may be radiopaque or radiopaque markers on the distal ends of the inner and outer catheter can be provided and the radiopaque material detected by an external fluoroscope or x-ray to determine when the stent is at the desired prior balloon angioplasty site to position the stent properly. Hemostasis valve connectors at the proximal ends of the inner and outer catheters control bleeding, and permit injecting radiopaque dye or other therapeutic agents at the stent site. The hemostasis valves also permit relative adjustment of the various catheters necessary for releasing the stent (100) within the artery.

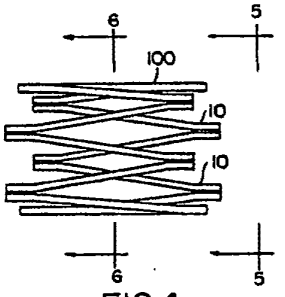


FIG.4

EP 0 346 564 A1

COMPRESSIVE STENT AND DELIVERY SYSTEM

TECHNICAL FIELD

The present invention relates to an intravascular stent which can be applied within the peripheral or coronary arteries of living animal or human being to maintain patency after a balloon angioplasty, either a percutaneous transluminal coronary angioplasty (PCTA) or a percutaneous transluminal angioplasty (PTA) procedure. The stent comprises a tubular shaped structure made up of individual wires welded together which can be compressed along the axis to a smaller tubular diameter to fit within an outer catheter to hold the stent compressed, which is used along with an inner catheter to release the stent and a guide wire which are used after a balloon angioplasty to insert, position and fix the stent permanently at the angioplasty site to prevent acute reocclusion and subsequent restenosis. The construction of the stent is such that the dimensions and material of the device can be selected to provide a given radial force against the interior of the artery adequate to maintain the shape of the vessel against any force tending to close it. These closure forces include not only acute reclosure due to intimal dissections, flaps and spasm but also plaque restenosis. The latter is prevented or slowed by neointimal overgrowth on the stent itself. The length of the stent can also be varied or more than one stent can be used at a single location to accomodate curvature and other unusual arterial characteristics. Radiopaque marker material on the end of the inner and outer catheters permits locating the stent at the desired site by external monitoring or the stent itself can be made of radiopaque material.

Background Art

In U.S. Pat No. 4,553,545 a device which can be expanded after insertion in a blood vessel by rotating a wire coil about its length to reduce the number of turns and thereby increase the diameter is disclosed. In U.S. Pat No. 4,503,569 a helically wound coil is formed of a memory Nitinol alloy which has a transition temperature in the range of 115 degrees to 125 degrees Farenheit. After placement in the vessel this coil is heated to regain its original larger shape. These approaches require either heat or mechanical forces to be applied to the apparatus, in order to expand the stent at the site, with the result ing trauma to the body.

In U.S. Patent 4,580,568 a stent is formed of stainless steel wire of 0.018 inches diameter arranged in a closed zig-zag pattern. The stent is compressed to reduce its size in order to position it within a sheath, which is used to locate the stent within the vascular system. A flat-ended catheter is used through the sheath to hold the stent in place in the passageway while the sheath is withdrawn, allowing the stent to expand into its original shape to hold the passageway open and enlarged. According to the specifications the only energy stored in this stent to restore it to its original shape is stored in the bends.

This device and delivery system suffers from a number of severe limitations and problems. Fashioning the stent from a continuous wire folded in a zig-zag fashion requires a sharp bend in the wire at each end of the stent to form this shape. A wire can only be bent at a ratio which is some multiple of the wire diameter. The exact multiple will vary according to the property of the material. The example cited in the patent as claimed uses a wire of 0.018 inches in diameter which is equivalent to 0.04572 centimeters and a bend ratio of no more than 0.2 centimeters. This is a ratio of approximately 1 to 4.37. Since the wire is bent to form the zig-zag shape there must be some angle formed between adjacent legs which limits the minimum spacing between these legs. A large amount of force is necessary to compress the stent when the stent is short since energy is only stored in the bends. If the stent is made relatively short in length with respect to the diameter then the amount of force necessary to bend the wires in order to compress the stent becomes large. This again is because the bends are the only place that energy is stored. Only if the stent is made relatively long with respect to the diameter is the force required to hold a vascular vessel open reduced. The claims specified stents of specific sizes 5.5 cm long x 4 cm diameter fully expanded and 3.0 cm long x 2.5 cm diameter fully expanded. This relatively long length and diameter results in forces which are compatible with the vascular system but can obviously only be used in very large peripheral arteries and veins. Another effect is the absolute minimum size to which the stent can be compressed. As mentioned earlier the angular relationship between adjacent wires at the ends limits the minimum spacing between adjacent wires which in turn limits the minimum diameter of the stent to a size which is incompatible with coronary arteries and like sized vessels.

In addition, since the diameter of the wire and the material composition is continuous throughout its length, these parameters are not varied to pro-

vide different characteristics at the bends vs. the stralght section of the zig-zag. Since only the material in the bends themselves are involved in storing energy the characteristics of the bends versus the straight sections are not necessarily compatible for all of these requirements in particular when the addltional necessity for utilizing a bio-compatible material is added. Further, to complete and close the zig-zag pattern made up of a single wire a sleeve must be placed over the two ends to connect them together which results in an anomoly at the point.

We have taken an entirely different approach to the problem to avoid these inherent limitations of the previous system by using individual parts welded together to avoid the necessity for a bend in the material completely. This overcomes all of the limitations and restrictions enumerated above. Our stent is adaptable for use in coronary arteries with their extremely small diameter where the other approach because of the bend diameters results in a stent which cannot be reduced to the required coronary size, unless a far fewer number of wires are used. If far fewer numbers of wires are used, this greatly limits both the force applied to and the surface coverage of the vessel wall.

The delivery system has no means of locating the position of the stent relative to the stenosis site from the exterior of the body. No guide wire is used and in use the stent is inserted from the proximal end of the catheter.

Summary of the Invention

The present invention is characterized by a prothesis stent which is useful in conjunction with a balloon angioplasty, either a percutaneous transluminal coronary angioplasty (PCTA) or a percutaneous transluminal angioplasty (PTA) of diseased coronary arteries or any other larger arteries to prevent acute reclosure or restenosis of the artery after the procedure. The stent is applied immediately after the balloon angioplasty as an extension of the procedure. The stent is in the fom of an open ended tube formed by a set of angled wires which are welded together at the ends resulting in an offset angle, then formed into a tubular shape and the end wires welded together. Using this construction the wires are connected obliquely from one end to the opposite end. The wires are made of spring material which can be bent closer together to form a smaller diameter tube and will store energy in the straight segments, but when the compressive force is removed the wires will be urged by the force from the oblique wires to self expand to the original tubular diameter. This restoring force must be adequate to maintain the artery in an expanded position as well as resist all other forces tending to close the artery. The stent structure chosen results in a small percentage of this structure supporting the artery to allow tissue overgrowth of a neointimal lining to prevent or retard restenosis from the plaque or other fibrotic growths. The stent is inserted percutaneously using an outer catheter to enclose and compress the stent, and an inner catheter which has the same size and the same diameter as the compressed stent to release the stent. A guide wire through the inner catheter assists in positioning the stent at the stenosis site while an optional guide catheter over the outer catheter aids in inserting the inner and outer catheters into the artery. The guide wire can be the same guide wire used in the previous balloon angioplasty.

The location of the stent itself is determined by monitoring radiopaque markers on the catheter ends using a fluroscope or similar device to permit locating the stent at the proper site. The stent itself can also be made of radiopaque material, such as platinum or platinum irridium to readily permit locating the stent at the stenosis site using the same fluroscope techniques. The stent ensures patency and prevents acute reocclusion and restenosis at this location.

Brief Desctiption of the Drawings

Fig. 1 is a front view of the individual wires aligned for attachment.

Fig. 2 is a front view of individual wires welded together.

Fig. 3 is a front view of the welded wires bent prior to being formed into a cylinder.

Fig. 4 is a side view of the stent.

Fig. 5 is a schematic representation of Fig. 4 taken along 5-5.

Fig. 6 is a schematic representation of Fig. 4 taken along 6-6.

Fig. 7 is a longitudinal-section of an artery with inner catheter, outer catheter, guide wire and loaded stent before placing stent in artery.

Fig. 8 is the view of Fig. 7 after placing stent in artery by retracting outer catheter and releasing the stent.

Fig. 9 shows the inner and outer catheters and guide wire assembled together with the Y-connecter hemostasis valves and guiding catheter.

Fig. 10 is a cross-section view of the stent loading tool in position for loading the stent into the outer catheter.

Fig. 11 is the cross-section view of Fig. 10 with the stent loaded into the outer catheter.

Description of the Preferred Embodiment

Referring to Fig. 1, individual wires 10 making up the device are shown before bending and shaping. In Fig. 2 welds 12 are shown connecting alternate ends of wires 10. The wires used can be any of the biocompatible metals. Biocompatible metals include some 300 series stainless steels, such as 316LSS, platinum and platinum-irridium alloys, certain cobalt-chromium alloys such as MP35N, and unalloyed titanium. The welds typically range in length from 1 to 2 millimeters for coronary artery applications. As an example, a Nd/YAG laser can be used at approximately 5 watts power to accomplish this weld although it is also possible to use other weld processes here such as resistance welding.

In Fig. 3 bends 14 in the wires 10 form a "V" at each weld 12. Twelve of these wires 10 shaped and welded together as shown in Fig. 3 are shown in Fig. 4 formed into a cylindrical configuration to form a tubular shaped stent 100 with cylinder completed by welding together the end wires. Bends 14 can be set after wires 10 are welded as illustrated in Fig. 3 or can be set before the weld, in either case the wires are spaced apart by these bends such that only a small percentage of the cylinder surface area, on the order of 10 to 25 percent, is made up of metal. The advantages of this minimal metal surface area will be discussed later.

This method of forming stent 100 permits utilizing any desired wire with any required characteristics since the ends of the wires are simply welded together. As an alternative, wires 10 can be bent to the desired angle, the bent wires formed and held into a cylinder shape, and the total structure welded closed using simple jigs and fixtures. The variables permitted by this approach include wire size, material used, wire length, weld length, the angle of bend and the cylinder diameter. For coronary arteries wires as small as 0.004 inches in diameter can be used with wire lengths which range from 4 to 15 millimeters and stent diameters of from 2 to 5 millimeters. The number of wires used in such coronary stents can vary from 8 to 16 over the range of stent diameters. These extremely small sizes which are necessary for coronary artery applications, can be readily manufactured and tailored for any desired coronary artery requirement. These ranges of wire size and stent size permit the external metal surface area of typically 10 to 25 percent of the total cylinder area stated above.

The larger peripheral arteries can utilize a wire diameter of .006 to .016 inches with a length of 10 to 25 millimeters and a stent diameter of 5 to 15 millimeters. The number of wires used here will vary from 8 to 16 over the range of stent diameters.

In Fig. 4 a side view of stent 100 is shown. This illustrates the tubular shape which the individual wires 10 form. Fig. 5 shows the uniform spacing between pairs of wires 10 at the ends where the wires are welded together while Fig. 6 shows the uniform spacing between the individual wires at the center of the stent length.

In Figs. 4, 5, and 6 stent 100 is shown completely unrestrained with wires 10 at their maximum separation storing no energy. In Fig. 7, stent 100 is shown compressed and enclosed within an outer catheter 16 with a guide wire 18 threaded through the longitudinal axis of stent 100. Stent 100 is sized such that the wire 18 will readily pass through the stent when it is compressed. An inner catheter 20 is sized to fit within outer catheter 16 but is sized and of materials such that inner catheter will readily slide within the outer catheter. Radiopaque markers 22 at the ends of both inner catheter 20 and outer catheter 16 provides a capability of determining the location of these catheters by using x-ray excitation and a fluoroscope monitoring device external to the body. An optional guide catheter 21 encloses outer catheter 16. All of these items are inserted within an artery 28, as will be described later. Artery 28 has a stenosis site 30 which encircles the artery. In Fig. 8 stent 100 is shown released from outer catheter 16 supporting stenosis site 30. The equipment and procedure used to accomplish the release of stent 100 at stenosis site 30 will be descirbed later.

In Fig. 9 the assembly of inner catheter 20, outer catheter 16, guide wire 18 and guide catheter 21 are shown. Standard Y-connector hemostasis valves 24 and 26 in conjunction with respective valve adjuster caps 25 and 27 control bleeding. Hemostatis valve 24 has a centered hole sized to permit inner catheter 20 to slide through. Hemostasis valve 26 has a centered hole to permit outer catheter 16 to slide through. Hub 23 has a centered hole sized to permit guide wire 18 to slide through. This arrangement permits inner catheter 20 and outer catheter 16 to slide relative to each other, whenever caps 25 and 27 are loosened which frees respective O-ring in each, not shown, from a closed position to permit the adjacent parts to slide. After the adjustments are made caps 25 and 27 are again tightened which again closes the O-rings against the adjacent parts which again prevents relative movement and seals against blood loss. Guide catheter 21 encloses outer catheter 16 and is secured to hemostasis valve 26 by proximal hub 26A.

In use a balloon angioplasty procedure is performed on the artery 28 shown in Fig. 7 to expand, remodel, or enlarge the vessel lumen through stenosis site 30. Guide wire 18 and guide catheter

21 can be the same items used in the balloon angioplasty and left in place to guide outer catheter 16. After the balloon angioplasty procedure then guide wire 18, inner catheter 20, outer catheter 16 and stent 100 are assembled as shown in Figs. 7 and 9 and located within artery 28 with the stent previous loaded in the end of the outer catheter, and the inner catheter bearing just proximal to the stent with the outer catheter enclosed in guide catheter 21, as shown in Fig. 9. The method of loading stent 100 in this fashion will be described later. All of these parts are previously sterilized then threaded through the vessels in the same manner and using the same path as that used for the balloon angioplasty procedure while monitoring the location of radiopaque markers 22 by illuminating the site by x-ray and observing the markers by a fluoroscope adjacent to the site. The stent 100, if made from one of the radiopaque materials, can also be monitored to determine its location.

Guide wire 18 is run inside inner catheter 20 and both the inner and outer catheter 20 are locked together at their proximal ends during the insertion and location of stent 100 at the stenosis site by tightening valve caps 25 and 27 as discussed earlier and illustrated in Fig. 9. Since inner catheter 20 bears against the proximal end of stent 100 as shown in Fig. 7, this will insure that the stent is held in the same relative position with respect to locked catheters 16 and 20 during this insertion and location of stent 100 within stenosis site 30. The distance from the end of inner catheter 20 and outer catheter 16 to stent 100 is known, consequently the location of the distal end of the stent can be determined. Further, as discussed earlier, if stent 100 itself is made radiopaque, it can readily be located by a fluoroscope. Guide wire 18 being more flexible than catheters 16 and 20 is used to steer the catheters into the artery. Guide catheter 21 is previously positioned just adjacent to the artery, and the remainder of the assembly slid through the guide catheter to complete the procedure. A fluoroscope adjacent to patient's body indicates when stent 100 is located adjacent stenosis site 30 in the position shown in Fig. 7. Then valve cap 25 is loosened, inner catheter 20 held in position by hub 23 and valve 24 moved proximally to withdraw outer catheter 16 from about the inner catheter until the stent is released as shown in Fig. 8. During this process inner catheter 20 holds stent 100 in place as outer catheter 16 is withdrawn. When stend 100 is released from outer catheter 16 the stent will self expand as shown to support and fixate against the area of stenosis site 30. After stent 100 is released then the entire assembly is withdrawn leaving only the stent in place within the vessel. This simple procedure requires only the same general catheterization techniques as the balloon angioplasty to locate stent 100 at the stenosis site.

Placement of stent 100 is thus a complimentary procedure to a balloon angioplasty which is performed during the same catheterization and which lengthens the balloon angioplasty procedure by only a few minutes. This brief extension of time results in this procedure being well tolerated by the body. When stent 100 expands it bears against the interior wall of the vessel at stenosis site 30 to provide a radial outwardly directed force in all directions.

This force has two major effects. One effect is to hold the vessel open against any inner directed force, such as spasm, and essentially tacks up intimal flaps or dissections generated by prior balloon angioplasty to assure the patency of the vessel. This force is tailored by a selection of the parameters which were discussed earlier. The second effect of this force is to securely fixate wires 10 within the interior wall of vessel 28. This second effect will assist in the early regeneration of tissue overgrowth or neointima over the wires 10 of stent 100 making restenosis less likely. The small percentage of metal surface area, noted earlier, permits this early regeneration, and also aids in prevention of acute closure due to thrombosis.

As mentioned earlier, the spring force developed by wires 10 is tailored for the given procedure. The force must be sufficient to maintain artery 28 fully open and to also resist vasoconstrictive forces, spasm and the possible progressive development of an additional plaque buildup at the location of stenosis site 30. The force must not be excessive beyond these requirements however to avoid traumatization of the vessel wall.

The diameter of stent 100, when squeezed to fit within outer catheter 16, is reduced from two to six times in size. This range of size adjustments plus the variation in spring constant possible permits the adjustment of the expansion forces to the amount desired.

As mentioned, typical sizes for stent 100 have a range from a minimum external diameter of 2 to 4 millimeters when compressed to fit within outer catheter 16 to 5 to 15 millimeters when released within a large arterial vessel, to a range from a minimum external diameter of 1 to 1 1/2 millimeters when compressed within outer catheter 16 to 2 to 5 millimeters when released within the coronary arteries.

The length of stent 100 is likewise adapted to the length of the stenosis, which may be quite variable from one case to the other, but should always be longer than the stenotic segment. To make the applications of stent 100 more flexible, in case of tortuosities or angulations of the vessel at or before the plaque or lesions site, the stent can

be made shorter than the stenosis with two or more stents placed in series to each other at the curved vessel site or in outer catheter 10 so that an angulation of the catheter can be obtained at the point between the end-to-end stents.

In order to load stent 100 into outer catheter 16 a special generally cylindrically shaped tool 32 is utilized. Tool 32, shown in cross section in Fig. 10, has a flared opening 34 extending inwardly from one end of the cylinder and a circular bore 36 from the outer end with a flat 38 between the two. Outer catheter 16 is inserted within tool 32 to the bottom of bore 36, and inner catheter 20 is positioned just short of entering the bore while guide wire 18 extends completely through the tool through both the bore and flared opening 34 of tool 32. Outer catheter 16, inner catheter 20 and guide wire 18 are locked together in this relationship using valve caps 25 and 27 in the manner previously described. Stent 100 is then pushed through flared opening 34 which guides the stent past flat 38 into bore 36 where it will spring open in the bore, as shown in Fig. 11, to complete the loading operation. Tool 32 is then removed from about outer catheter 16.

The stent is easy to fabricate and because the wires are attached together by welding the wire size and material can be selected based only upon the desired radial force and vessel size. Since welding results in a zero spacing between the wires at the point of attachment any size wire can be welded. The extremely small stents necessary for the coronary arteries can thus be readily fabricated using this technique.

The use of a radiopaque material as a marker on the ends of the outer and inner catheters permits locating the stent precisely using only a fluoroscope, as does using a radiopaque material for the stent itself. The use of an inner catheter which has a circular cross-section to positively engage the stent inside the outer catheter assures that the stent will be released easily because the expansion forces of the compressed stent will cause it to bear against the inner wall of the outer catheter. This device is simple in construction with para meters which can readily be adapted to meet any requirement.

The use of Y connecter hemostatis valves 24 and 26 permits the injection of liquid containing radiopaque dye if it is necessary to determine the shape and size of the artery at the location of stent 100. If desired guide wire 18 can be removed after stent 100 is in place and this space used to inject liquids.

While this invention has been described with reference to an illustrative embodiment, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiment, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments as fall within the true scope of the invention.

Claims

1. A stent comprising:

(a) a number of equally dimensioned and shaped wires each having an essentially straight center segment with end segments bent at oblique angles with respect to said center segment such that opposite said end segments of each said wire are essentially parallel one end segment to the other; and

(b) said wires oriented and equally spaced to form a tubular shape said bent end segments of each wire oriented parallel, overlapping and contiguous with each adjacent wire, resulting in an acute angle being formed by said center segments of each adjacent pair of wires, being secured together at all end segments; and

(c) said wires fashioned from spring metal biocompatible material, such that said wires can be bent to store energy in said wire segments to permit reducing the diameter of said stent to permit inserting said stent into an outer catheter sized to receive said stent when compressed to permit placing said stent percutaneously within a living organism; and

2. The structure as in Claim 1 and further comprising an inner catheter sized to slideably fit within said outer catheter with the walls of said inner catheter sized to bear against the end of said stent when said inner catheter is fit within said outer catheter and said stent compressed to fit within said outer catheter.

3. The assembly as in Claim 1 wherein said inner and outer catheter are tipped with a radiopaque marker at their distal ends adjacent to said stent.

4. The structure as in Claim 2 wherein a guide wire is threaded coaxially through said inner catheter and said stent and wherein said inner catheter and said stent are sized to permit said guide wire to be slid through their respective centers as an aid in threading said catheters through a circulatory system.

5. The structure as in Claim 4 wherein said outer catheter is threaded coaxially through a guide catheter sized to slideably receive said outer catheter to provide guiding means in said circulatory system for said outer and inner catheter.

6. The structure as in Claim 4 wherein said inner catheter can be slideably locked and sealed to said outer catheter by means of a first Y-connector hemostatis valve and said guide wire is exposed at the proximal end to permit slideable adjustment of said guide wire with respect to said inner catheter.

7. The structure as in Claim 5 wherein said inner catheter can be slideably locked and sealed to said outer catheter by means of a first Y-connector hemostasis valve and said outer catheter can be slideably locked and sealed to said guide catheter by means of a second Y-connector hemostasis valve and said guide wire is exposed at the proximal end to permit slideable adjustment of said guide wire with respect to said inner catheter.

8. The assembly as in Claim 1 wherein said wires are secured together by welding.

9. A generally cylindrical shaped tool having an axial bore from a first end and a flared axial opening from a second end joined by a coaxial segment, said tool being sized to provide a means for loading said stent within said outer catheter.

10. The assembly as in Claim 1 wherein said wires are made of a radiopaque material.

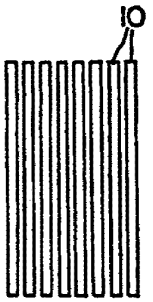


FIG.1

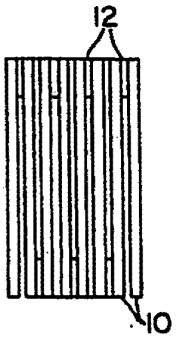


FIG.2

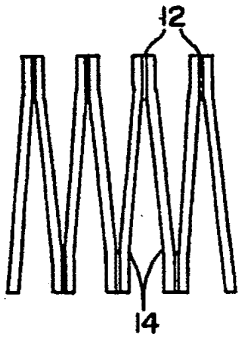


FIG.3

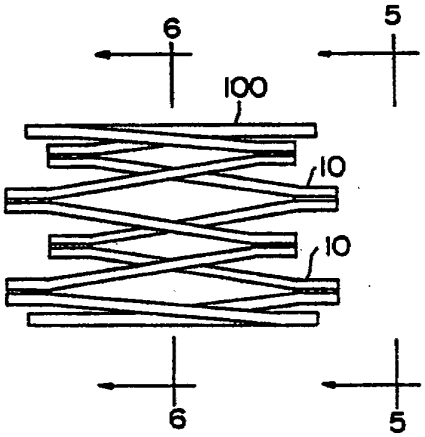


FIG.4

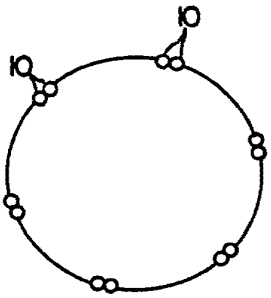


FIG.5

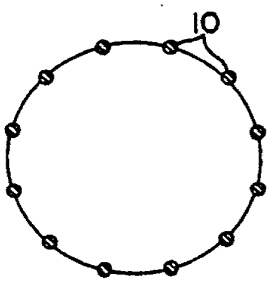


FIG.6

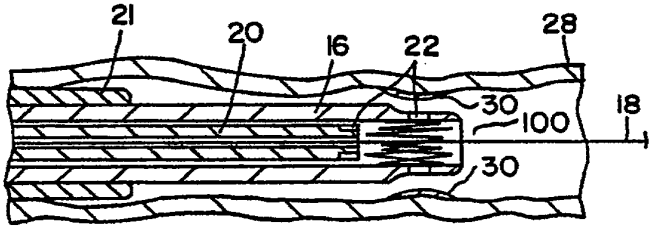


FIG.7

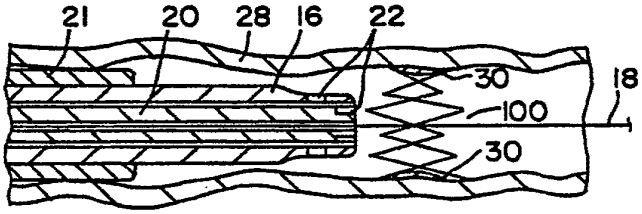


FIG.8

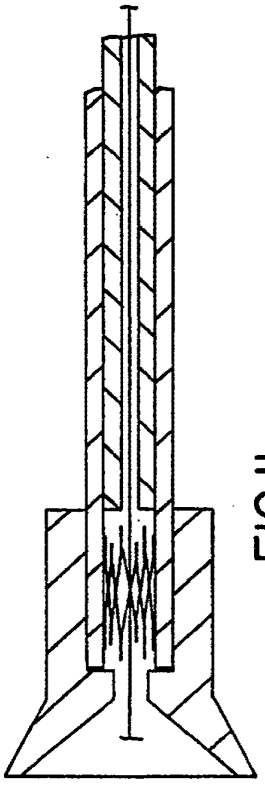


FIG.11

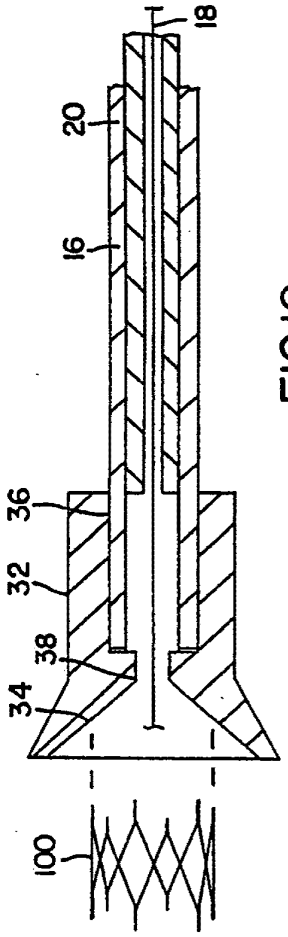


FIG.10

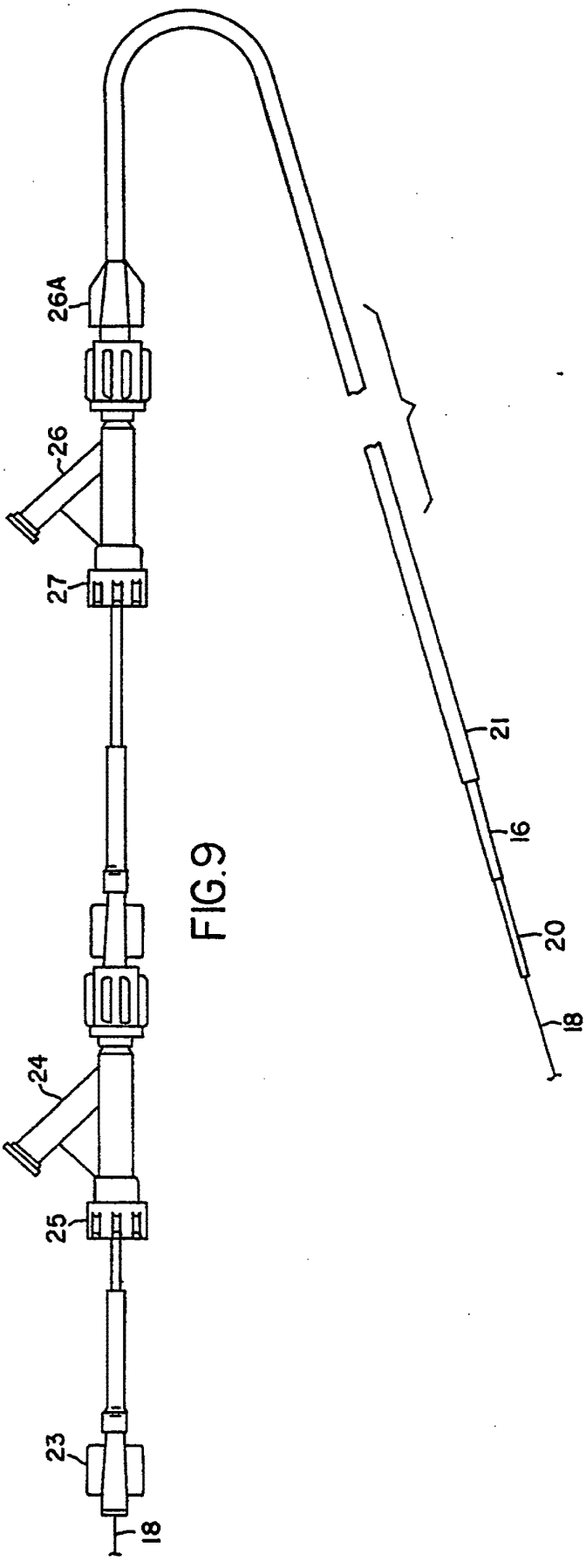


FIG.9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 10 2879

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	EP-A-0 221 570 (PALMAZ) * Abstract; figures *	1	A 61 F 2/06
D,A	EP-A-0 177 330 (COOK INC.) * Whole document *	1-3	
A	US-A-4 665 918 (GARZA) * Figures; claims 1,8,9 *	1-7	
A	DE-A-3 706 077 (SAVELIEV) * Column 7, lines 20-23; figures 6,7 *	9	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 F
A 61 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	15-09-1989	STEENBAKKER J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)

⑲日本国特許庁(JP)　　⑪特許出願公表

⑫公表特許公報(A)　　平4−500328

⑬公表　平成4年(1992)1月23日

⑤Int. Cl.[5]	識別記号	庁内整理番号	審査請求　未請求
A 61 F 2/06		7603−4C	予備審査請求　未請求　部門(区分)　1(2)

(全 10 頁)

⑭発明の名称　大動脈用継ぎ木、大動脈瘤を治療する埋込み装置及び方法

⑳特　願　平2−509878
㉒㉓出　願　平2(1990)6月15日
㉕翻訳文提出日　平3(1991)2月14日
㉖国際出願　PCT/US90/03322
㉗国際公開番号　WO90/15582
㉘国際公開日　平2(1990)12月27日

優先権主張　㉜1989年6月19日㉝米国(US)㉛367,716

㉒発明者　トラウト　ヒユー，エイチ．ザ　サード　アメリカ合衆国20008　ワシントン　デイー．シー．オードウエイ　ストリート，エヌ．ダブリユ．3037

㉑出願人　トラウト　ヒユー，エイチ．ザ　サード　アメリカ合衆国20008　ワシントン　デイー．シー．オードウエイ　ストリート，エヌ．ダブリユ．3037

㉔代理人　弁理士　浅村　皓　外3名

㉛指定国　AT(広域特許)，AU，BE(広域特許)，CA，CH(広域特許)，DE(広域特許)，DK(広域特許)，ES(広域特許)，FR(広域特許)，GB(広域特許)，IT(広域特許)，JP，KR，LU(広域特許)，NL(広域特許)，SE(広域特許)

請求の範囲

1．大動脈の部分の吻合をする大動脈継ぎ木であって、

頭部端及び尾部端を有しかつ軸線を有する大動脈継ぎ木装置と、

前記大動脈継ぎ木装置の前記頭部端及び尾部端に取付けられ前記大動脈継ぎ木装置を前記大動脈に固定する複数の取付け装置を有しており、前記取付け装置は、前記大動脈継ぎ木装置に取付けられ前記大動脈継ぎ木装置の前記軸線にほぼ平行に指向したベース装置と前記ベース装置に取付けられ前記大動脈継ぎ木装置からほぼ径方向外側に延びた支柱装置と、前記軸線に対しほぼ平行に指向し前記支柱装置の末端に取付けられ前記大動脈を通過し前記継ぎ木装置を前記大動脈に固定するフック装置を有していることを特徴とする大動脈継ぎ木。

2．請求の範囲第1項記載の大動脈継ぎ木において、前記大動脈継ぎ木装置がほぼ円筒状であることを特徴とする大動脈継ぎ木。

3．請求の範囲第1項記載の大動脈継ぎ木において、前記大動脈継ぎ木装置が弾性可撓性材料を有していることを特徴とする大動脈継ぎ木。

4．請求の範囲第1項記載の大動脈継ぎ木において、前記大動脈継ぎ木装置が体液に対して不活性な材料を有することを特徴とする大動脈継ぎ木。

5．請求の範囲第1項記載の大動脈継ぎ木において、前記フック装置がやじりフックを有していることを特徴とする大動脈継ぎ木。

6．請求の範囲第1項記載の大動脈継ぎ木において、前記大動脈継ぎ木装置がリテーナーリング装置を有しており前記大動脈継ぎ木の前記第1及び第2の端を前記大動脈の部分に係合当接して保持することを特徴とする大動脈継ぎ木。

7．大動脈の部分を吻合させる大動脈継ぎ木であって、第1及び第2の端を有するほぼ円筒状の大動脈継ぎ木装置と、前記大動脈継ぎ木装置の前記第1及び第2の端部に取付けられ前記大動脈継ぎ木装置を前記大動脈に固定する複数の取付け装置とを有しており、前記取付け装置は、前記大動脈継ぎ木装置の長手軸線とほぼ平行に前記大動脈継ぎ木装置に第1及び第2の端で取付けられたベース部材と、前記大動脈継ぎ木装置から径方向に延びて前記ベース部材に取付けられた支柱装置と前記大動脈を貫通して前記大動脈に前記継ぎ木装置を固定する前記支柱装置の末端に取付けられたフック装置とを有し、前記フック装置がやじりフックを有していることを特徴とする大動脈継ぎ木。

8．請求の範囲第7項記載の大動脈継ぎ木において、前記大動脈継ぎ木装置が弾性可撓性材料を有していることを特徴とする大動脈継ぎ木。

9．請求の範囲第7項記載の大動脈継ぎ木において、前記大動脈継ぎ木装置が体液に対して不活性な材料を有す

ることを特徴とする大動脈椎ぎ木。

１０．請求の範囲第７項記載の大動脈椎ぎ木において、前記大動脈椎ぎ木装置が前記大動脈の結合部に前記第１及び第２の端部を係合保持するリテーナーリング装置を有していることを特徴とする大動脈椎ぎ木。

１１．大動脈の部分を吻合する大動脈椎ぎ木であって、第１及び第２の端を有するほぼ円筒状の大動脈椎ぎ木と前記大動脈椎ぎ木装置の前記第１及び第２の端に取付けられ前記大動脈椎ぎ木装置を前記大動脈に固定する複数の取付け装置を有しており、前記取付け装置が、前記大動脈椎ぎ木装置の第１及び第２の端で前記大動脈椎ぎ木装置の内面に当接し前記大動脈椎ぎ木装置の長手軸線にほぼ平行であるベース部材と前記ベース部材に取付けられ前記大動脈椎ぎ木装置から径方向に前記大動脈椎ぎ木装置の第１及び第２の端を通して延びている支柱装置と前記支柱装置の末端に取付けられ前記大動脈を通過して前記大動脈に前記椎ぎ木装置を固定するフックとを有しており、前記フック装置がやじりフックを有しており、前記大動脈の結合部に前記第１及び第２の端を維持するリテーナーリング装置を備えていることを特徴とする大動脈椎ぎ木。

１２．請求の範囲第１１項記載の大動脈椎ぎ木において、前記大動脈椎ぎ木装置が弾性可撓性材料を有していることを特徴とする大動脈椎ぎ木。

１３．請求の範囲第１１項記載の大動脈椎ぎ木において、前記リテーナーリング装置は圧縮に対し前記リテーナーリングの径を弾性的に保持し互いに引っかかる一連の短い部分を有していることを特徴とする大動脈椎ぎ木。

１４．バルーンカテーテル及び大動脈椎ぎ木を用いて大動脈瘤を治療する方法において、前記動脈瘤に投影剤が満たされたカテーテルを、悪影響されていない血管組織に当接するように前記動脈瘤の直上の基端部まで挿入し、前記動脈瘤の直上の基端部の大動脈の径を計測し、前記投影剤で満たされたバルーンカテーテルを引いて、影響されていない血管組織に当接する動脈瘤の直下の末端部に悪影響された血管にカテーテルを再位置決めし、前記投影剤で満たされたバルーンを再膨張させ前記動脈瘤の直下の基端部の血管の径を計測し、前記投影剤で満たされたバルーンカテーテルを除去し、電波映像技術により前記頭部と尾部との距離を測定し、前記頭部及び尾部における前記大動脈のサイズよりほぼ１～１０ｍｍ大きい第１及び第２の端部を有する椎ぎ木をダブルバルーンカテーテルにそって挿入し、頭部バルーンの末端から前記頭部バルーンを膨らませ前記椎ぎ木の頭部の末端部のフックを前記頭部大動脈と整合させ、前記頭部バルーンが完全に膨らみ前記基端部のフックが前記頭部の基端部における前記大動脈と整合するまで前記頭部バルーンの末端部から前記頭部バルーンを膨張させつづけ、尾部バルーンを膨らませながら前記頭部バルーンの膨張を維持し、前記尾部バルーンの基端部から前記尾部バルーンを膨らませ前記椎ぎ木の尾部の前記基端位置のフックを前記尾部における大動脈と整合させ、前記尾部バルーンが完全に膨らみ前記末端のフックが前記尾部大動脈の前記末端の大動脈と係合するまで前記尾部バルーンの前記基端部から前記尾部バルーンと膨らませ続け、前記ダブルバルーンカテーテル装置を除去し、１つ以上のリテーナーを挿入し第３のバルーンカテーテル装置を挿入し、大動脈内の頭部尾部位置にリテーナーを保持し椎ぎ木を取付け、全てのカテーテルとワイヤを除去し、全ての大動脈の切り口を治し、大腿または腸骨大動脈に近づく切り口を治すことを特徴とする方法。

明　　細　　書

大動脈用椎ぎ木、大動脈瘤を治療する埋込み装置及び方法

本発明は大動脈椎ぎ木、大動脈瘤の治療に用いられる装置及び方法に関するものである。動脈瘤は、病気または他の要因による血管の弱い部分における血管壁の膨らみである。動脈瘤が治療されないと、動脈瘤が破裂し血液が流出することになる。

大動脈の動脈瘤は血管の動脈瘤で最も多いものであり生命の危険に関わるものである。大動脈は循環器系に血液を供給する主たる動脈である。大動脈は心臓の空洞から上方に延び心臓の後ろ側に曲がり胸郭及び腹部を降下する。腹部の大動脈は２つの側部血管を腎臓血管に送っている。腎臓血管の下方において、腹部大動脈は第４腰椎のレベルまで続いている。大動脈は腸骨動脈に分かれている。腸骨動脈は血液を下端部及び会陰部まで供給している。

大動脈瘤は腎臓動脈と腸骨動脈との間の腹部動脈に発生しやすい。腹部動脈のこの部分は特に弱いもので動脈瘤になりやすい。この部分の直径４ｃｍを越える大動脈瘤は悪いものである。治療されないと動脈瘤は破裂し、急激な大出血を起こす。

腹部動脈の動脈瘤は特に死亡率の高いものである。従

って現代の医学基準では腹部動脈瘤の手術は緊急に行なっている。腹部外科手術自体は身体に大きなストレスを与える手術である。大動脈瘤の死亡率は極めて高いものであるが、大動脈瘤を治療する外科的処置に関する死亡率及び罹患率も高い。本発明は、動脈瘤のある腹部血管壁を通して動脈瘤のある部分をバイパスまたは交換させることである。特に合成チューブのような人口装置がこの目的のために使われる。この継ぎ木は動脈瘤を循環器系から排除し動脈瘤のある弱い部分の圧力とストレスを取除くものである。

外科手段に動脈瘤の治療は主たるものである。さらに実質的な罹患率は手術を必要とし長い回復期間が必要である。最後に手術は高い死亡率を伴う。しかしながら外科的手術は高い危険性にも係らず動脈瘤の場合は必要とされるが腹部外科のストレスに患者が耐えられない場合もある。腹部外科手術に関する死亡率及び罹患率を低減することが望まれている。

最近は、腹部外科手術の危険性をなくした大動脈瘤を手術する方法が発達している。これらの例として米国特許第４，５６２，５９６号（１９８６年１月７日発行）「大動脈継ぎ木、腹部大動脈瘤の治療装置及び方法」及び米国特許第４，７８７，８９９号（１９８８年１１月２９日発行）「内部継ぎ木装置、システム及び方法」が知られている。

上記米国特許第４，５６２，５９６号は継ぎ木の安定性及び弾性に貢献する複数の支柱を有する可撓性チューブ材を有する大動脈継ぎ木を開示している。これらの支柱は、動脈瘤の上の動脈の内部に固着されるかかり部をその上端に有する曲がったフックを備えている。上記米国特許第４，５６２，５９６号の継ぎ木は当該特許に開示された管状装置を用いて挿入される。

しかしながら上記米国特許は動脈の継ぎ木の基端だけを固着するものである。上記特許は血管の下方へ向かう流れが継ぎ木の末端を保持し末端を機械的に止める必要がない。この点について上記米国特許のコラム８，２４～２７行を参照されたい。しかしながら腹部動脈の血圧は約１３０ｍｍＨｇである。継ぎ木の血流方向に係らず動脈瘤の末端における背圧は端部が機械的に取付けられないと生じてしまう。端部の取付けなしに上記特許の装置は血圧に関係する力とストレスから動脈瘤のある弱められた血管壁を効果的に排除することはできない。

上記米国特許第４，７８７，８９９号は継ぎ木の基端に取付けられた複数の針を用いた継ぎ木システムを開示している。この特許の針はバルーンカテーテルにより大動脈壁に押え付けられる。しかしながら米国特許第４，５６２，５９６号のように米国特許第４，７８７，８９９号は継ぎ木の端に取付けられた針を開示している。米国特許第４，７８７，８９９号には動脈瘤のレベルよりも低い末端大動脈に継ぎ木を機械的に取付けることは示されていない。

米国特許第４，７８７，８９９号も大動脈を修繕する様々な手段を開示している。これらは、バルーンカテーテルシステムを用いた様々な継ぎ木装置、ニチノルコイルの使用および外科的技術である。

従って近年ある技術は大動脈瘤を修繕する外科的手術を介したストレス、死亡率及びその危険を減少させるように発展しているが現在まで開発された技術は循環系の圧力やストレスから大動脈の影響された部分を排除したり大動脈を効果的に治療することができない。従来の装置は信頼性のある、かつ迅速な動脈瘤バイパスを提供することができない。

従って本発明の目的は動脈瘤の腹部外科手術に関するよりも罹患率や死亡率をより低減させる大動脈瘤の治療方法を提供することである。

本発明の他の目的は腹部外科手術に耐えられない患者の大動脈瘤を治療する手段を提供することである。

本発明の他の目的は広範囲な外科手術による死亡率や罹患率を低減することである。

本発明の他の目的は緊急手術として大動脈瘤から患者を迅速に守る手段を提供することである。

本発明の他の目的は主たる外科手術をすることなく腹部動脈瘤を治療する手段を提供することである。

本発明の他の目的は腹部動脈瘤を外科的に手術する場合の死亡率や罹患率を低減する腹部動脈瘤を治療する装置を提供することである。

本発明の他の目的は動脈瘤の外科手術に関する治療における費用を低減する腹部動脈瘤の手術方法及びシステムを提供することである。

本発明の付加的な目的は、医療費、リハビリテーション、罹患率及び回復時間を考慮して患者に対する費用を低減する腹部動脈瘤の手術方法及びシステムを提供することである。

発明の要約

添付図面及び請求の範囲に記載されたように本発明は大動脈の部分の吻合をする大動脈継ぎ木に関するものであり、頭部端及び尾部端を有しかつ軸線を有する大動脈継ぎ木装置と前記大動脈継ぎ木装置の前記頭部端及び尾部端に取付けられ前記大動脈継ぎ木装置を前記大動脈に固定する複数の取付け装置を有しており、前記取付け装置は、前記大動脈継ぎ木装置に取付けられ前記大動脈継ぎ木装置の前記軸線にほぼ平行に指向したベース装置と前記ベース装置に取付けられ前記大動脈継ぎ木装置からほぼ径方向外側に延びた支柱装置と、前記軸線に対しほぼ平行に指向し前記支柱装置の末端に取付けられ前記大動脈を通過し前記継ぎ木装置を前記大動脈に固定するフック装置を有していることを特徴とする大動脈継ぎ木を提供する。

明細書に記載されているように、本発明の大動脈継ぎ木はバルーンカテーテル及び大動脈継ぎ木を用いて大動脈瘤を循環から安全に除去する方法に用いられる。本発

明によると前記動脈瘤に投影剤が満たされたカテーテルを、悪影響されていない血管組織に当接するように前記動脈瘤の直上の基端部まで挿入し、前記動脈瘤の直上の基端部の大動脈の径を計測し、前記投影剤で満たされたバルーンカテーテルを除去し、影響されていない血管組織に当接する動脈瘤の直下の末端部に悪影響された血管にカテーテルを再位置決めし、前記動脈瘤の直下の基端部の血管の径を計測し、前記投影剤で満たされたバルーンカテーテルを除去し、電波映像技術により前記基端部と前記末端部との間の距離を測定し、前記基端部及び末端部における前記大動脈のサイズよりほぼ1～4mm大きい第1及び第2の端部を有する椎ぎ木をダブルバルーンカテーテルにそって挿入し、頭部バルーンの末端から前記頭部バルーンを膨らませ前記椎ぎ木の頭部の末端部のフックを前記頭部大動脈と整合させ、前記頭部バルーンが完全に膨らみ前記基端部のフックが前記頭部の基端部における前記大動脈と整合するまで前記頭部バルーンの末端部から前記頭部バルーンを膨張させつづけ、尾部バルーンを膨らませながら前記頭部バルーンの膨張を維持し、前記尾部バルーンの基端部から前記尾部バルーンを膨らませ前記椎ぎ木の尾部の前記基端位置のフックを前記尾部における大動脈と整合させ、前記尾部バルーンが完全に膨らみ前記末端のフックが前記尾部大動脈の前記末端の大動脈と係合するまで前記尾部バルーンの前記基端部から前記尾部バルーンを膨らませ続け、前記ダブルバルーンカテーテル装置を除去し、前記椎ぎ木に第1の膨張リングリテーナーを挿入する方法が提供される。

図面の簡単な説明

本発明の特徴は以下の添付図面により良く理解される。

第1図は椎ぎ木に組込まれるダブルバルーンカテーテルシステムを用いた本発明の大動脈椎ぎ木の冠状縫合の拡大図である。

第2図は本発明の好適実施例の取付け装置の拡大図である。

第3図は血管の径を測定するため動脈瘤の上の血管の頭部に挿入されたバルーンカテーテルの冠状図である。

第4図は血管の径を測定するために動脈瘤の腹部大動脈の尾部に挿入された投影剤が満たされたバルーンカテーテルの冠状図である。

第5図は腹部大動脈に挿入され大動脈椎ぎ木の頭部及び尾部がそれぞれ動脈瘤の上部及び下部の頭部及び尾部と整合する本発明の椎ぎ木とダブルバルーンカテーテルシステムの冠状図である。

第6図は頭部バルーンが膨張するときの取付け装置の血管壁への挿入を示す挿入された椎ぎ木及びダブルバルーンカテーテルシステムと動脈瘤上の頭部腹部大動脈の冠状図である。

第7図は取付け装置が動脈壁を貫通したときの頭部バルーンの膨張中の状態を示す第6図の椎ぎ木と頭部バルーンの冠状図である。

第8図は尾部バルーンが膨張したときの動脈壁を取付け装置が貫通することを示す椎ぎ木とダブルバルーンカテーテルシステムと動脈瘤の下部の尾部腹部動脈の冠状図である。

第9図は取付け装置が動脈壁を通過したときの尾部バルーンの膨張中の状態を示す第8図の椎ぎ木と頭部バルーンの冠状図である。

第10図は頭部及び尾部の取付け装置が動脈壁に取付けられダブルバルーンカテーテルシステムが除去されて動脈瘤を除いた後の本発明の大動脈椎ぎ木の冠状図である。

第11図は本発明のリテーナーリングの上面図である。

第12図は本発明のリテーナーリングの変更例を示す斜視図である。

第13図はバルーンカテーテルと頭部リテーナーリングの取付けを示す本発明の大動脈椎ぎ木の頭部を示す冠状図である。

第14図はバルーンカテーテルと尾部リテーナーリングの取付けを示す本発明の大動脈椎ぎ木の尾部の冠状図である。

第15図は大動脈瘤を除去する大動脈に埋め込まれた椎ぎ木を示す本発明の大動脈椎ぎ木の冠状図である。

本発明の椎ぎ木及び大動脈椎ぎ木を取付ける装置及び方法は以下の図面により詳述されるが本発明はこの実施例に限定されるものでなく添付の請求の範囲に基いて多くの変更が可能である。

実施例

第1図は腹部大動脈瘤12を治療する大動脈椎ぎ木手段10を示している。第3図に示されるように、大動脈瘤12は腎動脈15と腸骨動脈16との間の腹部大動脈11に位置している。

本発明の大動脈椎ぎ木10も添付請求の範囲において他の位置をとれることは当業者にとって自明である。例えば椎ぎ木は身体の他の部分または他の管に位置する動脈のような流体を連通させる管にも用いることができる。

実施例に示されるように、本発明の大動脈椎ぎ木装置10は頭部19、尾部20端及び本体21を有する大動脈椎ぎ木18を有している。本発明の大動脈椎ぎ木18は、好ましくはテフロン（ポリテトラフルオロエチレン）等の可撓性、弾性材料や他の同様に可撓性、弾性を有する材料からなる。天然または人口のポリマー材等の材料（ポリエステル繊維、ダクロン、マイラー、レーヨン、セルロースアセテート、セルロースプチネート）も使用できる。大動脈椎ぎ木18を構成する材質は生化学的に不活性であり大動脈椎ぎ木が埋められる組織と相性がよくなければならないことが重要である。この種の材料としては多くのものが知られている。

本発明の実施例においては、大動脈椎ぎ木18は複数のアタッチメント手段22とダブルバルーンカテーテルシステム35を有している。椎ぎ木は、大動脈の直径の

計測する第１のカテーテルシステム、アタッチメント手段２２を有する大動脈１８、ダブルバルーンカテーテルシステムである第２のカテーテルシステム、及び保持リング４５を有する第３のバルーンカテーテルシステム４８を有するキットとして衛生的に取扱われパッケージされている。本発明の大動脈椎ぎ木１８、ダブルバルーンカテーテルシステム３５及び第３のカテーテルシステム４８は様々なサイズに形成され本発明のシステムが個個の患者の大動脈瘤のサイズや形に適合するようになっている。

第２図に示されるように、本発明のアタッチメント手段２２はベース手段２３、支柱手段２４及びフック手段２５を有している。フック手段２５はチップ部２６を有しておりフック２５による大動脈１１の通過を容易にし、やじり２７を有しており大動脈１１に対する取付け位置において取付け手段を弾性的に保持している。本発明の好適実施例においては、大動脈椎ぎ木１８は、椎ぎ木１８の頭部１９及び尾部２０端に取付けられた複数の取付け手段２２を備えている。

本発明の好適実施例においてベース手段２３は金属やプラスチック等の生化学的に相性のいい材料からなる。ベース２３は大動脈椎ぎ木１８の軸の対してほぼ平行な金属性平坦小片である。ベース２３は大動脈椎ぎ木１８の頭部１９及び尾部２０端に取付けられる。この取付けは、これに限定されるものではないが、接着、溶接、リベット、単なるベース２３の位置決め等によりなされ、ベース２３の末端は大動脈椎ぎ木１８の内腔の末端面に当接し支柱２４の力により保持される。

支柱手段２４は好ましくはベース２３に対してほぼ直角な方向に向いた支柱である。本発明の好適実施例においては、支柱２４はベース２３の末端面に取付けられ支柱２４は、大動脈椎ぎ木１８に取付けられたとき大動脈椎ぎ木１８から径方向外側に延在する。ベース２３は生化学的に安定して支柱２４をベース２３に固着できる接着、リベット、溶接等の様々な手段を介して大動脈椎ぎ木１８に固定できる。ベース２３も大動脈椎ぎ木１８の内腔においてベース２３を取付けることにより大動脈椎ぎ木１８に固定でき、ベース２３の末端面が大動脈椎ぎ木１８の内腔基端面に当接し、支柱２４は大動脈椎ぎ木１８を通過する。支柱２４の基端にかかった力によりベース２３と支柱２４が保持される。

本発明の好適実施例においては、フック手段２５は支柱２４の末端に取付けられたフックである。フック２５はベース２３に対してほぼ平行であり、従って大動脈１１に取付けられたとき大動脈椎ぎ木１８の軸線に平行である。本発明の好適実施例においては、チップ２６が位置するフック２５の手の部分はチップ２６からのフック２５の端部よりも支柱２３からの長さが長い。さらにフック２５は取付け手段２２を保持する１つ以上のやじり２７と大動脈瘤１１の上下における腹部動脈の頭部１２及び尾部１３の大動脈１４に固定された大動脈椎ぎ木１８を保持している。

大動脈椎ぎ木手段１０はダブルバルーンカテーテルシステム３５を介して腹部大動脈１１に取付けられている。本発明のダブルバルーンカテーテルシステム３５は、バルーンがふくらんだときフック２５のチップ２６がほぼ平行な関係ではなく動脈１１の壁に係合してフック２５が本発明の大動脈椎ぎ木１８を大動脈１１に固定するのを容易にするように方向づけられている。

添付請求の範囲において本発明の取付け手段２２の構造や取付けを様々に変更することは当業者にとって自明である。例えば支柱２４のそれぞれの個のフック２５の相対的な長さは変更できる。また支柱２４は、支柱２４の端部が大動脈椎ぎ木１８から径方向に延びて大動脈１１を通過していれば様々な形状を有することができる。またフック２５は大動脈椎ぎ木が大動脈１１に取付けられたとき近くの器官を傷つけないように方向づけられていれば様々な形状や方向をとることができる。さらに取付け手段２２は、大動脈１１を通過しないように回転して大動脈１１を単純に押えつけるように方向づけてもよい。従って、本発明は、添付請求の範囲において様々な変更が可能である。

大動脈椎ぎ木手段１０の動作及び取付けは、ダブルバルーンカテーテルシステム３５の動作により最もよく説明できる。本発明の大動脈椎ぎ木手段の埋設は多くのステップを有している。まず大腿大動脈１７または腸骨大動脈１６に切込みを入れ、大動脈瘤１２に接近する。第３図に示すように、本発明による好適実施例においては、第１のバルーンカテーテル装置２８は大動脈１１のある重要な特徴を計測する。実施例におけるように、第１のバルーンカテーテル２８はガイドワイヤ２９、バルーン３０、供給チューブ３１、第１のバルーンカテーテルシース３２及び投影剤３３を有している。ガイドワイヤ２９は第１のカテーテル装置２８で大腿大動脈１７または腸骨大動脈１６の切込みを介して挿入される。バルーン３０は電波投影剤３３で満たされており、電波映像手段で可視化する。カテーテル装置２８は、そのバルーン３０が腹部大動脈１１の動脈瘤１２に挿入されるまで大腿大動脈１７または腸骨大動脈１６の開口に供給される。電波映像システム３４を用いて、バルーン３０は動脈瘤１２の上の腹部大動脈１１の頭部１３と整合される。バルーン３０は、動脈瘤１２の直上の腹部大動脈１１の頭部１３の内面と係合するまで膨張される。映像装置３４は大動脈瘤の上の腹部大動脈の頭部の径を測定する。

第４図に示されるように第１のカテーテル装置２８は、バルーン３０が動脈瘤１２の下方の腹部大動脈１１の尾部１４と整合するまで引かれる。バルーン３０は動脈瘤１２の下方の腹部動脈１１の尾部１４において腹部大動脈１１の内壁に到達するまで再び膨張される。映像装置３４は再び動脈瘤１２の下方の腹部大動脈の尾部におけ

る腹部動脈１１の径を測定する。この計測値は記録される。映像装置を介して集められたデータを用いて腹部大動脈１３の頭部１２と腹部大動脈１１の尾部１４との間の距離が動脈瘤１２の上下において大動脈１１の頭部１３と尾部１４の径と同様に決定される。この情報を用いて患者の大動脈椎ぎ木装置１０の適当な大きさが選択される。

実施例に示されるように大動脈椎ぎ木１８は映像装置３４により決定された腹部大動脈１１の頭部１３及び尾部１４の間の距離よりも好ましくは２～１０ｍｍ長くなっている。本発明の大動脈椎ぎ木装置１０は大動脈椎ぎ木１８、取付け装置２２及びダブルバルーンカテーテルシステム３５を有している。ダブルバルーンカテーテル装置３５も投影剤マーカー４２を有している。投影剤マーカー４２はダブルバルーンカテーテル３５の尾部バルーン３９の末端部４１と基端部４０と同様に頭部バルーン３６の端３７と末端３８に設けられている。第５図に示すように投影剤マーカー４２と映像装置３４を用いて大動脈椎ぎ木１０は、頭部バルーン３６が腹部大動脈１１の頭部１３と整合し尾部バルーン３９が腹部大動脈１１の尾部１４と整合するまで大腿大動脈１７または腸骨大動脈１６に挿入される。

頭部バルーン３６はここで膨張される。第６図に示すように頭部バルーン３６は頭部バルーン３６の端部３８から膨張され始める。頭部バルーン３６の末端３８が膨張されると当接した取付け手段２２が回転し、レース２３の末端が大動脈椎ぎ木１８の軸線から径方向外側に移動しベース２３の基端部は大動脈椎ぎ木１８の軸線近くに残る。この回転によりフック２５の先端部２６が腹部大動脈１１に対してほぼ非平行になる。頭部バルーン３６がさらに膨張するとチップ２６は腹部大動脈１１と係合する。頭部バルーン３６の膨張により先端２６は腹部大動脈壁１１を通過しフック２５が大動脈壁１１内に延びる。やじり２７は通過しフック２５の先端２６とやじり２７が腹部大動脈壁１１を通過しその外壁面に位置する。

第７図に示されるように頭部バルーン３６の膨張が続けられ、頭部バルーン３６が完全に膨張するまで腹部大動脈壁１１に取付け装置２２が取付けられる。頭部バルーン３６が完全に膨張すると大動脈椎ぎ木１８の頭部１９上の取付け装置２２は頭部１３の腹部大動脈壁１１を通過し腹部大動脈１１に大動脈椎ぎ木１８を永久的に固着する。頭部バルーン３６は完全に膨張し取付け装置２２と大動脈椎ぎ木１８の頭部１９は血管壁１１の基部１３に固着し頭部バルーンは完全に膨張されたままとなる。頭部バルーン３６の膨張により残る手術の間腹部大動脈１１を通る血流は効果的に開かれる。頭部バルーン３６の膨張により大動脈椎ぎ木１８の頭部が保持され大動脈椎ぎ木の尾部２０は腹部大動脈１１の尾部に取付けられる。

第８図に示されるように大動脈椎ぎ木１８の尾部２０は尾部バルーン３９の基端４０におけるダブルバルーンシステム３５の尾部バルーン３９を膨張することにより腹部大動脈１１の尾部１４に取付けられる。尾部バルーン３９の基端４０が膨張されると、大動脈椎ぎ木１８の尾部２０の取付け装置２２が頭部１９に対して上述のように回転し椎ぎ木１８の尾部の取付け装置２２が第９図に示されるように腹部大動脈１１の尾部１４に永久的に取付けられる。

第１０図に示されるように頭部バルーン３６と尾部バルーン３９とが完全にふくらまされると椎ぎ木１８は腹部大動脈１１の上下に位置する。このとき椎ぎ木１８の頭部１９及び尾部２０によりさらに上下の血液が動脈瘤１１に効果的に達しないようにしている。椎ぎ木１８の本体２１は動脈瘤１２の腹部動脈壁１１として働く。第１０図に示されるように椎ぎ木１８が腹部大動脈１１の頭部１３と尾部１４とに完全に位置するとダブルバルーンカテーテルシステム３５は取除かれる。大動脈椎ぎ木１８は腹部大動脈１１を循環する全圧力及びストレスを受け動脈瘤１２を効果的に排除し動脈瘤にかかるストレスを取除く。

本発明の好適実施例において大動脈椎ぎ木装置１０は保持手段４５を有している。保持手段４５は大動脈１１に椎ぎ木１８を保持する弾性リングである。実施例においてはリテーナー４５は本体４６とロック手段４７とを有している。第１１図に示されるように本発明の好適実施例においてはリテーナー４５は割りリングの２つの橋がスムーズなリングを形成するように形づくられた割りリングである。

請求の範囲において本発明の取付け装置２２の構造及び取付けには多くの変更が可能である。例えばリテーナー４５は第１２図に示されるような弾性メッシュ材であってもよい。メッシュ材の本体４６は好ましくは互いに取付けられるレッグを有しておりメッシュ材は挿入用に折りたたみ可能であり一旦取付けられ膨張されるとロックされる。従って本発明は請求の範囲において多くの変更例が可能であることは明らかである。

第１０図に示されるようにダブルバルーンカテーテル３５が腹部大動脈１１から取除かれるとガイドワイヤ２９は残ったままである。第１３図に示されるようにリテーナー４５は第３のカテーテルシステム４８を用いて腹部大動脈１１に挿入される。リテーナー４５と第３のカテーテル装置４８が腹部大動脈１１に挿入されると映像装置３４が腹部大動脈１４の頭部１３，１９と大動脈椎ぎ木１８に対してリテーナー４５の位置を追跡する。腹部大動脈１４の頭部１２，１９と大動脈椎ぎ木１８に対してリテーナー４５が整合すると頭部バルーン４９が膨張される。頭部バルーン４９が膨張されるとロック手段４７が開放位置の大動脈１１の固定リテーナーと係合する。バルーン３０が完全に膨らみリテーナー４５が完

全に膨張すると、リテーナー４５は大動脈椎ぎ木１８と大動脈１１とを膨張させ大動脈椎ぎ木１８と取付け装置２２を腹部大動脈１１の頭部１３に押付ける。

第１４図に示されるように尾部バルーン５０は膨張されリテーナー４５を大動脈椎ぎ木２０の尾部と大動脈１４をロックする。第３のカテーテルシステム４８はガイドワイヤ２９にそって取除かれる。手術が行なわれた大腿大動脈１７または腸骨大動脈１６の切込み部は閉じられる。下肢の循環は回復され大動脈椎ぎ木１８が循環から大動脈瘤１２を除去する。

本発明について様々な変更が請求の範囲において可能なことは当業者にとって明らかである。特に大動脈椎ぎ木装置１０はリテーナー４５とともに用いても用いなくてもよい。リテーナー４５は様々な係合及びサイズを有し大動脈椎ぎ木装置１０と腹部大動脈１４とを固定させる機能を有している。取付け装置２２もその形状について請求の範囲内において多くの変更が可能である。さらにダブルバルーンカテーテルシステム３５のそれぞれのバルーンが膨らまされる方向は取付け装置２２がバルーンの頭部３６尾部３９の膨張方向に対して方向づけられ大動脈１１の通過が容易にできればよい。従って本発明は請求の範囲において多くの変更例が可能である。

FIG. 1

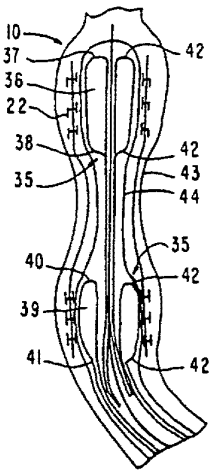


FIG. 2

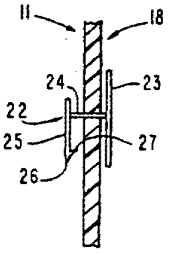


FIG. 3

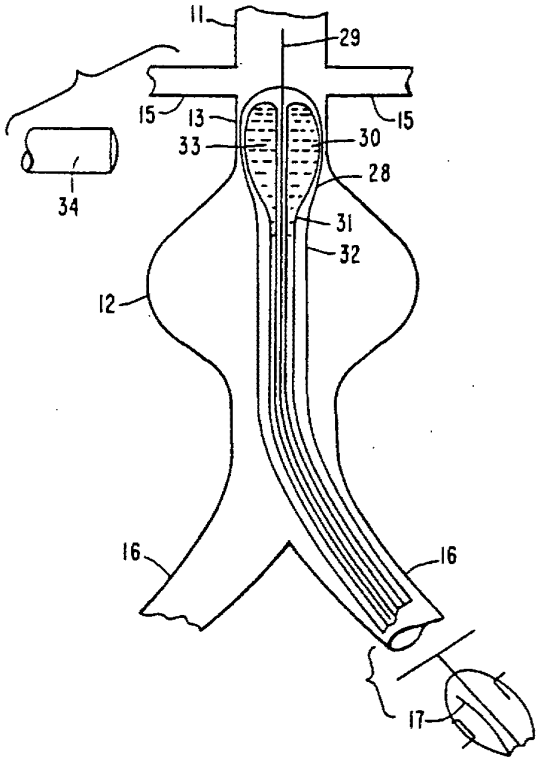


FIG. 4

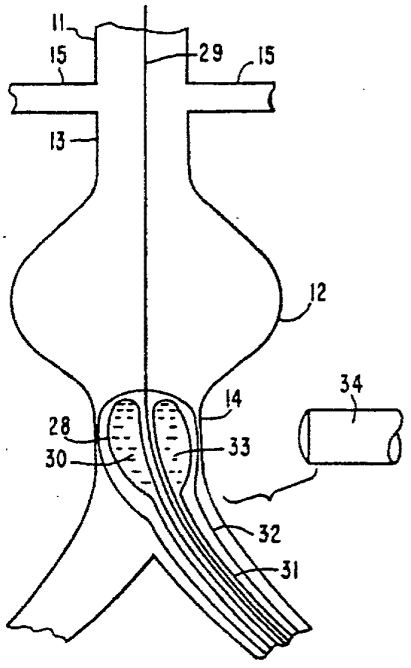


FIG. 5

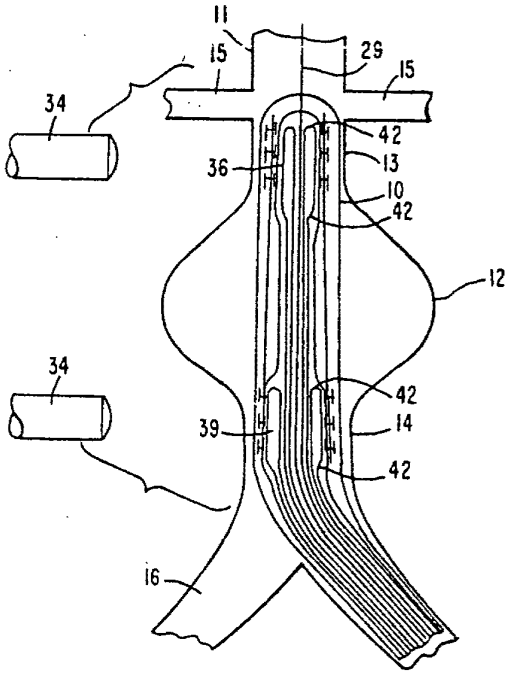


FIG. 6

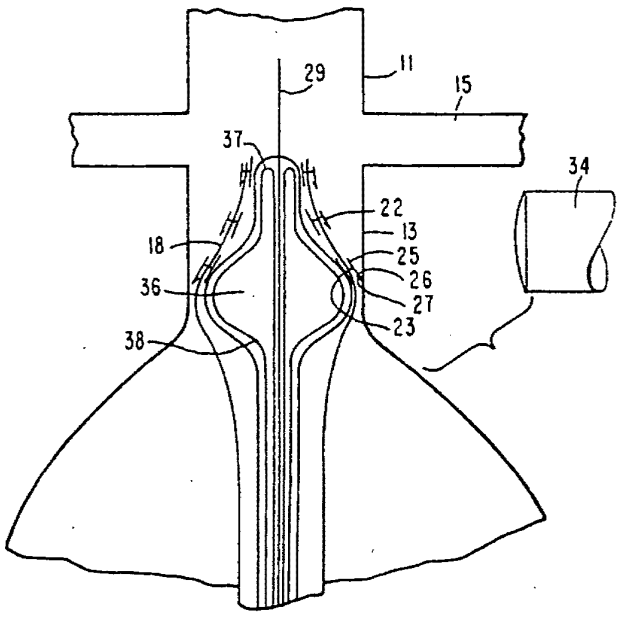


FIG. 7

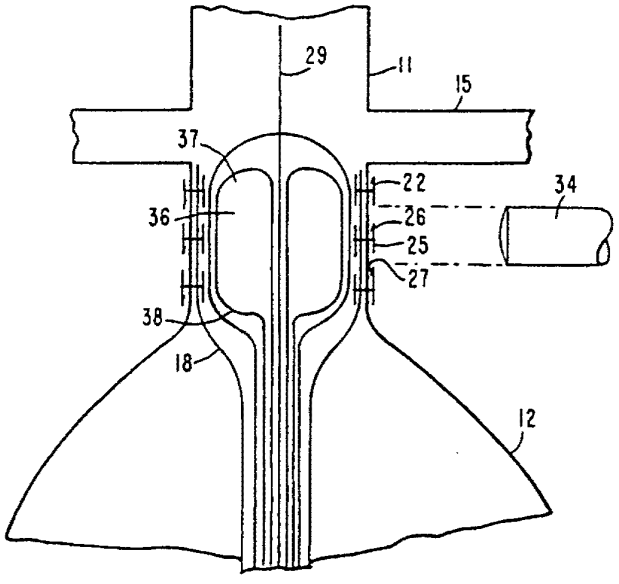


FIG. 8

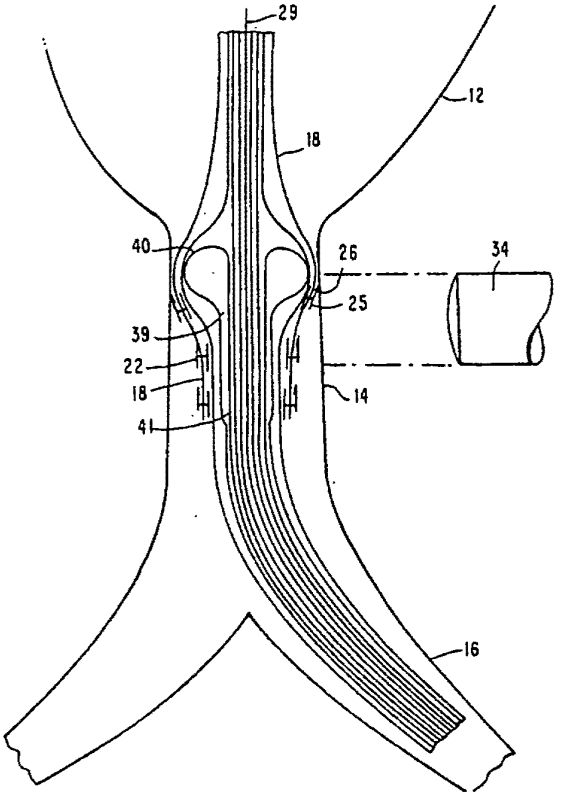


FIG. 9

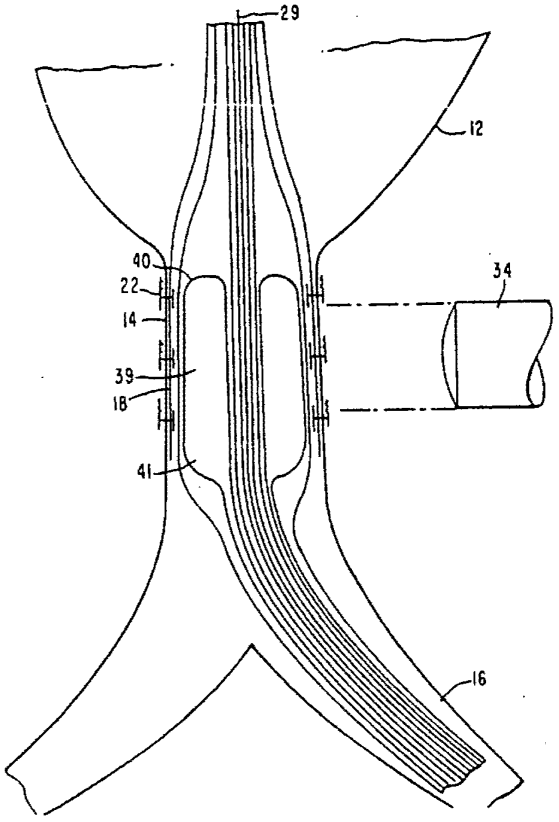


FIG. 10

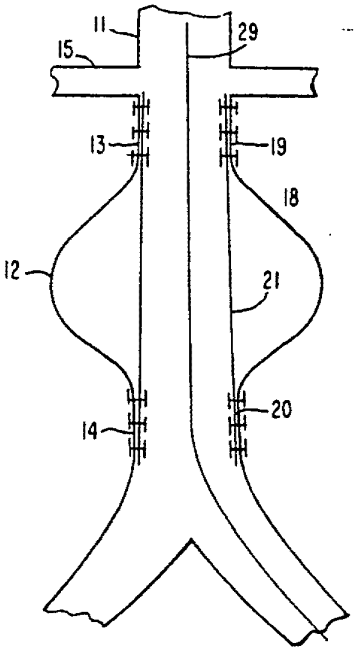


FIG. 11

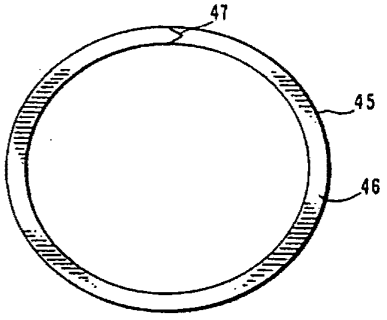


FIG. 12

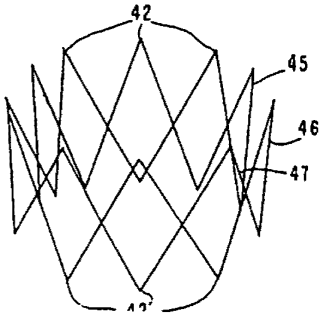


FIG. 13

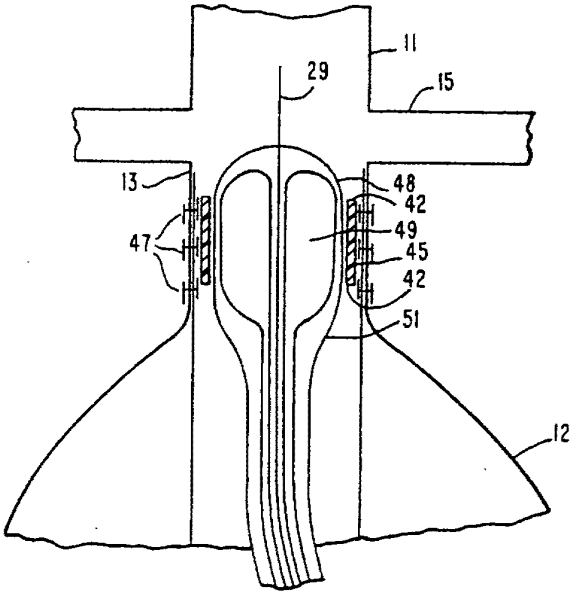


FIG. 14

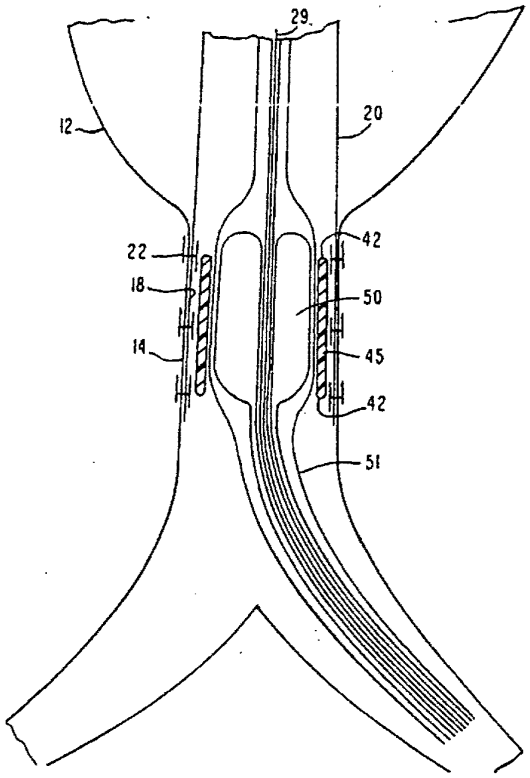
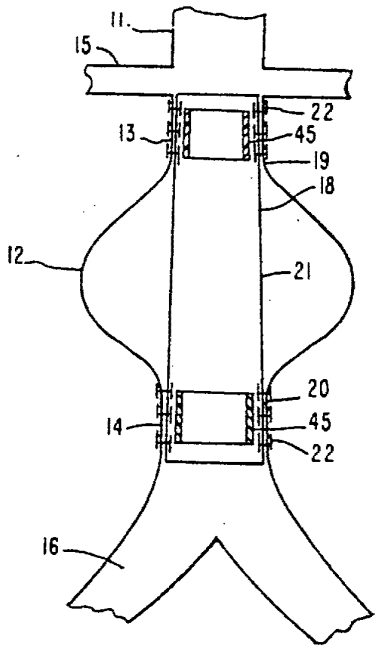


FIG. 15



国 際 調 査 報 告

International Application No PCT/US90/03322

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61F 2/06
U.S.Cl.: 623/1

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
U.S.	623/1 606/153,191,198,200 600/36,37

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X Y	US, A, 3,815,578 (BUCALO) 11 June 1974 See Figures 4 to 10 and Column 3, line 6 to column 6, line 3.	1-4 and 6 5 and 7-13
X,P Y,P	US, A, 4,872,874 (TAHERI) 10 October 1989 See Figures 1 and 9-12 and the passages of disclosure relevant thereto.	1-4 and 6 5 and 7-13
Y	US, A, 4,562,596 (KORNBERG) 07 January 1986 See Figures 2 and 5; Column 4, lines 28-47.	5 and 7-13

* Special categories of cited documents: 10
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search: 21 August 1990

Date of Mailing of this International Search Report: 26 OCT 1990

International Searching Authority: ISA/US

Signature of Authorized Officer: Paul Prebilic

INTERNATIONAL DIVISION

Form PCT/ISA/210 (second sheet) (Rev 1988)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 1

This international search report has not been established in respect of certain claims under Article 17(2) for the following reasons:

1. ☒ Claim numbers 14, because they relate to subject matter not required to be searched by this Authority, namely:

It relates to a method of treatment of the human body by surgery or therapy; see PCT Rule 39.1(iv).

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out 2, specifically:

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 3

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (additional sheet) (Rev 4-85)

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61F 2/06 — A1

(11) International Publication Number: WO 90/15582

(43) International Publication Date: 27 December 1990 (27.12.90)

(21) International Application Number: PCT/US90/03322

(22) International Filing Date: 15 June 1990 (15.06.90)

(30) Priority data:
367,716 19 June 1989 (19.06.89) US

(71)(72) Applicant and Inventor: TROUT, Hugh, H., III [US/US]; 3037 Ordway Street, N.W., Washington, DC 20008 (US).

(74) Agent: COYNE, Patrick, J.; Collier, Shannon & Scott, 1055 Thomas Jefferson Street, N.W., Washington, DC 20007 (US).

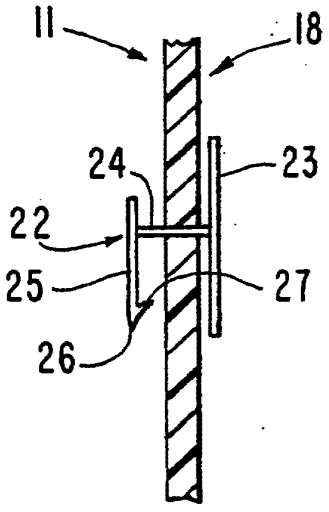
(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: AORTIC GRAFT AND METHOD FOR REPAIRING ANEURYSM

(57) Abstract

An aortic graft and system (10) and method for implanting the aortic graft are provided. The aortic graft (18) comprises a substantially cylindrical graft material with attachment means (22) which comprise a plurality of post (24) and hook (25) assemblies which are implanted with a double catheter system (35) to penetrate the aorta wall (11) above and below the aneurysm (12) to provide firm attachment of the aortic graft (18) and, thereby, exclude the aneurysm (12) from the circulatory system.



* See back of page

DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Monaco
AU	Australia	FI	Finland	MG	Madagascar
BB	Barbados	FR	France	ML	Mali
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Fasso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GR	Greece	NL	Netherlands
BJ	Benin	HU	Hungary	NO	Norway
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic of Korea	SE	Sweden
CG	Congo			SN	Senegal
CH	Switzerland	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
DE	Germany, Federal Republic of	LK	Sri Lanka	TG	Togo
DK	Denmark	LU	Luxembourg	US	United States of America

AORTIC GRAFT AND METHOD FOR REPAIRING ANEURYSM

The invention is an aortic graft, and a device and method of using that device for repair and treatment of arterial aortic aneurysms. An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture resulting in loss of blood through the rupture.

Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passing upward and bending over behind the heart and passing down through the thorax and abdomen. The abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. An aortic aneurysm larger than about 4 cm. in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid and usually fatal hemorrhaging.

Aneurysms in the abdominal aorta are associated with a particularly high mortality rate. Accordingly, current medical standards call for urgent operative repair of abdominal aortic aneurysms. Abdominal surgery itself is a major procedure resulting in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with surgical intervention to repair an aortic aneurysm. This intervention involves going through the abdominal wall to the location of the aneurysm to bypass or replace the diseased section

of the aorta at the aneurysm. A prosthetic device, typically a synthetic tube, is used for this purpose. This graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

Repair of an aortic aneurysm by surgical means is a major operative procedure. In addition, substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Finally, the procedure entails a substantial risk of mortality. While surgical intervention is nonetheless called for in the case of an aortic aneurysm in spite of these risks, certain patients may not be able to tolerate the stress of intraabdominal surgery. It is desirable to reduce the mortality and morbidity associated with intraabdominal surgical intervention.

In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intraabdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 (January 7, 1986) for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; and Lazarus, U.S. Patent No. 4,787,899 (November 29, 1988) for Intraluminal Graft Device, System and Method.

Kornberg discloses an aortic graft comprising a flexible tubular material having a plurality of struts to lend the graft stability and resiliency. The struts have angled hooks with barbs at their upper ends which are securely attached to the inside of the aorta above the aneurysm. Kornberg's graft is inserted using a tubular device also disclosed in his patent.

Kornberg, however, anchors only the proximal end of the graft in the aorta. Kornberg claims that the downward flow of blood holds the distal graft securely in place so that no mechanical attachment is necessary distally. Kornberg, U.S. Patent No. 4,562,596, Col. 6, lines 24-27. The blood pressure in the abdominal aorta, however, is typically in the magnitude of 130 mm of mercury. In spite of the direction of flow of blood through the graft, proximal to distal, substantial back pressures within the aneurysm

will result unless the distal end is also mechanically attached. Without distal attachment, the device of Kornberg will not effectively exclude the weakened arterial wall at the site of the aneurysm from the forces and stress associated with the blood pressure.

Lazarus discloses a grafting system that employs a plurality of staples mounted in the proximal end of the graft. Lazarus's staples are forced through the aorta wall by means of a balloon catheter. As does Kornberg, however, Lazarus discloses staples mounted only in the proximal end of the graft. There is no teaching or suggestion in Lazarus, U.S. Patent No. 4,787,899 as to the desirability or means for mechanically attaching the graft to the distal aorta below the level of the aneurysm.

Lazarus, U.S. Patent No. 4,787,899 also discloses various means for repairing the aorta. Among them are surgical techniques, the use of nitinol coil, and various graft systems that are implaced by the use of a balloon catheter system.

Hence, although in recent years certain techniques have been developed that avoid or reduce the stress, morbidity, and risk of mortality associated with surgical intervention to repair aortic aneurysms, the systems that have been developed do not effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with the circulation. None of the devices disclosed in the prior art provide a reliable and quick means to bypass an aneurysmal artery.

It is therefore an object of the invention to provide a method to repair an aortic aneurysm with a much lower risk of morbidity and mortality than that associated with intraabdominal surgical repair of the aneurysm.

A further object of the invention is to provide a means for repairing an aortic aneurysm in patients who cannot tolerate major abdominal surgery.

A further object of the invention is to reduce the risk of morbidity and mortality associated with extensive surgical procedures.

Another object of the invention is to provide a means to quickly stabilize patients suffering from an aortic aneurysm as an emergency procedure.

Yet a further object of the invention is to provide a means for treatment of abdominal aortic aneurysm without major surgical intervention.

A further object of the invention is to provide a device for repair of abdominal aortic aneurysms while reducing the morbidity and mortality associated with surgical procedures for repair of abdominal aortic aneurysms.

An additional object of the invention is to provide a procedure and system for repairing abdominal aortic aneurysms at greatly reduced cost in terms of medical resources relative to intraabdominal surgical repair of the aneurysm.

Yet, an additional object of the invention is to provide a procedure and system for repairing abdominal aortic aneurysms at greatly reduced cost to the patient in terms of medical expenses, rehabilitation, morbidity, and recovery time.

SUMMARY OF THE INVENTION

As illustrated in the accompanying drawings and disclosed in the accompanying claims, the invention is an aortic graft for performing an aortic anastomosis on a section of aorta, comprising, aortic graft means, having cephalic and caudal ends, and having an axis, a plurality of attachment means attached to said cephalic and caudal ends of said aortic graft means for securing said aortic graft means to the aorta, said attachment means having base means, oriented in substantially parallel relation to said axis of said aortic graft means, and attached to said aortic graft means, post means, attached to said base member and extending substantially radially away from said aortic graft means, and hook means oriented in substantially parallel relation to said axis, attached to the distal end of said post means for penetrating the aorta and securing said graft means to the aorta.

As set forth in the specification, the aortic graft of the invention is employed in a process for excluding from the circulation and, thus, rendering safe, an aortic aneurysm through the use of a balloon catheter and aortic graft comprising the steps of, inserting a contrast filled balloon catheter into the aneurysm to a proximal point just above the aneurysm abutting unaffected arterial tissue; measuring the diameter of the aorta at the proximal point just above the aneurysm; removing the contrast filled balloon catheter from the proximal point and placing it in the affected artery at a distal point just below the aneurysm abutting unaffected arterial tissue; measuring the diameter of the vessel at said distal point, just below the aneurysm; removing the contrast filled balloon catheter; measuring the distance between said proximal and distal points through radiographic techniques; inserting along with a double balloon catheter a graft having first and second ends substantially 1-4 mm larger than the size of the aorta at said proximal and distal points; blowing up the cephalic balloon from the distal end of the cephalic balloon to force hooks at the distal position of the cephalic end of said graft into mated relation

with said cephalic aorta; continuing to blow up said cephalic balloon from said distal end of said cephalic balloon until said cephalic balloon is fully inflated and said proximal hooks are forced into mated relation with said artery at said proximal end of the cephalic aorta; maintaining inflation of said cephalic balloon while inflating cuadal balloon; blowing up said cuadal balloon from the proximal end of said cuadal balloon to force hooks at said proximal position of said cuadal end of said graft into mated relation with said aorta at said cuadal point; continuing to blow up said cuadal balloon from said proximal end of said cuadal balloon until said cuadal balloon is fully inflated and said distal hooks are forced into mated relation with said artery at said distal end of the caudal aorta; removing the double balloon catheter system; and inserting into said graft a first expandable ring retainer.

BRIEF DESCRIPTION OF THE DRAWINGS

The characteristics and features of the present invention will be better understood through the following detailed description and accompanying drawings which are incorporated herein by reference:

Fig. 1 is an enlarged coronal view of the aortic graft of the present invention shown with a double balloon catheter system that is used to implant it.

Fig. 2 is an enlarged view of an attachment means of a preferred embodiment of the present invention.

Fig. 3 is a coronal view of a balloon catheter being inserted into the cephalic end of the affected artery above the aneurysm in order to measure the diameter of the vessel.

Fig. 4 is a coronal view of a contrast filled balloon catheter being inserted into the caudal end of the abdominal artery below the aneurysm to measure the diameter of the vessel.

Fig. 5 is a coronal view of the aortic graft and double balloon catheter system of the present invention inserted into the abdominal artery so that the cephalic and caudal ends of the aortic graft are aligned with the cephalic and caudal portions of the aorta above and below the aneurysm, respectively.

Fig. 6 is a coronal view of the cephalic abdominal aorta above the aneurysm with the aortic graft and double balloon catheter system inserted, showing the penetration of the aorta wall of the attachment means as the cephalic balloon is inflated.

Fig. 7 is a coronal view of the aortic graft and cephalic balloon of Fig. 6 shown at a subsequent stage during inflation of the cephalic balloon as attachment means have penetrated the aorta wall.

Fig. 8 is a coronal view of the caudal abdominal aorta below the aneurysm with the aortic graft and double balloon catheter system inserted, showing the penetration of the aorta wall of the attachment means as the caudal balloon is inflated.

Fig. 9 is a coronal view of the aortic graft and cephalic balloon of Fig. 8 shown at a subsequent stage during inflation of the caudal balloon as attachment means have penetrated the aorta wall.

Fig. 10 is a coronal view of the aortic graft of the present invention after attachment means of cephalic and caudal ends have been implanted in the aorta wall and the double balloon catheter system has been withdrawn, excluding the aneurysm.

Fig. 11 is a top view of a retainer ring of the present invention.

Fig. 12 is an oblique view of an alternative form of the retainer ring of the present invention.

Fig. 13 is a coronal view of the cephalic end of aortic graft of the present invention showing installation of retainer ring in cephalic end with a balloon catheter.

Fig. 14 is a coronal view of the caudal end of aortic graft of the present invention showing installation of retainer ring in caudal end with a balloon catheter.

Fig 15 is a coronal view of the aortic graft of the present invention showing the graft implanted in the aorta excluding the aortic aneurysm.

The aortic graft, and system and method of implanting an aortic graft of the present invention will now be described in further detail with reference to the drawings. The drawings and the detailed description of a preferred embodiment of the invention which follows are illustrative and explanatory only and in no way limit the scope of the invention as set forth in the appended claims.

DESCRIPTION OF A PREFERRED EMBODIMENT

Fig. 1 illustrates aortic graft means **10** for repairing an abdominal aortic aneurysm **12**. As illustrated in Fig. 3, the aortic aneurysm **12** is located in the abdominal aorta **11** between the renal arteries **15** and the iliac arteries **16**.

It will be apparent to those skilled in the art that the aortic graft **10** of the present invention can also be used in other locations without departing from the scope or spirit of the appended claims. For example, the graft could be used on any type of fluid conducting vessel such as sections of arteries located in other parts of the body or other types of vessels.

As embodied herein, aortic graft means **10** of the present invention comprises an aortic graft **18** having cephalic **19** and caudal **20** ends and a body **21**. The aortic graft **18** of the present invention is preferably fabricated from a flexible, yet resilient, material such as polytetrafluoroethylene (Teflon) or other material having similar flexible and resilient properties. Other substance such as natural or synthetic polymeric substances (such as polyester fabric, Dacron, Mylar, Rayon, cellulose acetate, cellulose butynate) may also be used. A critical consideration is that the substance of which the aortic graft **18** is made be biologically inert and be compatible with the tissues into which the aortic graft is to be implanted. Many materials of this type are well known in the art.

In a preferred embodiment of the present invention aortic graft **18** has a plurality of attachment means **22** and a double balloon catheter system **35**. The graft can be prepared and packaged under sterile conditions and assembled in a kit comprising first catheter system for measuring the diameter of the aorta, aortic graft **18**, with attachment means **22**, a second catherer system which is a double balloon catheter system **35**, and a third balloon catheter system **48** with retainer rings **45**. It is contemplated that the aortic graft **18**, double balloon catheter system **35**, and third catheter system **48** of the present invention be manufactured in various sizes so that the system of the present

invention is adaptable to the size and configuration of the aortic aneurysm of the individual patient.

As embodied herein and shown in Fig. 2, attachment means 22 of the present invention comprises base means 23, post means 24, and hook means 25. Hook means 25, in turn, further comprises tip 26 to facilitate penetration of aorta 11 by hook 25 and barb 27 to resiliently hold attachment means in implanted position relative to aorta 11. In a preferred embodiment of the present invention, aortic graft 18, is provided with a plurality of attachment means 22, mounted in the cephalic 19 and caudal 20 ends of aortic graft 18.

In a preferred embodiment of the present invention, base means 23, is constructed of a biologically compatible material such as metal or plastic. Base 23 can be a small flat strip of metal that is oriented in substantially parallel relation to the axis of aortic graft 18. Base 23 is attached to the cephalic 19 and caudal 20 ends of aortic graft 18. This attachment can be accomplished by a variety of means including, but not limited to, gluing, welding, riveting, or simply positioning base 23 so that the distal surface of base 23 abuts the proximal surface of the lumen of aortic graft 18 and is held in place by force exerted on post 24.

Post means 24 is a post that is preferably oriented in substantially perpendicular relation to base 23. In a preferred embodiment of the present invention, post 24 is mounted on the distal surface of base 23 so that post 24 extends radially outward from the axis of aortic graft 18 when base 23 is in mounted relation to aortic graft 18. Base 23 may be secured to aortic graft 18 through a variety of means including gluing, riveting, welding, or other means that are biologically compatible and will provide a secure attachment of post 24 to base 23. Base 23 can also be secured to aortic graft 18 by mounting base 23 in the lumen of aortic graft 18 so that the distal surface of base 23 abuts the proximal surface of the lumen of aortic graft 18 so that post 24 penetrates and

extends through aortic graft 18. Force exerted on the distal end of post 24 then holds base 23 and post 24 in place.

In a preferred embodiment of the present invention, hook means 25 is a hook that is mounted on the distal end of post 24. Hook 25 is oriented substantially parallel relation to base 23 and, thus, the axis of aortic graft 18 when it is implanted in aorta 11. In a preferred embodiment of the present invention, the limb of hook 25 on which tip 26 is located is longer as measured from post 23 than the end of hook 25 distal from tip 26. Further, hook 25 may have one or more barbs 27 for holding attachment means 22 and aortic graft 18 firmly in place relative to aorta 14 at the cephalic 12 and caudal 13 portions of the abdominal aorta above and below aneurysm 11 respectively.

Aortic graft means 10 is implanted in abdominal aorta 11 through the use of a double balloon catheter system 35. The double balloon catheter system 35 of the present invention, is oriented so that when the balloons are inflated, tip 26 of hook 25 engages the wall of aorta 11 in substantially non-parallel relation in order to facilitate hook 25 penetrates abdominal aorta 11 to secure aortic graft 18 of the present invention to aorta 11.

It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and implantation of attachment means 22 of the present invention without departing from the scope or spirit of the claimed invention. For example, the relative lengths of the limbs of hook 25 on each side of post 24 could be modified. Post 24 in turn could assume various configurations, provided the distal end of post 24 extends radially from aortic graft 18 to penetrate through aorta 11. Hook 25 could also assume various configurations and orientations, provided it is oriented in a manner so that it does not pose a hazard to nearby organs or systems when aortic graft 18 as implanted in aorta 11. Further, attachment means 22 could be oriented so that it does not rotate in order to penetrate aorta 11 but, rather, simply erodes through aorta 11. Hence, it is intended that the present invention cover the modifications and

variations of the invention, provided they come within the scope of the appended claims and their equivalents.

The operation and attachment of aortic graft means **10** can perhaps best be illustrated by the operation of the double balloon catheter system **35**. Implantation of the aortic graft means of the present invention involves several steps. First, an incision is made in the femoral artery **17** or iliac artery **16** to provide a means of access to aneurysm **12**. In a preferred embodiment of the present invention, as shown in Fig. 3, a first balloon catheter assembly **28** is employed to measure certain critical features of aorta **11**. First balloon catheter **28**, as embodied herein, comprises a guide wire **29**, a balloon **30**, a supply tube **31**, a first balloon catheter sheath **32**, and contrast material **33**. Guide wire **29** is inserted through the incision in femoral artery **17** or iliac artery **16** with first catheter assembly **28**. Balloon **30** is filled with a radioopaque contrast material **33** to allow visualization of balloon **30** by radiographic means. Catheter assembly **28** is threaded through the opening of femoral artery **17** or iliac artery **16** until balloon **30** of first catheter **28** has been inserted into aneurysm **12** in the abdominal aorta **11**. Using a radiographic system **34**, balloon **30** is aligned with the cephalic portion **13** of the abdominal aorta **11** above aneurysm **12**. Balloon **30** is then inflated until it engages the interior surface of the cephalic portion **13** of abdominal aorta **11** immediately above aneurysm **12**. Radiographic system **34** is then employed to measure the diameter of the abdominal aorta **11** at its cephalic portion **13**, above the aneurysm. This measurement is then recorded.

As shown in Fig. 4, first catheter assembly **28** is then withdrawn until balloon **30** is aligned with the caudal portion **14** of abdominal aorta **11** below aneurysm **12**. Balloon **30** is reinflated until it abuts the interior wall of abdominal aorta **11** at the caudal portion **14** of the abdominal aorta **11** below aneurysm **12**. Radiographic system **34** is again employed to measure the diameter of abdominal aorta **11** at the caudal portion of abdominal aorta below aneurysm **12**. This measurement is also recorded.

Using the data collected by the radiographic system, the distance between the cephalic portion 12 of abdominal aorta 13 and the caudal portion 14 of abdominal aorta 11, above and below aneurysm 12, respectively, as well as the diameter of the cephalic and caudal regions 13 and 14 of aorta 11, are then determined. Using this information, aortic graft means 10 of appropriate size for the patient is selected.

As embodied herein aortic graft 18 is preferably 2 to 10 mm longer than the distance between the cephalic 13 and caudal 14 portions of abdominal aorta 11 as determined by the radiographic system 34. Aortic graft means 10 of the present invention comprises aortic graft 18, attachment means 22, and double balloon catheter system 35. Double balloon catheter system 35 also comprises radioopaque markers 42. Radioopaque markers 42 are provided on the proximal 37 and distal 38 ends of cephalic balloon 36 as well as on the proximal 40 and distal 41 ends of caudal balloon 39, of double balloon catheter 35. As shown in Fig. 5, using radioopaque markers 42, and radiographic system 34, aortic graft 10 is inserted through the opening in femoral artery 17 or iliac artery 16 until cephalic balloon 36 is aligned with cephalic portion 13 of abdominal aorta 11 and caudal balloon 39 is aligned with caudal portion 14 of abdominal aorta 11.

Cephalic balloon 36 is then inflated. As shown in Fig. 6, inflation of cephalic balloon 36 begins at the distal end 38 of cephalic balloon 36. As distal end 38 of cephalic balloon 36 is inflated, abutting attachment means 22 rotate so that the distal ends of base 23 are moved radially outward from the axis of aortic graft 18 while the proximal ends of base 23 remain proximate to axis of aortic graft 18. This rotation orient tips 26 of hooks 25 in substantially non-parallel relation to abdominal aorta 11. As cephalic balloon 36 is inflated further, tip 26 engages abdominal aorta 11. Inflation of cephalic balloon 36 forces tip 26 to penetrate abdominal aorta wall 11 so that hook 25 extends through abdominal aorta wall 11. Barb 27 passes through the penetration so

that tip 26 and barb 27 of hook 25 penetrate abdominal aorta wall 11 and lie on the outer wall surface of abdominal aorta 11.

As shown in Fig. 7, inflation of cephalic balloon 36 continues in this manner, forcing attachment means 22 through abdominal aorta wall 11 until cephalic balloon 36 is fully inflated. When cephalic balloon 36 is fully inflated, attachment means 22 on cephalic portion 19 of aortic graft 18 will penetrate abdominal aorta wall 11 at cephalic region 13, firmly and permanently anchoring aortic graft 18 to abdominal aorta 11. Cephalic balloon 36 is fully inflated and attachment means 22 and cephalic portion 19 of aortic graft 18 are anchored in proximal portion 13 of vessel wall 11, cephalic balloon is left fully distended. The distention of cephalic balloon 36 effectively closes off the flow of blood through abdominal aorta 11 during the remainder of the procedure. Inflation of cephalic balloon 36 firmly holds the cephalic portion 19 of aortic graft 18 in place while the caudal portion 20 of aortic graft 18 is being implanted in the caudal portion 14 of abdominal aorta 11.

As shown in Fig. 8, caudal portion 20 of aortic graft 18 is implanted in caudal portion 14 of abdominal aorta 11 by inflating caudal balloon 39 of double balloon system 35 beginning at the proximal end 40 of caudal balloon 39. As proximal end 40 of caudal balloon 39 is inflated, attachment means 22 in caudal portion 20 of aortic graft 18 rotate as described above with respect to cephalic end 19 so that attachment means 22 of caudal portion of aortic graft 18 are firmly and permanently mounted in caudal portion 14 of abdominal aorta 11, as shown in Fig. 9.

As shown in Fig. 10, once cephalic balloon 36 and caudal balloon 39 are fully distended, aortic graft 18 is seated both proximally and distally in abdominal aorta 11. At that point, cephalic 19 and caudal 20 portions of aortic graft 18 effectively exclude further blood from the proximal or distal aorta from reaching aneurysm 11. Body 21 of aortic graft 18 functions as abdominal aorta wall 11 of aneurysm 12. As shown in Fig. 10, once aortic graft 18 is fully seated in cephalic 13 and caudal 14 portions of abdominal

aorta 11, double balloon catheter system 35 is removed. Aortic graft 18 then assumes the full pressure and stress of the circulatory flow through abdominal aorta 11 effectively excluding aneurysm 12 and, thereby, substantially relieving aneurysm 12 of the stresses on it.

In a preferred embodiment of the present invention, aortic graft means 10 further comprises retainer means 45. Retainer means 45 can be a resilient ring of material which functions to hold aortic graft 18 firmly in place in abdominal aorta 11. As embodied herein, retainer 45 comprises body 46, locking means 47. In a preferred embodiment of the invention, as shown in Fig. 11, retainer 45 can be a split ring which is configured so that the two ends of the split ring cooperate to form a smooth ring.

It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and implantation of attachment means 22 of the present invention without departing from the scope or spirit of the claimed invention. For example, retiner 45 can be a resilient mesh web as shown in Fig. 12. Body 46 of the web preferably comprises legs which are mounted in relation to each other so that the web can collapse to allow for for insertion and to lock in place once it has been implanted and expanded. Hence, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

As shown in Fig. 10, after double balloon catheter 35 is removed from abdominal aorta 11, guide wire 29 is left in place. As shown in Fig. 13, retainer 45 is inserted into abdominal aorta 11 through the use of third catheter system 48. Retainer 45 has radioopaque markers 42 on its proximal and distal surfaces. As retainer 45 and third catheter assembly 48 are inserted into abdominal aorta 11, radiographic system 34 tracks the location of retainer 45 relative to cephalic portion 13 and 19 of the abdominal aorta 14 and aortic graft 18, respectively. Once retainer 45 has been aligned with cephalic portion 12 and 19 of abdominal aorta 14 and aortic graft 18, respectively,

cephalic balloon 49 is inflated. As cephalic balloon 49 is distended, locking means 47 engage, fixing retainer 45 in the aorta 11 the open position. Once balloon 30 has been fully inflated so that retainer 45 is fully expanded, retainer 45 distends aortic graft 18 and aorta 11, forcing aortic graft 18 and attachment means 22 against cephalic portion 13 of abdominal aorta 11.

As shown in Fig. 14, caudal balloon 50 is then inflated, locking retainer 45 in the caudal portion of aortic graft 20 and aorta 14. Third catheter system 48 is then removed, along with guide wire 29. The incision in femoral artery 17 or iliac artery 16, through which the procedure was performed, is then closed and sutured. Circulation to the lower limbs is restored with aortic graft 18 excluding aneurysm 12 from circulation.

It will be apparent to those skilled in the art that various modifications and variations of the invention can be made without departing from the scope or spirit of the appended claims. In particular, aortic graft means 10 can be used with or without retainer 45. Retainer 45 could assume a variety of configurations, shapes and sizes while performing the function of securing aortic graft means 10 and abdominal aorta 14. Attachment means 22 could also assume a variety of configurations in accordance with the scope and spirit of the appended claims. Moreover, the direction in which each of the balloons of the double balloon catheter system 35 is inflated is not critical, provided attachment means 22 is oriented relative to the direction of inflation of cephalic 36 and caudal 39 balloons to facilitate penetration of aorta 11. Hence, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims or their equivalents.

I claim:

1. An aortic graft for performing an aortic anastomosis on a section of aorta, comprising,

aortic graft means, having cephalic and caudal ends, and having an axis,

a plurality of attachment means attached to said cephalic and caudal ends of said aortic graft means for securing said aortic graft means to the aorta,

said attachment means having

base means, oriented in substantially parallel relation to said axis of said aortic graft means, and attached to said aortic graft means,

post means, attached to said base member and extending substantially radially away from said aortic graft means, and

hook means oriented in substantially parallel relation to said axis, attached to the distal end of said post means for penetrating the aorta and securing said graft means to the aorta.

2. The aortic graft of claim 1, wherein said aortic graft means is subtantially cylindrical in shape.

3. The aortic graft of claim 1, wherein said aortic graft means comprises a resilient flexible material.

4. The aortic graft of claim 1, wherein said aortic graft means comprises a material inert to bodily fluids.

5. The aortic graft of claim 1, wherein said hook means further comprises barbed hooks.

6. The aortic graft of claim 1, wherein said aortic graft means further comprises retainer ring means for maintaining said first and second ends of said aortic graft in mated relation with abutting portions of the aorta.

7. An aortic graft for performing an aortic anastomosis on a section of aorta, comprising,

substantially cylindrical aortic graft means, having first and second ends

a plurality of attachment means attached to said first and second ends of said aortic graft means for securing said aortic graft means to the aorta,

said attachment means having

a base member attached to said aortic graft means at first or second ends thereof, oriented in substantially parallel relation to the longitudinal axis of said aortic graft means,

post means, attached to said base members and extending radially from said aortic graft means,

hook means attached to the distal end of said post means for penetrating the aorta and securing said graft means to the aorta,

said hook means further comprising a barbed hook.

8. The aortic graft of claim 7, wherein said aortic graft means comprises a resilient flexible material.

9. The aortic graft of claim 7, wherein said aortic graft means comprises a material inert to bodily fluids.

10. The aortic graft of claim 7, wherein said aortic graft means further comprises retainer ring means for maintaining said first and second ends in mated relation with adjoining portions of the aorta.

11. An aortic graft for performing an aortic anastomosis on a section of aorta, comprising,

substantially cylindrical aortic graft, having first and second ends

a plurality of attachment means attached to said first and second ends of said aortic graft means for securing said aortic graft means to the aorta,

said attachment means having

a base member abutting the interior surface of aortic graft means at said first or second end of said aortic graft means, said base member oriented

in substantially parallel relation to the longitudinal axis of said aortic graft means,

post means, attached to said base members and extending through said first or second end of said aortic graft means radially from said aortic graft means,

a hook, attached to the distal ends of said post means for penetrating the aorta and securing said graft means to the aorta,

said hook means further comprising a barbed hook, and

retainer ring means for maintaining said first and second ends in mated relation with adjoining portions of the aorta.

12. The aortic graft of claim 11, wherein said aortic graft means comprises a resilient flexible material.

13. The aortic graft of claim 11, wherein said retainer ring means comprises a series of short segments which ratchet past one another to resiliently maintain the diameter of said retainer ring against compression.

14. A process for repairing an aortic aneurysm through the use of a balloon catheter and aortic graft comprising the steps of,

Inserting a contrast filled balloon catheter into the aneurysm to a cephalic point, just above the aneurysm abutting unaffected arterial tissue;

Measuring to diameter and position of the aorta at the cephalic point, just above the aneurysm;

Withdrawing the contrast filled balloon catheter system from said cephalic point;

Repositioning the contrast filled balloon catheter in the affected artery to a caudal point, below the aneurysm abutting unaffected arterial tissue;

Reinflating the contrast filled balloon;

Measuring to diameter and position of the aorta at said distal point, just below the aneurysm;

Removing the contrast filled balloon catheter;

Measuring the distance between said cephalic and caudal points through radiographic techniques;

Inserting along with a double balloon balloon catheter a graft having first and second ends substantially 1-10 mm larger than the size of the aorta at said cephalic and cuadal points;

Inflating the cephalic balloon from the distal end of the cephalic balloon to force hooks at the distal position of the proximal end of said graft into mated relation with said cephalic aorta;

Continuing to blow up said cephalic balloon from said distal end of said cephalic balloon until said cephalic balloon is fully inflated and said proximal hooks are forced into mated relation with said artery at said cephalic point;

Maintaining inflation of said cephalic balloon while inflating caudal balloon;

Inflating said caudal balloon from the proximal end of said caudal balloon to force hooks at said proximal position of said caudal end of said graft into mated relation with said aorta at said caudal point;

Continuing to inflate said caudal balloon from said proximal end of said caudal balloon until said caudal balloon is fully inflated and said caudal hooks are forced into mated relation with said artery at said caudal point;

Removing the double balloon catheter system;

Inserting into said graft one or more retainers and a third balloon catheter system;

Implanting retainers at said cephalic and caudal positions inside aortic said graft;

Removing all catheters and wires;

Repairing all arterial incisions; and

Closing incision used to access femoral or iliac artery.

1/13

FIG. 1

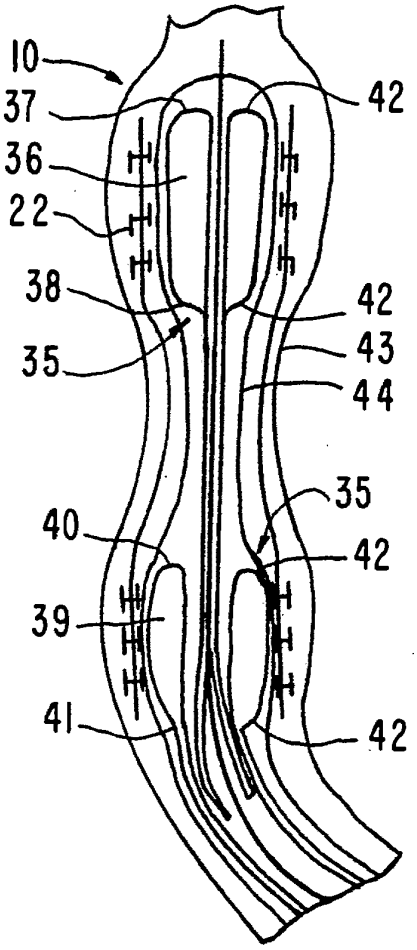


FIG. 2

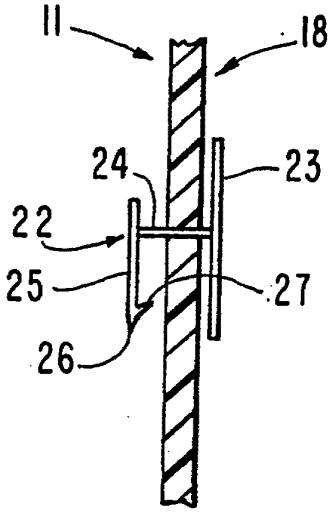


FIG. 3

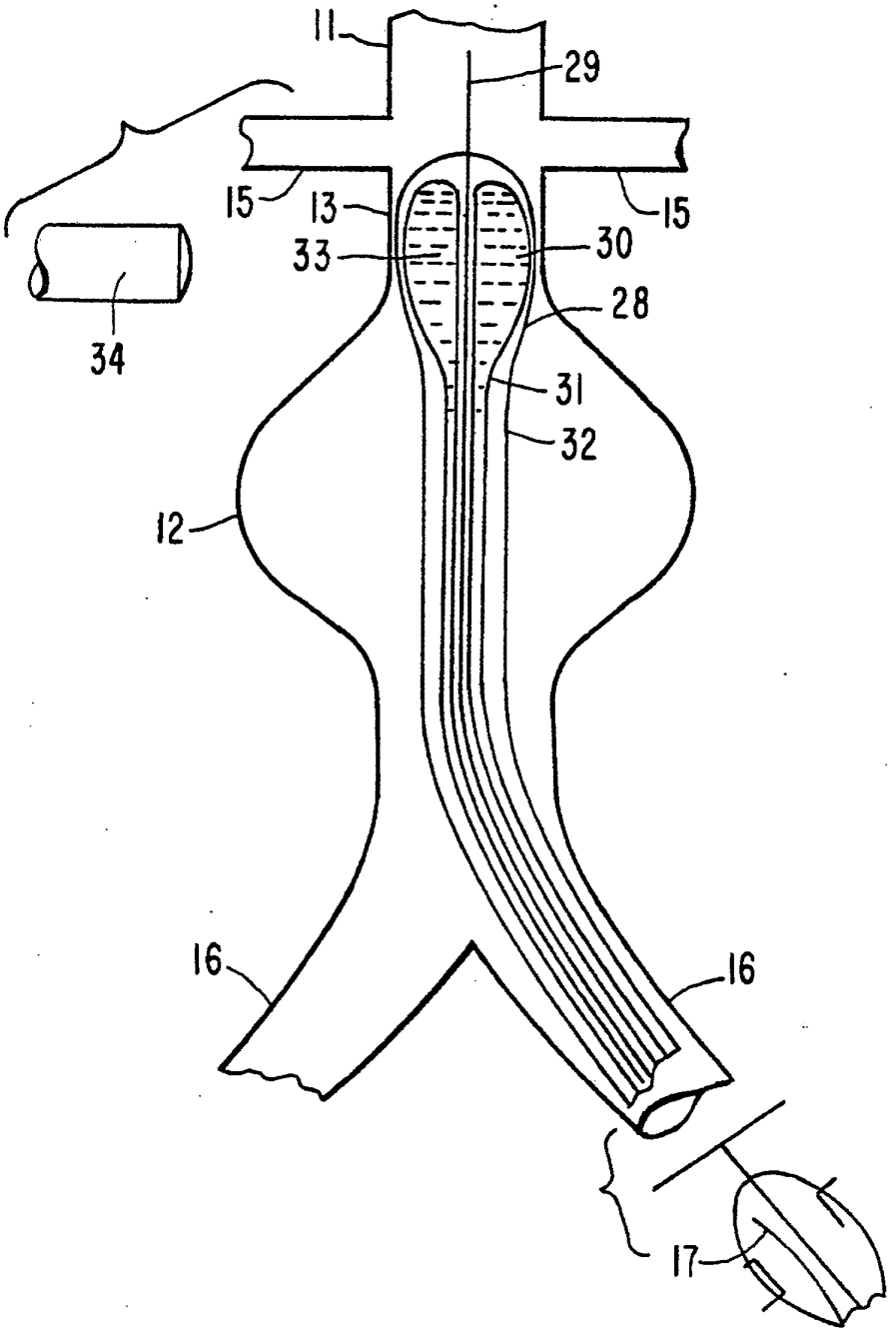


FIG. 4

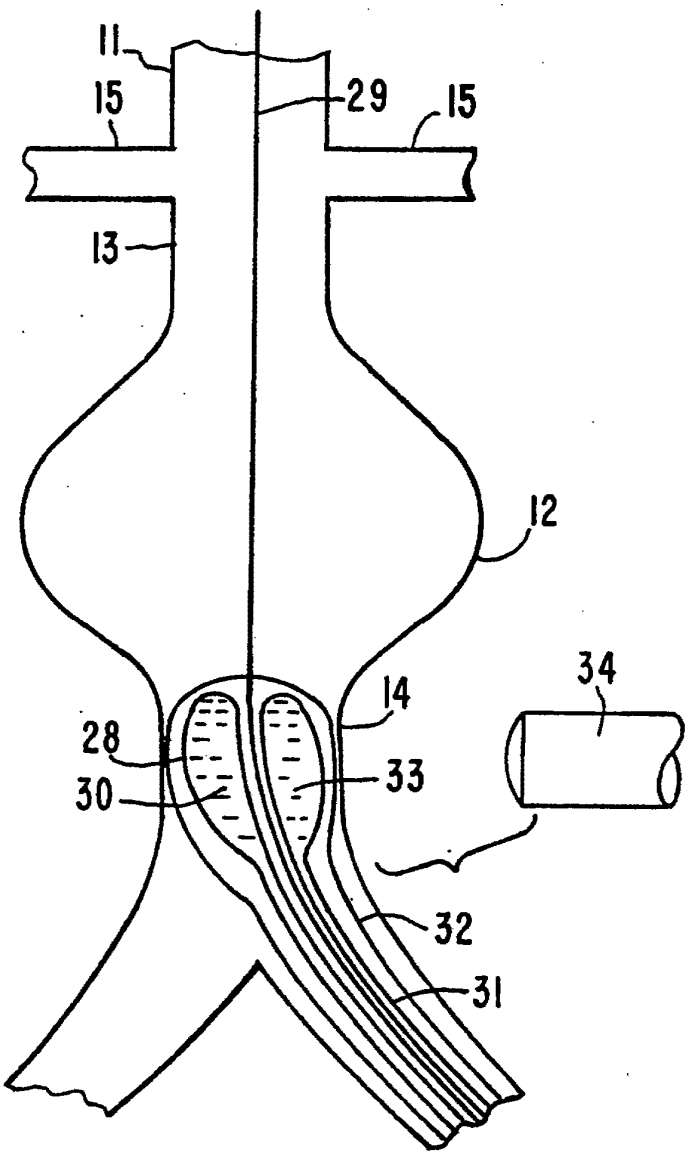


FIG. 5

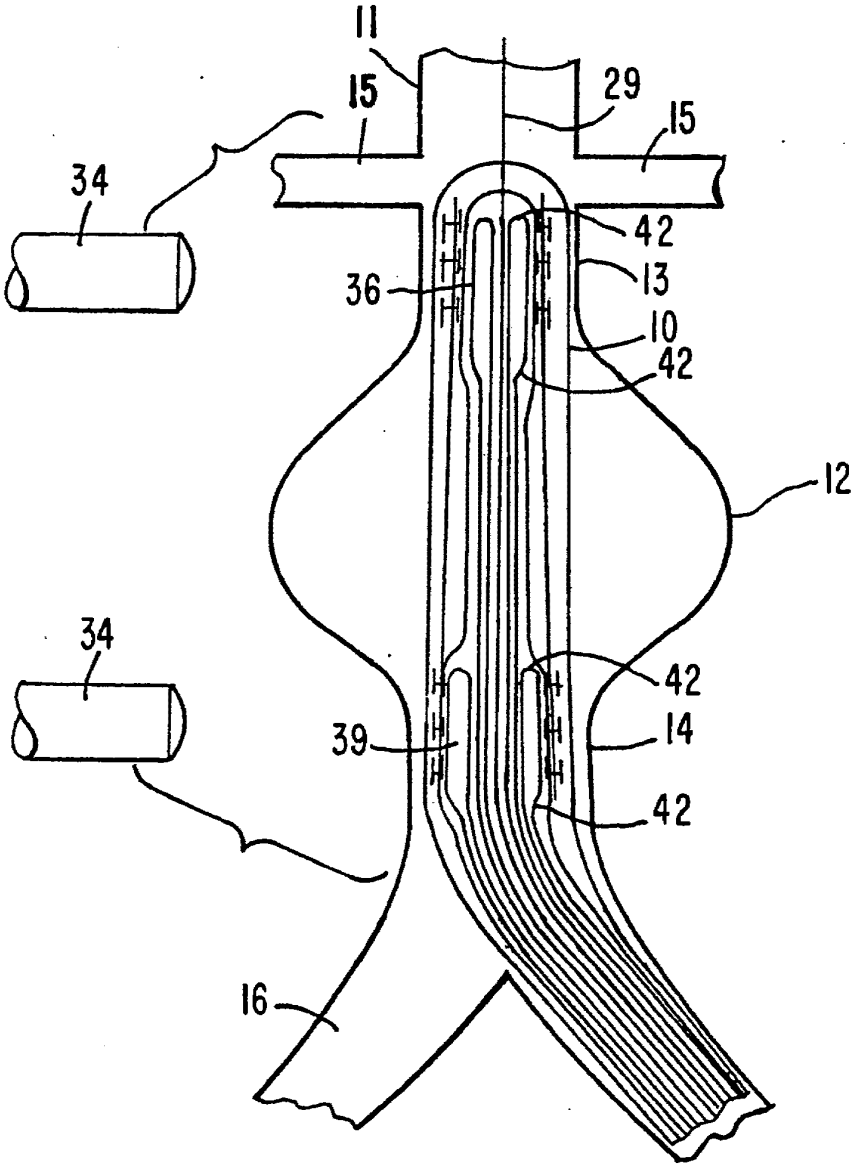


FIG. 6

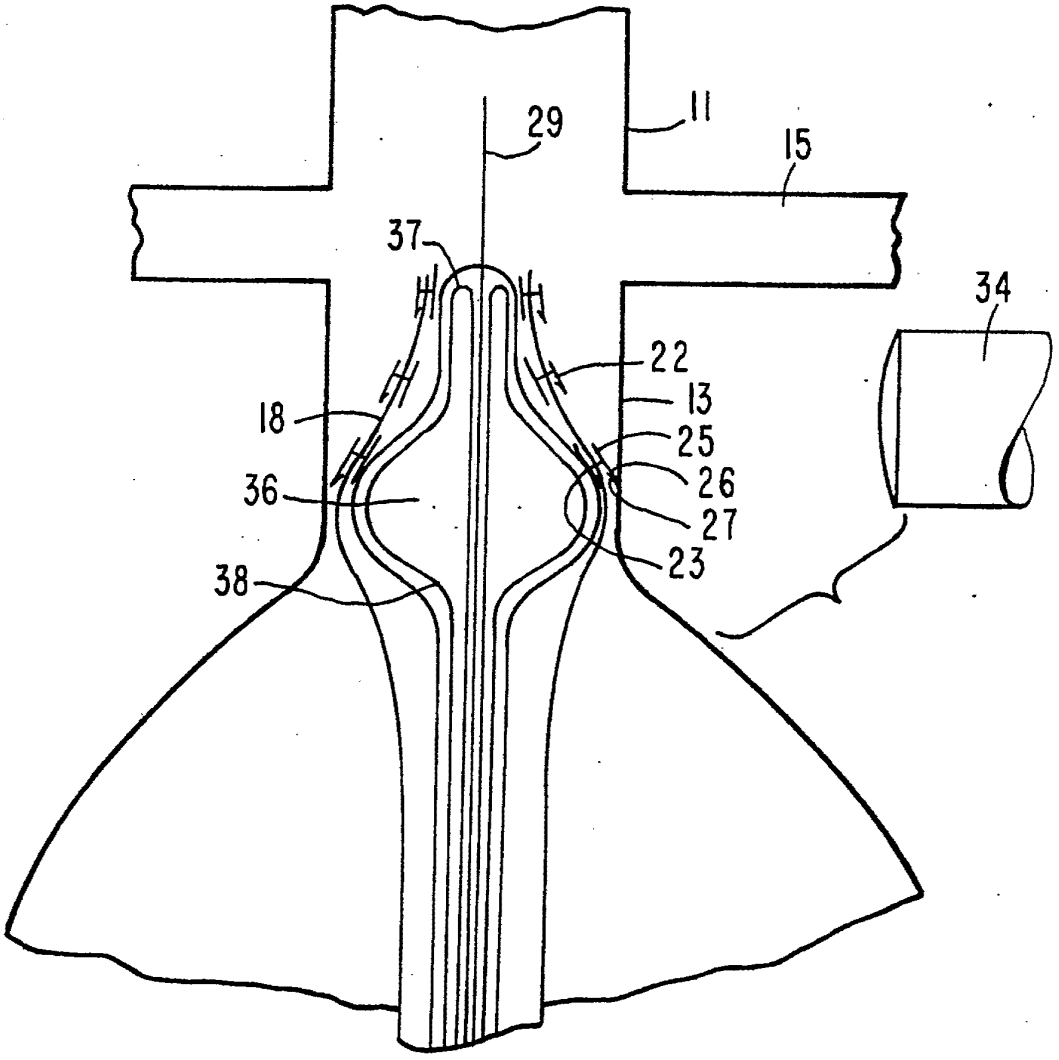


FIG. 7

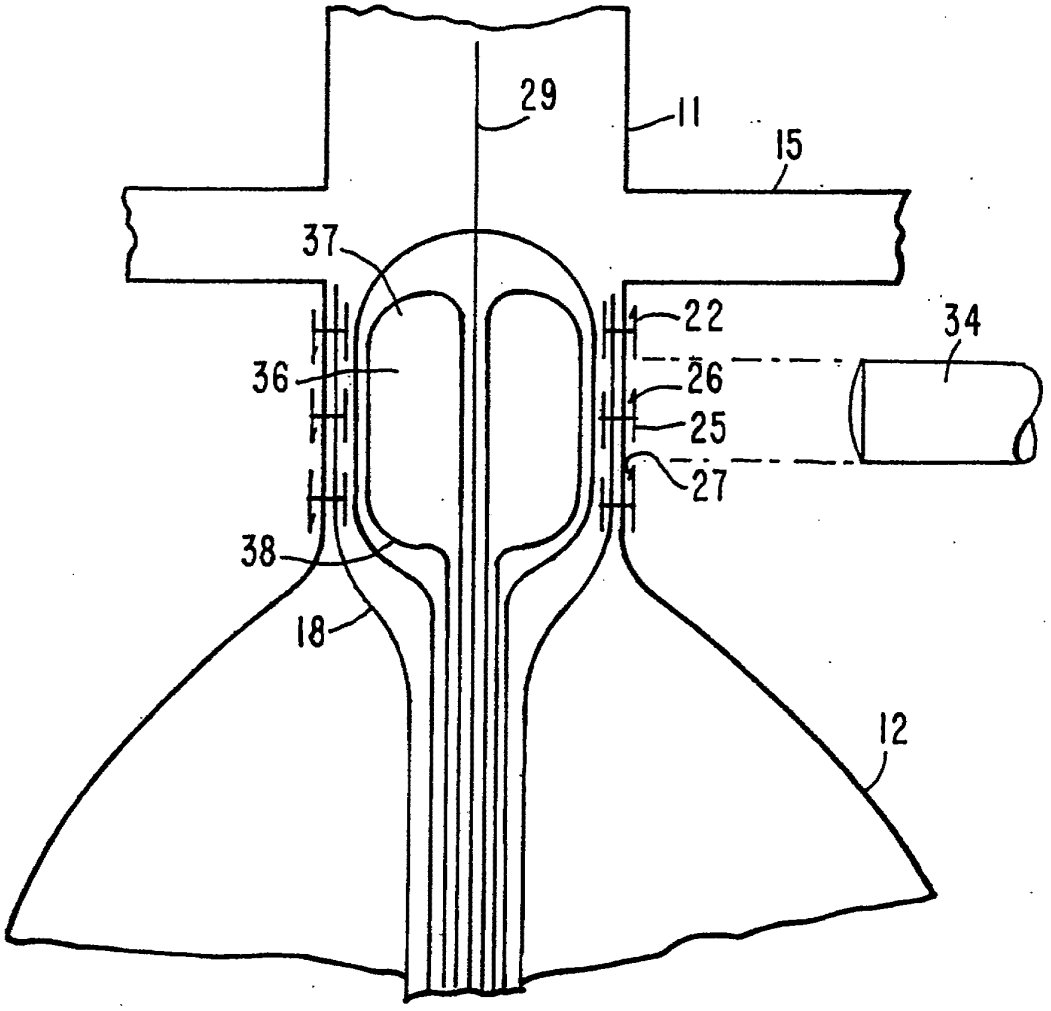


FIG. 8

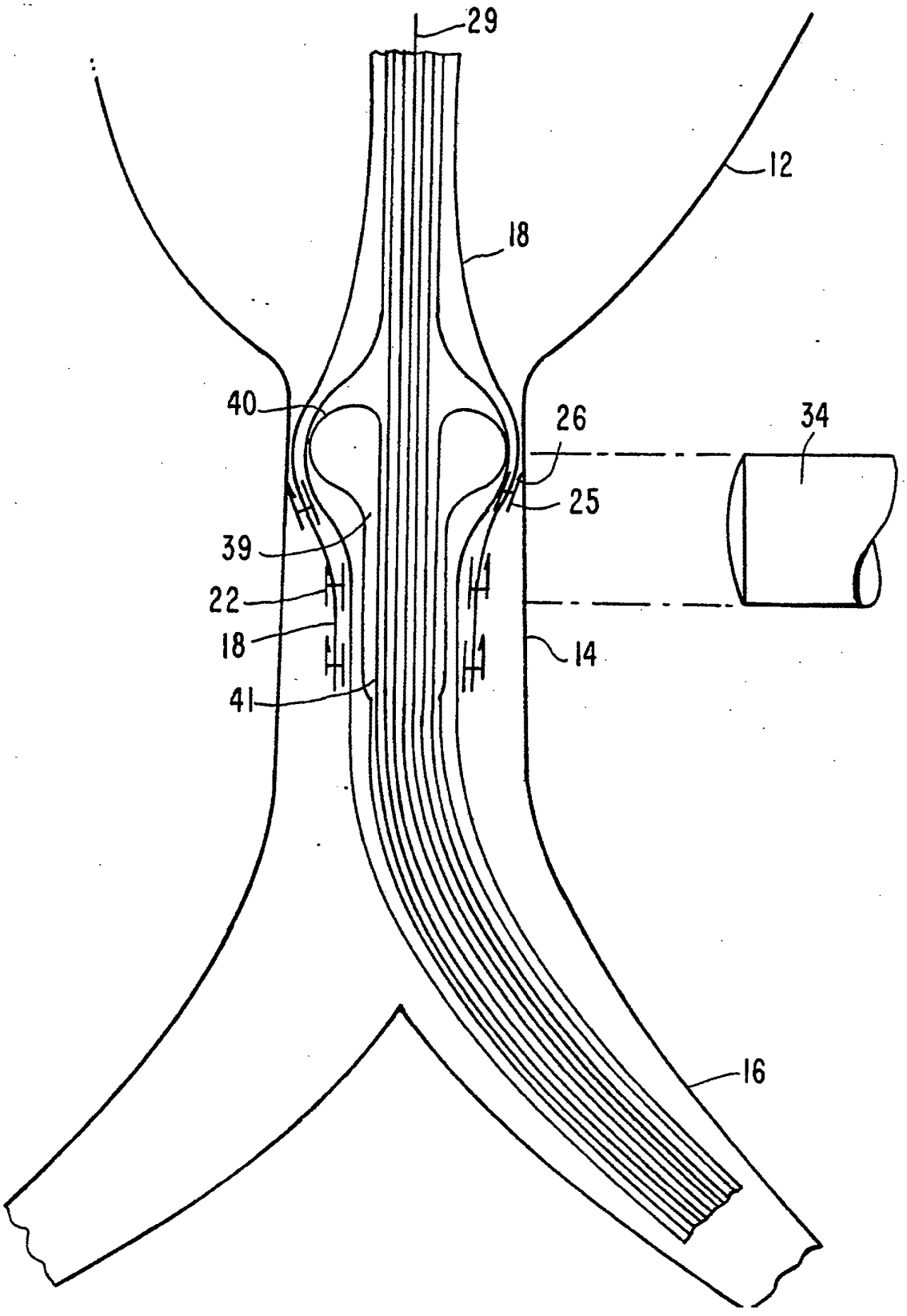


FIG. 9 8/13

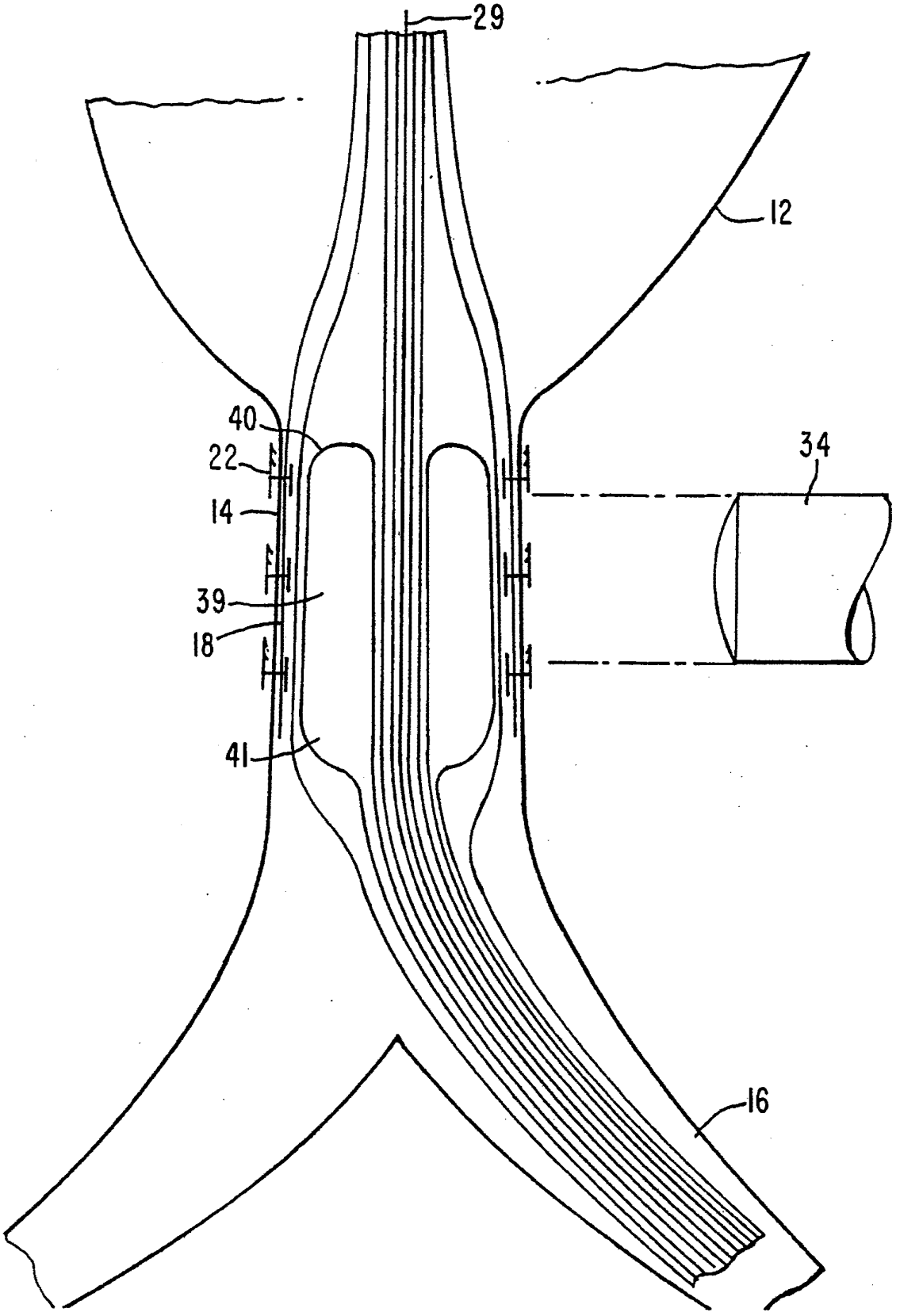


FIG. 10

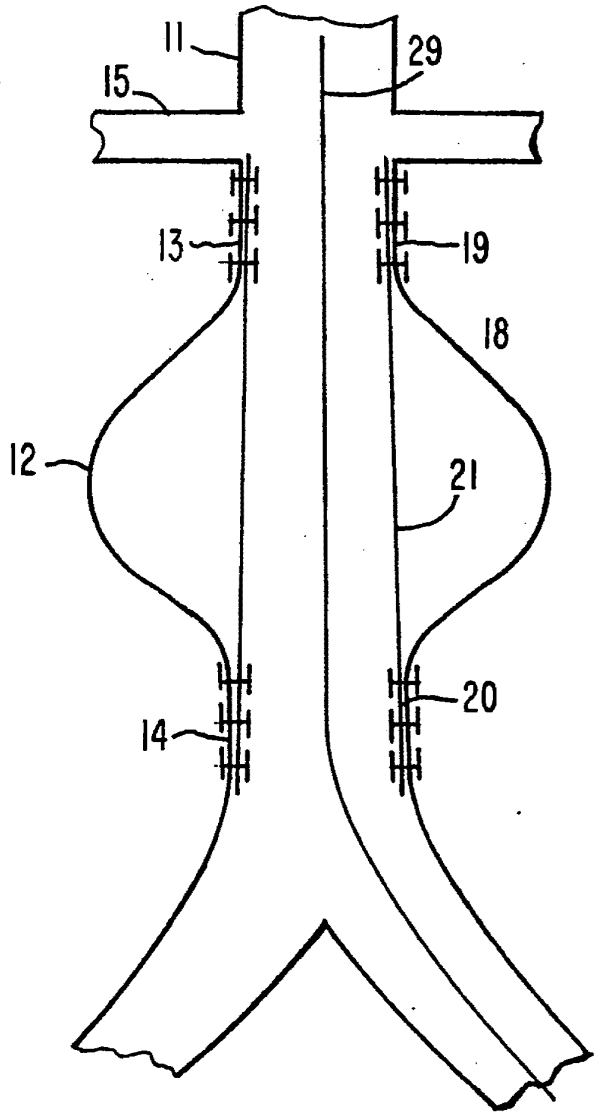


FIG. 11

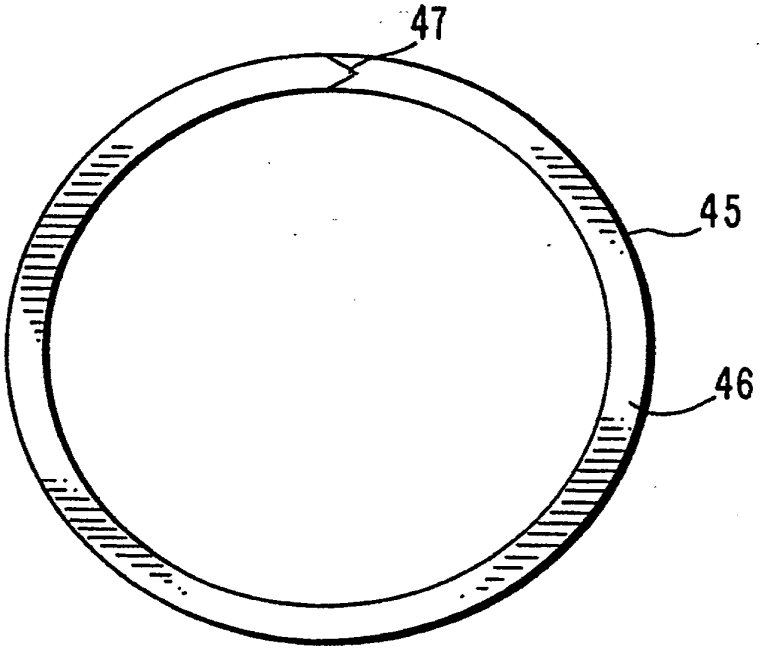


FIG. 12

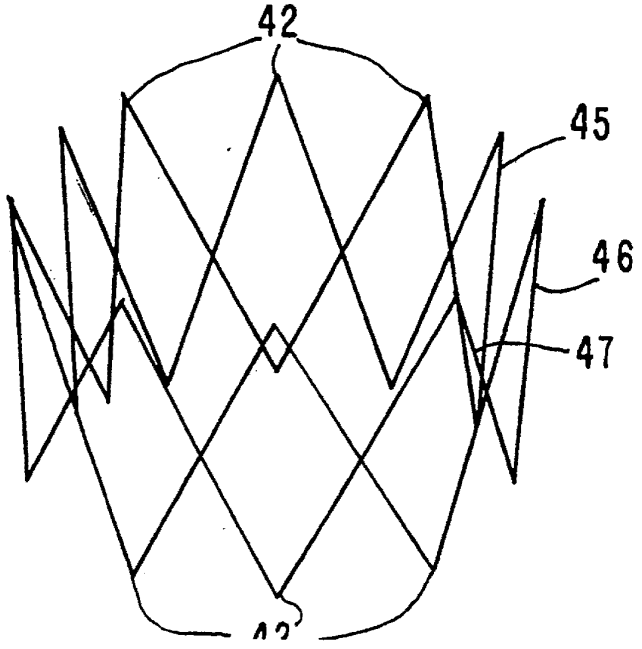


FIG. 13

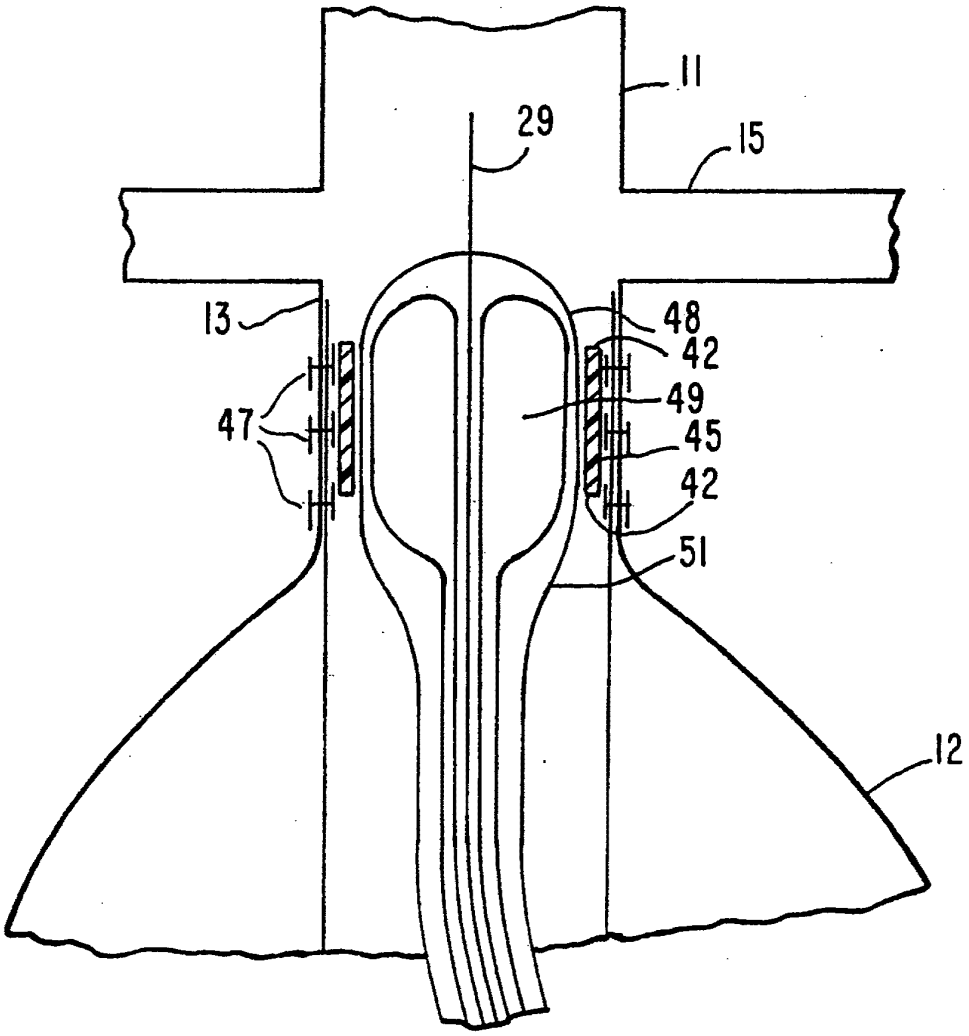


FIG. 14

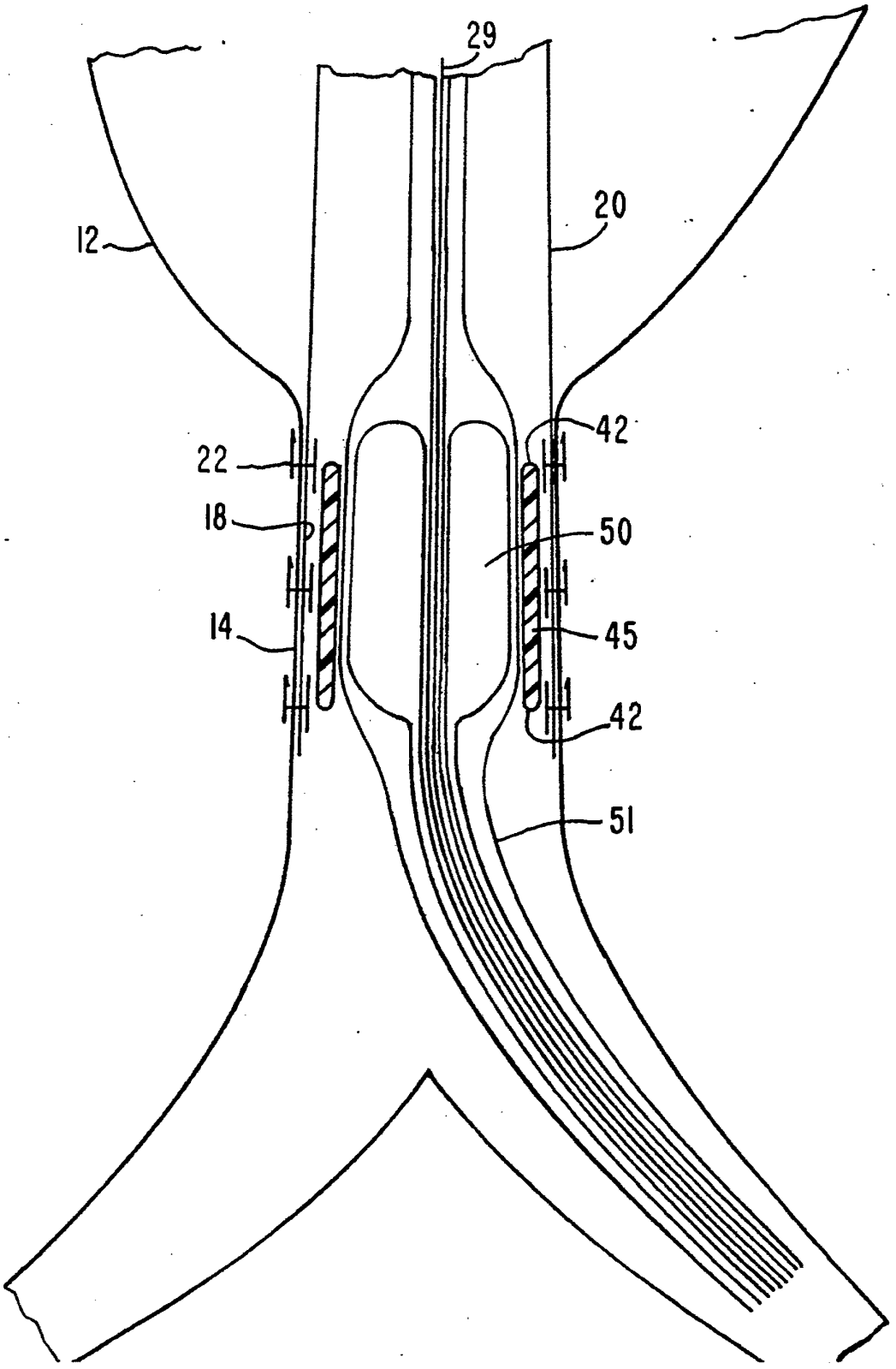
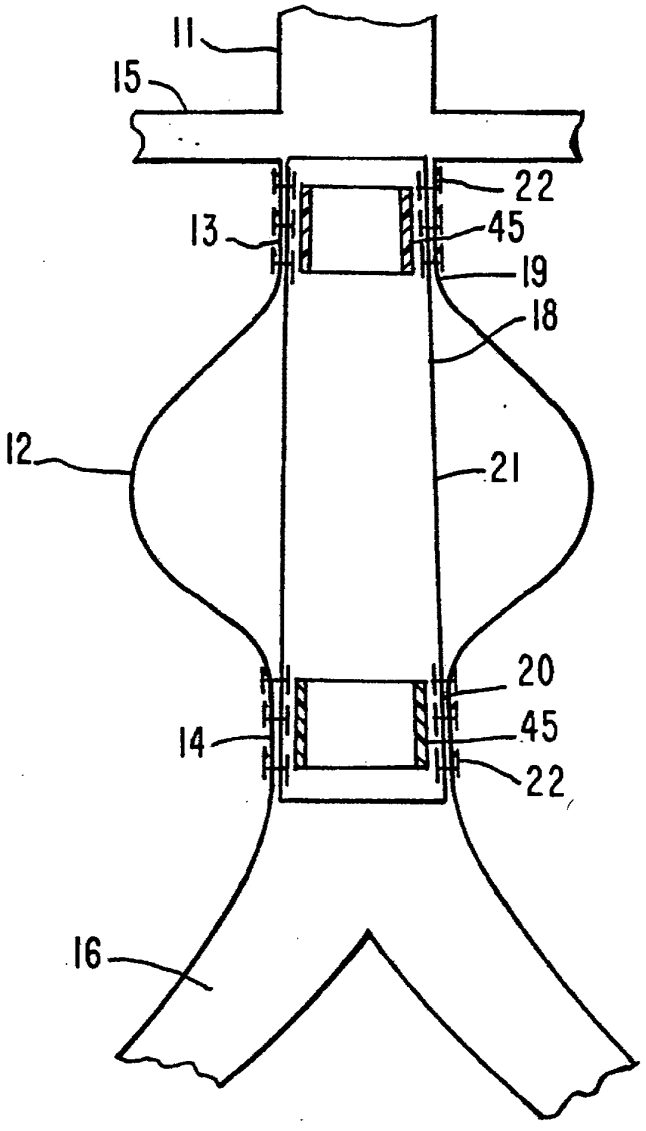


FIG. 15



INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/03322

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61F 2/06
U.S.Cl.: 623/1

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System [5]	Classification Symbols
U.S.	623/1 606/153,191,198,200 600/36,37

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X Y	US, A, 3,815,578 (BUCALO) 11 June 1974 See Figures 4 to 10 and Column 5, line 6 to column 6, line 3.	1-4 and 6 5 and 7-13
X,P Y,P	US, A, 4,872,874 (TAHERI) 10 October 1989 See Figures 1 and 9-12 and the passages of disclosure relevant thereto.	1-4 and 6 5 and 7-13
Y	US, A, 4,562,596 (KORNBERG) 07 January 1986 See Figures 2 and 5; Column 4, lines 28-47.	5 and 7-13

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [1]	Date of Mailing of this International Search Report [2]
21 August 1990	26 OCT 1990
International Searching Authority [1]	**Signature of Authorized Officer [11]**
ISA/US	For Paul Prebilic NGUYEN NGOC-HO INTERNATIONAL DIVISION

Form PCT/ISA/210 (second sheet) (May 1986)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☒ Claim numbers ..14. because they relate to subject matter [2] not required to be searched by this Authority, namely:

It relates to a method of treatment of the human body by surgery or therapy; see PCT Rule 39.1(iv).

2. ☐ Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [3], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [4]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

(19)日本国特許庁（ＪＰ）　(12)公開特許公報（Ａ）　(11)特許出願公開番号

特開平6－7454

(43)公開日　平成６年(1994)１月18日

(51)Int.Cl.[5]	識別記号	庁内整理番号	Ｆ Ｉ	技術表示箇所
Ａ６１Ｍ　29/00		9052－4Ｃ		

審査請求　未請求　請求項の数10(全 13 頁)

(21)出願番号　特願平5－87866

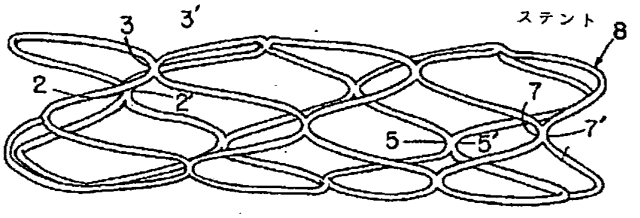
(22)出願日　平成５年(1993)３月24日

(31)優先権主張番号　８５８３０４
(32)優先日　1992年３月25日
(33)優先権主張国　米国（ＵＳ）
(31)優先権主張番号　８７４３４７
(32)優先日　1992年４月24日
(33)優先権主張国　米国（ＵＳ）
(31)優先権主張番号　９４３０００
(32)優先日　1992年９月10日
(33)優先権主張国　米国（ＵＳ）

(71)出願人　591048405
クック　インコーポレイティド
COOK　INCORPORATED
アメリカ合衆国、47402　インディアナ　ブルーミントン　サウス　カレー　パイク　925
(72)発明者　アーサー　ビー．フォンテイン
アメリカ合衆国　93720　カルフォルニア　フレスノ　イースト　ペリカン　361
(72)発明者　マイケル　ディー．デーク
アメリカ合衆国　カルフォルニア　スタンフォード　ゲローナ　ロード　665
(74)代理人　弁理士　木内　光春

(54)【発明の名称】　脈管ステント

(57)【要約】
【目的】　挿入時の非拡張状態において柔軟性を有し、挿入後の拡張状態においては、高い剛性と高い環状強度を有する脈管ステントとその製造方法を提供することである。
【構成】　本発明の管状ステントは、従来の折り込み構造に対し、共通平面構造を有している。この平面構造は、複数のセル３９を有し、このセルは、一本のワイヤを波状に形成し、それをマンドレルの周囲に巻回し、その波の山部と谷部とを接続することにより形成される。本発明の脈管ステントは、非拡張状態において柔軟性を有し、そのため、それらが挿入される血管の曲がりにくなった形状に適合できる。また、その拡張状態においては高い剛性と高い環状強度を有する。



1

【特許請求の範囲】

【請求項１】　複数の側面を有する複数のセル（３９）を有する管状体からなる脈管ステントにおいて、
前記管状体が非拡張状態にあるとき、前記セルの側面は前記管状体の縦軸にほぼ平行に伸び、
管状体が拡張状態にあるとき、少なくともあるセルの側面は前記縦軸に対して傾斜していること特徴とする脈管ステント。

【請求項２】　隣接するセルのある側面の内の隣接する側面は、前記ステントは拡張状態にあるとき、長斜方形を形成するような複数の相互接続セルを含むように互いに結合されることを特徴とする請求項１のステント。

【請求項３】　前記複数のセルは、隣接する側面が結合されるような隣接するセルでもって管状体に形成される連続したワイヤから形成されることを特徴とする請求項２のステント。

【請求項４】　前記隣接する側面は、側面毎に一点でスポット溶接されることを特徴とする請求項３のステント。

【請求項５】　ステントが拡張する際に、前記長斜方形のセルを形成するよう前記隣接する側面は結合点の周囲で回転することを特徴とする請求項３または４のステント。

【請求項６】　前記ステントが拡張する際に、前記連続ワイヤは可塑性限界を超えて変形して、拡張状態を維持することを特徴とする請求項３、４、５の何れかのステント。

【請求項７】　前記連続ワイヤは、その内側に向いて平坦な側面を有する半環状断面を有することを特徴とする前記請求項の何れかに記載したステント。

【請求項８】　ワイヤをサイン波形に形成するステップと、
前記ワイヤをマンドレルの周囲に巻回するステップとからなるステントの製造方法において、
前記波形は、マンドレルの縦軸に整合する直線部分を有し、
前記ワイヤは、ステントの内側に向いて平坦部分を有する半環状断面を有することを特徴とするステントの製造方法。

【請求項９】　隣接するセルの隣接する側面の場所でワイヤを結合するステップをさらに含み、
前記ステントはそれが拡張した際に、長斜方形を形成するよう、前記地点の周囲に回転する複数の相互接続セルを形成することを特徴とする請求項８の方法。

【請求項１０】　前記サイン波形はＵ字型の形状をして、巻回した際に軸方向に離間した谷は軸方向に離間した山と対応し、前記山と谷は結合され、
Ｕ字型のワイヤの隣接するセルの側面は拡張時に長斜方形のセルを形成するようワイヤが回転する特定場所で結合されることを特徴とする請求項９の方法。

2

【発明の詳細な説明】

【０００１】

【産業上の利用分野】本発明は脈管ステントに関する。

【０００２】

【従来の技術】一般的に、ステントは患者の体内に配置される管状体装置で、収縮した器官を拡大する。例えば、ステントは血管を開放状態に維持し、血管の手術の後、血管内の内部の突起を壁に張り付けている。より一般的な使用方法としては、ステントは血管以外の人間の器官内、例えば、食道、尿道、胆汁道にも使用される。血管形成外科の分野において、最も一般的な血管形成手術は、経皮的器官内貫通冠状動脈血管手術（ＰＴＣＡ）である。この手術は、心臓の近傍の狭い動脈を拡張する必要がある。この手術では、バルーンカテーテルを用いて、狭い血管を拡張する。このバルーンにより動脈が拡張した後、カテーテルの先端のバルーンを収縮させ、この拡張した動脈からこのカテーテルを取り除く。脈管ステントはＰＴＣＡの拡張作業の後、血管を拡張しておくのに用いられる。

【０００３】実際問題として、上記のＰＴＣＡ手術はいくつかの欠点がある。その一つはＰＴＣＡの患者の約三分の一には、血管を狭くするような組織の再成長、すなわち、再狭窄という症状が現れる。この再狭窄は、一般的に、手術後六ヶ月内に発生する。このような症状が発生すると、この患者は再びＰＴＣＡ手術をして、より危険な冠状動脈バイパスグラフト（接ぎ木）手術を受けなければならない。都合の悪いことに、ＰＴＣＡ手術を繰り返して受けた患者には、より高い頻度で再狭窄症状が発生する。

【０００４】第２の欠点としては、ときには致命的なものであるが、血管形成手術の合併症として、血管の拡張した部分が突然再閉塞することである。ＰＴＣＡ手術後の突然再閉塞の発生因子には色々なものがあり、破壊された壁組織の障害フラップ、血管壁の発作、拡張点における血栓形成である。脈管ステントは狭くなった血管を機械的にブリジする足場のように使用される。この突然閉塞の多くの要因は、狭窄と長期間の開通に対し大きな影響を有する。この点に関し、脈管ステントは再狭窄を防ぐのに非常に有益である。

【０００５】

【発明が解決しようとする課題】以上述べたごとく、本発明の目的は、血管内に挿入しやすく（柔軟性を有し）、挿入後は、その血管内にしっかり固定できる（高い剛性と環状強度を有する）脈管ステントとその製造方法を提供することである。

【０００６】

【課題を解決するための手段】本発明の管状ステントは、従来の織り込み構造に対し、共通平面構造を有している。本発明の脈管ステントは、非拡張状態において柔軟性を有し、そのため、それらが挿入される血管の曲が

りくねった形状に適合できる。挿入する間、この柔軟性を有するか否かは、年輩の患者に対しては非常に重要なことで、それは、彼らの血管は若い患者のそれよりは曲がりくねり、そして柔軟性に乏しいからである。本発明の脈管ステントは、その拡張状態においては高い剛性と高い環状強度を有する。本発明の剛性の高いステントがよい理由は、おそらくこの剛性が高いステントは血管内で波打つ可能性が低く、それ故に、それらが一旦血管内に配置されると、血管壁との間で擦り合うことが少ないためと思われる。

【０００７】

【実施例】本発明のステントは、連続するワイヤから形成される。本明細書で使用されるワイヤという用語は、必ずしも金属材料に限定されるものではない。実際、本発明のステントは、あらゆる種類のフィラメントから形成できる。本発明のステントは、連続するフィラメントを形成するために、一括して巻回されるフィラメントまたはファイバのグループから形成してもよい。またいくつかのフィラメントを一括して接続してもよい。非拡張状態のステントをモールドすることも可能である。

【０００８】ステントが患者の体内に挿入された後、非拡張状態に巻き戻るのを防ぐために、このステントは一旦変形された後は、元の形状に戻ることのない「低メモリ」材料から形成されるのがよい。あるいは、ワイヤのサイズは拡張状態のときに、ワイヤは降伏点を超えて応力がかけられるが、クラックやひび割れが入るような最終応力を超えないようにするのが好ましい。未形成ワイヤと非拡張状態のステントをアニールして、ステントの形成プロセスの間、ワイヤに生成する応力（ストレス）を減少させるのがよい。

【０００９】このステントの材料は放射線不透過材料が好ましい。放射線不透過材料製のステントは、蛍光透視法によりその存在場所を確認することができる。このステントは生物的に適合性を有する材料（ステンレス）及び／または生物吸収材料（ビニール）製で、周囲の組織及び血液のような体液に対し、ステントからの影響を最小にするようなスムーズな表面を有している。また、このステントは、血栓形成防止剤、あるいは、凝血防止剤（デクストラン、ヘペリン、ｔ－ＰＡ、ポリテトラフロロエチレン、超低温カーボン同位体）でコーティングされている。

【００１０】図１は、圧縮状態の平面状波形に形成されたフィラメント１１を表す。このフィラメント１１は、０．０１３－０．０５ｃｍの直径のステンレス製ワイヤである。しかし、チタン、タンタル、金、銅、銅合金、あるいはこれらの材料、あるいは低形状記憶レベルの生物的適合材料から形成されてもよい（本明細書において、低形状レベル記憶とは、ステントが患者の体内に挿入され内部で拡張した後は圧縮（非拡張）状態には戻らないことを意味する）。このフィラメント１１は、束ねて織られた数個の個別のより糸から形成することもできる。

【００１１】図１の圧縮状態の波形パターンは、圧縮状態のサイン波形が好ましいが、それと同様な波形でもよい。図において、ワイヤの端部１９、２１の波形は、ワイヤの中央部の大波形１５よりも小さい。この図は、端部１９、２１の各端部で４個の小波形１７を図示している。この小波形１７の高さは大きな波形１５の高さの２分の１から３分の２が好ましい。

【００１２】図２に示すように、図１の圧縮状態の波形は、軸方向センターラインに沿って、その端部を引き延ばすことによって、ほぼサイン波形となる。この点線は拡張した波形の軸方向センターラインを表す。端部１９と２１において、小波形１７のセンターラインは、ワイヤの中央部近傍の大波形１５の軸方向センターラインからずれている。例えば、端部１９において、小波形１７のセンターラインは点線の下にあり、端部２１においては、それとは反対に、小波形１７のセンターラインは点線の上にある。

【００１３】上記の波形は、周期が約８ｍｍが好ましい。この大波形１５は、振幅が８ｍｍで、小波形１７は、大波形１５の１／２から２／３の高さである。もちろん、他の大きさも使用可能である。波形のすべては同じ周期であるが、それらは必ずしもサイン波形に限らず、繰り返し波形であればその形状は問わない。

【００１４】図３、４は、本発明のステントを形成するのに使用される他の波形を表す。図３の各波形の周期は、図１の振幅の１／２が好ましい。図３において、小波形１７ａの端部における軸方向センターラインは互いに平行で、大波形１５ａのセンターラインは小波形１７ａのセンターラインに対し傾斜しており、その角度は約４５°が好ましい。図４において、その波形は、図３に類似しているが、波形１５ｂのセンターラインは、小波形１７ｂのセンターラインに直交している。即ち、小波形１７ｂのセンターラインは、大波形１５ｂのセンターラインに対し９０°傾いている。

【００１５】図５は、図３の拡大状態の波形を示し、マンドレル３１の周囲に螺旋状に巻回することによりステントが形成される。例えば、図４の波形が使用されると、大波形の軸方向センターラインは、マンドレル３１のセンターラインに平行で、マンドレル３１の周囲に巻回された波形のピークは、マンドレル３１のセンターラインに直交する。

【００１６】図５において、大波形１５ａのセンターラインは、マンドレル３１に沿って、螺旋状に構成される。大波形１５ａの一側面は、マンドレル３１の縦軸にほぼ平行に配置され、波形の残りの部分はマンドレル３１の縦軸に対し、小さな角度でもって形成される（図において、小さな角度は図示するために誇張している）。図において、ステントは非常に緊密な螺旋状に巻回され

ている。

【００１７】本発明のステントをマンドレルの周囲に緊密に螺旋状に巻回することにより、このステントを患者の器官内で拡張する際に、半径方向に主に広がり、その端部（長手方向）は若干移動するでけである。半径方向のより大きな拡張は、マンドレルの周囲に環状に波形を巻回することにより達成される。しかし、そのような半径方向に巻回した構造は、器官を支持するのに、一ユニットの表面当り大量のフィラメントを使用する、特に、フィラメントがオーバーラップするような場所で。

【００１８】図６において、ステントの端部の最後の三個の小さな波形１７ａが、マンドレルの周囲に巻回される。この三個の小さな波形のピーク（図６でそれぞれ”ａ”、”ｂ”、”ｃ”で表す）はマンドレルの端部からほぼ同一距離にあり、４個目の山”ｄ”はマンドレルの端部から若干離れている。ピーク”ａ”の近傍のステントの端部は、ピーク”ｄ”の頂上に接続され、この接続により、ピーク”ａ”、”ｂ”、”ｃ”はマンドレルの周囲でほぼ等間隔に配置され、マンドレルの端部からほぼ等距離にある。

【００１９】実際は、ループとフィラメントの間の接続は、フィラメント１１に沿って、スライド可能で、そのため半径方向に伸びることができる。この接続は図示したループを用いて形成できるが、例えば、ブラケットを用いて形成することも可能である。この接続は端部をフィラメントにハンダ付けしたり、溶接したり、接着することにより形成される。

【００２０】本発明のステントは、緊密な螺旋状でマンドレルの周囲に巻回されているが、ステントの非拡張形状では、従来のステントよりも低いプロファイルを形成し、非拡張状態のステントの歯は、ほとんど平行で、緊密にパックされている。このことは、ステントは小さな貫通口を介して収納され、外科手術の間、血液の流出を抑えるために重要なことである。さらに、このステントは、大きな血管内で使用可能なように約１０：１の拡張比を有する。

【００２１】図１２に示すように、フィラメント１１の端部の接続はステントの各端部で環状の輪を形成し、そこからは鋭いエッジ、またはポイントが血管内に突出しないようにしている。小波形のセンターラインはステントの周囲に配置されて、端部の輪は器官内に適切にフィットして、血液の流出を阻止する。言い替えると、このような構成により、輪は半径方向に広がって、器官内に拡張状態のステントを配置し、一方、軸方向の拡張を制限する。

【００２２】図７において、この波形はＵ字型のカーブした部分と各サイドに直線部を有するＵ字型ベンドから形成される。この直線部は、平行が好ましい。しかし、ある程度の角度をもって形成してもよい。このカーブした部分は半円状が好ましいが、各ベンドで直線部を接続する如何なる形状のものでも構わない。このカーブした部分は同一サイズ、または異なるサイズでもよい。このカーブ部分は各カーブの接線でもって、直線部に接続されて、フィラメントに不連続面ができないようにする。

【００２３】図８は、図７の他の実施例でＡ、Ｂ、Ｃの各部分に対するＵ字型のベンドの部分を示す。この波形のＡとＣの部分は互いに勝手違いで、上下反対方向である。図８の点線は等間隔で平行な基準線を示す。基準線の上部と下部は互いに平行であるが、或いは、不等間隔で互いに平行ではないようにステント形成することもできる。

【００２４】基準線の間の距離を１ユニットの測定値として定義すると、ＡとＢの部分のＵ字型のベンドの各部分は異なる長さを有する。例えば、Ｕ字型ベンド１は１ユニットの長さであり、Ｕ字型のベンド３は３ユニットの長さを有する。同様に、Ｕ字型ベンド７’は１ユニットの長さであるが、Ｕ字型ベンド５’は３ユニットの長さとなる。これに対し、Ｂ部の波長の各々は４ユニット長さの長足と３ユニット長さの短足とを有する。例えば、Ｕ字型ベンド５の左足は、４ユニット長さを有し、右足は３ユニット長さを有する。カーブした各々の部分は、フィラメントの端部を除いて、１ユニットの直径の半円形である。フィラメントの端部のカーブした部分は、半円アークの１／２である。しかし、他の形状比率も本発明のステントに使用することもできる。

【００２５】図９において、ステントはシリンダー状のマンドレルの周囲に図７の波形を巻回することによって形成される。しかし、マンドレルは他の形状のものでもよい。この波形は、マンドレルの周囲に巻回されて、Ｕ字型ベンドの各足はマンドレルの軸に対し平行である。この構成において、１本のワイヤが非常に剛性の高い環状構造に形成され、器官内での流れを阻害することのない非常に細い材料で構成される。しかし、この波形はマンドレルの周囲に緊密に螺旋状に巻かれてもよい。波形がマンドレルの周囲に巻回されると、同一基準線のカーブの外側端部は互いに背中合わせに構成される。例えば、カーブ１の外側端部は、カーブ１’の外側端部と背中合わせである。同様に、カーブ２の外側端部は、カーブ７’に隣接する。これらのＵ字型ベンドの外側端部は、従来の溶接、蝋付け、ハンダ接着により固着される。

【００２６】図１０、１１、１２は、図８の波形をシリンダー状マンドレルの周囲に巻回することにより形成され、基準線はマンドレルの周囲に構成される。図８の平行な基準線のラベルを付したＵ字型ベンドの各々は、図１０、１１でもって接続される。例えば、Ｕ字型のベンド７’は図１０の上部でＵ字型ベンド７に接続される。Ｕ字型ベンドは溶接されるのは好ましいが、フィラメントの接続部を単一の材料から形成して、Ｕ字型ベンドを互いに接続する必要性を無くすこともできる。フィラメ

ントの端部はフィラメントに接続して、自由端から取り除かれる余分なフィラメントを取り除くよう修正することもできる。

【００２７】この構造体の剛性の制御は、隣接するカーブ部分の溶接する点の数を変えることにより行われる。例えば、溶接されたＵ字型部分が半分のみ溶接されたステントは、全ての接点部分が溶接されたステントの剛性の約半分となる。このステントは、隣接するカーブ部分の間を接続することなしに使用することもできる。

【００２８】最も低いプロファイル（すなわち、円）は、カテーテルの軸に平行な各Ｕ字型ベンドの長足をアレンジすることにより提供される。このように構成することにより、ステントが拡張される直径を増加させ、同時に、ステントの端部長さを減少させることもできる。各Ｕ字型ベンドの長足の長さを増加させるか、または減少させることにより、プロファイルを変更することなく、拡張比を変えることができる。従って、ほぼ無制限の円周状拡張比が縦軸に沿ったステントを縮ませることなく得ることができる。

【００２９】この拡張比は、このプロファイルにはほとんど無関係である。拡張した際に、ステントのＵ字型部分の各々は斜方形状パターンを取り、Ｕ字型ベンドの足はすでに平行とはならない。このステントの拡張比は、拡張直径対非拡張直径で１０：１以上である。従って、血管に接触するステントの外部表面は小さく、一方、有効な支持面積は非常に大きい。この特徴は、血管内の血液流の流れを邪魔する可能性が非常に少ない。この大きな拡張比により小さな挿入口でもって、ステントを使用することができる。さらに、この形状によりステントは、半径方向にフレキシブルで、血管の脈流を収納できる。このステントの表面には血栓防止剤を塗布することもできる。

【００３０】図１３－１６において、上記の実施例によるステントの使用例を図示する。図１３は、４／５Ｆバルーン（４－１０ｍｍ）で、６／７Ｆシースに搭載されたステントを表す。図１３の装置は、０．０７８－０．０９１ガイドシースと共に使用される。図１４は、動脈瘤の治療に用いられるグラフト内のステントを表す。グラフト９内に配置されたステント８は動脈瘤１３をブロックする。このステント８はグラフト９内に完全に配置されたように図示されているが、グラフト９の端部の外側にまで伸びてもよい。

【００３１】図１５は、例えば、血管内の閉塞部２３をバイパスするグラフトの各端部に使用される２個のステント８、８を表す。図１６は、動脈瘤を治療する分岐グラフト９と共に３個のステント８、８、８が如何に使用されるかを図示する。このグラフト９は、動脈瘤３３内に配置されて、大動脈３５の一端に固定される。グラフトの他端は腸骨分岐３７内に挿入される。図１６は、図１７のカテーテルがステント８を器官内に如何に挿入するかを図示する。一般的に、小さな切込みが器官に形成され、その後、バルーンに搭載されたステントが、この切込み内に挿入される。ステントが配置されると、バルーンが拡張して、器官の内壁にステントを押し合って拡張させる。一旦、ステントが配置されると、バルーンは収縮し、ステントの内側と切込みを介して除去されて、ステントをその場に配置する。

【００３２】本発明のステントの利点は、従来のステントよりも少ない材料で形成できることである。それ故に、少量の異質物（ステント）を患者の器官内に挿入するだけでよい。また、本発明のステントは、器官内で構造的に最大の支持を与えることができる。また本発明のステントは、フィラメントの端部をフィラメントに接続するために、血管内の血栓形成を阻止し、器官の壁に対する損傷を阻止する。

【００３３】また本発明のステントは、軸方向に限られた移動だけでもって、半径方向に大きく拡張することができ、それ故に、器官内におけるステントの移動の問題を最小限にすることができる。特に、本発明のステントは、輪形状とその構成要素とでもってステントを器官の内壁に固定することにより、移動を少なくできる。また輪形状と構成要素とステントの螺旋形状とにより半径方向に拡張する間、ステントの軸方向の動きを阻止することができる。また本発明の利点は、曲がりくねた器官内に十分配置できるフレキシビリティを有する。これにより、従来のステントは、曲がりくねた器官、血管内に配置することが困難であった問題点が解決される。

【００３４】本発明のステントは、図１７に図示するような平面状の波形に形成された連続したワイヤから形成できる。図１７のパターンは、Ｕ字型の波形で周期がｐの山部１０と谷部１２とを有す、それらは直線部１４でもって相互に接続されている。この直線部１４は、図１７、１８、２０で互いにほぼ平行で、それ故に、図では垂直ラインとして描いている。しかし、本明細書において、ほぼ平行とは図１９と２１の圧縮平面波形に図示された直線部１４の形状を意味する。この山部１０と谷部１２は好ましくは半円状で、カーブした山部または谷部の接線でもって、直線部１４と接触して、ワイヤに不連続点がないようにする。しかし、他のカーブ、または直線形状を用いて、山部１０と谷部１２とを形成してもよい。各Ｕ字型の波は上昇サイド１４Ａと下降サイド１４Ｂとを含む。

【００３５】この波形の中央部の山部１０と谷部１２の最外側部分は、それぞれ平行軸１６と１８に沿って整合している。この平行軸１６、１８は、直線部分１４に対し、鋭角αを形成する。この角度αは好ましくは４５°で、直線部間の距離が１ユニットであると、中央部の各Ｕ字型波は３ユニット長の長さの一足と、図１７の水平基準線に平行線で表される４ユニット長の他足を有する。他の寸法または角度も用いることは可能である。カ

ーブしたステントを各第３の波の長さ分増加させ、対応する波の長さ分減少することにより形成して、アーチ状に形成し、管状体の一側面は他足より若干長いように形成することができる。

【００３６】同一長さの２つの側面を有するステントの各端部で異なる振幅の２つの波２０がある。波長の端部部分は、一端で山部１０ａ、１０ｂ、１０ｃ、他端で谷部１２ａ、１２ｂ、１２ｃを有する。谷部１２ａ、１２ｂ、１２ｃの外側端部は軸２８に沿って整合し、この軸２８は直線部１４（すなわち、図１７の水平部）に直交する。同様に、山部１０ａ、１０ｂ、１０ｃの端部は軸３０に整合し、この軸３０は波２２の直線部１４に直交し、軸３０からずれている。ワイヤ２４、２６の端部は、一端で谷部１２の半分に、他端で山部１０の半分に形成される。端部２６は小さな直線部（図示せず）を有し、この直線部は、直線部分１４に平行または直交する。

【００３７】図１８において、図１７の波形をマンドレル３１の周囲に巻回することによりステントが形成される。図１７の波がマンドレル３１の周囲に巻回されると、一つの波の山部１０は他の波の谷部１２と一致する。直線部１４はマンドレル３１の縦軸に整合する。図１８は、マンドレル３１の周囲に巻回された波の端部２４を表し、この２４は点２４’の接点である。同様に、端部２６は波が完全にマンドレル３１周囲に巻回されたときには２６’の接点である。接合部の一部または全ての端部２４、２６は互いに接合されて、蝋付け、ハンダ付け、接着剤接合等により端部２４’、２６’にそれぞれ接着して、ワイヤの端部は露出しないようにし、血管内のステントの配置と干渉しないようにする。

【００３８】実際、電気抵抗溶接が、接合プロセスの間酸化する量を最小にできる点で、金属対金属のボンドには最適なものである。ワイヤがマンドレルに巻回されると、山部１０と谷部１２の間の連続接合部のすべて、あるいは一部はステントが最終組立されるまで同様に接合される。このステントのフレキシビリティの制御は、山部１０を対応する谷部１１に接合する点の数を制御することにより行われる。

【００３９】その後、このステントは順次小さな直径のマンドレルに圧縮されて、図１７の直線部分１４はすでに平行ではなくなる。すなわち、マンドレル３１の縦軸に対し、１０°以下傾いている。そのため波長パターンは図１９と２１に図示したようなサイン波形をとる。図１７の平面波形は、直線部１４に直交方向に圧縮されて、マンドレル３１の周囲に巻回される前に図１９に図示されるほぼサイン波形を形成する。その後、このステントは、最も小さなマンドレルから取り除かれて、ステントはバルーンカテーテルに装着される。

【００４０】本発明のステントは、拡張するカテーテルバルーンの内部圧力により半径方向に拡張することができる。波形の間の山部１０と谷部１２は、フレキシブルな接合部として機能し、直線部１４が外側に振れ、すなわち、ステントの本体の中心軸に対し斜めになる。しかし、ステントが拡張した後は、ヒンジとは異なり、接合部は反対方向の直線部の動き（例えば、器官の圧縮力により、拡張したステントの直径が減少する方向の動き）に抵抗する。これらの接合部の圧縮に対する抵抗は、接合部の材料にその材料の塑性限界を超える応力をかけることにより行われ、接合部近傍の材料は可塑的に変形されて、ステントが器官内で崩壊する傾向に対し耐える。このワイヤと接合材料は低メモリ材料である。

【００４１】図１７、１８は、各波の周期ｐがマンドレルの周囲の４分の１である波形を表す。この構成によれば、波形の数と波形間の接合数とが十分に器官を支持するに必要なワイヤの量を最小にすることが分かった。図１７、１８の実施例においては、各ステントは３個のピーク１０Ａ、１０Ｂ、１０Ｃと３個の谷１２Ａ、１２Ｂ、１２Ｃをその拡張したステントの端部に有している。ピーク１０Ａ、１０Ｂ、１０Ｃの山頂部と谷部１２Ａ、１２Ｂ、１２Ｃは、１２０°、２４０°、３６０°で等間隔にステントの端部の周囲に配置されている。この形状は、最大の器官支持機能と非拡張状態で最小のプロファイル（すなわち、直径）となる。従来のステントは、周囲の３個以上のピークと谷部を持つ必要があり、その非拡張プロファイルを増加させ、多くの材料を必要とする。このステントが適切に拡張すると、ピーク１０Ａ－１０Ｃと谷部１２Ａ－１２Ｃの頂部は、ステントの管状体の縦軸から半径方向に離れるだけ移動する。従って、本発明のステントは拡張時器官内では移動しない。

【００４２】図２０、２１は、マンドレル３１の周囲に巻回された波形の構成を示し、これは非拡張状態を表す。この直線部分１４は、ステントの管状体の縦軸（センターライン）にほぼ平行である。図２２は、ステントが拡張状態の図２０または２１の波形パターンから形成されたセル３９の一つの拡大部分を表す。このセル３９は四個の側面３４、３６、３８、４０を有する斜方形状である。ここで、側面３４、３６は一つの直線部分１４から形成され、側面３８、４０は他の直線部分１４から形成され、それは他の直線部分と隣接している。このワイヤはセル３９の隣接する側面３４、３６と３８、４０の間で接点で結合される。図１０、１１、２２から明かなように、直線部分は管状体の中央軸に斜めに伸び、ステントは拡張すると、斜方形状のセルを形成する。

【００４３】ステントの拡張の最大程度または拡張比は、軸１８と軸２０との間の距離を規定する波形の高さを変えることにより調整できる。直線部分１４の長さを増加させると、圧縮状態、あるいは非圧縮状態の直径、すなわちプロファイルに影響を与えるステントの拡張比率を増加させることができる。従って、ステントの最大拡張直径は非拡張直径とは無関係で、ステントのサイズ

はほとんど如何なる種類サイズの器官にも使用できる。さらに大きな器官も小さな非拡張プロファイルを有するステントで支持されるので、ステントを挿入時、出血または血管の損傷は最小になる。実際、ステントは１：１から１０：１の拡張比率でよく機能する。しかし、より多くの拡張比率も可能である。最大拡張比率は波形の周期ｐ及び／または直線部分１４の距離を減少させることにより増加することができる。その結果、より多くの波形がステントの周囲に形成される。

【００４４】図２３は動脈瘤を治療するに使用されるグラフト内に配置されたステントを示す。このステント８は、グラフト４１内に配置されて、このグラフト４１が動脈瘤４２をブロックする。このステントは、グラフト４１内に完全に収納されて、図示されているが、その一部がグラフトの一端から突出しても構わない。

【００４５】本発明のステントの他の実施例は、断面が半円状の連続ワイヤから形成される。すなわち、この半円状は一方が半円で他方が直平面である。完全に組み立てられたステントにおいては、半円状のワイヤプロファイルはステントの外部方向に向き、ワイヤの直平面はステントの内側を向いている。その結果、ステントの内側はスムーズな表面を提供し、ステントの内側に沿って、血液の流れの乱れが最小となる。

【００４６】完全な円状のワイヤステントに比較して、この実施例の断面が半円状のステントは血管内でステントの移動をできるだけ少なくする。これが重要な点となるのは、ステントは異質物で、ステントを包囲したり、ステントを血管内に取り込むような組織の反応を強化するからである。全円状のワイヤステントに比較して、この実施例のステントは、器官内に突出し、流れる血液と接触する異質物の厚さを減少させる。このステントは、一般に血管壁を刺激するので、プロテーゼをカバーする再生組織の薄い層の繁殖を抑えられる。これにより、血管との適合性がよくなる。それ故に、この実施例のステントは、全円状のワイヤステントよりも大きな直径が可能となり、血管内を流れる血流の流れは損なわれることはない。

【００４７】この実施例においては、脈管プロテーゼステントはその圧縮状態では、十分低いプロファイルを有し、小さな開口から血管内に挿入可能で、出血や血管の損傷を最小限にできる。また、狭い血管内にも容易に移動可能となる。また、本発明の脈管プロテーゼステントは拡張比とは無関係な圧縮プロファイルを有する。すなわち、本発明のステントの最大拡張直径は圧縮状態のプロファイルの関数ではなく、幅広い直径の器官に使用することができる。

【００４８】本発明のステントは、圧縮状態において十分な柔軟性を有するが、拡張状態においては、高い剛性と高い環状強度を有する。圧縮状態の柔軟性は、曲がりくねた血管内にステントを挿入するためには重要なことである。この環状強度は、ステントが配置された後、血管からの半径方向の力に抗するのに重要な要素である。血管内で拡張した後、十分な剛性を有するので、血管内に対するステントの移動は、ステントが挿入された後は減少される。この移動量の減少は傷を減少させたり、血管の再生を促すので重要なことである。

【００４９】この実施例の脈管プロテーゼステントは管状体を有し、この管状体は複数の斜方形の解放セルを有する。このセルは管状体の周囲に交互に配置され、ステントは圧縮状態のときには各斜めのセルの長側面は、ステントの縦軸にほぼ平行である。隣接するセルは、通常セルの隣接する平行な側面の間の点で結合され、このステントが拡張の状態のときに、各セルの隣接する側面はステント軸に斜方向に伸びる。

【００５０】図２４－２６に示された脈管プロテーゼステントは、連続ワイヤから形成された管状体２２を有する。この管状体２２は、好ましくは複数のセルから構成され、そのセルは連続ワイヤから構成され、複数の側面を有している。このセルの側面は圧縮状態で管状体の縦軸にほぼ平行となる（図２４）。拡張状態では管状体の縦軸の斜めに伸びる（図２５）。図２８に示すようなステントの構造は、断面が半円状の連続ワイヤから形成されている。即ち、この半円状の断面のワイヤは半円状サイド２５と平面サイド２７とを有する。この平面サイド２７はワイヤの直径に対応する。この平面サイド２７はスムーズで研磨された開口を有する。

【００５１】ほぼ平面状の側面を有するステントは残りの周辺は必ずしも半円である必要はない。このワイヤの周囲の部分は鋭角、また鈍角でもかまわない。図２７において、半円状ワイヤ２５が管状体のステントの外周にあり、平面状部分２７はステントの内側にある。全円状に比較して、半円状のステントはステントの内部がスムーズな表面を有し、ステントの内部に沿って血液流の乱れを最小にして、プロテーゼをカバーするのに必要な再生組織の厚さを減少させる。

【００５２】上記のステントの使用方法について述べると、ステントは所望の位置に達するまで、血管に沿って移動する。そしてこのステントがバルーンカテーテルにより拡張されると、器官の内側に配置される。拡張後、ステントの外部の半円状のプロファイルが血管に押し付けられる。図２９のＡに示されるようにステントの外部が半円状のすべての部分が血管２９に埋設され、ワイヤの平面状部分は血管の壁と同一面となる。その結果、血管の内壁は埋設されたステントからスムーズとなる。図２４に示す構成のステントの利点は平滑な内面を提供し、ステントにより支持される器官の内面の血流の乱れをなくし、血小板の集積をなくす。その結果、この構成はステントが血管中を通る際に傷を和らげ、血管の再構築がなされる。

【００５３】全円状のステントに比較して、この実施例

のステントは、血管内でステントの動きを少なくする。この形状のステントは、血管の内壁とほぼ同一平面になるよう埋め込ことが可能である。従って、ステントの挿入による血管壁の再生殖反応は比較的薄く、全円状のワイヤを組み込むのよりも比較的繁殖が少なくて済む。図２９のＢはＡで組織がステントの上に再生殖された状態を表し、その組織の厚さは約１００オングストロームである。

【００５４】図３０と図３１のＡは、図１７と１８のステントと類似のワイヤの波形を表す。図３０において、山部１０と谷部１２は直線部１４で接続されている。この直線部１４は互いに平行である。この平行とは圧縮状態の図１４の構成と拡張状態の両方を含む。実際のところ、山部と谷部は半円状をしており、直線部分１４とカーブした山部と谷部を接線で接続している。その結果、このワイヤには不連続点はない。

【００５５】マンドレルの周囲にステントを形成する別の方法を示す。図３１に示すように各波は非対称である。すなわち、上り側のサイドは長く、下降側のサイドは短い。山部は長い上り側のサイドと短い下降側のサイドとの間に形成され、谷部は短い下降側のサイドと長い上り側のサイドとの間に形成され、この上り側のサイドと下り側のサイドは、管状体の縦軸に圧縮された状態ではほぼ平行である。同図においてワイヤの構成はｎ番目の山部はｎ＋３番目の谷部と同一接線となり、以下その順で山部と谷部が３つおきに同一接線、すなわち同一高さとなる。この接点はスポット溶接されて、複数のセルは、マンドレルの長軸にほぼ平行となるように構成される。ワイヤの長い側と短い側の比は４対３が好ましい。少なくともいくつかの山部と谷部が結合されて複数のセルを構成する。

【００５６】波形が、マンドレル３１の周囲に巻回されるので、半円状のワイヤの平面部分はマンドレルに接触する。すなわち、マンドレルの表面は平面状のワイヤと接触し、半円状のワイヤの半円表面はマンドレルの外側に面する。管状のステントがマンドレルから取り除かれると、図２４に示すような圧縮状態となる。波形の端部２４が、マンドレル３１の周囲に巻かれると、その点２４’に接線となる。同様に端部２６は点２６’の接線となり、波形は完全にマンドレル３１の周囲に巻回される。実際端部２４、２６は結合されて、ワイヤの端部は血管内のステントの配置と干渉しないようになる。

【００５７】この平面状の波形は、直線部１４に対し圧縮されて、マンドレル３１に巻回される前のパターンを形成する。この状態において、直線部１４は、管状体のステントの長軸にほぼ平行となる。図２４において、拡張状態のステントの側面プロファイルは、４個の側面による斜長方形の押されているセルにより規定される。ワイヤは隣接する側面の間の点に接点によって接合されたセルを形成する。上記の直線部分１４はステントが図２５に示すように拡張状態のときには管状体の中心軸に対し斜めに伸びる。

【００５８】次にステントの操作方法について述べる。圧縮状態のステント２２がカテーテルに搭載されて器官内に挿入される。その後埋め込み中、圧縮状態のステント２２とカテーテルバルーンは、カテーテルのシースの内側から引き抜かれて、シースは血管内をスライドする。その後、圧縮状態のステント２２が適当な位置に移動した後、シースは部分的に引き抜かれて、圧縮状態のステント２２とバルーンが血管内で露出する。このバルーンはその後拡張し、このステント２２は血管内で拡大する。最後にこのバルーンが収縮して、カテーテルは血管から取り除かれる。

【００５９】このステントの材料は低記憶合金が好ましく、変形後は元の形状を取り戻すことのない。このことはステントが埋め込む後、圧縮状態を再生することがないようにするため重要である。好ましい実施例において、このステントは約０．００６－０．０２０インチの直径でアニールしたタンタルワイヤが好ましい。このステントの材料は放射線不透過材料で、蛍光透視検査により血管内でその位置を確認できるからである。ステントは生物適用型材料（ステンレススチール）と生物吸収可能材料（ビニール）が好ましい。このステントは血栓防止剤、あるいは凝血剤（デックストラン、ヘペリン、ｔ－ＰＡ、ポリテトラフロロエチレン、超低温カーボン同位体）でもってコーティングされている。

【００６０】

【発明の効果】本発明のステントは、非拡張状態で低いプロファイル（直径）で、できるだけ少ない材料で形成される。そうすることにより血管内に可能な限り小さいな孔を貫通して挿入できて、血管に対する損傷、あるいは出血を制御できる。この低いプロファイル構成により、ステントは狭い血管内を容易に移動できる。さらにステントの非拡張状態のプロファイルは、拡張比に無関係である。すなわち、挿入の間はできるだけ小さいプロファイルが必要であるが、拡張状態のプロファイルに影響することなく、ステントの最大拡張比を変える必要がなく、そうすることにより一つのサイズのステントをあらゆる大きさの器官（血管）内で使用できる。また、本発明のステントは非拡張状態で、高いフレキシビリティを有し、拡張状態では、強い環状強度を有する。実際これらの両方の特性を備えたステントを設計するのは難しいが、曲がりくねた血管内にステントを挿入するためにはフレキシビリティが必要であり、一旦ステントが血管内に挿入され配置されるためには、血管からの半径方向の力に抗する環状強さが必要だからである。

【図面の簡単な説明】

【図１】本発明のフィラメントで、圧縮された平面波形に形成された状態図である。

【図２】本発明のステントを形成するのに用いられるサ

15

イン波形の軸方向センターラインに沿って拡張した図１の平面波形のフィラメントを表す。

【図３】本発明のステントを形成するのに使用される第２の波形を表す図である。

【図４】本発明のステントを形成するのに使用される第３の波形を表す図である。

【図５】マンドレルの周囲に螺旋状に巻回された図３の波形を表す図である。

【図６】図３の波形がマンドレルの周囲に巻回し終った後のフィラメントの端部の接続状態を表す図である。

【図７】本発明のステントを形成するのに使用される第４の波形を表す図である。

【図８】図１２の別の波形の部分で、Ｕ字形の曲げの部分を示す図である。

【図９】円筒状のマンドレルの周囲に巻回された図７の波形を示す図である。

【図１０】各曲げのカーブした部分を整合させるために環状にマンドレルの周囲に波形を巻回したことにより、図７の波形から形成された拡張状態のステントの側面展開図である。

【図１１】図１０のステントの反対側の側面展開図である。

【図１２】図１０と図１１のステントの端面を表す図である。

【図１３】器官内に挿入可能なバルーントップカテーテルに搭載されたステントを表す図である。

【図１４】動脈瘤を治療するグラフトと共に用いられるステントを表す図である。

【図１５】動脈の閉塞部をバイパスするグラフトと共に使用される二個のステントを表す図である。

【図１６】動脈瘤を治療するグラフトと共に使用されるステントを表す図である。

【図１７】本発明のステントを形成するために使用される平面状の波形を表す図である。

【図１８】マンドレルの周囲に巻回される図１７の波形を表す図である。

【図１９】マンドレルの周囲に巻回される図１７の別の波形を表す図である。

【図２０】図１８に示したようなステントが非拡張状態にあるときにマンドレルの周囲に巻回された波形の構成

16

図である。

【図２１】図１９に示したようなステントが非拡張状態にあるときにマンドレルの周囲に巻回された波形の構成図である。

【図２２】ステントが拡張状態にあるときに図２０と２１のステント内のセルの一つの拡大図である。

【図２３】図１４のステントの拡張状態を表す図である。

【図２４】本発明の他の実施例によるステントで、圧縮状態にある側面図である。

【図２５】図２４のステントが拡張状態にある側面図である。

【図２６】図２５のステントの端面図である。

【図２７】図２５の線４－４に沿って矢印方向から見た断面図である。

【図２８】図２６の線５－５の面に沿って矢印方向から見た拡大断面図である。

【図２９】血管内に埋設された図１のステントを表す図である。

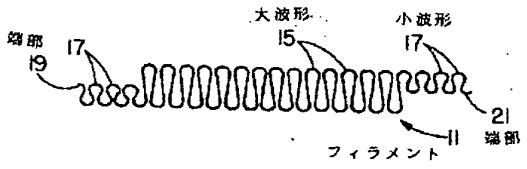
【図３０】図２４、２５のステントを形成するのに使用される連続ワイヤの平面波形を表す図である。

【図３１】圧縮状態で、ステントを形成するためにマンドレルの周囲に巻回された図２７の連続波形を表す図である。

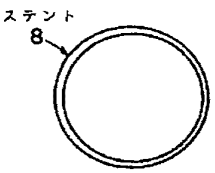
【符号の説明】

８　ステント
９　グラフト
１０　山部
１２　谷部
１４　直線部
１１　フィラメント
１２　閉塞
１３　動脈瘤
１４　大動脈
１５　大波形
１６　腸骨分岐
１７　小波形
１９　端部
２１　端部

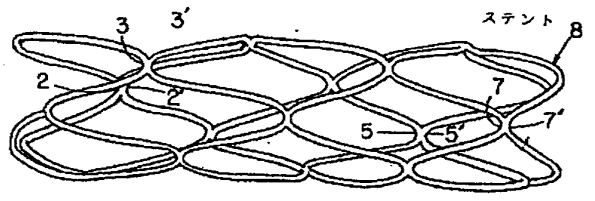
【図１】



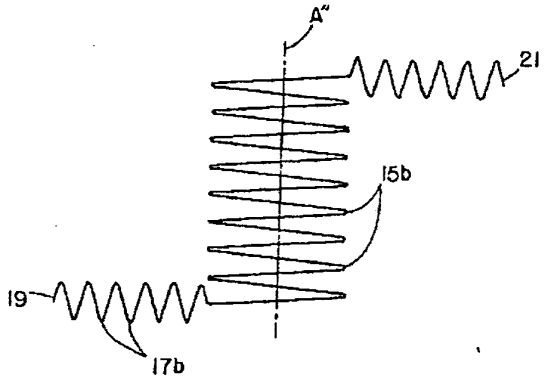
【図１２】



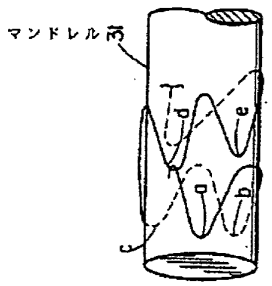
【図１０】



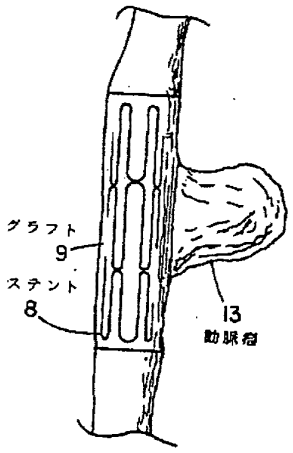
【図４】



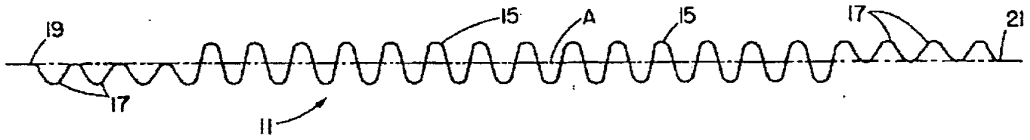
【図６】



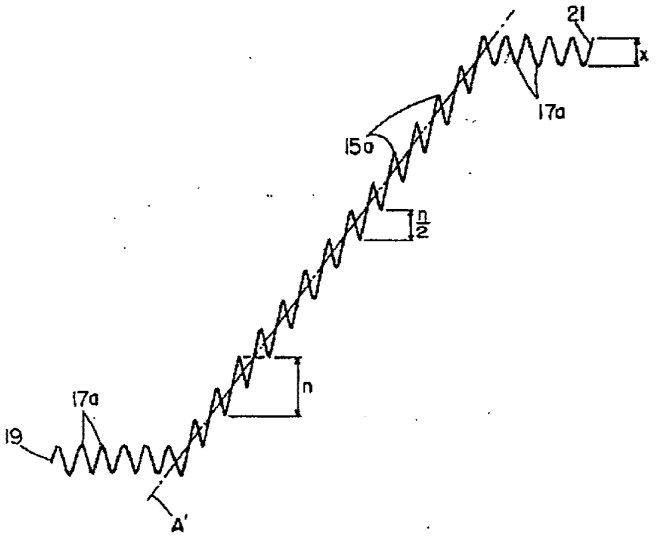
【図１４】



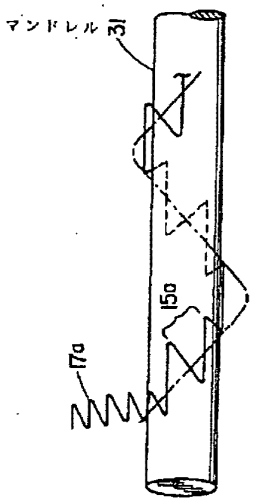
【図２】



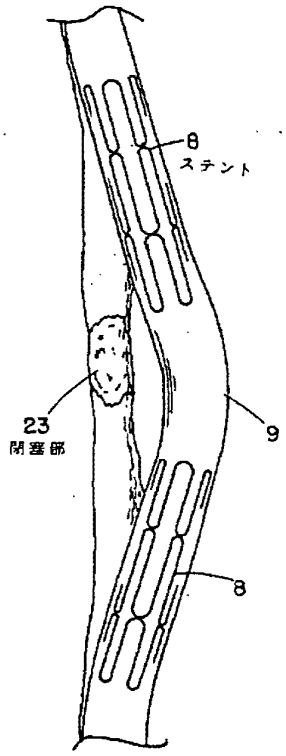
【図３】



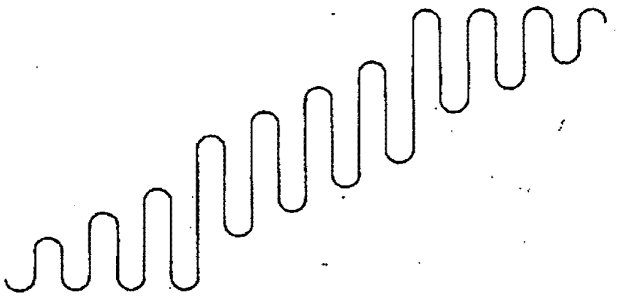
【図５】



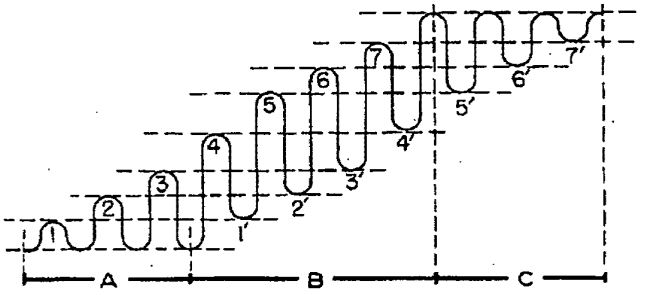
【図１５】



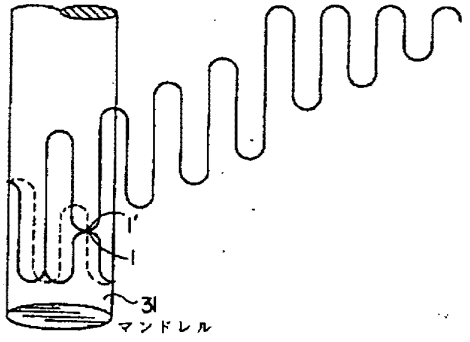
【図７】



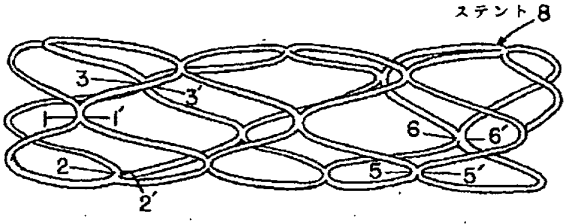
【図８】



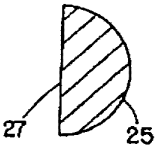
【図９】



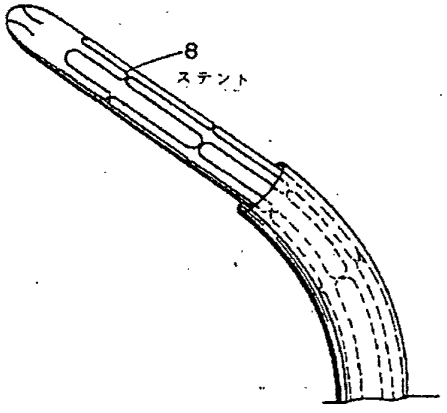
【図１１】



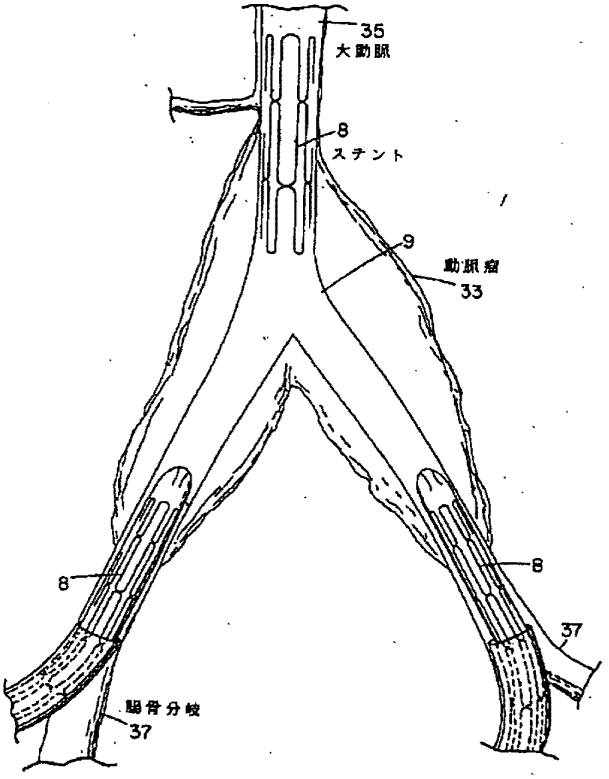
【図２８】



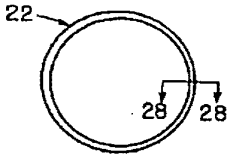
【図１３】



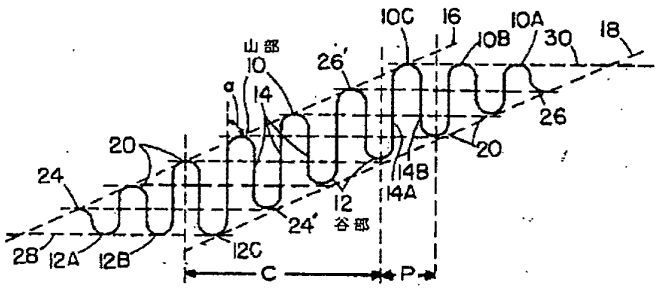
【図１６】



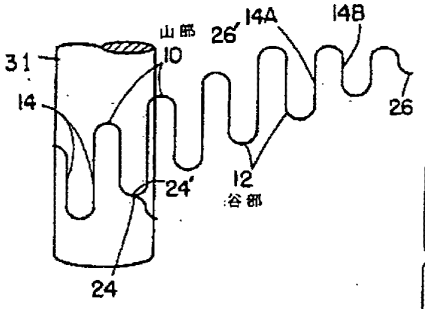
【図２６】



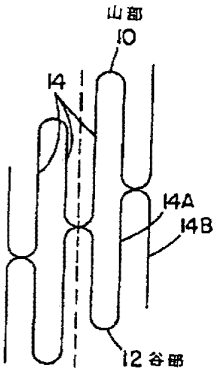
【図１７】



【図１８】

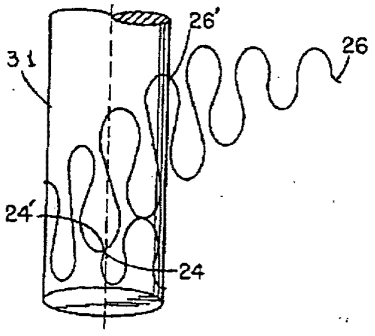


【図２０】

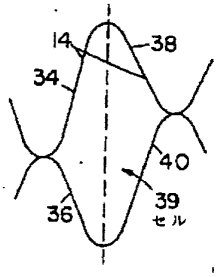


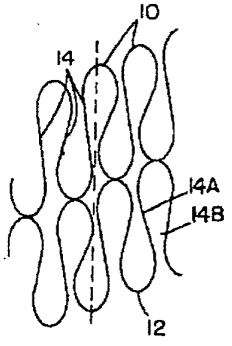
【図２１】

【図１９】

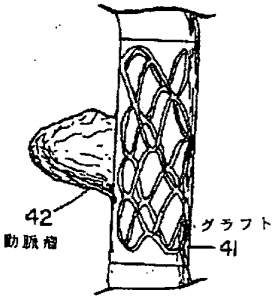


【図２２】

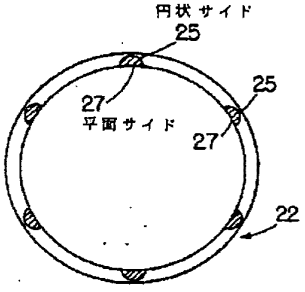




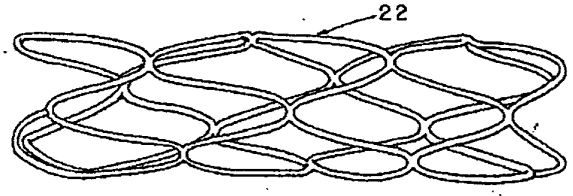
【図２３】



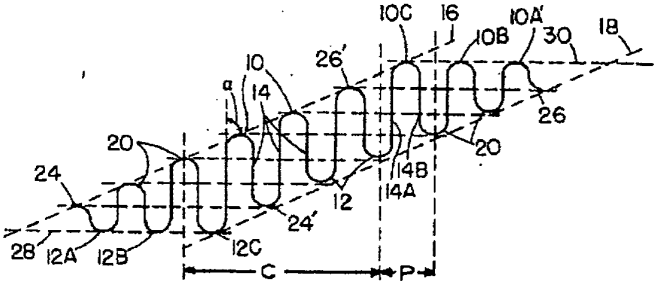
【図２７】



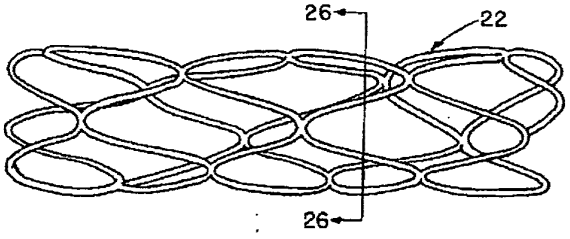
【図２４】



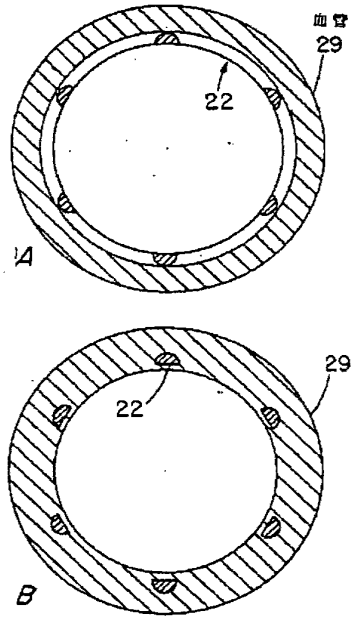
【図３０】



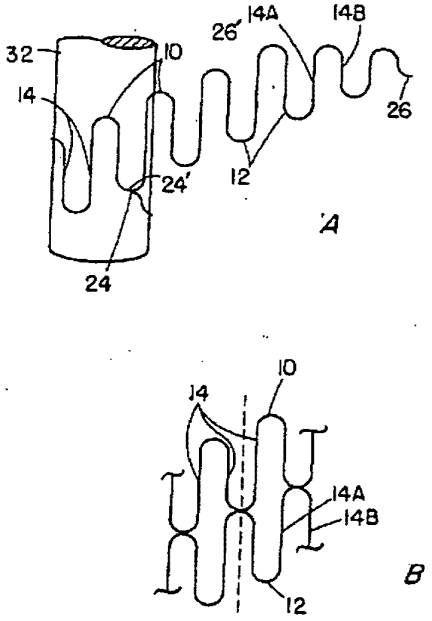
【図２５】



【図２９】



【図３１】



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number : **0 565 251 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number : **93302066.1**

(51) Int. Cl.[5] : **A61M 29/00**, A61F 2/06

(22) Date of filing : **18.03.93**

(30) Priority : **25.03.92 US 858304**
24.04.92 US 874347
10.09.92 US 943000

(43) Date of publication of application :
13.10.93 Bulletin 93/41

(84) Designated Contracting States :
DE ES FR GB IT

(71) Applicant : **Cook Incorporated**
925 South Curry Pike P.O. Box 489
Bloomington Indiana 47402 (US)

(72) Inventor : **Fontaine, Arthur B.**
361 East Pelican Court
Fresno, California (US)
Inventor : **Dake, Michael D.**
665 Gerona Road
Stanford, California (US)

(74) Representative : **Johnston, Kenneth Graham**
5 Mornington Road
Woodford Green Essex, IG8 OTU (GB)

(54) Vascular stent.

(57) A vascular stent (8) includes a continuous wire which is formed into a substantially tubular body having a plurality of oblong, open cells which are staggered around the circumference of the tube. When the body is formed in its unexpanded state, the long sides of each oblong cell are arranged substantially parallel to the longitudinal axis of the tubular body. Adjoining cells may then be bonded together at a point (2,2' ;3,3' ;5,5' ;7,7' ;) between adjacent parallel sides on a cell. When the body is expanded, the adjacent sides of each cell extend oblique to the longitudinal axis of the body.

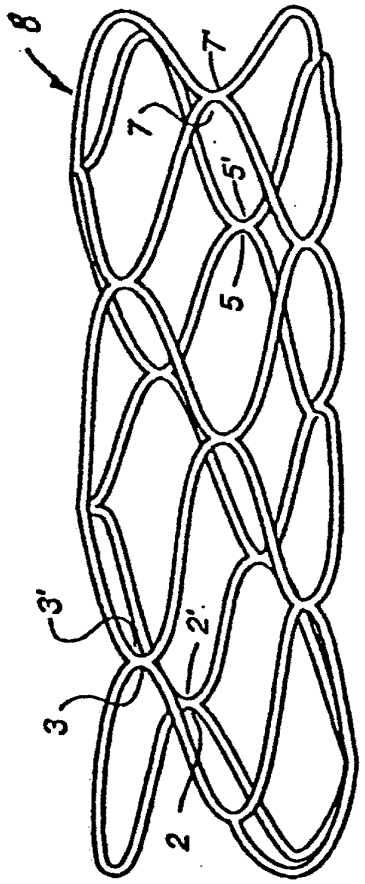


FIG._10

EP 0 565 251 A1

The present invention generally relates to vascular stents.

A stent, generally speaking, is a device that can be placed within the lumen, or interior space, of a tubular structure for supporting and assuring patency of a contracted, but otherwise intact, lumen. (Patency the state of being freely open, is particularly important in the field of angioplasty, which is concerned with the reconstruction of blood vessels.) Stents are used, for example, for holding blood vessels open or for back tacking intimal flaps inside vessels after angioplasty. More generally, however, stents can be used inside the lumina of any physiological condult including arteries, veins, vessels, the biliary tree, the urinary tract, the alimentary tract, the tracheobronchial tree, the genitourinary system, and the cerebral aqueduct. Furthermore, stents can be used inside lumina of animals other than humans.

In the field of angioplasty, the most common angioplasty surgical procedure is percutaneous transluminal coronary angioplasty, or "PTCA", which is employed for enlarging narrowed arteries near the heart. In a PTCA procedure, a balloon-tip catheter is maneuvered into position in a narrowed artery where the balloon is expanded in order to dilate this area of narrowing. After the arterial lumen is dilated, the balloon at the catheter tip is deflated and the catheter is removed from the enlarged artery. A vascular stent can be used to dilate an artery after a suboptimal PTCA dilation.

In practice, the above-described conventional PTCA procedure has several shortcomings. One drawback is that approximately one-third of all PTCA patients suffer from restenosis, a chronic regrowth of obstructive tissue that narrows the lumen. Typically, restenosis occurs within six months following an angioplasty procedure. Since a majority of these restenosis patients also display symptoms of deteriorating cardiac status, they frequently must undergo additional PTCA procedures or more risky coronary artery bypass graft surgery. Unfortunately, those patients who undergo repeated PTCA procedures tend to restenose at an even higher rate than first-time PTCA patients.

A second, and sometimes fatal, complication of coronary angioplasty is the abrupt re-closure of a previously dilated section of a vessel. There are many different factors that are thought to contribute to abrupt re-closure after PTCA including obstructive flaps of disrupted wall tissue, vessel wall spasms with luminal contraction, and thrombus formation at the site of dilation. Vascular stents can be used like a scaffold to mechanically bridge areas of narrowing (flaps or thrombus) and oppose spasms, and therefore, maintain artery patency.

Many of the factors responsible for abrupt closure (post balloon inflation) may also influence the development of restenosis, and therefore, long term patency. In this regard, vascular stents, by virtue of their ability to limit elastic recoil of the vessel wall and to eliminate the negative physical consequences of PTCA (including obstructing intimal flaps and dissection) may be useful in limiting restenosis.

Therefore, there are two potential benefits of vascular stents in the treatment of vascular disease: 1) prevention of abrupt arterial closure, and 2) prevention of restenosis.

Summary of the Invention

Generally speaking, the present invention provides a vascular stent for reducing hemodynamic disturbances caused by angioplasty and the stent itself. In a preferred embodiment, the stent is formed from a single filament of low memory bio-compatible material having a series of U-shaped bends. The lament is wrapped around a mandril in a circular fashion in order to align opposing curved portion of each bend which are then connected. The stent therefore provides a maximum amount of structural support for the lumen while minimizing the level of hemodynamic disturbance in side the lumen.

The tubular stent shown in the embodiments of the invention is a coplanar structure as opposed to a woven or knitted structure.

The present inventor has found that vascular stents require substantial flexibility in their unexpanded state in order to allow them to bend and conform to the tortuous shape of the vessel through which they are inserted. This need for flexibility during insertion is especially important for older patients since their blood vessels tend to be more tortuous and less flexible than those of younger patients. The present inventor has also found that, vascular stents should be rigid and have a high hoop strength in their expanded state. Although the reasons for the success of rigid stents are not entirely clear, it has been suggested that rigid stents are less likely to pulsate inside vessels, and therefore, they are less likely to rub against the vessel intima once they are in place.

Brief Description of the Drawings

Figure 1 shows a filament shaped into a compressed planar wave used to make the nearly sinusoidal waveform of Figure 2;

Figure 2 shows the planar wave of Figure 1 expanded along its longitudinal centerline to form a nearly sinusoidal waveform used in making a stent;

Figure 3 shows an alternative waveform that can also be used in making a stent;

Figure 4 shows another alternative waveform that can be used in making a stent;

Figure 5 shows the waveform of Figure 3 spirally wrapped around a round mandril;

Figure 6 shows a connection for the end of the filament after the waveform of Figure 3 is completely wrapped around the mandril;
Figure 7 shows a preferred alternative waveform that can be used in making a stent;
Figure 8 shows the relative positions of the U-shaft bends in each component section of the preferred alternative waveform of Figure 12;
Figure 9 shows the preferred alternative waveform of Figure 7 being wrapped around a cylindrical mandril;
Figure 10 shows in an expanded state a side elevation of a stent formed from the preferred alternative waveform of Figure 7 by wrapping it around a mandril in a circular fashion in order to align the curved portion of each bend;
Figure 11 shows an opposite side elevation of the stent in Figure 10;
Figure 12 shows an end view of the stents in Figures 10 and 11;
Figure 13 shows a stent mounted on a balloon-tip catheter ready for insertion into a lumen;
Figure 14 shows a stent being used with a graft to repair a pseudo-aneurysm in the common femoral artery;
Figure 15 shows two stents being used with a graft to bypass an occlusion in the femoral-popliteal artery;
Figure 16 shows a stent being used with a graft to repair an aorto-iliac aneurysm;
Figure 17 is a schematic illustration of a planar waveform which is used to form the stent;
Figure 18 illustrates the waveform of Figure 17 being wrapped around a mandril;
Figure 19 illustrates an alternative embodiment of the waveform of Figure 17 being wrapped around a mandril;
Figure 20 shows the arrangement of the waves around the circumference of the mandril when the stent is formed in its unexpanded state as in Figure 18;
Figure 21 shows the arrangement of the waves around the circumference of the mandril when the stent is formed in its unexpanded state as in Figure 19;
Figure 22 is an enlargement of one of the cells in the stent of Figures 20 and 21 when the stent is in an expanded state;
Figure 23 shows a stent being used with a graft;
Figure 24 is a side elevational view of a stent according to the other preferred embodiment in compressed condition;
Figure 25 is a side elevational view of the stent of Figure 24 in expanded condition;
Figure 26 is an end view of the stent of Figure 25;
Figure 27 is a cross-sectional view which is taken along the plane of the line 4-4 in Figure 25 for viewing in the direction of the arrows;
Figure 28 is an enlarged cross-sectional deuil, taken along the plane of the line 5-5 in Figure 26 for viewing in the direction of the arrows;
Figures 29A and 29B are views that correspond in orientation to Figure 4 and which schematically show the stent of Figure 1 embedded in the lumen of a blood vessel;
Figure 30 is a schematic illustration of a planar waveform of a continuous wire which is used to form the stent of Figures 24 and 25; and
Figures 31A and 31B are illustration of the continuous waveform of Figure 27 wrapped around the circumference of a mandrel for forming the stent in its compressed condition.

The stent is preferably formed from a continuous wire. The term "wire", as used here, should not be construed as limited to just metallic materials. In fact, the stent may be formed from any type of filament. The stent may also be made from groups of filaments or fibers which are wound or braided together in order to form a continuous filament. Also, several distinct laments may also be attached together by any conventional means such as butt-welding. It is also possible to mold the stent in its unexpanded state.

To prevent the stent from recoiling to its unexpanded state after it has been implanted, the stent is preferably made from a "low memory" material that does not try to resume its original shape after it is deformed. Alternatively, the size of the wire can be chosen so that when the stent is expanded, the wire is stressed beyond its plastic yield point but not beyond the ultimate stress at which the material cracks or breaks. Both the unformed wire and the unexpanded stent may be annealed in order to reduce the stresses which are created in the wire during the stent formation process.

The stent material is preferably radio-opaque so that the location of the stent can be verified through fluoroscopic examination. The stent should also be made from a biocompatible (e.g. stainless steel) and/or bioabsorbable (e.g. Vicryl) material with a smooth surface for minimizing the stent's effect on surrounding tissue and bodily fluids such as blood. The stent may also be coated with antithromblytic or anticoagulatory agents such as Dextran, Heperin, t-PA, polytetrafluoroethylene, or ultra low-temperature isotropic carbon.

Figure 1 shows a filament 11 formed in a compressed planar waveform. Preferably, the filament 11 is made from 0.013 to 0.05 cms (0.005 - 0.020 inch) diameter stainless steel wire; however, it can be made from materials such as titanium, tantalum, gold, copper and copper alloys, combinations of these materials, or any other biologically-compatible materials with a low shape-memory level. (In the present context, a low shape-memory level implies that the stent will not contract to its compressed shape after it is inserted and internally expanded in a lumen). The fila-

ment 11 can also be formed from several separate strands which are wrapped or woven together.

The compressed waveform pattern in Figure 1 is preferably formed generally in the shape of a compressed sinusoid, but can have any wave-like pattern. In the drawing, it should be noted that the waveforms at the ends 19 and 21 of the wire having smaller amplitudes than the waveforms 15 in the middle of the wire. The drawing shows, for example, four reduced amplitude peaks 17 at each of the ends 19 and 21, respectively. Preferably, the heights of the reduced amplitude waveforms are one-half to two-thirds of the heights of the larger waveforms.

In Figure 2, the compressed waveforms of Figure 1 are expanded along their longitudinal centerline into a nearly sinusoidal waveform by stretching the compressed waveforms from their ends. (The broken line shows the longitudinal centerline of the expanded waveforms). At both ends 19 and 21, the longitudinal centerline of the smaller waveforms is displaced from the longitudinal centerline of the waveforms near the middle of the wire. At one end 19, for instance, the centerline of the smaller waveforms 17 is displaced below the broken line; at the end 21, by way of contrast, the centerline of the smaller waveforms is displaced above the broken line.

In practice, the above-described expanded waveforms preferably have a period of about eight millimeters. The larger waveforms 15 preferably have a peak-to-peak amplitude of eight millimeters while the smaller waveforms 17 are one-half to two-thirds the height of the larger waveforms. However, other sizes may be used. Although all of the waveforms normally have the same period, they are not necessarily sinusoidal, regular, repeating, or continuous.

Figures 3 and 4 show the expanded state of two alternative waveforms that can be used to form the above-described stent. The period of each waveform in the waveform of Figure 3 is preferably one-half of the peak to peak amplitude of the waveform. In Figure 3, the longitudinal centerlines of the small waveforms 17a at the ends of the device are approximately parallel to each other, but the centerline of the large waveforms 15a is inclined relative to the longitudinal centerlines of the smaller waveforms, preferably at an inclination angle of approximately 45°. In Figure 4, the waveform is similar to that of Figure 3 except that the centerline of the larger waveforms 15b is perpendicular to the centerline of the smaller waveforms 17b; in other words, the inclination angle of the larger waveforms is approximately 90°.

Figure 5 shows the expanded waveform of Figures 3 formed into a stent by wrapping it, in a spiral, around a mandril 21. Similar waveforms could also be used. For instance, if the waveform of Figure 4 were used the longitudinal centerline of the large waveforms would remain parallel to the centerline of the mandril and the peaks of the waveforms would be wrapped around the mandril, perpendicular to the centerline of the mandril.

As shown in Figure 5, the centerline of the large waveforms 15a is arranged to spiral along the length of the mandril 31. One side of each of the larger waveforms 15a is arranged approximately parallel to the longitudinal axis of the mandril 31, and the remaining sections of each of the waveforms are arranged at a small angle to the longitudinal axis of the mandril. (In the drawing, the "small" angle has been greatly exaggerated for purposes of illustration). It will be appreciated that the shown arrangement allows the stent to be wound in a very tight spiral.

By forming the above-described stent as a tight spiral on a mandril, the stent expands primarily in the radial direction, with relatively slight movement at the ends, as it is expanded internally in a lumen. Even greater radial expansion might be achieved by the wrapping the waveform as a circle around the mandril. However, such a radially-wrapped configuration would use an excessive amount of filament per unit surface area to support the lumen, especially where the filaments were allowed to overlap.

In Figure 6, each of the last three smaller waveforms 17a (from Figure 5) at the end of the stent is wrapped with its longitudinal centerline around the circumference of the mandril. It should be noted that the peaks of the last three smaller waveforms (indicated in Figure 6 by the letters "a", "b" and "c" respectively) are approximately the same distance from the edge of the mandril, and the fourth peak "d" is slightly further away from the end of the mandril. Also, the end of the stent near peak "a" is connected to the apex of peak "d", the result of this connection is that peaks "a", "b" and "c" are substantially equally spaced around the circumference of the mandril and are all at the approximately same distance from the end of the mandril.

In practice, the connection between the loop and the filament is slidable along the filament 11, thereby allowing for radial expansion. Although this connection can be easily made using a loop as shown, it can also be made by, for example, using a bracket. The connector could also be made by brazing, welding, or gluing the end to the filament.

When the above-described stent is wound around a mandril in the shape of a tight spiral, the non-expanded form of the stent provides a prole that is lower than conventional stents, and the "tines" of the non-expanded stent are almost parallel and packed closely together. This is important because such stent can be accommodated through a smaller incision and, therefore, reduces blood loss during surgery. Furthermore, such a stent can provide an expansion ratio of about 10:1, enabling it to be used in large arteries.

As shown in Figure 12, the connections at the ends of the filament 11 create a circular hoop near

each end of the stent with no sharp edges, or point, protruding from the perimeter to project into a lumen or to catch on the balloon or plaque inside of a vessel. Also, because the centerline of the smaller waveforms is arranged along the circumference of the stent, the end hoops allow the stent to fit snugly inside the lumen and prevent migration. In other words, in this arrangement, the hoops expand radially to lock the expanded stent in place in a lumen while permitting only limited longitudinal expansion.

Figure 7 shows a preferred alternative waveform which can be used in making a stent. The waveform of Figure 7 is formed from a series of U-shaped bends having substantially straight legs on each side of the curved portion of each "U". The legs are preferably parallel; but they may also be formed at angles to each other. The curved portions are preferably semicircular; however, other shapes of curves can be used to connect the straight legs in each bend. The curved portions may have the same or different sizes. It is also preferred that the curved portions are connected to the straight portions at the tangent of each curve in order to prevent any discontinuities in the length of the filament.

Figure 8 shows the relative positions of the U-shaped bends for each component section A, B, C of the preferred alternative waveform of Figure 7. Sections A and C of the waveform are upside down mirror images of each other. The broken lines in Figure 8 are reference lines which are preferably equally spaced and parallel. However, it is also possible to form the stent so that the top and bottom reference lines are parallel to each other but not equally spaced from or parallel to the other reference lines.

Defining the distance between the reference lines as one unit of measurement, then each of the U-shaped bends in end sections A and C each have a different length. For example, U-shaped bend 1 is one unit long while U-shaped bend 3 is three units long. Similarly, U-shaped bend 7' is one unit long while U-shaped bend 5' is three units long. In contrast, each of the waveforms in section B has one long leg which is four units long and one short leg which is three units long. For example, the left leg of U-shaped bend 5 is four units long while the right leg is three units long as measured between the reference lines. Each of the curved portions, except for the ends of the lament, are preferably semicircular with a diameter of one unit. The curved portion at each end of the filament is preferably one half of the semicircular arc. However, other shapes and proportions may also be used to appropriately size the stent.

As shown in Figure 9, the stent is formed by wrapping the waveform of Figure 7 around a mandril which is preferably cylindrical. However, mandrils with other shapes could also be used. The waveform is preferably wrapped around the mandril so that the legs of each U-shaped bend are parallel to the axis of the mandril. In this configuration, a single wire may be formed into an extremely rigid tubular structure with very little material to disturb how inside the lumen. However, the waveform might also be wrapped around the mandril in a slightly spiral manner. Once the waveform is wrapped around the mandril, the outside edge of curves on the same reference line will be arranged back-to-back adjacent to (or overlapping with) each other. For example, the outside edge of curve 1 will be back-to-back with the outside edge of curve 1'. Similarly, the outside edge of curve 7 will be adjacent to curve 7'. The outside edges of these U-shaped bends can then be fastened together by any conventional means such as welding, brazing, soldering, or gluing.

Figures 10, 11, and 12 illustrate the stent which is formed by wrapping the waveform of Figure 8 around a circular mandril with the reference lines arranged on the circumference of the mandril. It will be apparent that each of the labeled U-shaped bends on parallel reference lines in Figure 8 have been connected in Figures 10 and 11. For example, U-shaped bend 7' is shown to be connected to U-shaped bend 7 at the top of Figure 10. Although it is preferred that the U-shaped bends are welded, it is also possible to form the connecting portions of the filament from a single piece of material in order to eliminate the need for connecting each of the appropriate U-shaped bends. The ends of the filament are also connecting back to the filament and trimmed in order to remove any excess filament precluding from the free end.

The rigidity of the structure may be controlled by welding less than all of the adjacent curved portions. For example, a stent with only half the U-shaped portions welded together would be approximately half as rigid as a stent with all the tangent points welded together. Of course, the stent can also be used without any connections between adjacent curved portions.

The lowest possible profile (i.e. diameter) is provided by arranging the long leg of each U-shaped bend parallel to the axis of the catheter before it is inserted into a lumen. This arrangement increases the diameter to which the stent can be expanded without, at the same time, decreasing the end-to-end length of the stent. By increasing or decreasing the length of the long leg of each U-shaped bend, one can alter the expansion ratio without altering the profile. Consequently, a nearly unlimited circumferential expansion ratio may be created without contracting the stent along its longitudinal axis. The expansion ratio is therefore nearly independent of this profile.

When expanded, each of the U-shaped portions in the stent may assume a rhomboidal pattern where the legs of each U-shaped bend are no longer parallel. The expansion ratio of the stent may therefore exceed 10 to 1 in terms of the expanded diameter versus the unexpanded diameter of the stent. Consequently, the outside surface of the stent touching the

vessel is small while the effective support area is very large. This feature dramatically reduces the possibility of causing any hemodynamic disturbances inside the vein or artery because of the stent. The large expansion ratio also allows the stent to be used with smaller incisions. Moreover, this configuration allows the stent to be flexible in the radial direction in order to accommodate the pulsation of an artery.

The stent may also be coated with antithrombolytic agents in order to limit the thrombotic formation which often accompanies angioplasty.

Figures 13-16 illustrate a typical stent of which could represent any one of the embodiments described above. Figure 13 shows a typical stent mounted on a 4/5 F balloon (4-10mm) with a 6/7 F sheath. The apparatus of Figure 13 is preferably used with a.078-.091 guide sheath. Figure 14 shows the stent, inside a graft, being used to repair a pseudo-aneurysm in a common femoral artery. The stent 8 is placed inside graft 9 which blocks off pseudo-aneurysm 13. Although the stent is shown to be completely inside graft 9, it may also extend outside the edges of the graft in order to provide additional support for the incisions at the end of the graft.

Figure 15 shows two stents being used at each end of a graft to bypass an occlusion 23 in, for example, the femoral-popliteal artery. Figure 16 illustrates how three stents can be used with a branched graft to repair an aorto-iliac aneurysm 33. The graft 9 is placed inside the aneurysm and secured at one end to the aorta 35. The other ends of the graft are similarly stented to iliac branches 37.

Figure 16 also illustrates how the catheter of Figure 17 can be used to insert the stent 8 inside a lumen. Typically, a short incision is made in the lumen (for example, a vein or artery) and the stent, which is mounted on the balloon, is then slipped into the incision. When the stent is in place, the balloon is expanded in order to expand the stent against the inside walls of the lumen. Once the stent is in place, the balloon is deflated and removed through the inside of the stent and the incision in order to leave the stent in place.

Various advantages of the present invention can now be understood. For example, the above-described stent uses substantially less material than conventional stents (especially knitted ones with overlapping wires) and, therefore, introduces a substantially lesser quantity of foreign material into a lumen. The stent also provides a maximum amount of structural support with a minimum amount of material. As another example, the above-described stent connects its filament ends back onto the lament to prevent thrombosis in blood vessels or damage to any type of a lumen wall such as is caused by stents that have loose wire ends that protrude into a lumen.

Another advantage of the above-described stent is that it provides substantial radial expansion with only limited longitudinal migration and, therefore, reduces the problem of migration inside a lumen. More particularly, the hoops and end component sections at each end of the above-described stent reduce migration by securing the stent inside of a lumen. In the preferred embodiment, the hoops, end component sections, as well as the spiral shape of the stent itself are oriented to inhibit longitudinal growth of the stent during radial expansion.

Yet another advantage of the above-described stent is that it provides sufficient flexibility to allow implantation in tortuous lumens and in applications where lumen bending is required. This overcomes the problem with conventional stents that are so stiff that they are difficult to negotiate through a tortuous vessel during implantation. Furthermore, a stiff stent can cause damage to certain vessels, such as those around joints, that require flexibility.

The stent is formed from a continuous wire shaped into the planar pattern or waveform illustrated in Figure 17. The pattern in Figure 17 includes a series of alternating U-shaped waves having a period p with peaks 10 and valleys 12 interconnected by substantially straight sections 14. The straight sections 14 are substantially parallel to each other in Figures 17, 18 and 20 and are therefore depicted as straight vertical lines in those figures. However, the term "substantially parallel" also refers to the configuration of the straight portions 14 illustrated in the compressed planar (and generally sinusoidal) waveforms of Figures 19 and 21. The peaks 10 and valleys 12 are preferably semicircular and arranged to intersect straight portions 14 at the tangent of each curved peak or valley so that there are no discontinuities in the wire. However, other curved or linear shapes may also be used to form the peaks 10 and valleys 12. Each U-shape wave includes an ascending side 14a and a descending side 14b.

The outermost portions of the peaks 10 and valleys 12 in the middle section of the waveform are aligned along parallel axes 16 and 18, respectively. The axes 16 and 18 form an acute angle α with respect to the straight portions 14. The angle α is preferably 45 degrees so that if distance between each straight section is one unit, then each U-shaped wave in the middle section has one leg that is three units long while the other leg is four units long as illustrated by the parallel horizontal reference lines in Figure 17. Other relative dimensions and angles, however, can be used. A curved stent can also be formed by, for example, slightly increasing the length of every third wave and decreasing the length of a corresponding wave in order to form an arched configuration where one side of the tubular body is slightly longer than another side.

There are two waves 20 of different amplitudes at each end of the stent which each have two sides of the same length. The end sections of the waveform

include peaks 10a, 10b, and 10c at one end of the stent and valleys 12a, 12b, and 12c at the other end. The outer edges or apexes, of valleys 12a, 12b, and 12c are aligned along axis 28 which is substantially perpendicular to the straight portions 14 (i.e. horizontal in Figure 17). Similarly, the apexes of peaks 10a, 10b, 10c are aligned with an axis 30 which is also perpendicular to the straight portions 14 of the waves 22 but displaced from axis 30. The ends of the wire 24, 26 are preferably formed into half a valley 12 at one end and half of a peak 10 at the other end. The ends 26 may also include a small, straight portion (not shown) which may be parallel or perpendicular to the straight portions 14.

Referring to Figure 18, the stent is formed by wrapping the waveform of Figure 17 around a mandril 32. The peak 10 of one wave coincides with the valley 12 of another wave when the waveform of Figure 17 is wrapped around mandril 32 with straight portions 14 aligned with the longitudinal, or central, axis of the mandril 32. Figure 18 illustrates the end 24 of the waveform wrapped around the mandril 32 so that the end 24 is tangent to point 24'. Similarly, end 26 will be tangent to point 26' when the wave is completely wrapped around the mandril 32. The ends 24, 26 of some or all of the junctions are then bonded to one another over relatively short lengths to form bonded cells by spot welding, spot brazing, soldering, tying, looping, adhesive bonding, or other suitable means to the points 24' and 26' respectively, so that the ends of the wire are not exposed where they could snag or otherwise interfere with the placement of the stent in the vessel.

In practice, electric resistance welding has been found to offer the most secure metal to metal bond by minimizing the amount of oxidation that occurs during bonding process. As the wire is wrapped on the mandril, some or all of the successive junctions between the peaks 10 and valleys 12 may be bonded in a similar manner until the stent is complete. The flexibility of the stent can be controlled by bonding fewer than all of the peaks 10 to corresponding valleys 11.

The stent may then be compressed on consecutively small diameter mandrils so that the straight sections 14 in Figure 17 are no longer exactly parallel, but still "substantially parallel", i.e. less than 10° from being parallel, to the longitudinal axis of the mandril so the wave pattern takes on a generally sinusoidal shape such as the one illustrated in Figures 19 and 21. The planar waveform of Figure 17 may also be compressed perpendicular to straight sections 14 in order to form the nearly sinusoidal pattern illustrated in Figure 19 before being wrapped around the mandril 32. The stent is then removed from the smallest mandril and the stent is arranged on the balloon catheter.

The structure of the stent of the present invention is capable of expanding radially when subjected to the internal pressure of an expanding catheter balloon. The peaks 10 and valleys 12 between the waves operate like flexible junctions or hinges to allow the straight portions 14 to swing outwardly, oblique to the central axis of the body of the stent. Unlike hinges, however, after the stent is expanded, the junctions resist displacement of the straight sections in the opposite direction (for example, due to the compressive force of the lumen) which would tend to reduce the diameter of the expanded stent. The resistance of these junctions to compression (i.e. hoop strength) is caused by placing a stress on the material at the junction which exceeds the elastic limit of the material, so that the material near the junction is plastically deformed and thus resists any tendency for the stent to collapse inside a lumen. The wire and the bonding material should therefore be a low memory material.

Figures 17 and 18 illustrate a waveform where the period (or wavelength) of each wave p is roughly one-fourth of the mandril circumference c. This configuration has been found to minimize the number of waves, the number of bonds between waves, and amount of wire required to adequately support the lumen. For the embodiments illustrated in Figures 17 and 18, the end of the stent will have three peaks 10a, 10b and 10c, and three valleys 12a, 12b and 12c exposed on the end of the expanded stent. The apex of peaks 10a, 10b and 10c and valleys 12a, 12b and 12c are equally spaced at 120, 240 and 360 degrees, respectively, around the end face of the stent. This preferred configuration provides the maximum lumen support and minimum profile (i.e. diameter) in the unexpanded state using the least possible amount of foreign material inside the body. Conventional stents have been found to use more than three peaks or valleys around the end circumference of the body which increases their unexpanded profile and uses more material than is necessary. When the stent is properly expanded, each apex of peaks 10a-10c and valleys 12a-12c moves only in the radial direction away from the longitudinal axis of the tubular body of the stent. Consequently, the present stent will not migrate inside a lumen during expansion.

Figures 20 and 21 illustrate the arrangement of the waves (from the waveforms of Figures 18 and 19, respectively) around the circumference of the mandril 32 or body of the stent when the stent is in its unexpanded state. In both Figures 20 and 21, the straight portions 14 are "substantially parallel" to longitudinal axis of the tubular body of the stent which is illustrated by the centerline in each of the Figures.

Figure 22 shows an enlargement of one of the cells 39 formed from the wave pattern of Figures 20 or 21 when the stent is in an expanded state. The cell 39 can also be described as a rhombic shape having four sides 34, 36, 38 and 40 where sides 34 and 36 are formed from one straight portion 14 and sides 38 and 40 are formed from another straight portion 14

which is adjacent to the other straight portion. The wire is preferably bonded at the point of tangency between adjacent sides 34, 36 and 38, 40 of cell 39. It is clear from Figure 10, 11 and 22 that the straight portions will extend oblique to the central axis of the tubular body (shown by the centerline in the figures) when the stent is expanded to form a rhombic shaped cell.

The ultimate degree of expansion or expansion ratio of the stent can be adjusted by changing the height of the waves defined by the distance between axis 18 and axis 20. Increasing the length of straight sections 14 increases the ultimate expansion ratio of the stent without affecting its compressed or unexpanded diameter or profile. Consequently, the ultimate expanded diameter of the stent is independent of its unexpanded diameter so that one size stent can be used with almost any size lumen. Moreover, even large lumens can be supported with a stent that has a small unexpanded profile so that bleeding and vessel damage is minimized during implantation. In practice, the stent has been found to work well with expansion ratios of between 1:1 and 10:1; however, larger expansion ratios are also possible. The ultimate expansion ratio can also be increased by decreasing the period of the waves p and/or the distance between straight sections 14 so that more waves are created around the circumference of the stent.

Figure 23 shows the stent, inside a graft, being used to repair a pseudo-aneurysm in a common femoral artery. The stent 8 is placed inside graft 41 which blocks off pseudo-aneurysm 42. Although the stent is shown to be completely inside graft 41, it may also extend outside the edges of the graft in order to provide additional support for the incisions at the end of the graft.

In another preferred embodiment, a vascular prosthesis stent according to the present invention is constructed from a continuous wire that is half-round (i.e. semi-circular) in transverse cross-section. In other words, in transverse cross-section, the wire has a semi-circular side and a substantially planar side. In a completed stent, the semi-circular wire profiles are all on the exterior of the stent body while the planar portions of the wire are all on the interior. As a result, the interior of the stent -- comprised of the cross-sectional diameters of the wires -- provides a generally smooth surface that minimizes blood flow turbulence along the interior of the stent.

As compared to full-round wire stents, the stent of this embodiment provides less topography or elevation of the stent in a vessel. This is important because the stent is a foreign body relative to the vessel and will elicit a tissue reaction that covers the stent and incorporates it into the vessel wall. In comparison to full-round wire stents, the stent of this embodiment reduces the thickness of foreign material which projects into the lumen and is in contact with flowing blood. Because the stent is generally flush with the vessel wall, it will incite a less exuberant, thinner layer of healing tissue to cover the prosthesis. This results in less compromise of the vessel lumen. Therefore, in comparison to full-round wire stents of the other embodiments, the stent of this embodiment will allow a larger luminal diameter than full-round wire stents and, therefore, provides a relatively larger internal flow diameter of blood flow through a vessel.

In this preferred embodiment, the vascular prosthesis stent has a sufficiently low profile (i.e. external diameter) in its compressed state that the stent can be inserted through a relatively small aperture in a blood vessel wall, thereby minimizing bleeding and damage to the vessel. Also, the low prole allows the stent to be easily moved through narrow vessels.

Further, the vascular prosthesis stent has a compressed profile which is independent of its expansion ratio. In other words, the ultimate expanded diameter of the stent is not a function of its compressed profile and, therefore, one size stent can be used for lumens of a wide range of diameters.

Still further in this preferred embodiment, the vascular prosthesis stent has substantial flexibility in its compressed state while being generally rigid and having a high hoop strength in its expanded state. The flexibility of the compressed stent is important, as mentioned above, for inserting the stent through tortuous lumens. The hoop strength is important for resisting the radial forces from the artery after the stent is in place. Also, with the stent being substantially rigid after it is expanded inside a vessel, movement of the stent against the vessel intima is reduced after the stent is implanted. The reduction in movement is important for reducing trauma and for promoting healing of the vessel.

Even further still, the vascular prosthesis stent of this embodiment, has a tubularly-shaped body comprised of a plurality of oblong, open cells which are staggered around the circumference of the body such that when the stent is in its compressed condition, the long sides of each oblong cell are substantially parallel to the stent's longitudinal axis. The adjoining cells normally are bonded together at a point between adjacent parallel sides on a cell so that, when the stent is expanded, the adjacent sides of each cell extend at an oblique angle to the longitudinal axis of the stent.

A vascular prosthesis stent, as shown in Figures 24 to 26, has a tubularly-shaped body 22 formed from a continuous wire or the like. The tubularly-shaped body preferably is comprised of a plurality of cells that are formed from the continuous wire, with each of the cells having a plurality of sides. The cell sides extend substantially parallel to the longitudinal axis of the tubularly-shaped body when it is compressed (Figure 24), but extend obliquely to the longitudinal axis of the tubularly-shaped body when it is expanded (Figure 25). The construction of the stent is as described

above except that, as can be seen in Figure 28, the continuous wire that forms the tubularly-shaped stent body is half-round (i.e., semi-circular) in transverse cross-section. In other words, in transverse cross-section, the wire has a semi-circular side 25 and a substantially planar side 27. The substantially planar side 27 generally corresponds to the diameter of the wire. In practice, the planar side is smooth and has a polished appearance.

From the following, it can be understood that it is important for the stent wire to have a substantially planar side, but it is not necessary that the remainder of the periphery of the wire be semi-circular. Indeed, the remainder of the periphery of the wire can have a variety of arcuate and non-arcuate shapes.

As can be seen in Figure 27, the continuous wire is wound such that the semi-circular wire profiles 25 are all on the exterior of the tubularly-shaped stent body while the planar portions 27 are all on the interior of the stent. As compared to a full-round wire design, the orientation of the half-round wire is important so that the interior of the stent -- comprised of the cross-sectional diameters of the wires -- provides a generally smooth surface that minimizes blood flow turbulence along the interior of the stent and reduces the thickness of reactive tissue required to cover the prosthesis and incorporate it into vessel wall.

In use of the above-described stent, the stent is maneuvered along a blood vessel until it reaches desired location, whereat the stent is expanded by a balloon catheter for lodging inside of a lumen. When so expanded, the semi-circular profiles of the wires on the exterior of the stent press into the vessel wall. In fact, as suggested by Figure 29A, the stent may expand sufficiently that all of the semi-circular profiles on the exterior of the stent are embedded in a vessel wall 29 to the extent that the planar portions of the wire are substantially flush with the vessel wall. As a result, the interior of the lumen is generally smooth without impedance from the embedded stent.

There are several benefits to the stent to the configuration shown in Figure 24. One benefit, as mentioned above, is that the stent offers a generally smooth surface that reduces turbulence on blood flowing along the lumina supported by the stent and encourages blood platelet aggregation. As a result, this configuration minimizes the traumatic effect of the stent on vessels and blood cells. Further, this configuration promotes healing of the vessel.

As compared to full-round wire stents, the stent of this embodiment provides less topography, or elevation, of the stent in the vessel. This is important because the stent configuration allows its planar surface to be embedded in a manner substantially flush with the inner surface of the vessel wall. Consequently, the normal healing reaction of the vessel wall in response to the stent insertion is relatively thin and less exuberant than that required to incorporate a full-round wire design which projects further into the lumen from the vessel wall. As an example, Figure 29B shows the vessel of Figure 29A with tissue healed over the stent; typically, the tissue layer (intimal hyperplasia) is about 100 angstroms thick.

Also in comparison to full-round wire stents, the stent of this embodiment requires less reactive tissue to incorporate the stent into the vessel wall. Again this is important because the neointimal layer will be completed faster when the reaction requires less reactive tissue. Finally in comparision to full-round wire stents, because the stent of this embodiment elicits a thinner circumferential layer of tissue having, it can yield a larger luminal diameter than full-round the stents and, therefore, provides a larger internal flow diameter for blood flow.

Figures 30 and 31 A show patterns or waveforms of the wire that forms the stent similar to that described in connection with Figures 17 and 18.

As further shown in Figure 30, the peaks 10 and valleys 12 are interconnected by substantially straight sections 14. The straight sections 14 are substantially parallel to each other and, for that reason, are depicted as straight vertical lines in the drawings. (The term "substantially parallel" is intended to encompass the configuration of the straight portions 14 in the compressed and expanded stent.) In practice, the peaks and valleys are generally semicircular in shape and arranged to intersect the straight portions 14 at the tangent of each curved peak or valley, with the result that there are no discontunuities in the wire.

The formation of the stent about the mandrel in the other preferred embodiment can be summarized by observing that the continuous wire is formed into an asymmetric undulating wave pattern around the circumference of the tubularly-shaped stent body with each wave having a long ascending side and a short descending side, with a peak between the long ascending side and the short descending side valley between the short descending side and a long ascending side of an adjacent wave, and the ascending and descending sides of each wave being arranged substantially parallel to the longitudinal axis of the body when the body is in compressed condition. Further, as the continuous wire is wound around the cylindrical mandril, the wire configuration is adjusted so that the n^{th} peak comes into tangency with the valley immediately following peak $n^{th}+3$, and so forth so that all peaks and valleys are in tangency. Then pairs of the tangent points are fixed together over relatively short lengths by means of for example a spot weld to form a plurality of cells arranged substantially parallel to the long axis of the mandrel. Preferably, the long side of the wave and the short side of the wave are in a ratio of about 4:3. Also, as mentioned above, at least some of the peaks and valley of the waves are bonded together to form a plurality of cells.

It should be particularly noted the waveform is

wrapped around the mandrel 32 so that the planar face of the half-round wire is in contact with the mandrel. That is, the mandrel surface is tangent to the substantially planar face of the half-round wire and the semi-circular surface of the half-round wire faces outward from the mandrel. Thus, when the tubularly-shaped stent is removed from the mandrel, it is in the compressed condition shown in Figure 24.

It should also be noted that the end 24 of the waveform is wrapped around the mandril 32 so it is tangent to point 24'. Similarly, end 26 is tangent to point 26' when the wave is completely wrapped around the mandril 32. In practice, the ends 24, 26 are bonded (as by welding, brazing, soldering, tying. looping, adhesive bonding, or other suitable means) so that the ends of the wire are not exposed to snag or otherwise interfere with the placement of the stent in the vessel.

The planar waveform is compressed perpendicular to straight sections 14 to form an undulating pattern before being wrapped around the mandril 32. In these conditions, the straight portions 14 are substantially parallel to longitudinal axis of the tubularly-shaped stent body.

Referring again to Figure 24, it can be seen that the side profile of the stent in its expanded state is defined by cells that have generally rhombic shapes with four sides. As mentioned above, the wire is bonded at the tangent points between adjacent sides to form bonded cells. The above-discussed straight portions 14 extend obliquely to the central axis of the tubularly-shaped body when the stent is expanded as shown in Figure 25.

In operation, the compressed stent is mounted on a catheter for insertion into a lumen. Then, during implantation, the compressed stent 22 and a catheter balloon are withdrawn inside the sheath onto the catheter while the sheath is slid inside a vessel lumen. Then, after the compressed stent 22 is moved to its appropriate position, the sheath is partially withdrawn so that the compressed stent 22 and the balloon are exposed inside the lumen. The balloon is then inflated and the stent 22 is expanded inside the lumen. Finally, the balloon is deflated and the catheter is removed from the lumen without the stent.

The stent material preferably has "low memory," which is to say that it does not try to resume its original shape after it is deformed. This is important for preventing the stent from recoiling to its compressed condition after implantation. In one preferred embodiment, the stent is formed from about 0.006 to 0.020 inch diameter annealed tantalum wire. The stent material may also be radio-opaque to allow its location in a vessel to be verified through fluoroscopic examination. Preferably, the stent is made from a biocompatible material (such as stainless steel) or a bio-absorbable material (such as Vicryl). The stent may also be coated with anti-thrombolytic or anti-coagulant agents such as Dextran, Heperin, t-PA, polytetrafluoroethylene, or ultra low-temperature isotropic carbon.

It is important for the stent wire to have a substantially planar side, but the remainder of the periphery of the wire can have a variety of arcuate and non-arcuate shapes.

It has been found by the present inventor that an ideal vascular prosthesis should include several features. The stent should be formed from as little material as possible with a low profile (i.e. diameter) in its unexpanded state so that it can be inserted through the smallest possible hole in the vessel wall in order to control bleeding and damage to the vessel. A low profile also allows the stent to be more easily moved through narrow vessels. Furthermore, it is preferable that the unexpanded profile of the stent be independent of its expansion ratio. In other words, besides needing the smallest possible profile during insertion, there is also a need to be able to change the ultimate expansion ratio of the stent without affecting its unexpanded profile so that one size stent can be used with almost any size lumen.

The stent should also have high flexibility in its unexpanded state and excellent hoop strength in its expanded state. In practice, it has been found to be difficult to design a stent with both of these characteristics. Flexibility is needed to insert the stent through tortuous lumens while hoop strength is needed to resist the radial forces from the artery once the stent is in place. The stent should also be rigid once it is expanded inside a vessel in order to minimize its movement against the vessel intima after it is in place and to promote healing of the vessel after placement. Furthermore, the flexibility of the design should be adjustable without changing the size or configuration of the stent.

The stent should be altraumatic to vessels and blood cells. It should therefore be formed from as little biocompatible material as possible. The stent should not have any exterior tines or sharp edges which could damage the wall of the vessel. It should also not have any interior tines which could damage the catheter balloon or cause hemodynamic disturbances which might interfere with the flow of blood through the stent. The material from which the stent is formed is preferably a low memory, radio-opaque material. In other words, the stent should maintain its shape without recoil once it is expanded inside the vessel and should be visible during fluoroscopy in order to be able to verify that the stent has not migrated from its intended position.

In the preferred embodiments, the vascular stent includes a continuous wire which is formed into a substantially tubular body. The wire forms a plurality of oblong, open cells which are staggered around the circumference of the tube. When the body is formed in its unexpanded state, the long sides of each oblong cell are arranged substantially parallel to the longitu-

dinal or axis of the tubular body. Adjoining cells may then be bonded together at a point between adjacent parallel sides on a cell. When the body is expanded, the adjacent sides of each cell extend oblique to the longitudinal axis of the body.

Claims

1. A vascular stent comprising a tubular body with a plurality of cells, each with a plurality of sides formed by wire, CHARACTERISED IN THAT the sides of the cells extend substantially parallel to a longitudinal axis of the tubular body when the latter is in an unexpanded state, and in that the sides of at least certain of the cells extend obliquely to the longitudinal axis when the tubular body is in an expanded state.

2. A stent according to claim 1, CHARACTERISED IN THAT adjacent sides of at least certain sides of adjacent cells are interconnected by coupling or fixing together in such a manner that the stent comprises a plurality of interconnected cells which when in an expanded state are formed into rhomboid shape.

3. A stent according to claim 2, CHARACTERISED IN THAT the plurality of cells are formed from a continuous wire shaped into a substantially tubular body with adjacent cells whose adjacent sides have been coupled or fixed together.

4. A stent according to claim 3, CHARACTERISED IN THAT the said adjacent sides are spot welded together at one distinct location per side.

5. A stent according to claim 3 or 4, CHARACTERISED IN THAT upon expansion of the stent, each said adjacent side rotates about the point of the coupling or fixing, in order to form the said rhomboid shaped cells.

6. A stent according to claim 3, 4 or 5, CHARACTERISED IN THAT upon expansion, the continuous wire is deformed past its elastic limit, whereby the expanded tube will retain its expanded state.

7. A stent according to any one preceding claim, CHARACTERISED IN THAT the wire is of substantially semicircular cross-section with the flat side thereof inward facing.

8. A method of making a vascular stent, comprising the steps of forming a wire into a substantially sinusoidal wave pattern, and wrapping the wire around a mandril to form the stent, CHARACTERISED IN THAT the said wave pattern has substantially straight portions which are substantially aligned with the longitudinal axis of the mandril, and in that the wire optionally has a semicircular cross-section with the flat portion facing the interior of the stent.

9. A method according to claim 8, further CHARACTERISED BY the step of coupling or bonding together at discrete locations on adjacent sides of adjacent cells so that the stent is formed into a plurality of interconnected cells each of which can rotate about the said discrete locations to form a rhomboid shape upon expansion of the stent.

10. A method according to claim 9, CHARACTERISED IN THAT the substantially sinusoidally shaped wire is substantially U-shaped arranged so that upon winding longitudinally spaced valleys coincide with longitudinally spaced peaks, and in that the peaks and valleys are coupled or fixed together, and in that substantially straight adjacent cells sides of the U-shaped wires are fixed together at specific locations about which the wire rotates upon expansion to form the rhomboid shaped cells.

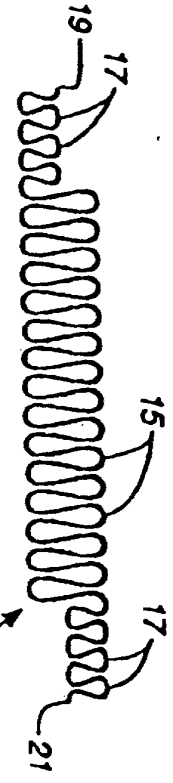


FIG._1

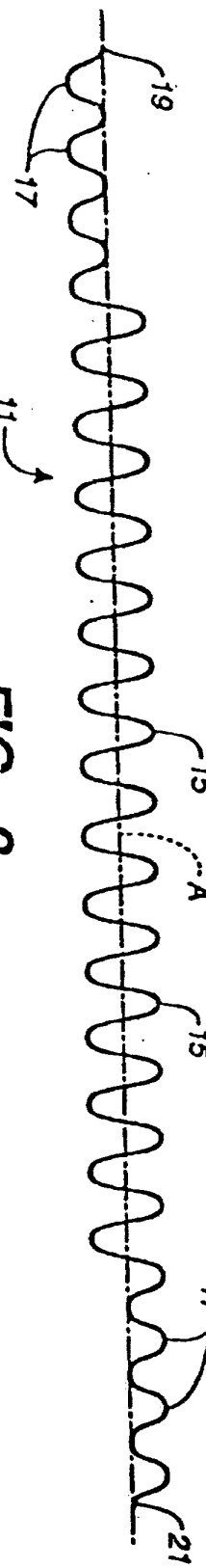


FIG._2

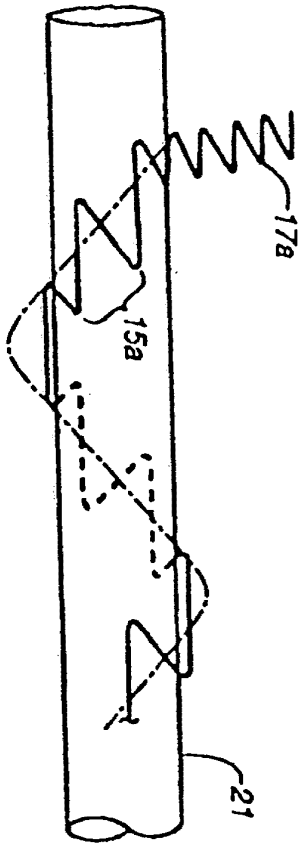


FIG._5

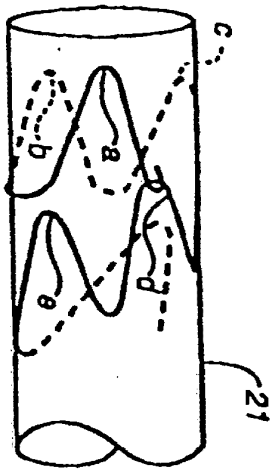


FIG._6

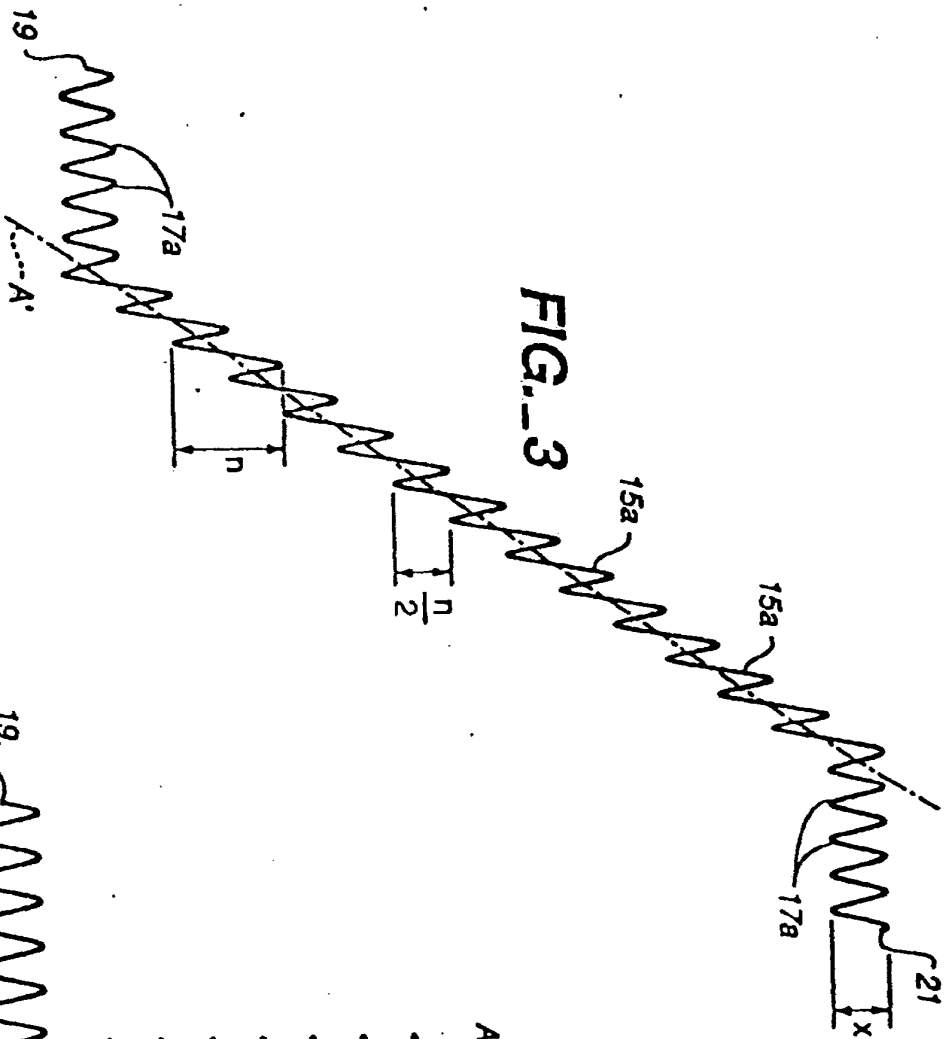


FIG._3

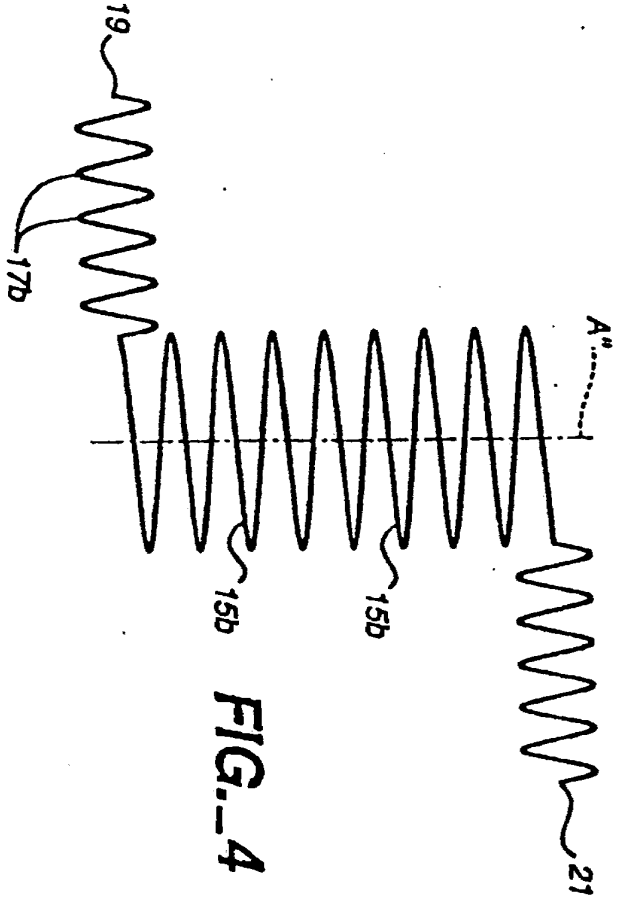


FIG._4

FIG._7

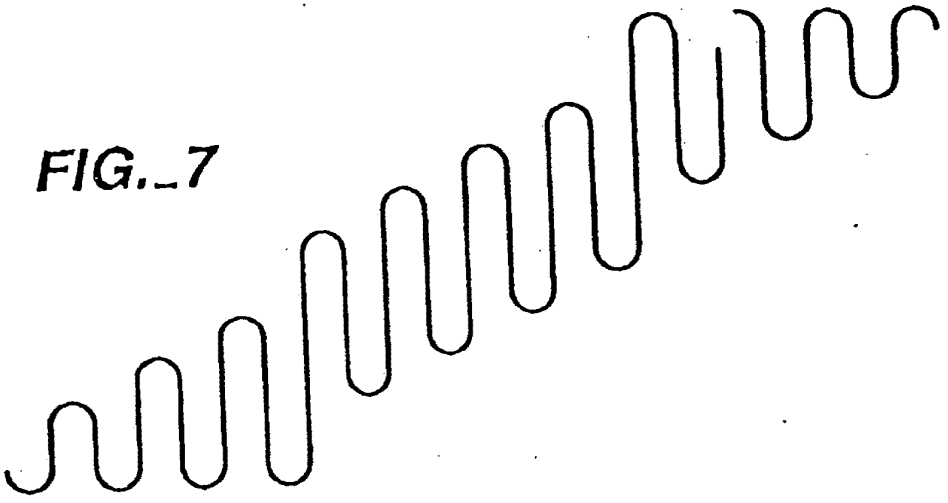
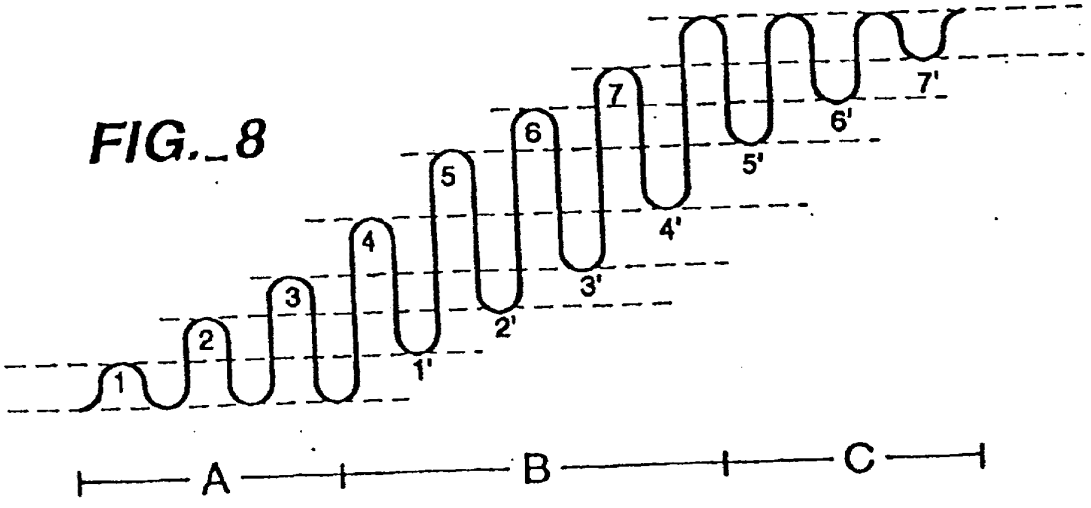


FIG._8



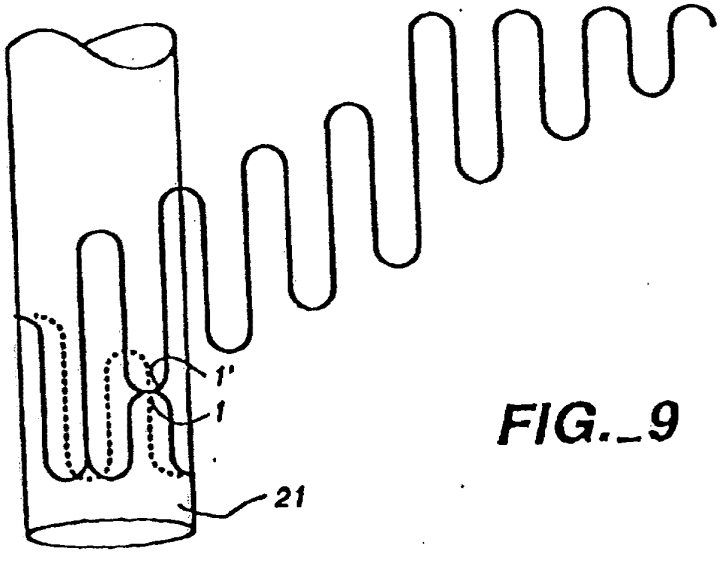


FIG._9

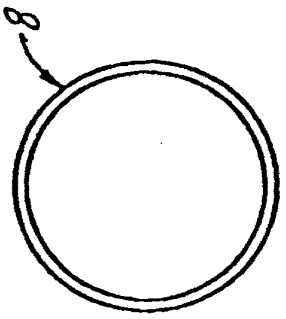


FIG._12

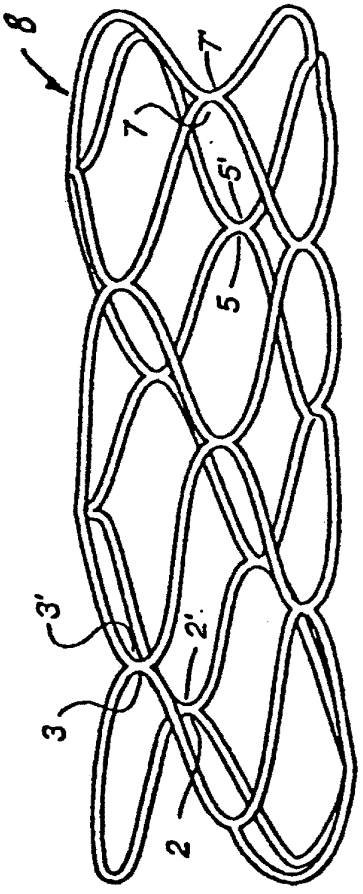


FIG._10

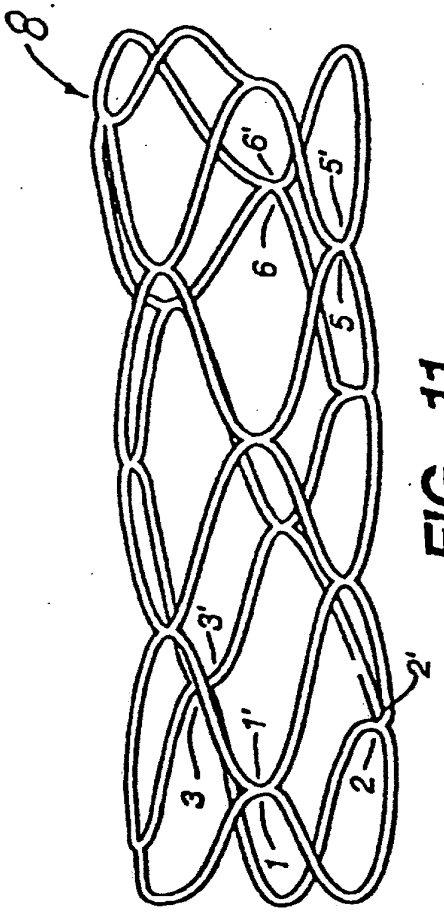


FIG._11

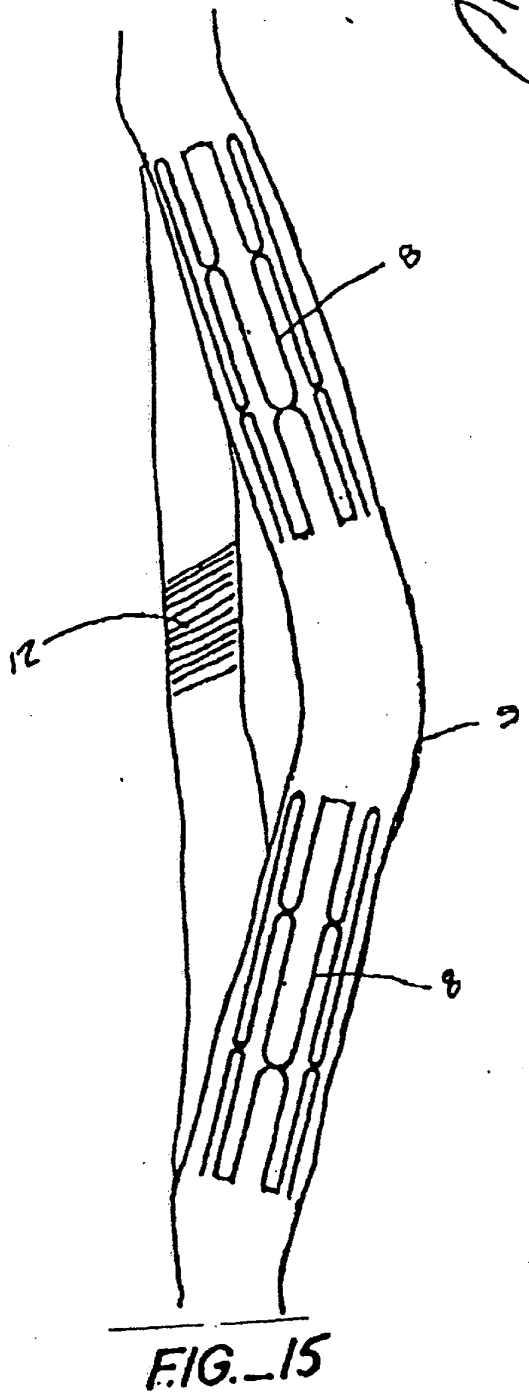


FIG._15

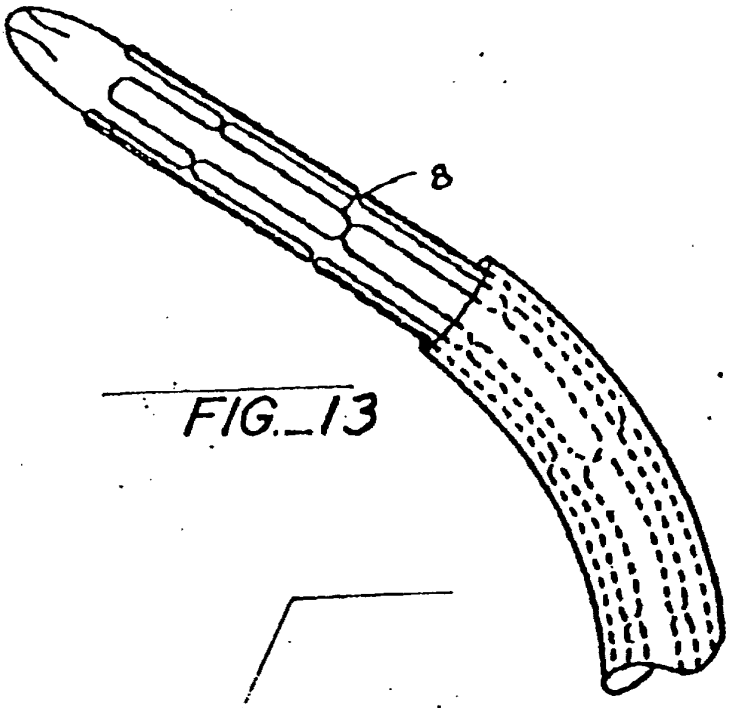


FIG._13

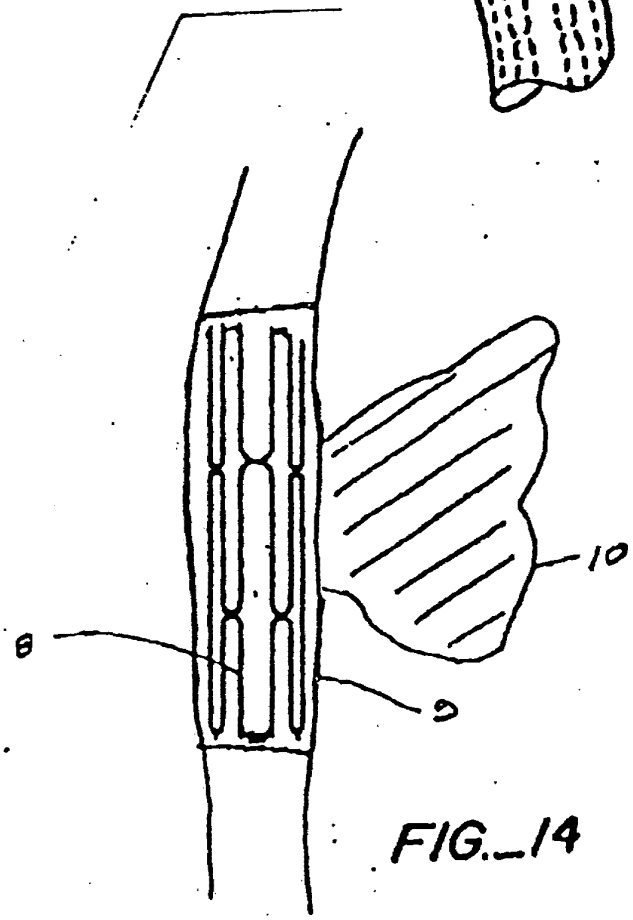


FIG._14

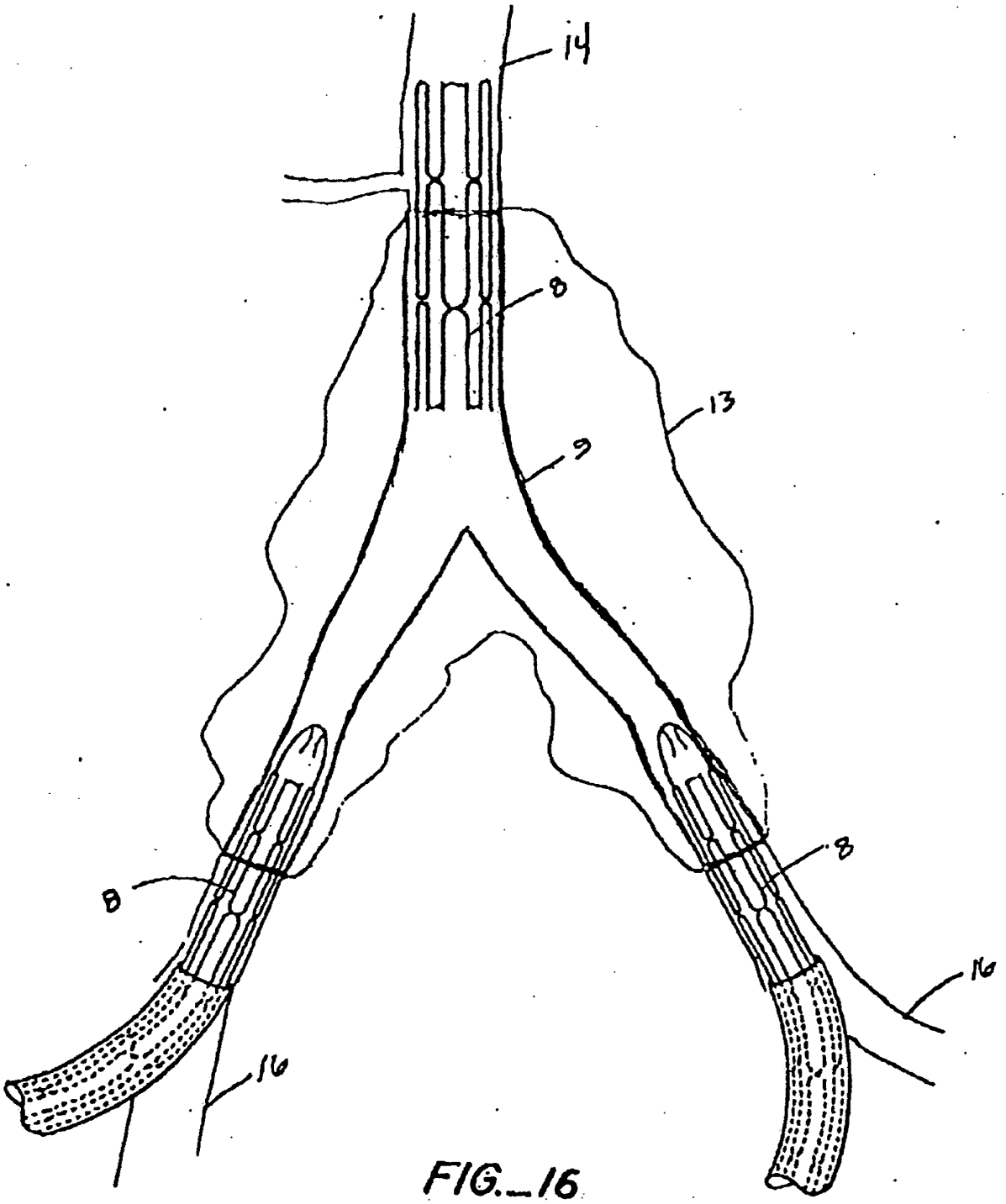


FIG._16

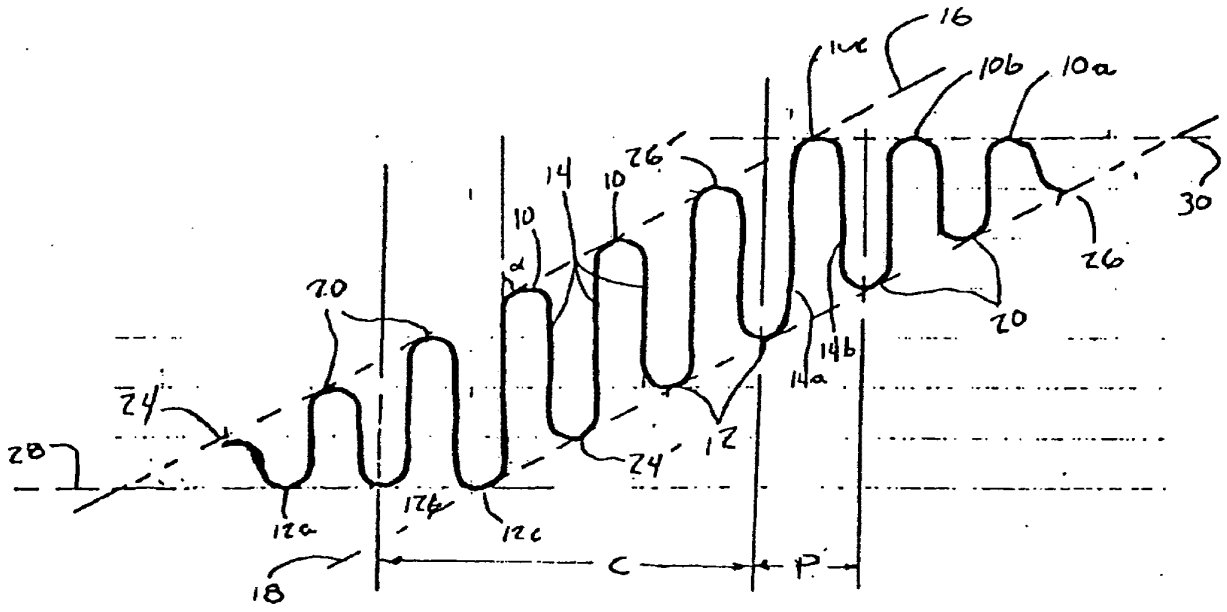

16
10c
10b
10a
26'
14
10
10
26'
30
26
20
20
14b
14a
24'
24'
12
28
12a
12b
12c
18
C
P

FIG.—17

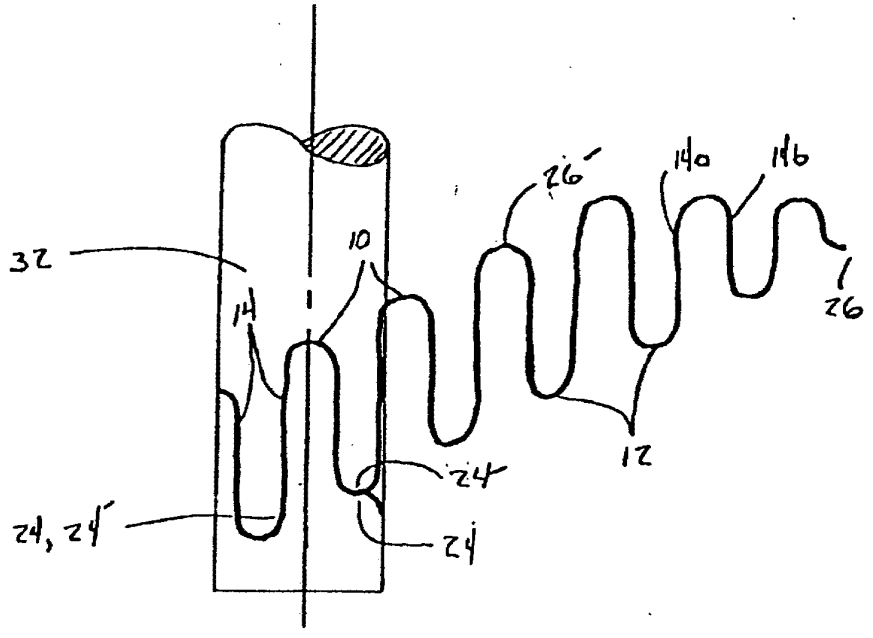

26'
14a
14b
32
10
14
26
24
24, 24'
24'
12

FIG.—18

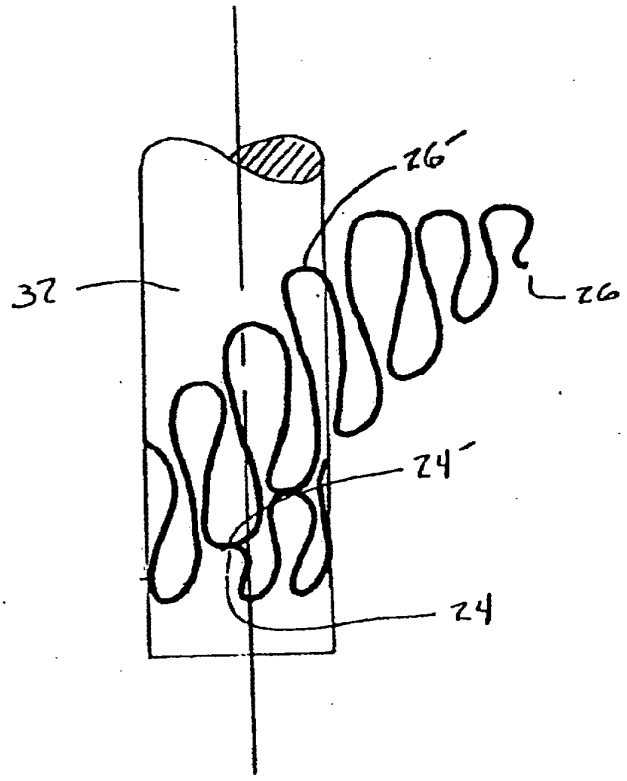


FIG. 19

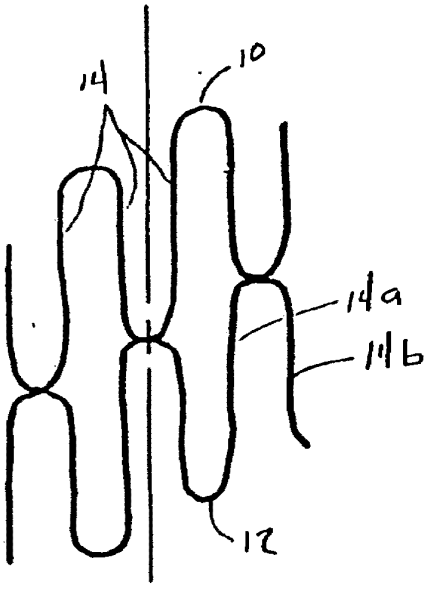


FIG. 20

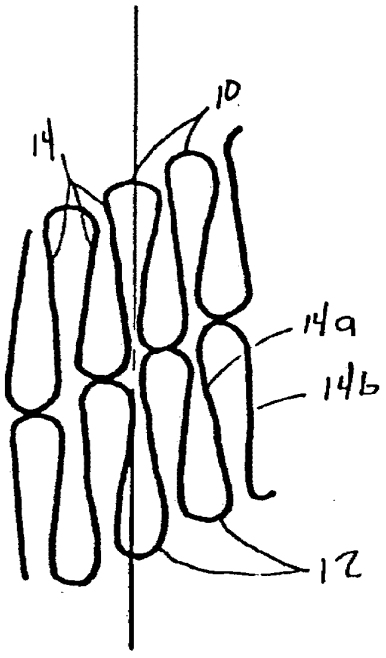


FIG. 21

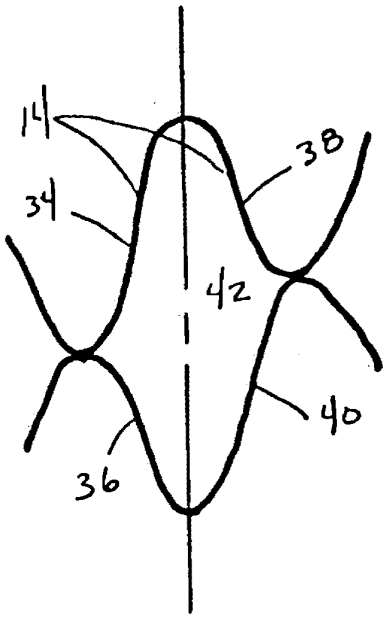


FIG._22

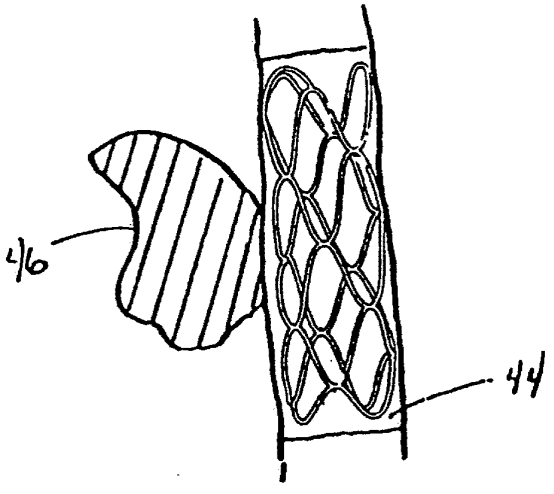


FIG._23

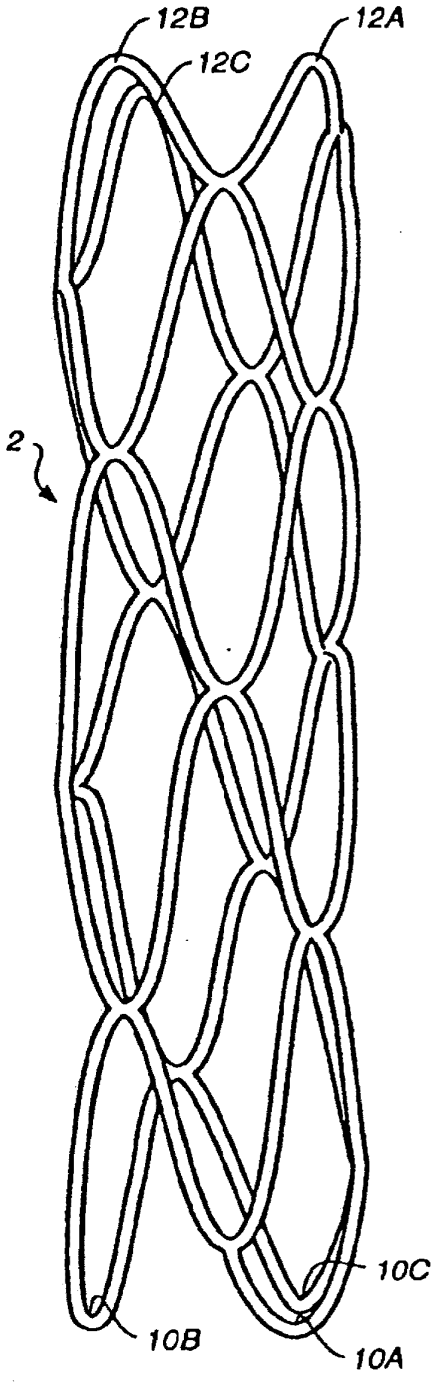


FIG._24

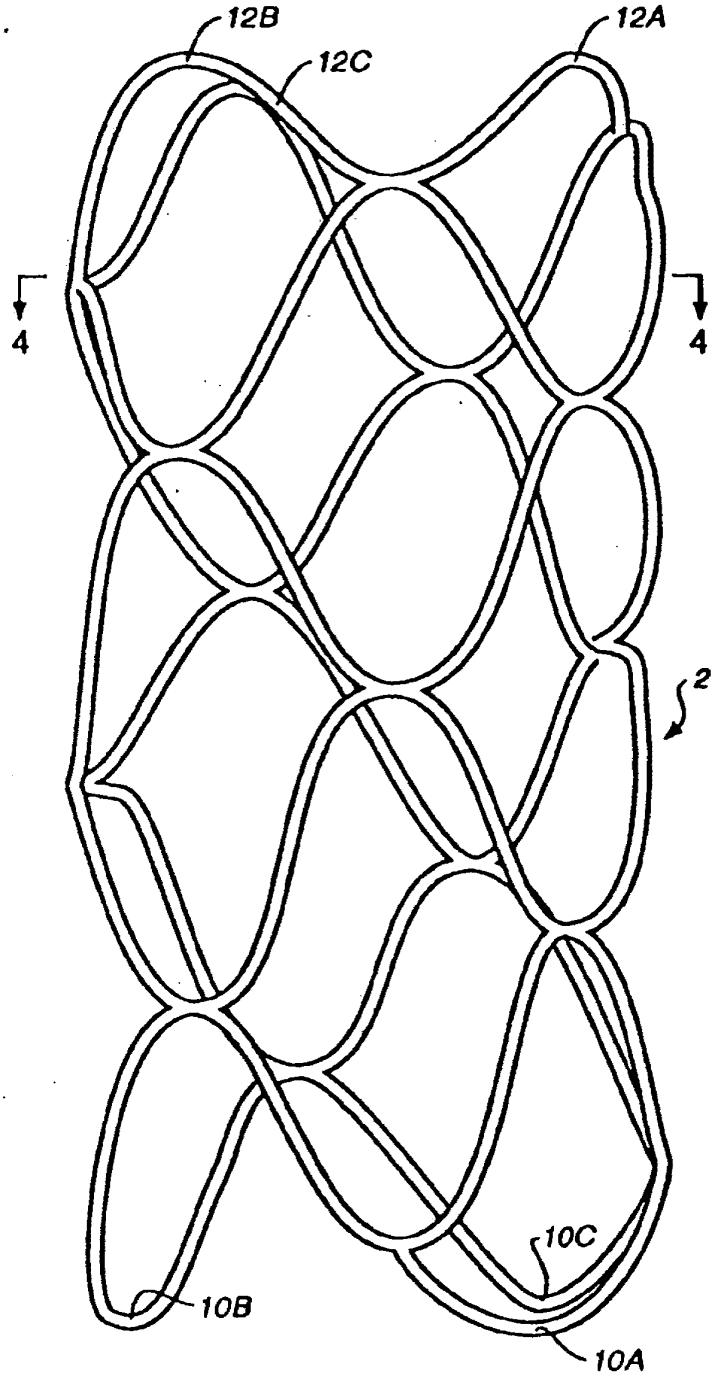


FIG._25

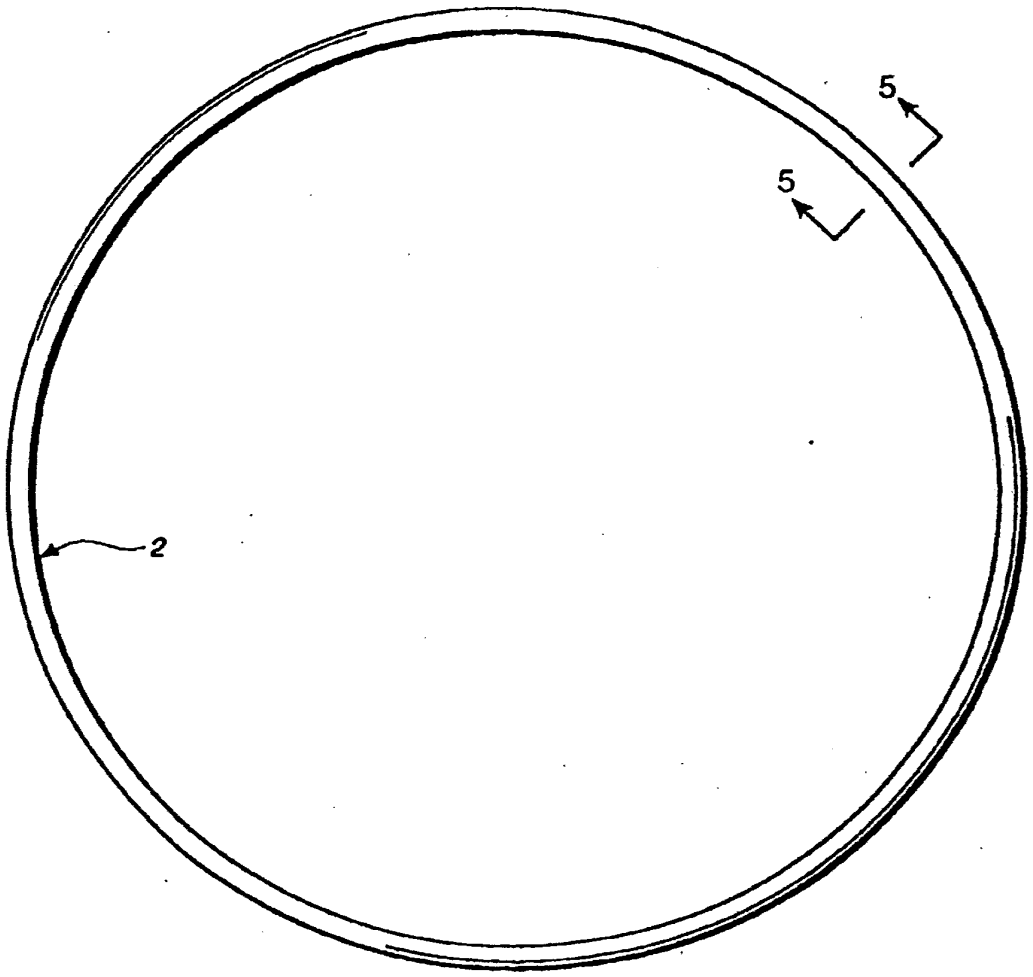


FIG._26

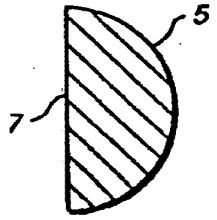


FIG._28

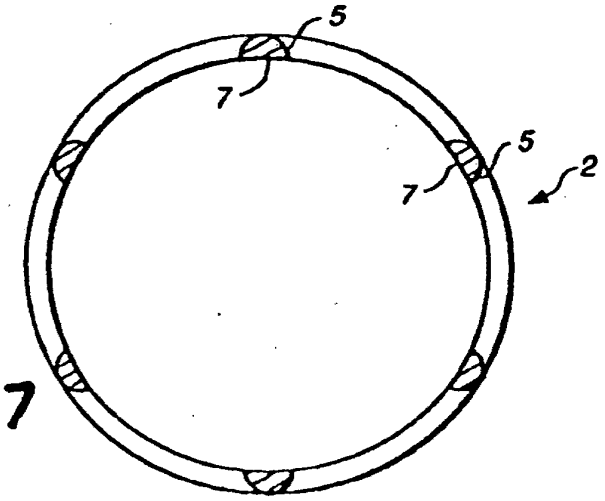


FIG._27

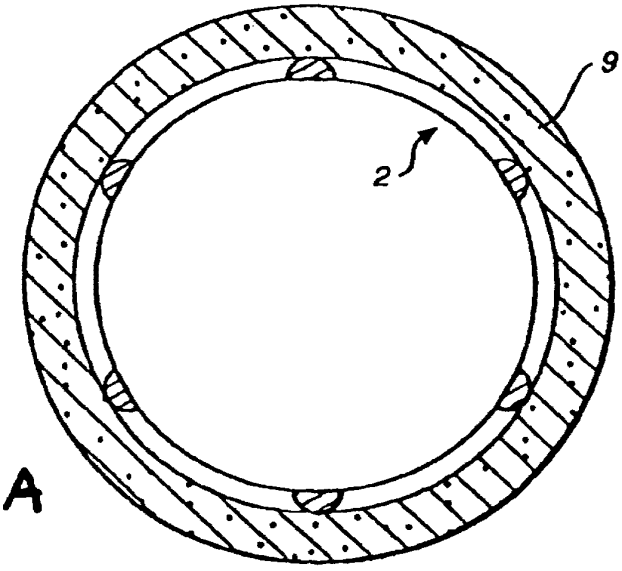


FIG._29A

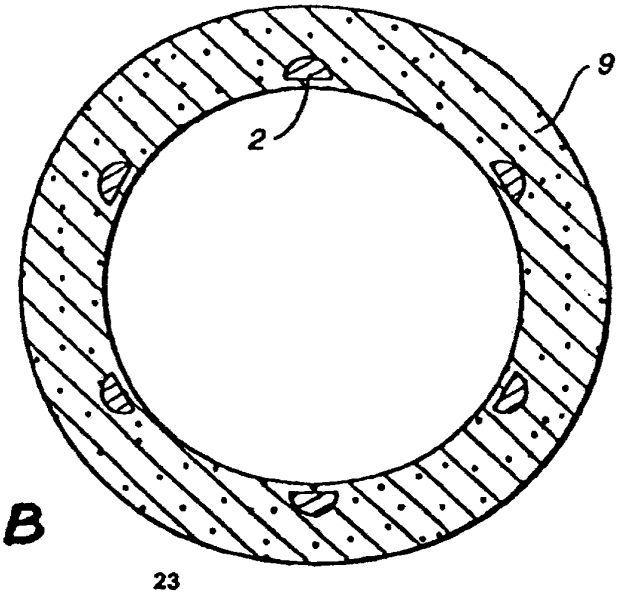
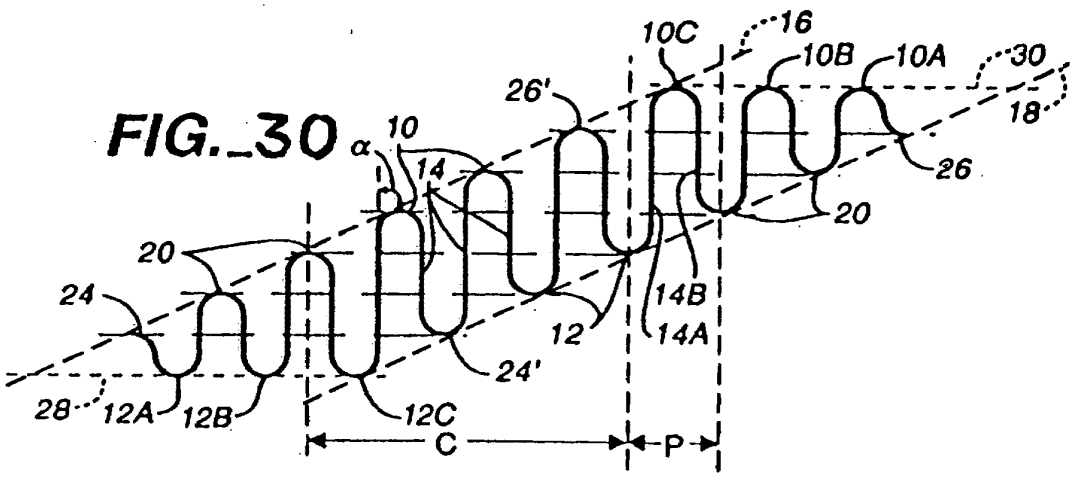


FIG._29B

FIG._30



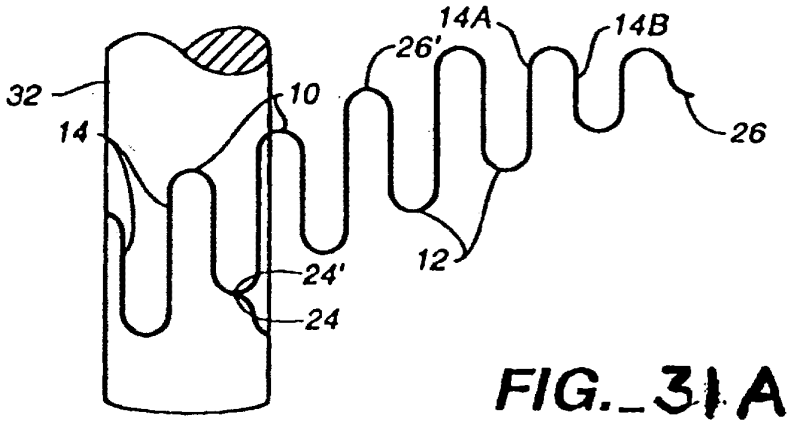


FIG._31A

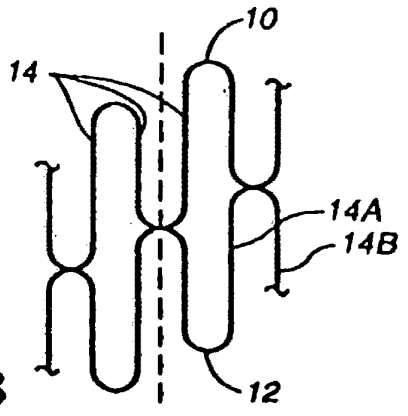


FIG._31B

European Patent Office

EUROPEAN SEARCH REPORT

Application Number EP 93302066.1

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	US - A - 4 733 665 (J.C. PALMAZ)	1-6	A 61 M 29/00 A 61 F 2/06
A	* Fig. 1A-2B; column 5, line 24 - column 6, line 52; column 6, line 67 - column 7 line 28 *	7,9	
A	US - A - 4 800 882 (C. GIANTURCO) * Totality *	8	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F
A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	09-07-1993	LUDWIG

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)

⑲日本国特許庁(JP)　　⑪特許出願公表

⑫公表特許公報(A)　　平5−509008

㊸公表　平成5年(1993)12月16日

㊿Int.Cl.⁵	識別記号	庁内整理番号	審査請求 未請求	
A 61 M 29/02		9052−4C	予備審査請求 有	部門(区分) 1(2)

(全12頁)

㊹発明の名称　生体吸収性ステント

㉑特　願　平3−510977
㊱㉒出　願　平3(1991)5月17日
㊲翻訳文提出日　平4(1992)11月18日
㊳国際出願　PCT/US91/03454
㉗国際公開番号　WO91/17789
㉗国際公開日　平3(1991)11月28日

優先権主張　㉜1990年5月18日㉝米国(US)㉛524,884

㉒発明者　スタツク、リチヤード・エス　アメリカ合衆国、ノース・カロライナ州　27514、チヤペル・ヒル、フアルコン・ブリツジ・ロード　6913
㉑出願人　スタツク、リチヤード・エス　アメリカ合衆国、ノース・カロライナ州　27514、チヤペル・ヒル、フアルコン・ブリツジ・ロード　6913
㉔代理人　弁理士　鈴江　武彦　外3名

㉛指定国　AT(広域特許),AU,BE(広域特許),CA,CH(広域特許),DE(広域特許),DK(広域特許),ES(広域特許),FR(広域特許),GB(広域特許),GR(広域特許),IT(広域特許),JP,LU(広域特許),NL(広域特許),SE(広域特許)

最終頁に続く

請求の範囲

1．第1の端部、第2の端部、及び前記第1の端部から第2の端部まで連通して定義された流路を有する管状の主要部分を含む管腔内のステントであって、前記管状の主要部分は、身体経路内の管腔配置に合わせた大きさであり、前記主要部分は実質的に円筒状に巻かれた生体吸収性材料からなり、生体吸収性材料は多孔質であるか又は孔を有しており、主要部分は第1の減少した断面の大きさから、第2の拡大した断面の大きさまで自己膨脹し、それによって、主要部分は身体経路の目的部位まで管腔内的に移動し、前記身体経路の目的部位に係合しかつ支えるように、第2の拡大された直径まで膨脹し、主要部分は前記生体吸収性材料を縮径形状に保持するための手段と、生体吸収性材料を拡大径形状に保持するための手段とを含み、前記ステントは、その上に被覆された又はその中に組み込まれた治療上に有効量の薬剤を有することを特徴とするステント。

2．前記生体吸収性材料がポリマー材料である請求項1に記載のステント。

3．基端部と先端部とを有する導入カテーテル、基端部と先端部とを有する外部シース部材、及び基端部と先端部とを有する内部シース部材を包含し、前記外部シース部材は導入カテーテル内に摺動可能に取り付けられ、前記内部シース部材は外部シース部材内に摺動可能に取り付けられ、ステントは内部シース部材の先端方向の、外部シース部材の先端部に取り付けられたカテーテルアセンブリとの組合わせである請求項1に記載のステント。

4．先端部と基端部と、前記先端部に与えられた膨脹可能なバルーンとを含み、膨脹可能なバルーンの外表面にステントが取り付けられた請求項1に記載のステント。

5．前記ステントが生体親和性ニカワ及び生体親和性接着剤の1つで膨脹可能なバルーンに接着された請求項4に記載のステント。

6．前記ポリマー材料がポリ−L−ラクチドを含む請求項2に記載のステント。

7．前記生体吸収性材料が、生体吸収性ポリエステルと薬理的に受容可能な酸とを含む請求項1に記載のステント。

8．前記ポリエステルが、ポリ−L−ラクチドを含み、前記酸がフマル酸である請求項7に記載のステント。

9．前記生体吸収性材料が、下記式

$$-NH-(CH_2)_n-CO-$$ 又は

$$-NH-(CH_2)_x-NH-CO-(CH_2)_y-CO-$$

（式中、nは6〜13、xは6〜12、yは4〜16である）

のポリアミドを含む請求項1に記載のステント。

10．前記生体吸収性材料が、下記式

$$HO_2C-C_6H_4-O-(CH_2)_n-OC_6H_4-CO_2-H$$

（式中、nは2〜8である）

のポリハイドライドを含む請求項1に記載のステント。

11．生体吸収性材料が、

$(RO)_3C-X-C(OR)_3$と
$(HOCH_2)CH-Y-CH(CH_2OH)_2$
（式中、Rは低級アルキル基であり、
X及びYは、個々に$-C_6H_4-$、又はnが1～12の$-(CH_2)_n-$、又はそれらの組み合わせである）
の反応により生じたポリオルトエステルを含む請求項1に記載のステント。

12．前記薬剤が平滑筋細胞抑制剤である請求項1に記載のステント。

13．前記薬剤が血管拡張剤である請求項1に記載のステント。

14．前記薬剤が抗血小板剤又は抗血栓剤である請求項1に記載のステント。

15．前記薬剤がコラーゲン抑制剤である請求項1に記載のステント。

16．i）ステントの外層の膨潤を与えるような条件下で、前記フィラメントを膨潤させる溶媒に、ステントが形成されているフィラメントを接触させること、及び
ii）工程i）で得られたフィラメントを、前記フィラメントの膨潤した外層内に試薬が拡散するような条件下で、前記フィラメントに対して非溶媒である試薬であって、前記溶媒をともなう溶液で形成された試薬に接触させ、それによって、前記フィラメントの外層中の相分離と細孔形成とを引き起こすこと
を含む請求項1に記載のステントの表面の細孔の形成方法。

17．前記細孔が、フィラメントからのステントの形成に先立ってフィラメントの外層中に形成される請求項16に記載の方法。

18．前記細孔が、フィラメントからのステントの形成後にフィラメントの外層中に形成される請求項16に記載の方法。

19．i）ステントが形成されているフィラメントの外層に細孔を形成すること、
ii）薬剤とゲル形成剤とを含む組成物を、細孔内に導入すること、及び
iii）前記組成物をゲルとして硬化させること
を含む請求項1に記載のステント中に薬剤を取り込む方法。

20．第1の端部、第2の端部、及び前記第1の端部から第2の端部まで連通して定義された流路を有する管状の主要部分を含む管腔内のステントであって、前記管状の主要部分は、身体経路内の管腔内の配置に合わせた大きさであり、前記主要部分は実質的に円筒状に巻かれた生体吸収性材料からなり、生体吸収性材料は多孔質であるか又は孔を有しており、主要部分は第1の減少した断面の大きさから、第2の拡大した断面の大きさまで膨張可能であり、それによって、主要部分は、身体経路の目的部位まで管腔内的に移動し、前記身体経路の目的部位に係合しかつ支えるように、第2の拡大された直径まで膨張させ、主要部分は前記生体吸収性材料を縮径形状に保持するための手段と、生体吸収性材料を拡大径形状に保持するための手段とを含み、前記ステントは、その上に被覆された又はその中に組み込まれた治療上に有効量の薬剤を有することを特徴とするステント。

21．保持手段が、前記生体吸収性材料の第1及び第2の周辺の端部の摩擦的な係止を含む請求項20に記載のステント。

22．前記生体吸収性材料が少なくとも1つの細片状であり、前記保持手段が、生体吸収性材料の細片の第1の端部に取り付けられた伸びた接合部材であり、生体吸収性材料の第2の端部が前記接合部材に対して摺動可能である請求項20に記載のステント。

23．第1及び第2の接合部材が与えられ、接合部材の1つが、生体吸収性材料の前記シートの第1の端部に堅く取付けられた請求項22に記載のステント。

24．前記接合部材のそれぞれが、材料の細片を受け取るための摺動可能な手段を含む請求項23に記載のステント。

25．複数の生体吸収性材料の細片が与えられる請求項22に記載のステント。

26．前記主要部分が、複数の尖叉受容空洞と複数の尖叉部材とを含み、前記尖叉部材がその第1の端部で尖叉受容空洞の第1の端部に接合され、尖叉部材の第2の端部が尖叉受容空洞の第2の端部に挿入された請求項20に記載のステント。

27．第1の端部、第2の端部、及び前記第1の端部から第2の端部まで連通して定義された流路を有する管状の主要部分を含む管腔内のステントであって、前記管状の主要部分は、身体経路内の管腔内配置に合わせた大きさであり、前記主要部分は多孔質であるか又はそれを通った孔を有する生体吸収性材料からなり、それによって、主要部分の組織内包が促進されて、血液がその中を通って流れることが可能となり、前記生体親和性材料は、その上に被覆された、その内部に含浸させた、又はその中に内包された薬剤を有するステント。

明　細　書

生体吸収性ステント

発明の分野

本発明は、身体経路の開通性を維持するためのステントに関する。開通性を維持することに加えて、ステントは、局部的な薬理治療を行なうための薬剤放出手段として役立つ。本発明は、冠動脈の血管形成の分野に特に適用され、それに関して説明される。その理解において、本発明は主として、急性動脈閉鎖を治療するため、及び血管形成後の再狭窄を防止するための、冠動脈のような血管内に配置するための生体吸収性の（即ち生体分解性の）ステントに関する。一方、本発明ではまた、尿管及びファロピウス管のような他の身体経路の開通性を膨脹させ維持することに適用することが有利であることがわかっている。

従来の技術

冠動脈の血管形成は、局部麻酔のもとで、大腿動脈を通して導かれ、冠動脈中の狭窄病変の部位に進む拡張カテーテルを有するカテーテルシステムの使用を典型的に含む。膨脹カテーテルは、例えば、冠動脈の目的とする狭窄部位の中に一旦設置されると、流体で膨脹せしめられるバルーンカテーテルである。バルーンが膨脹するに従って、血管壁に沿ったアテローム性動脈硬化症物質は圧縮され、それによって冠動脈を通る流路は拡張する。

バルーン血管形成は、比較的通常の満足すべき手段となったが、血管形成後の再狭窄が、しばしば発生する。さらに、アテローム性動脈硬化症プラークは膨脹中に亀裂を生じ、冠動脈が後に潰れる可能性を非常に増大させる。

それゆえ、アテローム性動脈硬化症プラークを圧縮された状態に維持し、一方それと同時に血管の潰れを避けることによって、冠動脈のような血管の再狭窄を避ける、又は最小限にすることは望ましい。

前述の目的に伴って金属製ステントが開発され、バルーンカテーテルによって血管部分を拡張させた後に、又はアテローム性動脈硬化症プラーク圧縮の際に、冠動脈の狭窄部位に設置するために適された。

そのような金属製ステントの１つは、ヨーロッパで提案され、試験され、Ｓｉｇｗａｒｔ等の論文“Ｉｎｔｒａｖａｓｃｕｌａｒ　Ｓｔｅｎｔ　ｔｏ　Ｐｒｅｖｅｎｔ　Ｏｃｃｌｕｓｉｏｎ　ａｎｄ　Ｒｅｓｔｅｎｏｓｉｓ　ａｆｔｅｒ　Ｔｒａｎｓｌｕｍｉｎａｌ　Ａｎｇｉｏｐｌａｓｔｙ”　Ｎｅｗ　Ｅｎｇｌａｎｄ　Ｊｏｕｒｎａｌ　ｏｆ　Ｍｅｄｉｃｉｎｅ，Ｖｏｌ．３１６，１２，Ｍａｒｃｈ　１９，１９８７，ｐｐ．７０１－７０６に記載された。このステントは、直径を拡げ、一方同時に長さを減少させ、また直径を縮小し、一方同時に伸ばすことができる金属製の“Ｃｈｉｎｅｓｅ　ｆｉｎｇｅｒ　ｈａｎｄｃｕｆｆ”である。ステントは、歪み力が取り除かれた後は、その歪んだ形状を維持する。

金属ステントは、金属メッシュの細長い管から所望の長さを切断することによって作製される。結果として、長さ切断工程からの金属プロングは、ステントの長さ方向の両端部に残るという欠点がある。末端プロングとともにステントを形成するために使用される金属の本来の硬さは、目的とする血管への経路に沿った健康な組織を傷つけるという観点からの危険性と同様に、目的とする狭窄病変部位への血管の案内をも困難にする。さらに、ステントが、一旦目的とする血管中に永久に設置されると、患者の心臓の鼓動は、末端プロングが、内皮被包の後でさえ動脈の狭窄部位の隣りの健康な血管壁を傷つけることを引き起こす。結局、金属製ステントは長期に渡って血管内に埋め込まれることを意図されるので、血液へのステントの連続した露出は、血管内における望ましくない血栓の形成に導く。

発明の概要

それゆえ、冠動脈のような血管内に設置するためのステントを提供することは望ましく、そのステントは、潰れに対して血管を支えるのに十分な環強度を有し、冠動脈の狭窄部位の位置への、安全で効果的な導入のために十分に柔軟である。埋め込み後に心臓の鼓動の連続的な応力に曝された際ですら、ステントの両端部における動脈の破壊、又は動脈瘤の形成を避けるために、柔軟なステントを提供することもまた望ましい。

或いは、必ずしも必要ではないが、好ましくは生体吸収性シートとしてそのようなステントを形成することが望ましく、そのシートは、実質的に円筒状に巻かれ、生体吸収又は生体分解が血管の内腔内ではなく血管の壁の内部に生じるように、内皮細胞をステントの内側及び外側に成長させるように、さらに、例えばステントが血管の分岐を横切る場合、ステントを通して血液が流れるように、その中に細孔、及びそれを通して定義された孔の少なくとも一方を有する。

血管形成部位の治癒の後に、血管壁内部に吸収されることによって、長期にわたった埋め込みの制限を避けるステントを提供することもまた望ましい。生体吸収性／生体内分解性材料のストランドのメッシュ状、又はラセン状配列の生体吸収性ステントを形成することも、さらに望ましい。それは、生体内分解が、溶解した物質の塞栓形成を導く血管の内腔内ではなく、血管壁の内部に生じるように、血管形成部位の内皮細胞が、ステントの内側及び外側に成長することを可能にする。

生体吸収性ステントは、本発明にしたがって提供され、冠動脈血管形成後の血管壁を支持することができるが、従来技術の金属製ステントの欠点を克服する。より具体的には、本発明は、例えば、冠動脈の狭窄部位のような位置に設置される生体吸収性ステントに関し、このステントは、冠動脈の目的部位への安全で有効な導入のために、及び心臓の鼓動からの連続的な応力に曝される間、動脈の破壊又は動脈瘤の形成を避けることができるように柔軟である。本発明にしたがって形成されたステントは、生体吸収性材料の複数のストランドから形成された自己膨脹性ステントとすることができる。このステントは、冠動脈の目的部位へのステントの導入を容

易にする縮径を有するように変形させることができ、一旦動脈の目的部位に設置されると、予め形成された形状まで膨脹させて、血管のその部位を拡大して支持することができる。或いは、本発明にしたがったステントは、生体吸収性又は生体内分解性材料のシートとすることができ、実質的に円筒状に巻かれ、比較的縮小された形状にステントを維持している力が取り除かれた場合、材料の記憶によって、直径を膨脹させる傾向がある。

本発明にしたがって提供された自己膨脹性ステントは、ステントをコンパクトな縮径の形状に保持するカテーテル内における、動脈の狭窄部位へ移動させることができる。その後、ステントは、狭窄病変の位置でカテーテルデリバリーシステムから放出され、そこで予め決められた形状に戻される。或いは、本発明のステントは、ステントの配置が望まれるまで、直径が減少された形状にステントを維持する膨脹可能なデリバリーデバイスに取り付けられることができる。つぶれた形状にステントを維持する力は、予め決められた所望の形状までステントを膨脹させるために緩和される。最終形状までのステントの膨脹は、例えば、バルーンカテーテルを膨らませることによって増大及び／又は促進させることができ、それによってステントを血管壁に接触させ、ステント構造物の被包を引き起こすとともに、血管の最大の支持を保証する。その点で、ステントの膨脹が狭窄病変の位置において促進される場合には、プラークは、前膨脹よりも又はそれに加えて、ステントが設置された時に圧縮されることができる。

当業者は、本発明にしたがって形成されたステントはまた、縮径の形状から膨脹可能であること（自己膨脹とは反対に）を理解するであろう。そのようなステントは、膨脹可能なカテーテルの先端部における縮径した形状の病変の部位まで運ばれることができ、組み合わされたカテーテルの膨脹可能な部分の膨脹によって、支持する直径まで生体内で膨脹させることができる。本発明にしたがった膨脹可能なステントは、以下に詳述するようなメッシュタイプの形状でもよく、生体親和性、好ましくは生体吸収性材料のシートの形状とすることが有利である。本発明にしたがった膨脹可能なステントは、互いに接合した複数の生体吸収性材料のシート又は細片から形成することもでき、前記生体吸収性材料の細片を互いに接合するための手段は、縮径の形状にステントを保持するための手段と、膨脹又は拡大した形状にステントを保持するための手段とを提供する。減少又は膨脹した形状に生体吸収性ステントを保持するための手段は、特にステントが生体吸収性材料のシート又はセグメントである場合に、生体吸収性シートの隣接する部分間の単なる摩擦力で有り得る。

他の目的、構造の関連部材の操作及び作用の方法、及び製造の部分と経済性との組み合わせのみならず、本発明の特徴は、図面を参照した以下の詳細な記述の考察によって、より明らかになるであろうが、それらは全て、本発明の一部を構成するものである。

図面の簡単な説明

図１は、冠動脈内の狭窄病変の部位に、本発明にしたがって与えられたステントの導入の立面図。

図２は、図１に示すタイプのカテーテルデリバリーシステム内に設置された、本発明にしたがって与えられたステントの拡大した立面図。

図３は、血管の目的部位内に設置された本発明のステントを示す拡大した部分立断面図。

図４は、デリバリーカテーテルアセンブリからはずした後の、図３と同様の拡大した立面図。

図５は、バルーンカテーテルの潰れたバルーンに取り付けられた縮径の、本発明にしたがって形成されたステントの斜視図。

図６は、バルーンカテーテルが膨脹してステントの緩和及び膨脹の後の本発明のステントを示す斜視図。

図７は、本発明の他の態様のステントを示す斜視図。

図８は、縮径の形状における図７のステントの断面図。

図９は、図８の部分Ａの拡大図。

図１０は、図８の部分Ｂの拡大図。

図１１は、拡大した断面形状における図７のステントの断面図。

図１２は、図１１の部分Ｃの拡大図。

図１３は、図１１の部分Ｄの拡大図。

図１４は、本発明のさらに他の態様の斜視図。

図１５は、直径を減少させて巻いた形状における図１４の態様を示す端面図。

図１６は、拡張した形状における図１４のステントの端面図。

図１７は、本発明のまたさらに他の態様を示す斜視図。

図１８は、図１７の態様の端面図。

発明の好ましい実施例の詳細な説明

本発明のステントは、膨脹可能型又は自己膨脹型のいずれかである。自己膨脹タイプのステントの詳細な説明は、以下で与えられる。本発明にしたがって提供された自己膨脹ステントは、複数の生体内分解性材料のストランドで菱形連続模様（ｄｉａｍｏｎｄ－ｂｒａｉｄｅｄ）状に織ることができる。例えば、自己膨脹性ステントは、生体吸収性ポリマーの８本のストランドから織ることができる。こうして、生体吸収性ステントを形成するためのストランドは、押出されて引き出され、その後、基本となる管状ステント状に編まれる。その後、ステントの長さを切断して熱硬化させる。ステントの切断された両端部は、例えばレーザー、加熱、超音波、又はニカワによって互いに接合される。そのようにして形成されたステントは、長さ及び／又は直径が歪むと、外部の力が緩和された際に予め決められた形状に戻る、又は戻る傾向であるような記憶特性を有する。こうして、ステントは、その直径を減少させるように歪ませ、続いて緩和させた場合、自己膨脹する。結局、ステントはある材料で形成され、２００ｍｍＨｇを越えるつぶれ圧力に耐え得るように編まれる。

本発明の生体吸収性ステント１０を狭窄病変の位置まで移動させるために、ステントが血管を容易に進んで、冠動脈の目的部位に至り、動脈の縮径部内に配置することができるよ

うに、ステントの外径を減少させる必要がある。こうして、ステントは、例えばステントを伸ばすことによって縮小されなければならず、対応する直径の減少を可能にし、デリバリープロセスの間、そのような縮径の又はつぶれた形状を維持される。冠動脈の目的部位に達すると、ステントの直径を減少させる傾向の力は緩められ、それによって、ステントは、冠動脈の狭窄部分を支持及び／又は拡張させることができる。

図１及び２を参照すると、本発明にしたがった、つぶれた又は縮径の生体吸収性ステント１０は、縮径のステントをデリバリーシース１２内に設置することによって、血管の目的部位に移動させることができる。ガイドシース１２は、右又は左の冠動脈口まで、大動脈１６を通して、ガイドカテーテル１４を通して順に導かれる。その後、ステント運搬シース１２は、ガイドワイヤー１８に沿ってガイドカテーテル１４の先端部から、目的冠動脈内に、そして狭窄病変２０の位置に進む。

第２シース２２はつぶれたステント１０の基部に設けられ、外部シース１２からのステント１０の除去を容易にするために用いられる。より具体的には、図３及び図４を参照すると、シース１２が冠動脈の目的とする狭窄部位２０に設置されると、内部の基部シース２２が、その場所に保たれる一方、外部シースは、ステント１０の基部の方向に引き込まれる。外部シース１２の除去は、ステント１０をつぶれた形状に保持する力を取り除き、こうして、ステントが、冠動脈の狭窄部位２０内で自己膨脹し、血管壁を支持してかつ拡張する（図４）ことを可能にする。内部シース２２は、ステント１０が、外部シース１２とともに基部の方向に移動することを妨げる。その後、ガイドワイヤー１８及びガイドカテーテル１４と同様に、内部及び外部シース２２、１２を、導管システムから取り除くことができる。或いは、内部及び外部シースは、取り除かれることができ、バルーンカテーテル（図３及び４には図示せず）は、ガイドカテーテル１４を通してガイドワイヤー１８に沿って、膨脹したステント１０の内部に導かれた。その後、バルーンは、冠動脈の壁にステントを堅く係止させるため、及び／又はステントのみによって与えられた動脈の拡張を増大させるために、ステント内部で膨らませることができる。

或いは、図５及び６を参照すると、本発明にしたがって形成されたステントは、バルーンカテーテル３０上の冠動脈の狭窄部分の位置に移動させることができる。より具体的には、図４を参照すると、わずかに伸びた形状の縮径のステント１０は、バルーンカテーテル３０の端部に設けられたつぶれたバルーン３２の外表面にしっかりと取り付けられることができる。ステント１０は、適切な生体親和性ニカワ又は接着剤で取り付けられる。

ステント１０がしっかりと取り付けられたバルーンカテーテル３０は、その後、ガイドワイヤー３４に沿って、冠動脈のような血管の狭窄部位の位置に導かれる。バルーンカテーテル３０が適切に位置すると、端部のバルーン３２が膨脹する。バルーン３２の膨脹は、ステント１０とバルーン３２との間の接着剤の接着の点を乱すことにより、バルーンの外表面からステント１０を放す。ステント１０の接着剤の接着が放されると、ステントは解放されて、予め決められた形状に戻る傾向になり、こうして、再膨脹又は自己膨脹する。バルーン３２の膨脹と同時に、自己膨脹性ステントが十分に膨脹し、血管を支持して保護することを保証する。さらに、バルーンの膨脹は、同時に血管の狭窄部位の膨脹をもたらし、又は促進する。こうして、バルーンカテーテル３０は、本発明のステントのためのデリバリーシステムを与えるのみならず、ステントが適切な位置で十分に膨脹し、同時に、血管の目的部分を膨脹させることを保証する。

メッシュ状のステントを与える代わりに、自己膨脹性、又は積極的に膨脹可能かを問わず、本発明にしたがったステントは、生体吸収性材料のシート又は複数のシート若しくは細片として形成することができ、それは、冠動脈のような身体経路の壁を膨脹及び支持するための実質的に円筒形状を定義するように、形成され又は巻かれる。こうして、図７に示される本発明の特定の態様、すなわち、本発明にしたがったステント５０は、生体吸収性材料の一連の細片５２からなり、これは、予め決められた間隔をあけた関係で、第１及び第２の細長い支持及び固定リボン５４、５６に支持される。細片状のリボンは、生体吸収性である。

リボン５４は、通路開口部６０とともに室５８を有する。複数の室５８が与えられてもよく、又は連続の若しくは断続的な開口部を有する連続的な室５８でもよい。生体吸収性材料の各細片５２は、拡大された長さ方向の端部を有し、又は比較的大きい長さ方向の端部６２を与えるように、そこに取り付けられた球状部材を有する。図示するように、各生体吸収性細片５２の球状端部６２は、リボン５４に定義されたスリット又はスロット６０を通して、球部６２の通過を促進する一方、逆方向に生体吸収性細片が入ることを妨げるように、先細の壁を有する。リボン５４は、複数の通む通路６４をさらに含み、その通路を生体吸収性材料の各細片５２が通過する。

第２の伸びたリボン５６もまた、生体吸収性細片５２の球部６２を受け取るための室６６を含み、そのようなそれぞれの受容室６６のために、第１及び第２の通路６８、７０が与えられる。リボン５６の壁厚は、球部受容室６６の各側で異なる。一方の側においては、壁は、生体吸収性細片５２の球部の傾斜した表面の係止した壁の偏向を可能にするための比較的薄い部分７２を有する。他方の壁は、球部６２の傾斜した壁との係止が偏向しない、比較的厚い部分７４を含み、こうして、柔軟な壁７２を通して入っている球部６２は、室６６内に保持され、室６６の対向する壁７４から抜け出ることはできない。生体吸収性細片５２の対向する長さ方向の端部７６は、図１０に示すように、第２リボン５６に取付けられている。適切な手段は全て、そのような取付けのために与えられるが、そのような取付けは、生体親和性ニカワで与えられると最良であることを留意するべきである。

身体経路への生体吸収性ステントの挿入に先立ち、ステントは、特に図８に示すようなコンパクトな形状にある。

図８に示すステント５０が、冠動脈のような狭窄した身体経路の所望の部分内で膨脹する場合、ステントを膨脹させるために、ステントの中心から外に向かって力が適用される。これは、生体吸収性シートの球部６２又は細片５２が、第１リボン５４の外に向かって（図９中の左に）、球部受容室５８の外側へ、押し進められることを引き起こす。同時に、生体吸収性細片は、第１リボン５４中の通路６４を通って、図９に示すように左に導かれる。加えて、生体吸収性細片は、第２リボン中の球部受容室６６を通って（図１０中の右に）移動する。結局、図１１に示すように、ステントは最大直径に達し、そのとき、生体吸収性細片５２の球部６２は、第２リボン中の室６６の壁７２を偏向させてその室内に入るが、比較的厚い室壁７４によって、さらに室６６を通過することはできない。こうして、図７に示されるステント５０は、図１１に示す第２の形状まで拡大させるために、ステントに積極的に力が適用されるまで、縮径形状（図８）を保持する。ステントが膨脹すると、球部６２は、第２リボン中に取り込まれ、偏向可能な壁７２を通って戻る、又は室の前方の壁を通って室６６の外に出ることはできない。こうして、ステントは、大きな直径の形状を同様に保持するであろう。

生体吸収性細片が、ステントの長さに沿って個々に間隔をあけているので、血液はステント内部から隣り合う生体吸収性細片の間の外部へ流出することができ、血液が生体吸収性ステント材料を通って、直接流れる孔を与える必要はない。しかしながら、そのような孔は設けることができ、組織の内部成長を促進するために望ましい。さもなければ、生体吸収性材料の細片は、血液流と組織成長とを可能にするために、その中の細孔及び／又は孔を有することが有利である。細片の幅が十分に狭い場合、それは、ステントの長さに沿って延びた寸法が小さく、そのとき、前記細孔及び／又は孔は必要ない。

また或いは、本発明にしたがって形成された生体吸収性ステント８０は、生体吸収性材料の１組のシートの形状８２とすることができ、そのシートは、尖叉（ｔｉｎｅ）受容空洞に内部で接合されている複数の尖叉８６の形状を有するいくつかの固体生体吸収性材料をともなう、尖叉受容空洞８４を定義するために、相互連結されている。こうして、尖叉部材８６は、図１４に示すように尖叉受容空洞８４の第１の端部に相互連結されており、生体吸収性構造物は、各尖叉部材８６が、尖叉受容空洞８４の対向する端部に挿入された状態で、実質的に円筒状に巻くことができる。実質的に減少した形状の生体吸収性ステント部材を提供するために、尖叉部材は、図１５に示すように尖叉受容空洞の中に挿入される。縮小した形状のステントの内側に膨脹力を適切に適用することによって、尖叉部材８６は、尖叉受容空洞８４を定義する生体吸収性シート８２に対して摺動し、こうして、図１６に示すように、ステントの内径が拡大する。本発明のこの態様によれば、ステントは、尖叉部材８６と尖叉受容空洞８４との摩擦の内部作用によって縮径形状を保持される。同様に、拡大した径の形態において、摩擦力は、ステント８０の尖叉部材８６と尖叉受容空洞８４とを所望の配置に保持する。

図１４に模式的に示すように、孔８８は、血液がそれらを通して流れること、及び／又は内皮組織が内部成長することを可能にするように、尖叉受容空洞８４を定義する生体吸収性シート８２と尖叉部材８６とを通して定義される。尖叉と尖叉受容空洞とを定義する生体吸収性材料はそれ自体、組織の内部成長を可能にするため、及び／又は以下でより詳述するような、その中での薬剤の取り込みを可能にするために、多孔質とすることができる。図１４に模式的に示すような孔８８は、説明の目的のためだけであり、孔８８及び生体吸収性材料の相対的な大きさは、必ずしもその図に示すようなものである必要はない。

特に図１７及び図１８に示すような本発明のさらに他の態様によれば、本発明のステント９０は、生体吸収性材料のシート９２を単純に巻き上げた形状とすることができる。生体吸収性材料が、形状保持記憶を有する場合、例えば熱硬化されて予め決められた直径のロールとするために、生体吸収性材料を形成することができる。その後、ステントは、材料をさらに巻くことによって直径が減少した形状に強制され、その形状は、ステント９０自体によって与えられたバックル状保持部材の手段、又はカテーテル部材の内部若しくはその上のステント９０を捕らえることのいずれかによって維持される。その後、直径が縮小された形状にステントを維持する傾向の力が緩和されると、ステント９０は、本来の直径まで、又は本来の直径に近い直径まで自己膨脹するであろう。

ステントが膨脹可能、すなわち、歪んだいかなる形状をも実質的に維持する場合、ステントは、それが本来維持する縮径形状に巻くことができ、その後、その内部表面に膨脹力を適用することによって、所望の直径まで膨脹させることができ、膨脹力をゆるめた際に、実質的に拡大した径の形状を保持するであろう。

図１７に特に模式的に示すように、本発明のこの態様によって与えられる生体吸収性シート９２は、複数の細孔及び／又は孔９６をも有し、それらは、ステント９０を通る血液の流れ、及び／又は内包のための組織の内部成長を可能にするために定義された。生体吸収性材料は、多孔質とすることができ、さらに、それらを通して組織の内包、血液流を高めるため、及び／又は、治療される入体経路の目的領域まで薬剤を運んで受け取るための空洞を与えるように定義された孔を含んでもよい。或いは、以下でも詳述するように、ステントの材料は、形成されたときに、その中に取り込まれた薬剤を有してもよく、その薬剤は、そこから次に述べる体内の配置に滲出するであろう。特に図１７に示された孔の相対的な大きさは、模式的であって実際の実施においては、ステントを通る細孔又は孔は、これらに示されたより大きくても小さくてもよい。

上述したように、本発明により形成されたステントは、好ましくは生体内分解性ポリマー材料で形成される。選択され

る特有のポリマー及びその厚さは、特に、生体分解及び生体吸収の速度を決定し、生体分解及び生体吸収の間のステントの構造特性は、それゆえ、所望の吸収時間及びステントの特性にしたがって選択されるべきである。

本発明に係るステントの形成に使用するために適切な材料は、所望の幾何学的構造に織られた場合、少なくとも１００ｍｍＨｇ、好ましくは少なくとも２００ｍｍＨｇのつぶれ圧力に耐える十分な強度をステントにもたらすようなものである。適切な材料は、毒性反応を起こさず、又はステント位置で存在する環境レベルにおいて、発癌物質として作用しない。適切な材料は分解し、生理的に受理できる分解生成物の生成をともなって吸収され、強度及び質量の損失は、特有の生体環境及び臨床作用条件に適切である。

本発明の好ましい態様によれば、ステントは、ポリ－Ｌ－ラクチドで形成される。他の好ましいステント形成材料は、β－ヒドロキシ酪酸のホモポリマー及び他のヒドロキシ脂肪酸をともなうその共重合体と同様に、ＤＬ－ラクチド、Ｄ－ラクチド、又はグルコライドをともなうＬ－ラクチドの共重合体を含む。ｎが好ましくは５～１３の$HO(CH_2)_n CO_2H$のω－ヒドロキシ酸のポリマー、及びｘが好ましくは４～１６である$HO_2C-(CH_2)_x-CO_2H$、ｙが好ましくは２～１８である$HO-(CH_2)_y-OH$の脂肪族二塩基酸及びジオールのポリマーもまた、加水分解速度を変えることによって特徴付けられるステントをつくるために使用することができる。

ｎが好ましくは６～１３の$-NH-(CH_2)_n-CO-$、及びｘが好ましくは６～１２であって、ｙが好ましくは４～１２である$NH-(CH_2)_x-NH-CO-(CH_2)_y-CO-$のポリイミドもまた、特に、ポリ－Ｌ－ラクチドで活性化されたものより遅い分解が有利な場合に使用することができる。

ｎが好ましくは２～８の$HO_2C-C_6H_4-O-(CH_2)_n OC_6H_4-CO_2H$の二塩基酸からの無水物ポリマーは、ある範囲のヤング率と吸収速度を与え、例えば、炭素数約１２までのα－ω－脂肪族二塩基酸とこれらの共重合体は、ある種の環境下で有利な、速められた生体吸収速度を有するステントを与えるために使用されることができる。

Ｒがアルキル基、好ましくはCH_3-又はC_2H_5-のような低級アルキル基であって、Ｘ及びＹが、例えば、$-C_6H_4-$、ｎが１～１２の$-(CH_2)_n-$、又は$-C_6H_4-$基と$-CH_2-$基との組合わせである$(RO)_3C-X-C(OR)_3$と$(HOCH_2)_2CH-Y-CH(CH_2OH)$との反応により形成されたようなポリオルトエステルもまた、使用することができる。そのようなポリオルトエステルは、生体環境下で分解し、生体吸収された生成物を生じる。Ｒ、Ｘ、及びＹを変化させることによって、ある範囲の疎水特性及びヤング率を達成することができ、その結果、堅さと生体内分解性とを変化させたステントが得られることを、当業者は理解するであろう。

上に示したように、ポリラクチドは、ステント形成のために好ましい材料である。ポリラクチドのようなポリエステルの加水分解は、酸及び塩基によって触媒作用を受ける。血液のｐＨ（７．３～７．４）は、加水分解に触媒作用を及ぼすのに十分でない。しかしながら、ポリマーの内部で生じる加水分解は、ゆっくりと拡散して分解を自動的に促進する触媒として作用する酸性分解物（乳酸及びそのオリゴマー）を生じるであろう。望ましい場合には、ポリマープロセスの間に、クエン酸、フマル酸、又は比較的非毒性のその他の酸のような賦形剤を加えることによって、分解速度をさらに速めることができる。酸の添加は、好ましくは、埋め込みに先立って、ポリマーの分解を最小にするためのポリマープロセスの間の最終加熱後に行なう。例えば、フマル酸は、乾式紡糸に先立って、ポリ－Ｌ－ラクチドの溶液（例えば、塩化メチレン溶液）中に混合することができる。溶媒は、例えば、暖気中で容易に蒸発させることができ、繊維はステントの形に織られて成形される。ポリマー中へのフマル酸の添加量は、０．１～１．０％が好ましい。酸賦形剤を伴うステントの貯蔵寿命は、それらを乾燥させして保ち、高温を避けることによって、延ばすことができる。

γ照射に晒すことは、結果として生じる、ステントの分解を促進する酸基の形成をともなう鎖の切断を引き起こすためにもまた、使用することができる。線量が高くなると、ステントはより早く分解するであろう。

ステントの分解及び吸収を促進するために使用することができるその他の添加物は、それ自体は酸性ではないが、加水分解してポリマーよりも急速に酸を生じる物質である。例は、ラウリン酸又はｄｉｔｅｒｔ．ブチルフマレートのような酸のｔｅｒｔ．ブチルエステルである。そのような添加剤は、暖かく湿った酸性環境中で生体内分解を開始させるために分解され、さらに分解を促進する触媒が発生する。

生体内ポリマーの分解を促進する添加物の設計に使用される同様の原理は、また、分解を促進するラクチドとともに使用するためのコモノマーをつくるために使用することができる。例えば、酒石酸の低分子量ポリマーは、エチルオルトアセテートで酒石酸を処理し、エチルアルコールとエチルアセテートとを蒸発させることによってつくることができる。２，３のオルトエステル単位を含むこの低分子量ポリエステルは、ラクチドの中に組み込まれ、重合条件に供されて、カルボキシル酸を生じる加水分解可能な基をともなうラクチド／酒石酸共重合体を与えることができる。ポリマー添加物と同様に、そのような可能性を有する多数のコモノマーが存在することを、当業者は理解するであろう。生体内で使用する場合、炎症性又は毒性の反応を引き起こさないもの、及び生体内で使用する場合に、分解及び吸収の所望の再生率を与えるものが好ましい。

加水分解の際に緩衝作用を与えるコモノマー又は添加剤は、より遅い分解材料が必要な場合に、生体内分解を抑制するために使用することができる。例えば、ラクチドと共重合させた少量（約１～５％）のアラニンは、生体内分解を抑制するために使用することができる。その他のアミノ酸は、分解を

抑制するために、共重合を経て組み込まれ、nが1～17、好ましくは5～10の－NH－（CH_2）$_n$－CO－のようなセグメントを与えることができる。

以下に示す、本発明を限定するものではない実施例は、ステント製造プロセスにおける溶融紡糸の使用を説明する。当業者は、溶融紡糸が分子量を低下させることを理解するであろう。すなわち、重合の間に達成された分子量は、ポリマーが溶融した場合、かなり急速に減少する。最終生成物中のより高い分子量は、以下のことを与えるので有利である：　i）強度及び靭性を増加させる；ii）変形後の弾性再生を改善する；及び iii）分解及び吸収速度を減少させる。

溶液からの紡糸は、高温（約190℃）溶融押出の代わりに使用することができる。塩化メチレン（b．p．55℃）は、そのようなプロセスに好ましい溶媒である。溶媒は、i）紡糸口金から下降するプロトファイバーから、暖気で溶媒を蒸発させること（乾式紡糸として当業者に既知である）、又はii）ポリマー溶液を液浴中に噴出させること（湿式紡糸として当業者に既知である）、なお、この液体はポリマーの非溶媒であるが、紡糸溶液中の溶媒、例えばメチルアルコールと混合できる；によって紡糸プロセスの間に除去することができる。

本発明のステントは、その中に組み込まれた、又はその上に被覆された、平滑筋細胞抑制剤（例えば、成長因子抑制剤、又は細胞障害剤）、コラーゲン抑制剤、血管拡張剤（例えば、プロスタグランジン又はその類似物）、又は抗血小板物質及び／又は抗血栓物質（例えば、アルピリン、ヘパリン又は組織プラスミノーゲンアクチベーター）のような1又はそれ以上の薬剤を有することができる。（放射線不透過充填剤のような映像剤もまた、ヒドロゲルのような流線形の血液流を改善する薬剤として使用することができる。）そのようなステントは、危険を伴う局部的に高い薬剤濃度を、直接、例えば再狭窄のような領域において達成するために使用することができ、また一方、計画性のある薬剤投与に関連する、例えば、毒性のような問題を避けることができるので、優れた薬剤放出手段である。ステントからの薬剤の時間を決められた放出は、ステント形成ポリマー自体からの遅い拡散が行なわれるように、ステントを形成すること、又は被覆を通して又は被覆からの薬剤のゆっくりとした拡散が行なわれるように、ステントを被覆することのいずれかによって達成することができる。

好ましい態様においては、ステントの外部（"外皮"）は、薬剤を収容するためにステントを作製した後に、多孔質につくられる。細孔は、真空及び静水圧（例えば、6，000～20，000psi）を交互に用いて、マトリクスを形成する薬剤／ゲルで満たされてもよい。必要ならば、その後、ステントは、マトリクスがゲルとして硬化することを引き起こす薬剤と接触させることができる。

多孔質の外皮は、ステント、又はそれからステントが形成されるフィラメントを、フィラメントの外層を膨潤させる溶媒中に浸漬することによって形成することができる。理論的には、溶媒の拡散は、かなりゆっくり起こるが；拡散は、例えば溶媒を冷却することによって遅くすることができる。このようにして、フィラメントのコアは、溶媒に供している間に影響されない。膨潤した外層を有するフィラメントは、その後、フィラメントがつくられているポリマーに対して"非溶媒"である試薬に浸漬され、その試薬は、膨潤溶媒により溶液を形成する。この試薬は、好ましくは、第1の溶媒より急速に拡散する。加熱は、膨れた領域への試薬の拡散を促進するために使用することができ、こうして、ステントフィラメント上の多孔質外皮の形成をもたらす相分離を引き起こす。ポリ－L－ラクチドをポリマーとして使用した場合、膨潤溶媒としてクロロホルムを、相分離を引き起こす試薬としてメチルアルコールを使用することができる。細孔形成は、溶媒として、例えば、オルトエステル（メチル又はエチルオルト蟻酸、又はオルト酢酸）、及び塩化メチレン、非溶媒として水の混合物を用いて、ポリ乳酸／ポリ酪酸ポリマー及び共重合体中で行なわれる。オルトエステル／水の反応生成物のCEDの変化は、相分離を生じさせると予想され、オルトエステルの分子量は、溶媒外への低速の拡散を引き起こす。ナイロン6／6をポリマーとして使用した場合、膨潤溶媒として75%水性蟻酸が、相分離試薬として5%水性蟻酸が使用される。その他の適切なポリマー／溶媒／試薬の組合わせもまた、用いることができる。当業者は、特有のポリマーに使用するべき適切な溶媒／試薬を容易に決定することができる。

適切なゲル化システムの例は、アルギン酸ナトリウムと中性ヘパリンとの混合物を含む。これが細孔中に導かれた後、フィラメントは、アルギン酸のゲル化を引き起こす水性塩化カルシウム中に浸漬される。

上述したように、運ばれる薬剤は、ステント中に取り込まれることができる。薬剤が取り込まれる方法は、用いられる紡糸技術（溶融紡糸、乾式紡糸、又は湿式紡糸）に依存する。（一般的には、Rodgiquiz．参照）

当業者は、紡糸がその融点を越えるポリマーの加熱を含むとき、この方法と関連して使用される薬剤の範囲は、幾分制限されることを理解するであろう。一方、高温において十分に安定で、非反応性の薬剤は、押出しに先立ってポリマーと混合することができる。

乾式紡糸において、ポリマーは溶媒に溶解し、溶液は押出されて、溶媒は暖気によって除去される。溶融紡糸のときと同様の分析を行なうことができるが、温度は実質的により低く、取り込まれ得る薬剤の数は増加する。

湿式紡糸においては、ポリマーは溶媒中に溶解し、ポリマーに対する"非溶媒"である第2の液体中に押出されるが、それは、ポリマーに対する溶媒を抽出し、ファイバーを凝集させるであろう。このプロセスについての分析は、2種類の液体の相対的な拡散性について上述した、多孔質外皮の開発についての場合と同様であるが、湿式紡糸は、ファイバー直径の全体に細孔を与える。薬剤は、凝集後にファイバーを浴に通して、洗浄することにより取り込まれる。その後、細孔

は、引張り、加熱、又は溶媒に曝すことによって部分的につぶれ、それによって、フィラメントをとおして薬剤を閉じ込める。感熱性薬剤が取り込まれると、そのとき、用いられるその後のプロセスは、高温を避けなければならない。例えば、熱硬化プロセスは、化学的硬化と取り替えることができる（以下参照）。

その他の方法もまた、本発明のステント中に薬剤を取り込むために使用することができる。例えば、水への溶解度が小さい粒子は、押出しの前にポリマーに加え、製造後に滲出させて細孔を発生させることができる。単量体のラクチドは、押出しの前に取り込まれ、その後、滲出させることができる。非常に小さい細孔は、押出し後のどの工程においても、プロパンのような超臨界流体中で、ポリマーを膨潤させることによって発生させることができ、その後、液相がまったく存在しないように、圧力を減少させる。すべての場合において、薬剤を含む溶液は、静水圧によって、ゲル化試薬とともに、又はともなわずに細孔内に強いられて、薬剤の外への拡散を制御することができる。

当業者は、上述の記載から、本発明に係るステントは、事実上、全ての薬剤の放出のための手段として使用することができることを理解するであろう。しかしながら、製造プロセス、特に薬剤がステント中に取り込まれるこれらの状況においては、運ばれるべき薬剤の活性が減少したり無効にならないように選択されることを保証するために、注意を払わなければならない。さらに、上で示した紡糸技術を使用するために、ステント形成の硬化工程の温度もまた、考慮しなければならない。アニールにかわるものとして、１１０～１４０℃の範囲内の温度まで加熱することが含まれ、化学的硬化を使用することができる。とりわけ、ステントは、蒸気、又は貧溶媒、若しくは酢酸エチルのような弱い膨潤試薬の溶液、その後、溶媒／試薬を除去するために空気、又は真空乾燥に曝すことができる。

特に熱的失活性の薬剤（例えば、プロテイン、組織プラスミノーゲン活性剤を含む）は、好ましくは、上述したようなステントに形成された多孔質外皮内に取り込まれる。そのような薬剤の場合のステントの殺菌は、γ照射を用いて行なわれる。

当業者は、ステント内に取り込まれた、又はその上に被覆された薬剤の量が、求められる治療に依存することを確認するであろう。そのような決定は、過度の実験なしに行なうことができる。

以下の制限のない実施例を読むことから、当業者は、分子量、大きさ、引張り比、温度、及び溶媒の変更は、実質的に生成ステントを変えることなく、全て可能であることを理解するであろう。

実施例

ステント製造

３５，０００ダルトンの平均質量を有するポリ－Ｌ－ラクチドの溶融押出しによって得られた長方形、又は円柱状のモノフィラメントを、その長さの６００％まで引張り、円柱状フィラメントについて０．１８ｍｍの最終直径を与えた。これらのファイバーは、直径３．１７ｍｍ、４～８フィートのテフロン製マンドレル上で、８本の端部を用いて編組みプロセスで編組んだ。（４本のフィラメントは右回りに移動し、４本のフィラメントは左回りにらせん状に移動し、各フィラメントは、交差するフィラメントの上又は下を交互に動く）その後、フィラメントは、それぞれの間隔が所望のステントよりわずかに長くなるような間隔で（典型的には、長さ０．５～２．０ｃｍ）、２つのワイヤーツイストでマンドレルにしっかりと取り付けられた。２つのワイヤーツイストの間隔は、アニール中にファイバーが収縮するのを抑制する一方、アニール後にマンドレルとファイバーとが、単ステント長さを与えるために、ワイヤーの間で切断することができるような間隔である。（アニールの目的は、アニール後に歪んだ場合、ファイバーが螺旋状に戻らないように、熱硬化させることである。）アニールは、１４０℃で１５分間行なわれた。（より高い温度（融点未満）は、より短いアニール周期を可能にし、約１１０℃のより低い温度は、より長時間でより有効に作用する。）アニールは空気中で行なわれるが、窒素のような不活性雰囲気、又は真空アニールは、幾分高い分子量の製品をもたらす。

部分的に形成されたステントのフィラメントは、所望の端部の交点において、クロロホルムのような揮発性溶媒中のポリ－Ｌ－ラクチドの溶液の小滴で互いに接着され、それによって最終長さを決定し、マンドレルから取り除かれる。溶媒が実質的に蒸発したとき、ステントを切り取って、接合箇所を越えたファイバーのほとんどを除去し、接合箇所は、両端部を溶融させて、滑らかにする熱したワイヤーの近くに至らせた。

本発明は、最も実際的で好ましい態様と考察される点に関して説明されたが、本発明は開示された態様に制限されず、反対に、クレームの範囲内に含まれる種々の変更や同等の装置に及ぶものであることを理解すべきである。例えば、予め形成されたステントは、正確な円筒である必要はないが、ステントの長さに沿って変化する断面を有してもよい。さらに、熱的アニールの代わりに、溶媒硬化を用いることができる。溶媒硬化は、薬剤がステント中に取り込まれる場合に、特に有利である。加えて、本発明の自己膨張ステントは、尿管やファロピウス管のような、冠動脈以外の身体経路に有利に使用されることができ、そのような他の用途及び形状は、クレームによってのみ制限される。

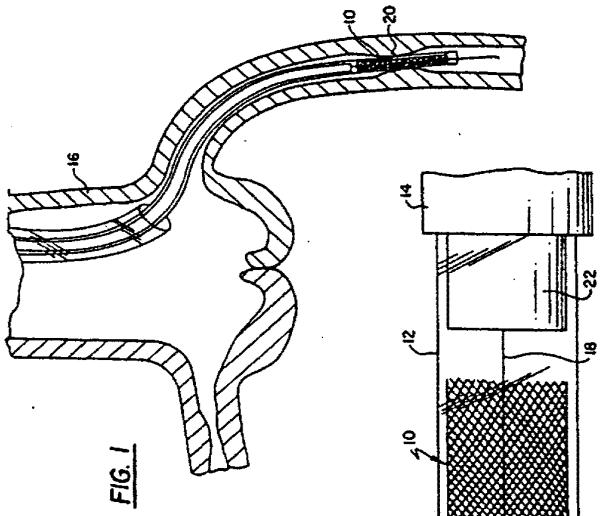


FIG. 1

FIG. 2

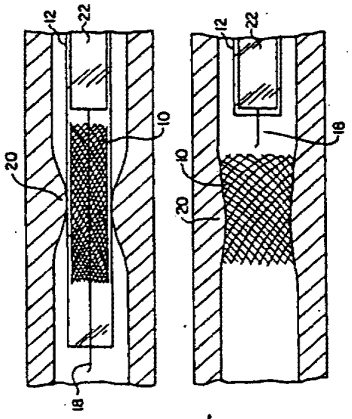


FIG. 3

FIG. 4

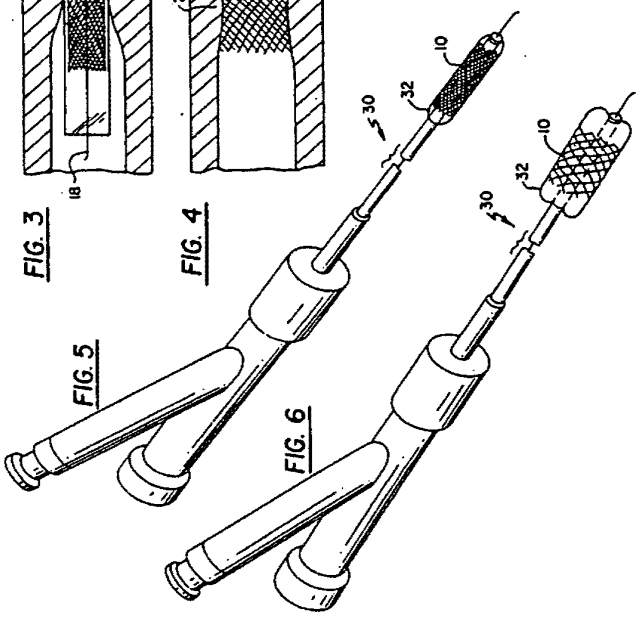


FIG. 5

FIG. 6

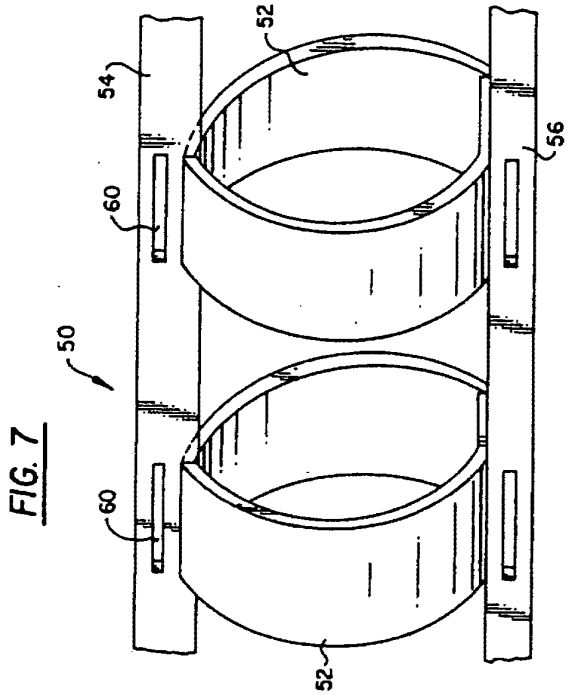


FIG. 7

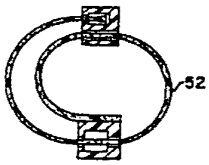


FIG. 8

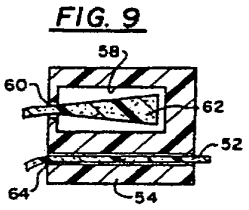


FIG. 9

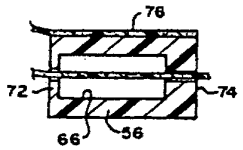
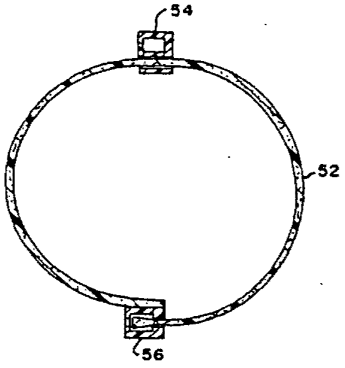


FIG. 10

FIG. 11



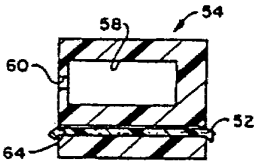
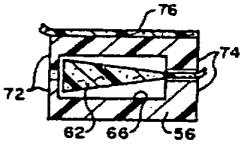


FIG. 12

FIG. 13



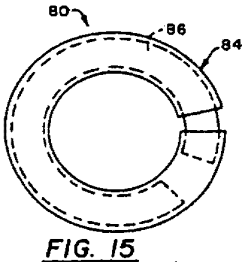


FIG. 15

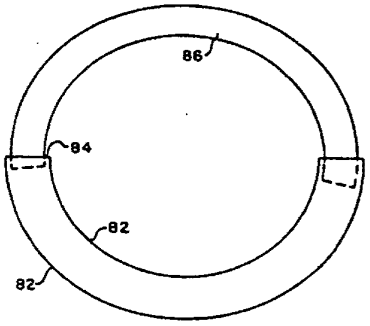


FIG. 16

FIG. 14

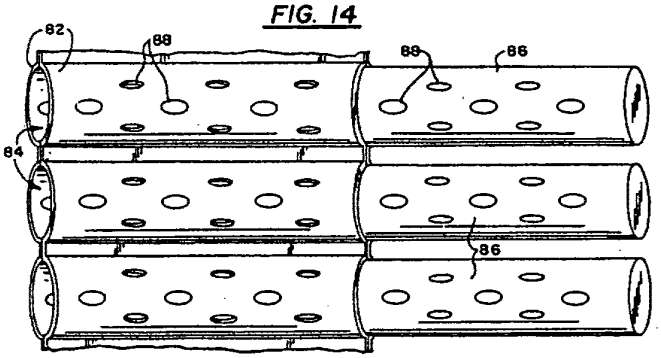
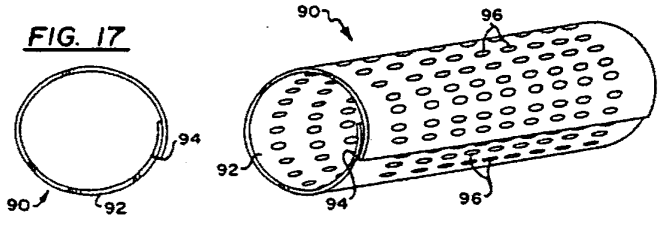


FIG. 18

FIG. 17



要約書

血管のような身体経路の狭窄部位に設置するための生体吸収性ステント（10，50，80，90）であって、このステントは、鼓動の連続的な応力に晒される間の、動脈破壊又は動脈瘤形成のような長期的な埋め込みの不都合を避けるために、例えば血管のような狭窄部位までの、安全かつ効果的な導入のために柔軟である。ステントは、生体吸収性材料から形成され、ステントの組織内部成長及び内包を促進するように、多孔質又はそれらを通して定義された孔を有する。ステントは、日、週、又は月の所望の期間内で、内包の後に、内包及び生体内分解、又は生体吸収され、それによって、溶解した物質の塞栓形成の可能性、又はその他の危険性を最小限にし、長期にわたる埋め込みの不都合を避ける。

国 際 調 査 報 告

International Application No PCT/US91/03454

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

IPC(5): A61M 29/02
US Cl.: 606/108, 198; 128/898

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
US	606/108, 198, 191, 151, 153-156 128/898

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	US, A, 4,655,771 (Wallsten) 07 April 1987 See entire document	1-4,6-27
Y,E	US, A, 5,019,090 (Pinchuk) 28 May 1991 See entire document	1-4,6-27
Y	US, A, 4,740,207 (Kreamir) 26 April 1988 See entire document	1-4,6-27
Y,P	US, A, 5,007,926 (Derbyshire) 16 April 1991 See entire document	1-4,6-27

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22 July 1991	04 SEP 1991
International Searching Authority	Signature of Authorized Officer
ISA/US	INTERNATIONAL DIVISION Michael Thaler

Form PCT/ISA/210 (second sheet) (May 1986)

第1頁の続き

優先権主張 ㉜1991年2月21日㉝米国(US)㉛658,708

㉒発 明 者	クラーク、ハワード・ジー、ザ・サード	アメリカ合衆国、ノース・カロライナ州 27705、ドウルハム、ボックス 76ビー、ルート 1
㉒発 明 者	ウオーカー、ウイリアム・エフ	アメリカ合衆国、ニューヨーク州 14469、ホルコム、エデイ・ロード 7507
㉑出 願 人	クラーク、ハワード・ジー、ザ・サード	アメリカ合衆国、ノース・カロライナ州 27705、ドウルハム、ボックス 76ビー、ルート 1
㉑出 願 人	ウオーカー、ウイリアム・エフ	アメリカ合衆国、ニューヨーク州 14469、ホルコム、エデイ・ロード 7507

Citation 3'

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/02 — A1

(11) International Publication Number: WO 91/17789

(43) International Publication Date: 28 November 1991 (28.11.91)

(21) International Application Number: PCT/US91/03454

(22) International Filing Date: 17 May 1991 (17.05.91)

(30) Priority data:
524,884 18 May 1990 (18.05.90) US
658,708 21 February 1991 (21.02.91) US

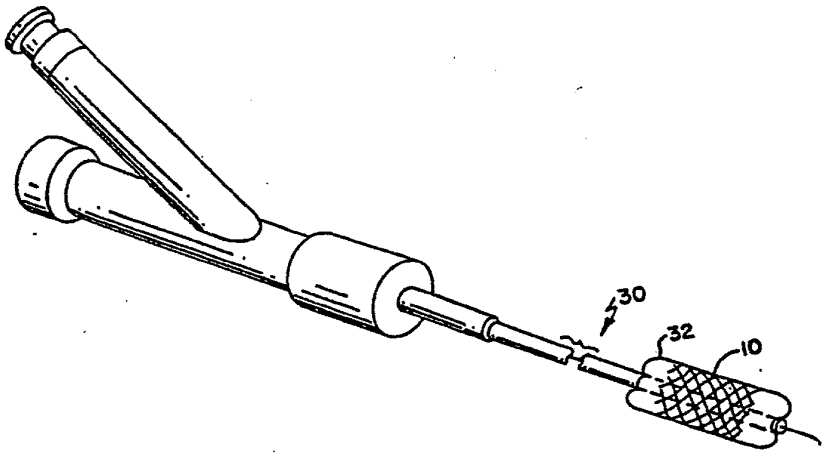
(71)(72) Applicants and Inventors: STACK, Richard, S. [US/US]; 6913 Falcon Bridge Road, Chapel Hill, NC 27514 (US). CLARK, Howard, G., III [US/US]; Route 1, Box 76B, Durham, NC 27705 (US). WALKER, William, F. [US/US]; 7507 Eddy Road, Holcomb, NY 14469 (US).

(74) Agents: WEST, William, K., Jr., et al.; Cushman, Darby & Cushman, Eleventh Floor, 1615 L Street, N.W., Washington, DC 20036 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: BIOABSORBABLE STENT



(57) Abstract

A bioabsorbable stent (10, 50, 80, 90) for placement at the locus of a stenotic portion of a body passage, such as a blood vessel, which is flexible and compliant for safe and effective delivery to the site of the stenotic portion of, for example, a blood vessel, so as to avoid the disadvantages of chronic implantation, such as arterial rupture or aneurism formation while exposed to the continuous stresses of a beating heart. The stent is formed from a bioabsorbable material and is porous or has apertures defined there through to facilitate tissue ingrowth and encapsulation of the stent. The stent is encapsulated and biodegrades or bioabsorbs within a period of days, weeks or months as desired following encapsulation to thereby minimize the likelihood of embolization or other risks of the dissolved material and to avoid the disavantages of chronic implantation.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

BIOABSORBABLE STENT

This is a continuation-in-part of Application No. 07/658,708 filed February 21, 1991 and a continuation-in-part of Application No. 07/524,884 filed May 18, 1990 which is in turn a continuation-in-part of Application No. 07/066,345 filed June 25, 1987. This is also a continuation-in-part of Application No. 07/649,534 filed February 1, 1991 which is a continuation of Application No. 07/066,345, the disclosures of all of the listed applications being incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a stent for maintaining the patency of a body passage. In addition to maintaining patency, the stent can serve as drug delivery vehicle to effect localized pharmacologic therapy. The invention has particular application in the field of coronary angioplasty and will be described with reference thereto. In that realization the invention primarily relates to bioabsorbable (and thus biodegradable) stents for placement within a blood vessel, such as a coronary artery, to treat acute arterial closure and to prevent restenosis following angioplasty. However, the invention may also advantageously find application in dilating and maintaining the patency of other body passages, such as the ureters and the fallopian tubes.

2. Description of the Related Art

Coronary angioplasty typically involves the use of a catheter system including a dilation catheter which is introduced via the femoral artery under local anesthesia and is advanced to the site

of a stenotic lesion in a coronary artery. The dilation catheter is for example a balloon catheter which is inflated with a fluid once it has been disposed within the targeted stenotic portion of the coronary artery. As the balloon is inflated, the atherosclerotic material along the vessel walls is compressed to thereby dilate the flow passage through the coronary artery.

While balloon angioplasty has become a relatively common and successful procedure, restenosis following angioplasty frequently occurs. Furthermore, the atherosclerotic plaque can crack during expansion which greatly increases the likelihood that the coronary artery will subsequently collapse.

It would therefore be desirable to avoid or minimize restenosis of a blood vessel, such as a coronary artery, by maintaining atherosclerotic plaque in its compressed disposition while at the same time preventing vessel collapse.

With the foregoing object, metallic stents have been developed and carried to stenotic portions of coronary arteries for placement after the vessel segment has been dilated by a balloon catheter or at the time of atherosclerotic plaque compression.

One such metallic stent has been proposed and tested in Europe and described in the article of Sigwart, et al titled "Intravascular Stent to Prevent Occlusion and Restenosis after Transluminal Angioplasty", published in the New England Journal of Medicine, Vol. 316, 12, March 19, 1987, pp. 701-706. That stent is a metallic "Chinese finger handcuff" which can be expanded in diameter while simultaneously reduced in length and compressed in diameter while simultaneously elongated. The stent remains in its distorted configuration after the distorting force is removed.

The metallic stent is made by cutting a desired length from an elongated tube of metal mesh. As a result, it has the disadvantage that metal prongs from the length cutting process remain at the longitudinal ends of the stent. The inherent rigidity of the metal used to form the stent together with the terminal prongs make navigation of the blood vessels to the locus of the targeted stenotic lesion difficult as well as risky from the stand point of injury to healthy tissue along the passage to the target vessel. Further, once the stent has been permanently disposed within the target vessel, the beating of the patient's heart can cause the terminal prongs to damage the healthy vessel walls adjacent to the stenotic portion of the artery, even after endothelial encapsulation. This damage can lead to arterial rupture or aneurysm formation. Finally, because the metallic stent is intended to be chronically implanted within the vessel, continued exposure of the stent to blood can lead to undesirable thrombus formation within the blood vessel.

SUMMARY OF THE INVENTION

It would therefore be desirable to provide a stent for disposition within a blood vessel, such as a coronary artery, that has sufficient hoop strength to support the vessel wall against collapse and yet is flexible and compliant enough for safe and effective delivery to the site of a stenotic portion of a coronary artery. It would also be desirable to provide a stent which is soft and compliant to avoid arterial rupture or aneurysm formation at the ends of the stent even when exposed to continuous stresses from the beating heart following implantation.

It would be desirable, in the alternative to form such a stent as a sheet of preferably though not necessarily bioabsorbable material which has been rolled into a substantially cylindrical configuration and which has at least one of pores therein and apertures defined therethrough so as to allow endothelial cells to grow into and over the stent so that bioabsorption or degradation will occur within the vessel wall rather in the lumen of the vessel and further to allow blood flow through the stent where, for example, the stent traverses a branch of the blood vessel.

It would even further be desirable to provide a stent which avoids the limitations of chronic implantation by being absorbed into the blood vessel wall after healing of the angioplasty site. It would further be desirable to form such a bioabsorbable stent in a mesh-like or helical array of strands of biodegradable/bioabsorbable material which will enable endothelial cells at the angioplasty site to grow into and over the stent so that biodegradation will occur within the vessel wall rather than in the lumen of the vessel which could lead to embolization of the dissolved material.

A bioabsorbable stent is provided in accordance with the present invention which can support a vessel wall following coronary angioplasty but which overcomes the deficiencies of prior art metallic stents. More particularly, the present invention relates to a bioabsorbable stent for placement at the locus of, for example, a stenotic portion of a coronary artery which is flexible and compliant for safe and effective delivery to the targeted portion of the coronary artery and so as to avoid arterial rupture or aneurysm formation while exposed to continuous stresses from the beating

heart. The stent formed in accordance with the present invention can be a self-expanding stent formed from a plurality of strands of biodegradable material which can be deformed so as to have a reduced diameter which facilitates delivery of the stent to the targeted portion of a coronary artery and, once disposed at the target portion of the artery, can be allowed to expand to its preformed configuration to dilate and support that portion of the blood vessel. In the alternative, the stent formed in accordance with the present invention can be a sheet of bioabsorbable or biodegradable material which has been rolled in to a substantially cylindrical configuration which, through the memory of the material, will tend to expand in diameter when a force maintaining the same in a relatively reduced configuration is released.

The self-expanding stent provided in accordance with the present invention can be transported to a stenotic portion of an artery within a catheter which retains the same in its compact, reduced diameter configuration and then ejected from the catheter delivery system at the site of the stenotic lesion where it is allowed to return to its preformed configuration. In the alternative, the stent of the invention can be mounted to an expandable delivery device which maintains the stent in its reduced diameter configuration until deployment of the stent is desired. The forces maintaining the stent in its collapsed configuration are released to allow the stent to expand to its desired, preformed configuration. Expansion of the stent to its final configuration can be augmented and/or facilitated by, for example, inflating a balloon catheter therewithin to urge the stent into contact with the vessel walls to ensure maximal support of the blood

vessel as well as prompt encapsulation of the stent structure. In that regard, where dilation of the stent is encouraged at the site of the stenotic lesion, plaque can be compressed at the time of stent placement rather than or in addition to prior dilation.

One skilled in the art will appreciate that a stent formed in accordance with the present invention can also be expandable from a reduced diameter configuration (as opposed to self-expanding). As such, the stent can be delivered to the locus of a lesion in a reduced diameter configuration on the distal end of an expandable catheter and can be expanded in vivo to its supporting diameter by expanding the expandable portion of its associated catheter. An expandable stent in accordance with the invention, may be a mesh type configuration or as detailed herein below may be advantageously in the form of a sheet of biocompatable and preferably bioabsorbable material. An expandable stent, in accordance with the invention, may also be formed from a plurality of sheets or strips of bioabsorbable material which are interconnected and wherein the means for interconnecting the strips of bioabsorbable material provide a means for retaining the stent in a reduced diameter configuration and a means for retaining the stent in its expanded or dilating configuration. The means for retaining the bioabsorbable stent in its reduced or expanded configuration, particularly where the stent is a sheet or segment of bioabsorbable material, can be merely the frictional forces between adjacent portions of the bioabsorbable sheet.

Other objects, features and characteristics of the present invention, as well as the methods of operation and functions of the

related elements of the structure, and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following detailed description with reference to the accompanying drawings, all of which form a part of this specification.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view illustrating the delivery of a stent provided in accordance with the present invention to the site of a stenotic lesion within a coronary artery;

FIGURE 2 is an enlarged elevational view of a stent provided in accordance with the present invention disposed within a catheter delivery system of the type illustrated in FIGURE 1;

FIGURE 3 is an enlarged elevational view partly in cross-section showing the stent of the invention disposed within a targeted portion of a blood vessel, prior to disengagement from the delivery catheter assembly;

FIGURE 4 is an enlarged elevational view similar to FIGURE 3 but following disengagement from the delivery catheter assembly;

FIGURE 5 is a perspective view of a stent formed in accordance with the present invention in its reduced diameter configuration mounted to the collapsed balloon of a balloon catheter;

FIGURE 6 is a perspective view showing the stent of the invention following release and expansion of the stent upon expansion of the balloon catheter;

FIGURE 7 is schematic perspective view showing a stent in accordance with an alternate embodiment of the invention;

FIGURE 8 is a cross-sectional view of the stent of FIGURE 7 in its reduced diameter configuration;

FIGURE 9 is an enlarged view of portion A of FIGURE 8;

FIGURE 10 is an enlarged view of portion B of FIGURE 8;

FIGURE 11 is a cross-sectional view of the stent of FIGURE 7 in its enlarged cross-sectional configuration;

FIGURE 12 is an enlarged view of portion C of FIGURE 11;

FIGURE 13 is an enlarged view of portion D of FIGURE 11;

FIGURE 14 is a schematic perspective view of a further alternate embodiment of the invention;

FIGURE 15 is a schematic end view showing the embodiment of FIGURE 14 in its reduced diameter rolled configuration;

FIGURE 16 is a schematic end view of the stent of FIGURE 14 in its enlarged configuration;

FIGURE 17 is a perspective view of yet a further alternate embodiment of the invention;

FIGURE 18 is a schematic end view of the embodiment of FIGURE 17.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EXEMPLARY EMBODIMENTS

The stent to which the present invention relates can be either expandable or self-expanding in form. A detailed description of a stent of the self-expanding type is provided below. The self-expanding stent provided in accordance with the present invention can be woven from a plurality of strands of biodegradable material into a diamond-braided pattern. For example, the self-expanding

stent can be woven from 8 strands of a bio-absorbable polymer. Thus the strands for forming the bioabsorbable stent are extruded, drawn and then braided to form the basic tubular stent. The stent is then cut to length and heat set. The severed ends of the stent are welded together by means of laser, heat, ultrasound or glue, for example. The stent so formed has memory characteristics such that if it is distorted in length and/or diameter, it will return or tend to return to its preformed configuration upon the release of external forces. Thus the stent is self-expanding when distorted so as to reduce the diameter thereof and subsequently released. Finally, the stent is formed from a material and braided such that the stent can withstand collapse pressures in excess of 200 mmHg.

In order to deliver the bioabsorbable stent 10 of the invention to the site of a stenotic lesion, it is necessary for the external diameter of the stent to be reduced so that the stent can easily traverse the blood vessels leading to a targeted portion of a coronary artery and disposed within the reduced diameter portion of the artery. Thus, the stent must be reduced by for example elongating the stent, allowing for a corresponding reduction in diameter, and maintained in such a reduced diameter or collapsed configuration during the delivery process. Once at the targeted portion of the coronary artery, the forces tending to reduce the diameter of the stent are released whereby the stent can support and/or dilate the stenotic portion of the coronary artery.

With reference to FIGURES 1 and 2, the collapsed or reduced diameter bioabsorbable stent 10 in accordance with the present invention can be delivered to a targeted portion of a blood vessel by placing the reduced diameter stent within a delivery

sheath 12 which is turn fed through a guide catheter 14 through the aorta 16 to the left or right coronary ostium. The stent carrying sheath 12 is then advanced from the distal end of the guide catheter 14 over a guide wire 18 into the targeted coronary artery and to the site of a stenotic lesion 20.

A second sheath 22 is provided proximally of the collapsed stent 10 and is used to facilitate removal of the stent 10 from the outer sheath 12. More particularly, with reference to FIGURES 3 and 4, once the sheath 12 has been disposed at the targeted stenotic portion 20 of the coronary artery, the inner, proximal sheath 22 is held in place while the outer sheath is retracted or pulled proximally with respect to the stent 10. Removal of the outer sheath 12 removes the forces which retain stent 10 in its collapsed configuration and thus allow the stent to self-expand within the stenotic portion 20 of the coronary artery to support and dilate the vessel walls (FIGURE 4). The inner sheath 22 prevents stent 10 from moving proximally with outer sheath 12. The inner and outer sheaths 22, 12 as well as the guide wire 18 and guide catheter 14 can then be removed from the vascular system. In the alternative, the inner and outer sheaths can be removed and a balloon catheter (not shown in FIGURES 3 and 4) fed through the guide catheter 14 over the guide wire 18 and into the expanded stent 10. The balloon can then be inflated within the stent so as to urge the stent into firm engagement with the walls of the coronary artery and/or to augment the dilation of the artery effected by the stent alone.

With reference to FIGURES 5 and 6, in the alternative, a bioabsorbable stent 10 formed in accordance with the present invention can be delivered to the site of a stenotic portion of a

coronary artery on a balloon catheter 30. More particularly, with reference to FIGURE 4, the stent 10 in its reduced diameter, slightly elongated configuration can be secured to the exterior surface of a collapsed balloon 32 provided on the end of a balloon catheter 30. The stent 10 can be secured to the balloon with any suitable biocompatable glue or adhesive.

The balloon catheter 30 with stent 10 fixedly secured thereto is then fed over a guidewire 34 to the site of a stenotic portion of a blood vessel, such as a coronary artery. Once the balloon catheter 30 has been properly located, the distal balloon 32 is inflated. Inflation of the balloon 32 disengages the stent 10 from the exterior surface of the balloon by disturbing the points of adhesive securement between the stent 10 and the balloon 32. Once the adhesive securement of the stent 10 has been released, the stent is free to and tends to resume its preformed configuration and thus re-expands or self-expands. Simultaneous inflation of the balloon 32 ensures that the self-expanding stent fully expands and is in supporting engagement with the blood vessel. In addition, the dilation or inflation of the balloon can simultaneously effect or encourage the dilation of the stenotic portion of the blood vessel. Thus, the balloon catheter 30 not only provides a delivery system for the stent of the invention but ensures that the stent is fully expanded once in place and can simultaneously dilate the targeted portion of the blood vessel.

In the alternative to providing a stent in the form of a mesh, whether self expanding or positively expandable, a stent in accordance with the invention may be formed as a sheet or plurality of sheets or strips of bioabsorbable material which are formed or are rolled so as to define a

substantially cylindrical configuration for expanding and supporting walls of a body passage, such as a coronary artery. Thus, in the embodiment of the invention illustrated in particular in FIGURE 7, a stent 50 in accordance with the invention is in the form of a series of strips 52 of bioabsorbable material which are supported in predetermined spaced relation by first and second elongated supporting and fastening ribbons 54,56. The ribbons, like the strips are bioabsorbable.

Ribbon 54 has a compartment 58 with an access opening 60. A plurality of compartments 58 may be provided or a continuous compartment 58 with continuous or intermittent opening(s). Each strip 52 of bioabsorbable material has an enlarged longitudinal end or has a bulbous element mounted thereto so as to provide a relatively large longitudinal end 62. As shown, the bulbous end 62 of each of bioabsorbable strip 52 has tapered walls so that it gradually increases in cross-section to facilitate passage of the bulbous portion 62 through the slit or slot 60 defined in the ribbon 54, while preventing entry of the bioabsorbable strip in the reverse direction. Ribbon 54 further includes a plurality of transverse passages 64 through which each strip 52 of bioabsorbable material passes.

The second elongated ribbon 56 also defines a chamber 66 for receiving the bulbous portion 62 of the bioabsorbable strip(s) 52 and provides first and second passages 68,70 for each such receiving chamber 66. The wall thickness of ribbon 56 differs on each side of the bulbous portion receiving chamber 66. On one side, the wall has relatively thin wall portions 72 to allow deflection of the wall upon engagement of the inclined surfaces of the bulbous portion 62 of the bioabsorbable strip 52. The other wall includes

relatively thick wall portions 74 which do not deflect upon engagement with the inclined walls of the bulbous portion 62 and, thus, the bulbous portion which enters through the flexible walls 72 will be retained within the chamber 66 and cannot escape from the opposite side walls 74 of the chamber 66. The opposite longitudinal end 76 of each bioabsorbable strip 52 is secured to the second ribbon 56 as shown in FIGURE 10. Any suitable means can be provided for such attachment but it is envisioned that such securement can best be provided with a biocompatable glue.

Prior to insertion of the bioabsorbable stent into the body passage, the stent is in a compacted configuration as illustrated in particular in FIGURE 8.

When the stent 50 illustrated in FIGURE 8 is to be expanded within a desired portion of a stenotic body passage, such as a coronary artery, a force is applied from the radial center of the stent outwardly to expand the stent. This causes the bulbous portion 62 of the bioabsorbable sheets or strips 52 to be urged outwardly of the first ribbon 54 (to the left in FIGURE 9) and out of the bulbous portion receiving chamber 58. At the same time, the bioabsorbable strip is fed through the passage 64 in the first ribbon 54, to the left as shown in FIGURE 9. Likewise, the bioabsorbable strip moves through the bulbous receiving chamber 66 in the second ribbon 56 (to the right as illustrated in FIGURE 10). Ultimately, as shown in FIGURE 11, the stent will have attained its maximal diameter at which time the bulbous portion 62 of the bioabsorbable strip 52 has deflected the walls 72 of the chamber 66 in the second ribbon 56 and entered that chamber, but is incapable of further passing through the chamber 66 by virtue of the relatively thick chamber

walls 74. Thus, the stent 50 illustrated in FIGURE 7 is retained in its reduced diameter configuration (FIGURE 8) until a force is positively applied to the stent to enlarge it to its second configuration, shown in FIGURE 11. Once the stent has been expanded, the bulbous portion 62 is captured in the second ribbon 56 and cannot exit that chamber 66 either back through the deflectable walls 72 or forwardly through walls 74 of that chamber. Thus, the stent will similarly be retained in it large diameter configuration.

Because the bioabsorbable strips are spaced apart along the length of the stent, blood can flow outwardly from within the stent to without, between the adjacent bioabsorbable strips and it is unnecessary to provide apertures allowing blood flow directly through the bioabsorbable stent material. However, such apertures can be provided and may be desirable to encourage tissue ingrowth. Otherwise, the strips of bioabsorbable material may advantageously have pores therein and/or apertures to allow both blood flow and tissue ingrowth. If the strips are sufficiently small in width, that is small in the dimension extended along the length of the stent, then such pores and/or apertures may be unnecessary.

As yet a further alternative, the bioabsorbable stent 80 formed in accordance with the present can be in the form of a pair of sheets 82 of bioabsorbable material which have been interconnected so as to define tine receiving cavities 84 with pieces of a solid bioabsorbable material in the form of plurality of tines 86 interconnected to the tine receiving cavities. Thus, the tine elements 86 are interconnected to first ends of the tine receiving cavities 84, as shown in FIGURE 14, and the bioabsorbable structure

can be rolled into a substantially cylindrical configuration with each tine element 86 inserted in the opposite end of the tine receiving cavity 84. To provide a bioabsorbable stent element in a substantially reduced configuration, the tine elements are inserted well into the tine receiving cavities as shown in FIGURE 15. By suitably applying a expansion force to the interior of the reduced diameter stent, the tine elements 86 will slide relative to the bioabsorbable sheets 82 defining the tine receiving cavities 84 and thus enlarge the internal diameter of the stent as shown in FIGURE 16. In accordance with this embodiment of the invention, the stent is retained in its reduced diameter configuration by the frictional interaction of the tine elements 86 and the tine receiving cavities 84. Likewise, in the enlarged configuration, frictional forces retain the tine elements 86 and tine receiving cavity portions 84 of the stent 80 in the desired orientation.

As schematically shown in FIGURE 14, apertures 88 are defined both through the bioabsorbable sheets 82 defining the tine receiving cavities 84 and the tine elements 86 themselves so as to allow blood flow therethrough and/or endothelial tissue ingrowth. The bioabsorbable material itself which defines the tines and the tine receiving cavities can be porous to allow tissue ingrowth and/or to allow the incorporation of drugs therein as described more fully below. The apertures 88 schematically illustrated in FIGURE 14 are for illustrative purposes only and the relative dimensions of the apertures 88 and the bioabsorbable material need not necessarily be as shown in that FIGURE.

In accordance with yet a further alternative embodiment of the invention as

illustrated in particular in FIGURES 17 and 18, the stent 90 of the invention can be simply in the form of a rolled up sheet 92 of bioabsorbable material. Where the bioabsorbable material has shape retaining memory, the bioabsorbable material can be formed so as to be a roll of predetermined diameter which has been for example heat set. The stent is then forced, by further rolling the material, into a reduced diameter configuration which is maintained either by means of a buckle-like retention element 94 provided on the stent 90 itself or by capturing the stent 90 within or on a catheter element. When the force tending to maintain the stent in its reduced diameter configuration is released, then, the stent 90 will self expand to its original or close to its original diameter.

Where the stent is expandable, that is, one which retains substantially any shape into which it is distorted, the stent can be rolled into a reduced diameter configuration, which it retains naturally, and then, by applying an expanding force to the interior surface thereof, can be expanded to a desired diameter and will retain that substantially enlarged diameter upon the release of the expanding force.

As schematically illustrated in particular in FIGURE 17, the bioabsorbable sheet 92 provided in accordance with this embodiment of the invention also has a plurality of pores and/or apertures 96 defined therethrough to allow blood flow through the stent 90 and/or tissue ingrowth for encapsulation. The bioabsorbable material can be porous and further can include apertures defined therethrough to enhance tissue encapsulation, bloodflow, therethrough and/or to provide cavities for receiving and carrying a drug to a targeted area of a body passage to be treated. In the alterative, as

also detailed herein below, the material of the stent can have a drug incorporated therein when formed, which drugs will leach therefrom following placement in the body. The relative size of the apertures illustrated in particular in FIGURE 17 is schematic and in actual practice, the pores or apertures through the stent may be larger or smaller then those illustrated.

As noted above, the stent formed in accordance with the present invention is preferably formed from a biodegradable polymeric material. The particular polymer selected and the thickness of the same, in particular, will determine the rates of biodegradation and bioabsorption and the structural characteristics of the stent during degradation and absorption should therefore be selected in accordance with the desired absorption period and characteristics of the stent.

Materials suitable for use in forming the bioabsorbable stents to which the invention relates are such that, when fabricated in the desired geometry, afford the stent sufficient strength to withstand collapse pressures of at least 100 mmHg, preferably at least 200 mmHg. Suitable materials do not produce toxic reactions, or act as carcinogens at the exposure levels present at the stent site. Suitable materials degrade and are absorbed with the production of physiologically acceptable breakdown products and the loss of strength and mass are appropriate to the particular biological environment and clinical function requirements.

In accordance with a preferred embodiment of the invention, the stent is formed of poly-L-lactide. Alternative preferred stent forming materials include copolymers of L-lactide with DL-lactide or D-lactide or glycolide, as well as homopolymers of beta-hydroxybutyric acid and its

copolymers with other beta-hydroxy aliphatic acids. Polymers of omega hydroxy acids of the form $HO(CH_2)_nCO_2H$ where n is, preferably, 5-13 and polymers of aliphatic diacids and diols of the form $HO_2C-(CH_2)_x-CO_2H$ and $HO-(CH_2)_y-OH$, where x is, preferably, 4-16 and y is, preferably, 2-18, can also be used to make stents characterized by varying rates of hydrolytic degradation.

Polyamides of the form $-NH-(CH_2)_n-CO-$ and $NH-(CH_2)_x-NH-CO-(CH_2)_y-CO-$, where n is, preferably, 6-13 and where x is, preferably, 6-12 and y is, preferably, 4-16, can also be used particularly where degradation slower than that achieved with poly-L-lactide is advantageous.

Polyanhydrides from diacids of the form $HO_2C-C_6H_4-O-(CH_2)_nOC_6H_4-CO_2H$, where n is, preferably, 2-8, give a range of values of Young's modulus and absorption rates, and copolymers of these with, for example, aliphatic alpha-omega diacids of up to about 12 carbon atoms can be used to provide stents having accelerated bioabsorption rates, advantageous in certain circumstances.

Polyorthoesters, such as are formed by the reaction of $(RO)_2C-X-C(OR)_2$ with $(HOCH_2)_2CH-Y-CH(CH_2OH)_2$, where R is an alkyl group, preferably a lower alkyl such as CH_3- or C_2H_5-, X and Y are, for example, $-C_6H_4-$ or $-(CH_2)_n-$ where n is 1-12, or combinations of $-C_6H_4-$ and $-CH_2-$ groups, can also be used. Such polyorthoesters degrade in a biological environment to yield products that are bioabsorbed. One skilled in the art will appreciate that by varying R, X and Y, a range of hydrophobic character and Youngs modulus can be achieved thus providing stents of varying stiffness and biodegradability.

As indicated above, polylactide is a preferred material for stent formation. The hydrolysis of polyesters such as the polylactides is

catalyzed by both acid and base. The pH of blood (7.3-7.4) is not sufficient to catalyze the hydrolysis. However, any hydrolysis taking place in the interior of the polymer will produce acidic breakdown products (lactic acid and its oligomers) that slowly diffuse and act as catalysts to autoaccelerate the degradation. The rate of degradation can be further accelerated, where desirable, by adding excipients such as citric acid or fumaric acid, or other relatively nontoxic acids during the polymer processing. The addition of acids is, preferably, carried out after the last heating during the polymer processing to minimize degradation of the polymers prior to implantation. For example, fumaric acid can be incorporated into a solution of poly-L-lactide (for example, a methylene chloride solution) prior to dry spinning. The solvent can be readily evaporated, for example, in warm air, and the fibers fabricated into stents and set in shape. A loading of 0.1-1.0% fumaric acid in the polymer is preferred. Shelf life of stents with acid excipients can be extended by keeping them dry and away from high temperatures.

Exposure to gamma radiation can also be used to effect chain scission with resulting formation of acid groups which accelerate stent degradation. The higher the dose, the more quickly the stent will degrade.

Other additives that can be used to accelerate stent degradation and thus absorption are substances that are not themselves an acid but which hydrolyze to produce an acid more rapidly than the polymer. An example is the tert. butyl ester of an acid, such as lauric acid or ditert. butyl fumarate. Such additives break down in warm, wet acidic environments, so that once in vivo degradation is

initiated, catalysts are generated that further accelerate degradation.

The same principles used to design additives that accelerate degradation of the polymer in vivo can also be used to make comonomers for use with lactide which accelerate degradation. For example, a low molecular weight polymer of tartaric acid can be made by treating tartaric acid with ethyl ortho acetate, evaporating off ethyl alcohol and ethyl acetate. This low molecular weight polyester which can contain a few ortho ester units can be incorporated into lactide and subjected to polymerizing conditions to give a lactide/tartrate copolymer with hydrolyzable groups which produce carboxylic acids. One skilled in the art will appreciate that there are a large number of such possible comonomers as well as polymer additives. Preferred are those that do not produce significant inflammatory or toxic reactions when used in vivo and those that give desired reproducible rates of degradation and absorption when used in vivo.

Comonomers or additives that give a buffering effect upon hydrolysis can be used to retard biodegradation when a slower degrading material is desired. For example, a small amount (about 1-5%) of alanine copolymerized with lactide can be used to retard biodegradation. Other amino acids can be incorporated via copolymerization to give segments such as $-NH-(CH_2)_n-CO-$ where n = 1-17, preferably, 1 and 5-10, in order to retard degradation.

The non-limiting Example that follows describes the use of melt spinning in the stent preparation process. One skilled in the art will appreciate that melt spinning lowers the molecular weight. That is, the molecular weight achieved during polymerization is reduced, fairly rapidly,

when the polymer is melted. Higher molecular weight in the final product can be advantageous in that it gives: i) increased strength and toughness; ii) improved elastic recovery after deformation; and iii) a reduced rate of degradation and absorption.

Spinning from solution can be used in lieu of high temperature (about 190°C) melt extrusion. Methylene chloride (b.p. 55°C) is a preferred solvent for use in such a process. The solvent can be removed during the spinning process by: i) evaporating solvent from the protofibers descending from a spinneret with warm air (known in the art as dry spinning), or ii) squirting the polymer solution into a liquid bath, the liquid being a non-solvent for the polymer but miscible with the solvent in the spinning solution, e.g. methyl alcohol (known in the art as wet spinning).

The stents to which the invention relates can have incorporated therein, or coated thereon, one or more drugs, such as smooth muscle cell inhibitors (for example, growth factor inhibitors or cytotonic agents) collagen inhibitors, vasodilators (for example, prostaglandins or analogs thereof), or anti-platelet and/or anti-thrombotic substances (for example, aspirin, heparin or tissue plasminogen activator). (Imaging agents, such as radio-opaque fillers can also be used, as can agents that improve streamlined blood flow, such as hydrogels.) Such stents are excellent drug delivery vehicles as they can be used to achieve high local drug concentrations directly at the area at risk, for example, for restenosis, while at the same time avoiding problems associated with systemic drug administration, for example, toxicity. Timed release of the drug from the stent can be achieved either by forming the stent so that slow diffusion from the stent-forming polymer itself is effected or

by coating the stent in a manner such that slow diffusion of the drug through, or from, the coating is effected.

In a preferred embodiment, the outer portion of the stent (the "skin") is made porous after the stent has been fabricated to accommodate the drug. The pores can be filled with a drug/gel forming matrix by alternating vacuum and hydrostatic pressure (for example, up to 6,000-20,000 psi). If necessary, the stent can then be contacted with a reagent that causes the matrix to set as a gel.

The porous skin can be formed by dipping the stent, or filaments from which the stent is to be formed, into a solvent that swells the outer layer of the filaments. Ideally, diffusion of the solvent is effected fairly slowly; diffusion can be slowed, for example, by chilling the solvent. In this way the core of the filament is not affected during the time of exposure to solvent. The filament with swollen outer layer can then be dipped into an agent that is a "nonsolvent" for the polymer of which the filaments are made, which agent forms a solution with the swelling solvent. This agent, preferably, diffuses more rapidly than the first solvent. Warming can be used to promote diffusion of the agent into the swollen area thus causing phase separation that results in the formation of a porous skin on the stent filament. If poly-L-lactide is used as the polymer, chloroform can be used as the swelling solvent and methyl alcohol as the agent that causes phase separation. Pore formation can also be effected in polylactic/glycolic acid polymers and copolymers using a blend of, for example, orthoesters (such as a methyl or ethyl orthoformate or orthoacetate) and methylene chloride as solvent and water as non-solvent. The change in CED of the orthoester/water

reaction product can be expected to produce phase separation and the molecular weight of the orthoester will produce a low rate of diffusion out of the solvent. If nylon 6/6 is used as the polymer, 75% aqueous formic acid can be used as the swelling solvent and 5% aqueous formic acid as the phase separation agent. Other suitable polymer/solvent/agent combinations can also be used. One skilled in the art can readily determine appropriate solvents/agents to be used with any particular polymer.

An example of a suitable gelling system includes a mixture of sodium alginate and neutral heparin. After this is introduced into the pores, the filaments can be dipped in aqueous calcium chloride which causes the alginate to gel.

As indicated above drugs to be delivered can be incorporated into the stent. The manner in which the drug is incorporated depends on the spinning technology used (melt spinning, dry spinning or wet spinning). (See, generally, Rodriquiz.)

One skilled in the art will appreciate that, as melt spinning involves the heating of the polymer above its melting point, the range of drugs that can be used in conjunction with this method is somewhat limited. Drugs that are sufficiently stable and unreactive at the high temperatures involved can, however, be blended with the polymer prior to extrusion.

In dry spinning, the polymer is dissolved in a solvent and the solution is extruded, the solvent being removed by warm air. The same analysis applies as in melt spinning but the temperatures can be substantially lower, increasing the number of drugs that can be incorporated.

In wet spinning, the polymer is dissolved in a solvent and extruded into a second liquid that is a "nonsolvent" for the polymer but which will extract the solvent for the polymer and coagulate the fibers. The analysis for this process is the same as for the development of porous skin discussed above with respect to the relative diffussivities of the two liquids, but wet spinning gives pores throughout the fiber diameter. Drug can be incorporated by running the fibers through a bath post-congulation, and rinsing. The pores can then be partially collapsed by stretching, heating, or solvent exposure thereby trapping the drug throughout the filament. If a heat sensitive drug is incorporated, then subsequent processing steps used must avoid high temperature, e.g., the heat setting step can be replaced by chemical setting (see below).

Other methods can also be used to incorporate drugs into the stents of the present invention. For example, small water soluble particulates can be added to the polymer before extrusion and leached out post-fabrication to create pores. Monomeric lactide can be incorporated before extrusion and subsequently leached out. Very small pores can be created by swelling the polymer at any stage post-extrusion in a supercritical fluid such as propane and then reducing the pressure so that no liquid phase exists. In all cases, drug containing solutions can be forced into the pores by hydrostatic pressure with or without a gelling agent to control out-diffusion of the drug.

One skilled in the art will appreciate from the foregoing that the stent to which the invention relates can be used as a vehicle for delivering virtually any drug. Care must be taken, however, to ensure that the fabrication process,

particularly in those situations where the drug is to be incorporated into the stent, is selected such that the activity of the drug to be delivered is not diminished or destroyed. In addition to use of the spinning technologies noted above, the temperature of the setting step of stent formation must also be considered. As an alternative to annealing, which involves heating to temperatures in the range of 110-140°C, chemical setting can be used. Specifically, the stent can be exposed to vapors or liquid of a poor solvent or weak swelling agent such as ethyl acetate, then air or vacuum drying to remove the solvent/agent (0-40°C).

Drugs particularly sensitive to thermal deactivation (for example, proteins, including tissue plasminogen activator) are preferably incorporated into a porous skin formed on the stent, as described above. Sterilization of the stent in the case of such drugs can be effected using gamma radiation.

One skilled in the art will recognize that the amount of drug to be incorporated into, or coated on, the stent will depend on the therapy sought. Such determinations can be made without undue experimentation.

From a reading of the following non-limiting Example, one skilled in the art will appreciate that variations in molecular weights, dimensions, draw ratios, temperatures and solvents are all possible without substantially altering the product stent.

EXAMPLE

Stent Preparation

Rectangular or cylindrical monofilaments made by melt extrusion of poly-L-lactide with an average weight of 35,000 daltons were drawn to 600%

of their original length to give a final diameter for the cylindrical filaments of 0.18mm. These fibers were braided onto a 4- to 8-foot Teflon mandrel, 3.17mm in diameter, using 8 ends in the braiding process (four filaments moving in clockwise and four in counterclockwise helices, each filament alternately going over and under the intersecting filaments). The filaments were then secured to the mandrel with two wire twists at intervals such that each interval was slightly longer than the desired stent (typically, 0.5-2.0 cm in length). The spacing of the two wire twists was such that after annealing the mandrel and fiber could be cut between the wires to give a single stent length while constraining the fibers form shrinking during annealing. (The purpose of annealing is to heat set the fibers so they will return to a helical form if distorted after annealing.) The annealing was carried out at 140°C for 15 minutes. (Higher temperatures (below the melting point) allow shorter annealing cycles and lower temperatures down to about 110° work better with longer times.) The annealing was done in air although an inert atmosphere such as nitrogen or vacuum annealing result in somewhat higher molecular weight products.

The filaments of the partially formed stents were glued together at the desired terminal intersections, thereby determining the final length, with a small drop of a solution of poly-L-lactide in a volatile solvent such as chloroform, and removed from the mandrel. When the solvent has substantially evaporated, the stents are trimmed to remove most of the fibers beyond the glue joints and each joint is brought into proximity with a hot wire causing the ends to fuse and become smooth.

* * * * *

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but, on the contrary, is intended to cover various modifications and equivalent arrangement included within the spirit and scope of the appended claims. For example the preformed stent need not be a right cylinder but could have a cross-section which varies along the length of the stent. Further, solvent setting can be used in lieu of thermal annealing. Solvent setting is particularly advantageous where drugs are to be incorporated into the stent. In addition, the self expanding stent of the invention could advantageously be used in body passages other than the coronary arteries, such as the ureters or the fallopian tubes, such alternative applications and configurations being limited only by the appended claims.

WHAT IS CLAIMED IS:

1. A intraluminal stent comprising a tubular main body portion having a first end, a second end, and a flow passage defined therethrough from said first end to said second end, said tubular main body portion being sized for intraluminal placement within a body passage, said main body portion being formed from a bioabsorbable material which has been rolled into a substantially cylindrical configuration, said bioabsorbable material being one of porous and apertured, said main body portion being self-expanding from a first, reduced cross-sectional dimension to a second enlarged cross-sectional dimension whereby said main body portion can be transported intraluminally to a targeted portion of a body passage and expanded to a second enlarged diameter so as to engage and support said targeted portion of said body passage, said main body portion including means for retaining said bioacompatable material in said reduced diameter configuration and means for retaining said biocompatable material in said enlarged diameter configuration, wherein said stent has a therapeutically effective amount of a drug coated thereon or incorporated therewithin.

2. A stent as in claim 1 wherein said bioabsorbable material is a polymeric material.

3. A stent as in claim 1, in combination with a catheter assembly including a guiding catheter having a proximal end and a distal end, an outer sheath element having a proximal end and a distal end and an inner sheath element having a proximal end and a distal end, said outer sheath element being slidably mounted within said guide

catheter and said inner sheath element being slidably mounted within said outer sheath element, said stent being mounted within said distal end of said outer sheath element, distally of said inner sheath element.

4. A stent as in claim 1, in combination with a catheter assembly comprising a balloon catheter having a distal end and a proximal end and an inflatable balloon provided at said distal end, said stent being mounted to an exterior surface of said inflatable balloon.

5. A stent as in claim 4, wherein said stent is secured to said inflatable balloon with one of a biocompatable glue and a biocompatable adhesive.

6. A stent as in claim 2 wherein said polymeric material comprises poly-L-lactide.

7. A stent as in claim 1 wherein said bioabsorbable material comprises a bioabsorbable polyester and a pharmaceutically acceptable acid.

8. A stent as in claim 7 wherein said polyester comprises poly-L-lactide and said acid is fumaric acid.

9. A stent as in claim 1 wherein said bioabsorbable material comprises a polyamide of the formula:

$-NH-(CH_2)_n-CO-$ or $-NH-(CH_2)_x-NH-CO-(CH_2)_y-CO-$

wherein n is 6-13, x is 6-12 and y is 4-16.

10. A stent as in claim 1 wherein said bioabsorbable material comprises a polyhydride of the formula

$$HO_2C-C_6H_4-O-(CH_2)_n-OC_6H_4-CO_2-H$$

wherein n is 2-8.

11. A stent as in claim 1 wherein said bioabsorbable material comprises a polyorthoester resulting from the reaction of $(RO)_3C-X-C(OR)_3$ with $(HOCH_2)CH-Y-CH(CH_2OH)_2$,
where

R is a lower alkyl group, and

X and Y are, independently, $-C_6H_4-$ or $-(CH_2)_n-$, where n is 1-12, or combination thereof.

12. The stent according to claim 1 wherein said drug is a smooth muscle cell inhibitor.

13. The stent according to claim 1 wherein said drug is a vasodilator.

14. The stent according to claim 1 wherein said drug is an anti-platelet or antithrombotic agent.

15. The stent according to claim 1 wherein said drug is a collagen inhibitor.

16. A method of forming pores on the surface of said stent according to claim 1, comprising:

i) contacting filaments from which said stent is formed with a solvent that swells said filaments under conditions such that swelling of an outer layer of said filaments is effected; and

ii) contacting said filaments resulting from step (i) with an agent that is a nonsolvent for

said filaments, which agent forms a solution with said solvent, under conditions such that said agent diffuses into said swollen outer layer of said filaments thereby causing phase separation and pore formation in said outer layer of said filaments.

17. The method according to claim 16, wherein said pores are formed in said outer layer of said filaments prior to formation of said stent from said filaments.

18. The method according to claim 16, wherein said pores are formed in said outer layer of said filaments after formation of said stent from said filaments.

19. A method of incorporating a drug into the stent according to claim 1, comprising:

i) forming pores in an outer layer of filaments from which said stent is formed;

ii) introducing into said pores a composition comprising said drug and a gel forming agent; and

iii) effecting setting of said composition as a gel.

20. An intraluminal stent comprising a tubular main body portion having a first end, a second end, and a flow passage defined therethrough from said first end to said second end, said tubular main body portion being sized for intraluminal placement within a body passage, said main body portion being formed from a bioabsorbable material which has been rolled into a substantially cylindrical configuration, said bioabsorbable material being one of porous and apertured, said main body portion being expandable from a first,

reduced cross-sectional dimension to a second enlarged cross-sectional dimension whereby said main body portion can be transported intraluminally to a targeted portion of a body passage and expanded to a second enlarged diameter so as to engage and support said targeted portion of said body passage, said main body portion including means for retaining said bioacompatable material in said reduced diameter configuration and means for retaining said biocompatable material in said enlarged diameter configuration, wherein said stent has a therapeutically effective amount of a drug coated thereon or incorporated therewithin.

21. A stent as in claim 20, wherein said means for retaining comprises frictional engagement of first and second circumferential ends of said biocompatable material.

22. A stent as in claim 20, wherein said biocompatable material is in the form of at least one strip, said means for retaining comprises an elongated connector element mounted to a first end of said strip of bioabsorbable material, a second end said of bioabsorbable material being slidable relative to said connector element.

23. A stent as in claim 22, wherein first and second connector elements are provided, one of said connector elements being fixedly secured to a first end of said sheet of bioabsorbable material.

24. A stent as in claim 23, wherein each of said connector elements includes means for slidably receiving said strip of material.

25. A stent as in claim 22, wherein a plurality of strips of biocompatable material are provided.

26. A stent as in claim 20, wherein said main body portion includes a plurality of tine receiving cavities and a plurality of tine elements said tine elements, being connected at a first end thereof to a first end of said tine receiving cavities and a second end of said tine elements being inserted into a second end of said tine receiving cavities.

27. An intraluminal stent comprising a tubular main body portion having a first end, a second end, and a flow passage defined therethrough from said first end to said second end, said tubular main body portion being sized for intraluminal placement within a body passage, said main body portion being formed from a bioabsorbable material having at least one of pores and a plurality of apertures therethrough whereby tissue encapsulation of the main body portion is facilitated and the blood flow there through is possible, wherein said biocompatable material has a drug one of coated thereon, impregnated therein, and encapsulated therewithin.

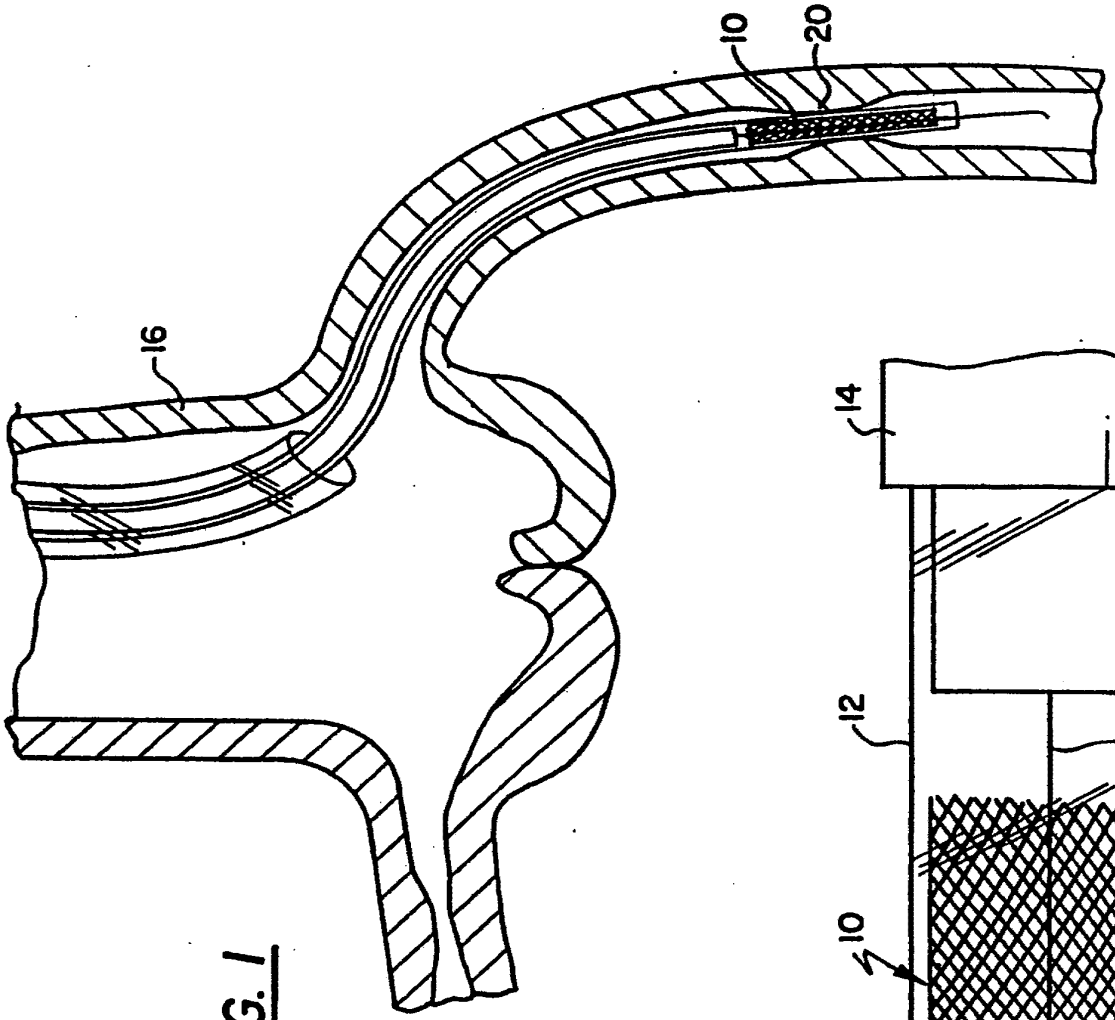


FIG. 1

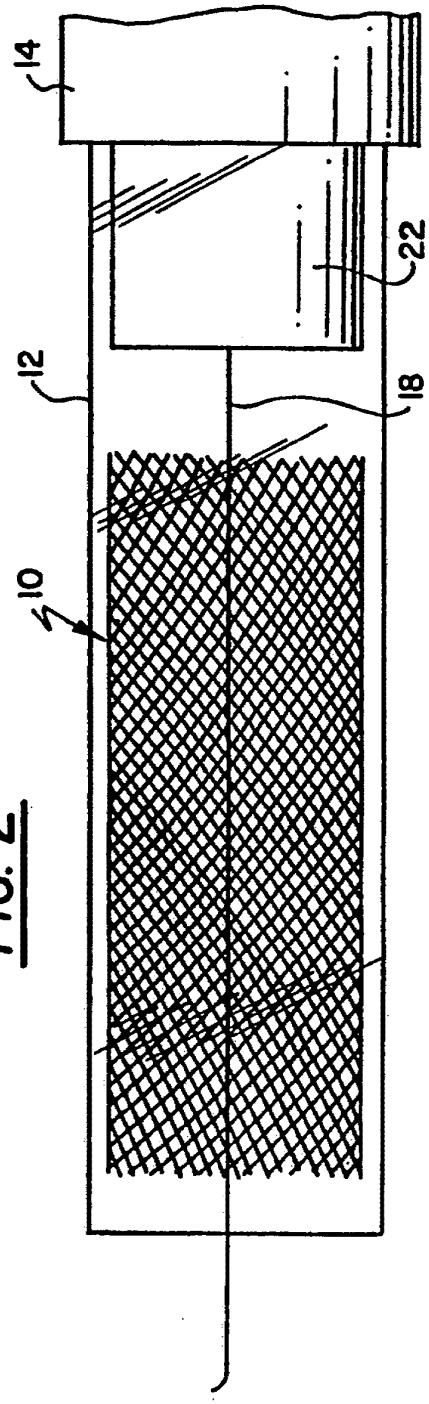


FIG. 2

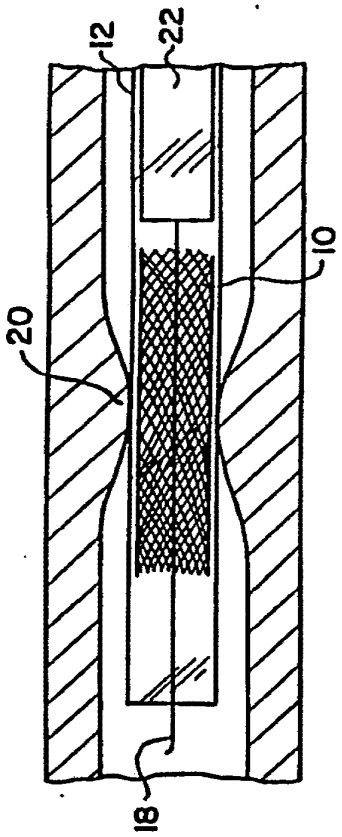


FIG. 3

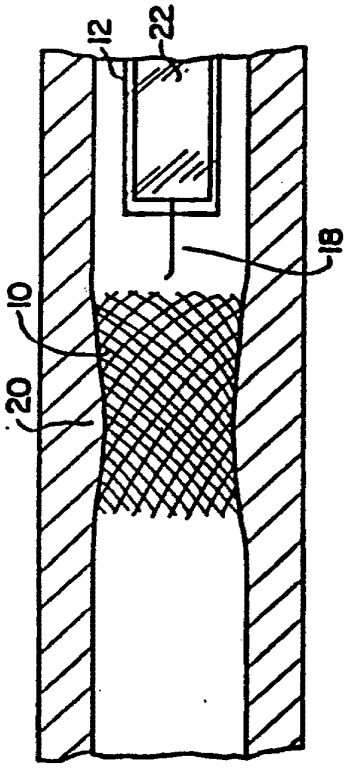


FIG. 4

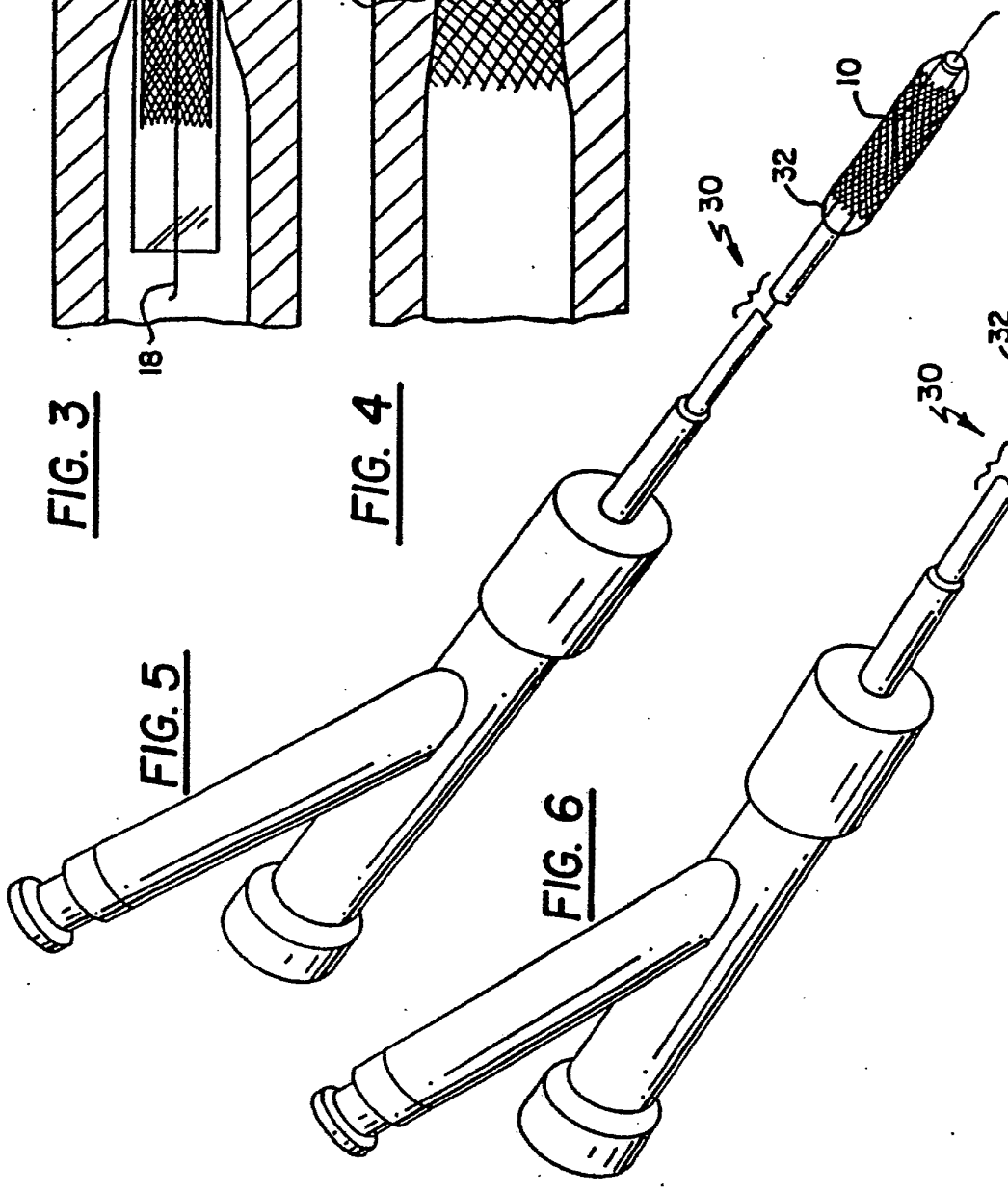


FIG. 5

FIG. 6

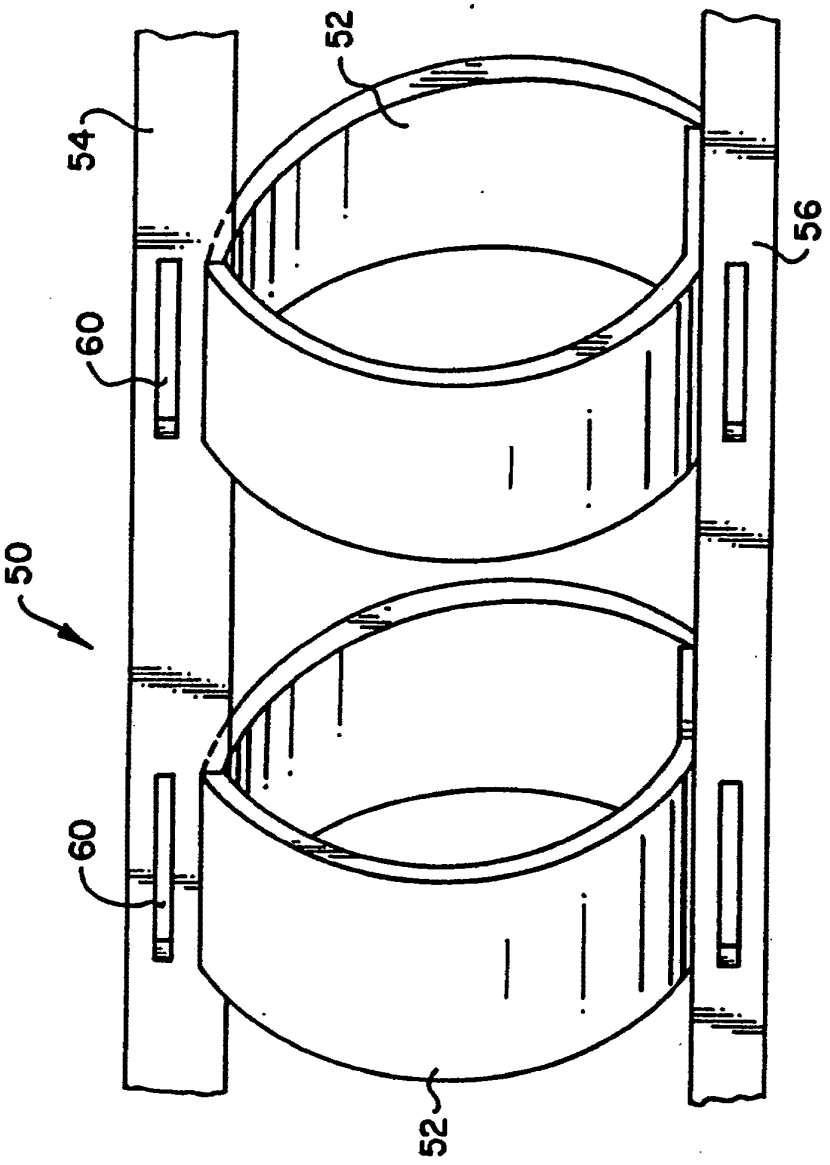


FIG. 7

FIG. 9

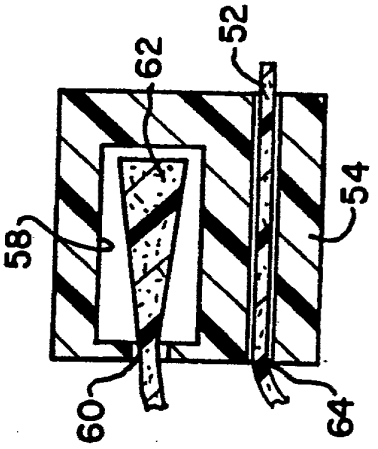


FIG. 10

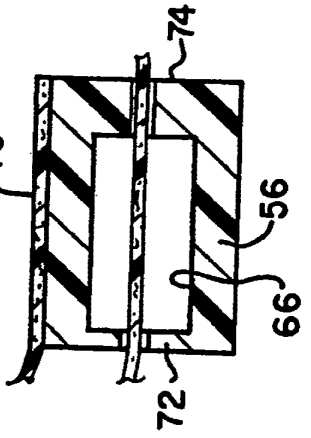
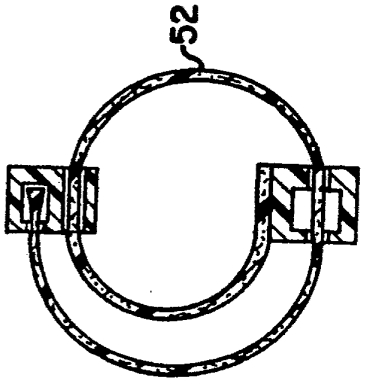


FIG. 8



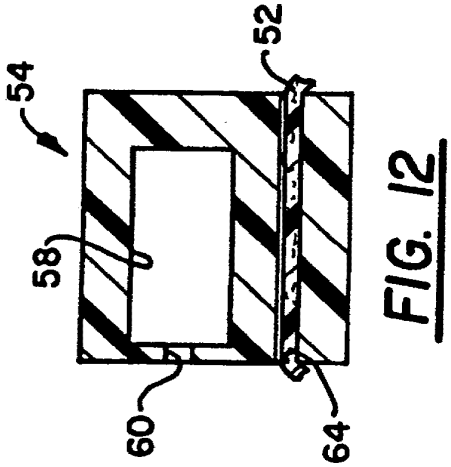


FIG. 12

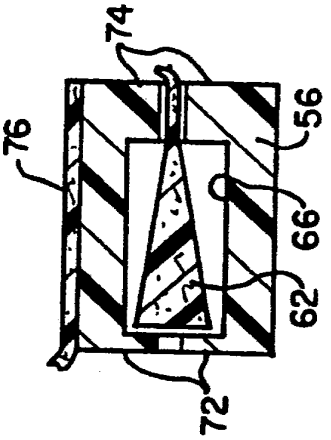


FIG. 13

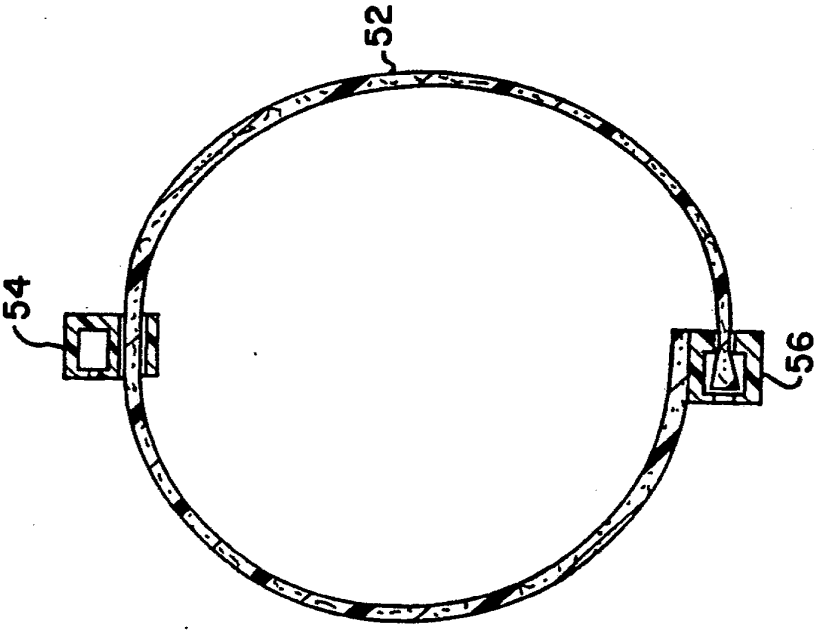


FIG. 11

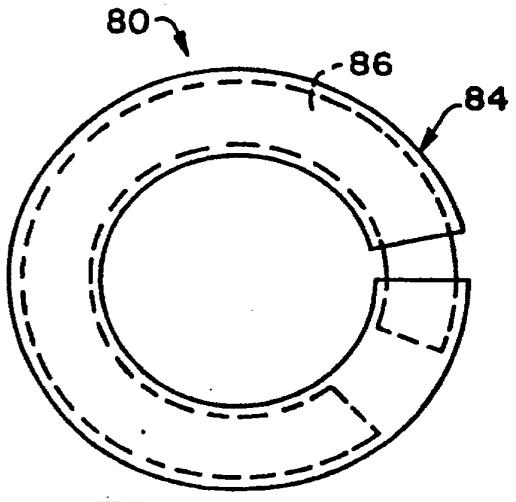


FIG. 15

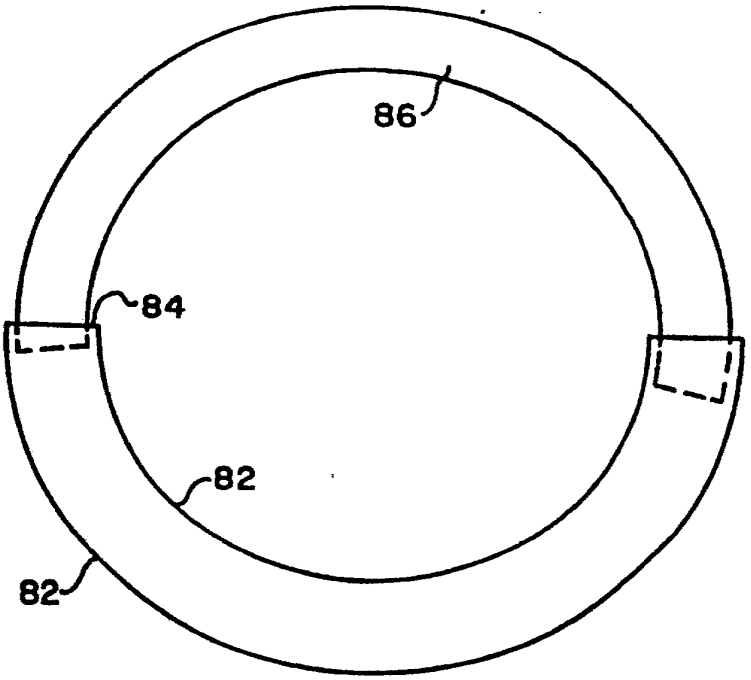


FIG. 16

FIG. 14

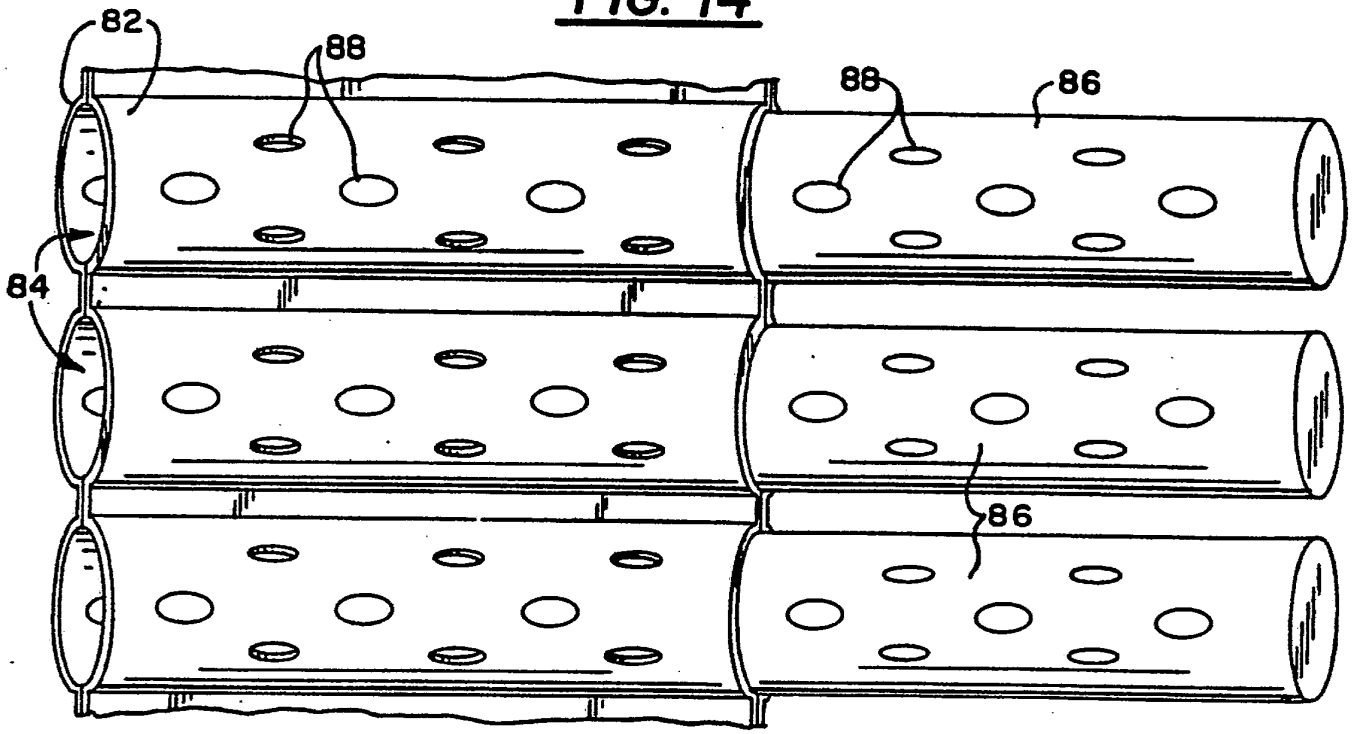


FIG. 18

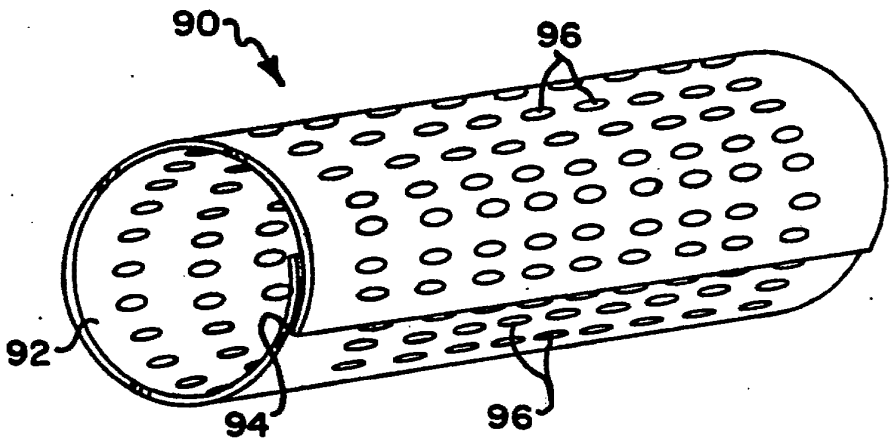
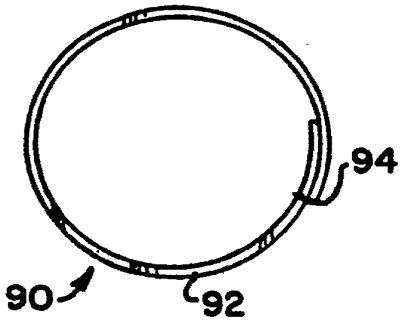


FIG. 17



INTERNATIONAL SEARCH REPORT

International Application No PCT/US91/03454

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 29/02
US Cl.: 606/108, 198; 128/898

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	606/108, 198, 191, 151, 153-156 128/898

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	US, A, 4,655,771 (Wallsten) 07 April 1987 See entire document	1-4,6-27
Y,E,	US, A, 5,019,090 (Pinchuk) 28 May 1991 See entire document	1-4,6-27
Y	US, A, 4,740,207 (Kreamir) 26 April 1988 See entire document	1-4,6-27
Y,P	US, A, 5,007,926 (Derbyshire) 16 April 1991 See entire document	1-4,6-27

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [3]
22 July 1991	04 SEP 1991
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	NGUYEN NGOC-HO INTERNATIONAL DIVISION for Michael Thaler

Form PCT/ISA/210 (second sheet) (May 1986)

⑲日本国特許庁(JP)　⑪特許出願公開

⑫公開特許公報(A)　平2−68052

⑤1Int. Cl.⁵	識別記号	庁内整理番号	④3公開　平成2年(1990)3月7日
A 61 F 2/04		7603−4C	

審査請求　未請求　請求項の数 21　(全10頁)

⑤4発明の名称　半径方向に膨張可能な体内補装具及びその製造方法

②1特　願　平1−171024

②2出　願　平1(1989)7月1日

優先権主張　③2 1988年9月1日 ③3米国(US) ③1240000

⑦2発明者　レオナード・ピンチヤク　アメリカ合衆国フロリダ州33186，マイアミ，サウス・ウエスト・ワンハンドレッドサーテイサード・プレース 9722

⑦1出願人　コーヴイタ・コーポレーション　アメリカ合衆国フロリダ州33174，マイアミ，ウエスト・フラグラー・ストリート 10555

⑦4代理人　弁理士 湯浅 恭三　外4名

明　細　書

1．[発明の名称]

半径方向に膨張可能な体内補装具及びその製造方法

2．[特許請求の範囲]

1．半径方向に膨張可能な体内補装具であって、互いに実質的に隣接しかつ互いに略軸方向に方向決めされ、よって、全体として体内補装具を画成し得るようにした複数の略円周方向部分を備え、

前記略円周方向部分の少なくとも1つが、該略円周方向部分に対して半径方向への膨張可能性を付与する膨張可能な部片を有し、よって、前記円周方向部分が非膨張状態の挿入円周部と、及び前記非膨張状態の挿入円周部よりも大きい膨張状態の埋め込み円周部とを備え、

前記略円周方向部分の前記膨張可能な部片が、略閉じられた方向と略開放した方向との間にて屈曲可能な実質的に折り畳み可能な部材であり、よって前記略円周方向部分に半径方向の膨張可能性を付与することを特徴とする半径方向に膨張可能な体内補装具。

2．前記折り畳み可能な部材が略エルボ状の部材を備えることを特徴とする請求項1記載の体内補装具。

3．前記折り畳み可能な部材が一対の脚部を単一体的に接続する能動的なヒンジを備えることを特徴とする請求項1記載の体内補装具。

4．前記略円周方向部分が略円筒状の体内補装具を形成することを特徴とする請求項1記載の体内補装具。

5．前記略円周方向部分が軸方向に伸長する体内補装具を画成する連続的なつる巻き体を形成することを特徴とする請求項1記載の体内補装具。

6．前記略円周方向部分の外側の1つが、前記円周方向部分の隣接する1つと係合するフック手段が形成された自由端を有することを特徴とする請求項5記載の体内補装具。

7．前記膨張可能な部片が略折り畳み可能な弾性のばね状部材であり、体内補装具の非膨張状態の挿入円周部がその上にあるシーズにより維持さ

れることを特徴とする請求項１記載の体内補装具。

８．前記膨張可能な部片が実質的に折り畳み可能な可鍛部材であり、膨張された埋め込み円周部がカテーテルの膨張可能な要素から作用される半径方向を向いた力により達成されることを特徴とする請求項１記載の体内補装具。

９．前記実質的に折り畳み可能な部材が略Ｕ字形であることを特徴とする請求項１記載の体内補装具。

１０．前記連続的なつる巻き体が複数の前記実質的に折り畳み可能な部材を備え、前記折り畳み可能な部材の各々が交互に実質的に反対方向に方向決めされた略Ｕ字形であることを特徴とする請求項５記載の体内補装具。

１１．前記略折り畳み可能な部材が略Ｖ字形であることを特徴とする請求項１記載の体内補装具。

１２．前記連続的なつる巻き体が複数の前記実質的に折り畳み可能な部材を備え、前記折り畳み可能な部材の各々が交互に実質的に反対方向に方向決めされた略Ｖ字形であることを特徴とする請求項５記載の体内補装具。

１３．前記体内補装具が略管状であり、それぞれの略円周方向部分のそれぞれの円周方向端縁が互いに実質的に隣接することを特徴とする請求項１記載の体内補装具。

１４．前記略円周方向部分の前記膨張可能な部片がストランドを形状心金に巻き付け、その後偏平にし、略平面状の形状にする巻き付けストランドを形成し得るようにしたことを特徴とする請求項１記載の体内補装具。

１５．半径方向に膨張可能な体内補装具を製造する方法であって、

狭い巻き付け面を形成し得るように比較的小さい断面積の心金を選択する段階と、

細長いストランドを前記狭い巻き付け面上に巻き付け、及び該ストランドを前記小さい心金から除去して、複数の巻き付け部分を有する巻き付けストランドを形成し、前記巻き付け部分が前記断面積の形状に実質的に適合し得るようにする段階と、

前記巻き付けストランドを偏平にする力を作用させ、実質的に単一平面状の波状のストランド体が形成されるようにする段階と、

前記比較的小さい心金の断面積よりも大きい断面積の別の心金を提供する段階と、及び

前記波状のストランド体を前記別の心金の周囲に実質的にら旋状に巻き付けかつ該別の心金を除去することにより、半径方向に膨張可能な体内補装具を提供する段階と、を備えることを特徴とする半径方向に膨張可能な体内補装具を製造するための方法。

１６．前記実質的にら旋状に巻き付ける段階の開始後、前記波状のストランド体の自由端を該波状のストランド体の隣接する部分上に掛止する段階をさらに備えることを特徴とする請求項１５記載の方法。

１７．前記別の心金を提供する段階が略円筒状の外面を有する別の心金を選択する段階を備えることを特徴とする請求項１５記載の方法。

１８．前記選択段階が、前記巻き付け面が略楕円形の形状であるように、比較的小さい心金を選択する段階であることを特徴とする請求項１５記載の方法。

１９．前記選択段階が、前記巻き付け面が略矩形の形状であるように、比較的小さい心金を選択する段階であることを特徴とする請求項１５記載の方法。

２０．前記選択段階が、前記巻き付け面が略レンズ状の形状であるように、比較的小さい心金を選択する段階であることを特徴とする請求項１５記載の方法。

２１．前記選択段階が、前記巻き付け面が円形の形状であるように、比較的小さい心金を選択する段階であることを特徴とする請求項１５記載の方法。

３．［発明の詳細な説明］

（産業上の利用分野）

本発明は、全体として、体内人工補装具、その製造方法及びその使用方法に関する。より具体的には、本発明は、実質的に膨張不能の挿入円周と

該非膨張状態の挿入円周よりも大きい膨張された埋め込み円周との間にて半径方向に膨張可能な略管状の体内人工補装具に関する。この人工補装具には、1又は2以上の実質的に円周方向部分が含まれ、該円周方向部分の1又は2が1又は2以上の膨張可能な部片を備えている。該膨張可能な部片は該補装具が実質上その非膨張の挿入される状態にあるときに略折り畳まれる一方、補装具がその膨張した埋め込まれる状態にあるときに略開放している屈曲可能な部材である。

（従来の技術及びその課題）

狭窄症、狭縮、動脈瘤等を治療するための体内補装具が公知である。しばしばステントと称される型式の体内補装具は典型的に、機械的な経内腔法により位置決めされ又は埋め込まれる。この型式の装置は、しばしば経皮的に血管系に埋め込まれ、血管等の部分的に閉塞し、弱体化し又は異常に拡張した局所部分が異常陥入しないように補強するために使用される。

この型式のステントは、又、尿路、胆道、腸管等に使用することも出来る。体内補装具又はステントを使用して、狭窄症を治療する場合、典型的には血管形成バルーンのような拡張要素と関係させて行われる。この場合、拡張要素又はバルーンが狭窄部分を開放し、その場所にステント等を位置決めし、狭窄を防止するか又は少なくとも狭窄の再形成を著しく遅らせる。

ステントの1つの特徴は半径方向に圧縮可能かつ膨張可能であり、収縮したときには血管等を容易に通過させることが出来るが、狭窄、狭縮部分等に達した後は膨張してその埋め込まれた箇所の寸法に適合し得ることである。又、ステントはその全長に亘って略可撓性を備え、血管等の屈曲部分及び湾曲部分を通るように容易に操作可能であることが望ましい。又、典型的にステント又は体内補装具は著しく広い開放スペースを有し、その長さ方向に内皮化させることにより、異体の反応を最小限にしかつ副行血管等の妨害を最小限にし得るようにすることが望ましい。ステント又は体内補装具は所望の位置に確実に位置することが重要である一方、除去が必要になったならば、経内腔的な経皮法の実行中、除去可能であるようにすることが望ましい。

現在公知の各種ステント製品は基本的につる巻きばねの構造を有している。このばね型式のステントは緊密にコイル状に巻かれたとき、その径は比較的小さく、血管等に挿入することが出来る。このばねが反発し又はよりゆるく巻かれたとき、ステントはその膨張した埋め込み状態となる。マアス（Maass）等の米国特許第4,553,545号は、この型式のつる巻きばねステント又は体内補装具を開示している。多条又は網状のステントも又公知である。この一般的な型式のステントは操作性が劣り、肉厚が比較的厚く、及び立方体であるという欠点がある。これらは、又、一旦埋め込んだならば除去することが困難であり、又多数の比較的鋭角又はギザギザのついた端部が露出している。パルマス（Palmaz）の米国特許第4,733,665号はこの一般的型式の膨張可能なステントの一例である。ギアンタルコ（Gianturco）の米国特許第4,580,568号は書類綴りばねに幾分似たパターンにて閉じジグザグの形態に配設された、ステンレス鋼にて形成した経皮的体内血管ステントを開示している。かかる構造は幾分非対称状であり、この型式の補装具のワイヤ間に一般に存在する極めて大きい開放したスペースにより、再閉塞の虞れがある。別型式のステントはスタッツ（Stats）のステントとして公知であり、これはその本体にエッチング処理して形成された縦方向のスロットを有する皮下管である。かかる補装具は非膨張時と膨張時の径の比が大きい一方、比較的剛性で鋭角な端縁を有し、湾曲した経路を通って操作することは難しく、又、経内腔的方法にて除去することは容易でない。

こうした現在公知のステント構造において、ステントの軸方向長さはステントの円周の増加に伴って短くなるが、これは一般的に欠点である。例えば、かかる長さの短縮は特定の埋め込み方法に適したステントの寸法を選択する上で考慮に入れなければならない。又、多数の従来型式のステント

のかかる特徴は、実行せんとする埋め込み方法に実際に必要とされる長さよりはるかに長い距離にわたって血管を通すことが必要となり、又はそれに対応した長さにしなければならない。これは、捩れ部分又は湾曲部分を有する経路にステントを通さなければならない方法の場合、特に容易に屈曲し得ないステント構造である場合、特に困難な問題である。

本発明の全体的な目的は、経内腔的に埋め込むことの出来る型式の改良された半径方向に膨張可能でかつ軸方向に伸長する体内補装具を提供することである。

本発明の別の目的は、半径方向への膨張性が極めて大きい構造とすることの出来る改良された体内補装具又はステントを提供することである。

本発明の別の目的は、極めて操作性に富み、湾曲した経路を通って移動させることの出来る改良された軸方向に膨張可能でかつ軸方向に伸長する体内補装具を提供することである。

本発明のさらに別の目的は、望むならば、例えば、係留又はカテーテルにより経内腔的に埋め込むことの出来る、改良された半径方向に伸長可能で軸方向に伸長した体内補装具を提供することである。

本発明のさらに別の目的は、体内補装具をその埋め込み箇所に装填し易いような方法にて離間して配設するか又は方向決めすることの出来る部材を備える改良された半径方向に膨張可能で軸方向に伸長した体内補装具を提供することである。

本発明のさらに別の目的は、カテーテル装置の膨張部材又はバルーンにより半径方向に膨張可能であり、及び/又は体内補装具のばね状の特性により半径方向に膨張可能な構造にて形成することの出来る改良された軸方向に伸長する体内補装具を提供することである。

本発明のさらに別の目的は、半径方向に膨張可能で軸方向に伸長した及び/又は略管状の体内補装具を製造するための改良された方法を提供することである。

本発明のさらに別の目的は、軸方向に伸長しかつ半径方向に膨張可能な体内補装具又はステントを経内腔的に埋め込むための改良された方法及びシステムを提供することである。

本発明のさらに別の目的は、すり切れた端縁の発生を防止し、及び幾多の半径方向の膨張位置において、その軸方向の長さを略維持し得る改良された半径方向に膨張可能な体内補装具を提供することである。

（課題を達成するための手段）

本発明は上述した従来技術の構造体の各種の欠点を解決し、体内補装具又はステント並びにその使用方法の重要かつ有利な特徴を提供するものである。要約すると、本発明の体内補装具は、それぞれの対向する略円周方向の端縁に沿って互いに略隣接する複数の実質的円周方向部分を備えている。これら実質的円周方向部分の少なくとも1つは、該実質的円周方向部分に半径方向への膨張可能性を付与する膨張可能な部片を有している。この膨張可能な部片は略収縮した位置又は閉じられた位置と略開放した位置間にて屈曲可能なエルボ状部材であり、完全に閉じた位置と完全に開放した位置間にて屈曲した形態をとり得る。この構造体により体内補装具又はステントは非膨張時の挿入円周及び該挿入円周より大きい膨張時の埋め込み円周を有している。さらに、この円周の差は、体内補装具又はステントの軸方向長さを著しく変えることなく実現することが出来る。このステントは比較的複雑でない方法により形成することが出来、一般的にいって、該ステントは必要であれば経内腔的に移植することも出来る。

（実施例）

本発明の上記及びその他の目的、特徴並びに利点は以下の詳細な説明から明確に理解されるであろう。

半径方向に膨張可能でかつ軸方向に伸長した体内補装具又はステントが全体として、第3図及び第4図に符号31で示されている。このステント31は、複数の円周方向部分32を有している。この図示した実施例において、該円周方向部分32の各々は第2図に図示した波状体のように、同

一の連続するつる巻き状体にて形成されている。

少なくとも1つの円周方向部分32が少なくとも1つの膨張可能な部片34を備えている。この膨張可能な部片34は典型的に1又は2以上の脚部35を備える屈曲可能な部材である。各脚部35は脚部35及び円周方向部分32の隣接部分と一体又は単一の構成要素であるいわゆる能動的継手又はヒンジにより円周方向部分32の他部分に屈曲可能に固着されている。例えば、第1図乃至第5図に図示した実施例において、各脚部分15は略円弧状の形状を有する一体の又は能動的ヒンジ36を介して別の脚部35に屈曲可能に結合されている。ステント31が膨張するとき、一体型ヒンジ36が脚部35の端部分37がさらに動いて離反するのを許容し、よってステント31の円周及び径を増大させる。勿論、ステント31の円周及び径はこれらの端部分37同士を互いに接近させる力により縮少させることが出来る。

第1図、第2図及び第3図を参照することにより、ステント31のような本発明による体内補装具の製造方法が理解されよう。第1図には、幾分楕円形の断面形状を有する心金38が図示されている。この心金38は例えば、略矩形の断面を提供し得るよう、2つの対向する縦方向部分が扁平であり、その2つの対向する端部分が円弧状又は円形であるようにした丸管又はロッドとすることが出来る。この心金は鋼等のような可鍛性材料にて形成することが望ましい。

ここで一般的に説明したワイヤ又はその他の材料によるストランド39は、該ストランド39が心金38の断面線に沿った断面形状を有するように全体として心金の上に緊密に巻き付けられる。このストランド39の巻き付けはストランド39の各個々の巻き付け部分間に相当な間隔が生ずるような方法にて行うことが望ましい。一般的にいって、このストランド39の巻き付けが緊密であればある程、及び心金の肉厚が薄ければ薄い程、完成されたステント31における膨張可能な部分34間の間隔は益々狭くなる。このストランド39の巻き付けが完了したならば、心金38上に巻き付けたストランド39は使用されるワイヤの型式に適した従来の焼鈍し方法によって加熱焼鈍しを行うことが望ましい。可鍛製心金を軸方向に延伸させ、その径が効果的に縮少されるようにすることにより巻き付けたストランドの除去が容易となる。次いで、巻き付けたストランド39を扁平にする力を加え、立方体として巻き付けられたストランド39を第2図に図示するような波状体の略平面状の形状にする。かかる作用力は任意の適当な手段により加えることが出来る。

例えば、巻き付けたストランド39は2つの平面状の表面間にて圧縮することが出来、この工程中、ストランド39の巻き付け部分は略単一の波状体が形成されるまで捩る。この波状体は略正弦波を形成する。

第3図に図示したステント31の製造を完了させるためには、その後、波状体33は第3図に略図示するように略つる巻き状に略円筒状の心金41の周囲に巻き付ける。この略つる巻き状の巻き付け工程は希望の数の円周方向部分が形成され、希望の長さのステント31が提供されるまで継続する。使用するワイヤの型式いかんにより、第3図のつる巻き状の巻き付け部分を加熱焼鈍しすることも出来る。

第5図を参照すると、全体として第3図に図示されたこの巻き付け工程は、完成したステント31に遊離した端部が形成されるのを回避し得る方法にて進行される。これは各端の円周方向部分42がステント31の隣接する部分上に容易に掛止する自由端43（例えば、端部の円周方向部分42に隣接しかつ中方に離間された円周方向部分32の一体形ヒンジ36のような自由端43）を有するように、ストランド39及び波状体33を形成することにより容易に実現される。第5図に図示した自由端43は一体形ヒンジ36内に容易に輪を作るか又は折り込まれるフック部分の性質を備えている。一部の実施例においては、このフックはヒンジ36に溶接することが望ましい。

第6図及び第7図に図示した実施例に関し、ストランド39がその周囲に巻き付けられる心金は

略矩形の心金４４である。その結果、その後形成される略平面状の構造体は波状体４５となり、この波状体４５は典型的に一体形ヒンジよりも小さい円弧状である単一型又は一体型ヒンジ又は能動的ヒンジ４７により接続された複数の脚部４６を有している。次いで、この波状体４５を円筒状心金４１のような構造体の上につる巻き状に巻き付けることにより、本発明の体内補装具又はステントが形成される。

別の実施例による体内補装具又はステントは、第８図及び第９図に全体的に図示した方法により形成される。ここで心金は、互いに背中合わせの状態にて位置決めされた２つの凸形面を画成すると説明し得る横方向断面を有する略レンズ形の心金５１である。その他の実施例と略同一の方法にて細長いストランド３９をこのレンズ形心金５１の周囲に巻き付け、その後、加熱焼鈍しすることが望ましい。心金５１はその後除去し、巻き付けたストランド３９が略単一の平面状になり、心金４１の周囲に巻き付けることにより、ステントの形成に適した波状体５２が形成され得るようにする。

本発明に従った別の実施例による体内補装具又はステントが全体として第１０図、第１１図及び第１２図に図示されている。この場合、ストランドは円形断面の小径の心金５３の周囲に巻き付けられている。該ストランドは緊密に巻き付けられたつる巻き状体５４として形成される。その後、心金５３を除去し、ストランドはよりゆるく巻き付けたつる巻き体５５として形成される。例えば、つる巻き体５５は約60°以下のピッチ角度となるように細長くすることが出来る。次いで、このつる巻き体５５は、例えば、10tの空気圧プレスにより略上述した方法にて平坦にし、略単一の平面状の波状体が形成されるようにする。希望するならば、この波状体５６は収容された金型内で軸方向に圧縮し、希望するピッチ角度が得られるようにすることが出来る。この波状体５６は円筒状の心金４１の周囲に巻き付けて体内補装体又はステントを形成するのに適している。

ここで図示したステントは典型的に血管系への埋め込み時に遭遇するであろう屈折した経路を通って移動していくことが出来る。かかるステントは損傷されたり又は大きい曲げ抵抗を受けることなく、比較的小さい半径にて容易に軸方向に曲げることが出来る。

図示した実施例において、各円周方向部分３２は略同一であることが理解されよう。又、本発明の精神の範囲内にて、かかる均一でない形状の円周方向部分を提供することも可能である。例えば、隣接する円周方向部分は異なる形状のものとし、厳密には正円筒体の形状ではないステントが形成されるようにすることが出来る。例えば、テーパ付きの切頭円錐形のステント又は段付きのステントを提供することも出来る。さらに、ある適用例には、膨張可能な部分でのみ構成されずに、膨張可能な部分により接続された膨張不能な部分を含む円周方向部分とすることが適している。又、本発明の精神の範囲内にて、円筒状心金４１等の周囲につる巻状に巻き付けずに、ステントを形成する１又は２以上の円周方向部分を備えるステントを提供することも可能である。

さらに、血管系等内の分岐部分にて治療しようとする狭窄、狭縮等に適用することを目的とする略二股状の構造体を有するステントを提供することも可能である。かかる二股のステント構造体は例えば、２つの異なる単一のステントの対向する端部の一部を接続し、全体として、二股のＹ字形等の構造体を提供することにより形成することが出来る。又、該ステントは複数のつる巻状ストランドを使用して、平行又は非平行の形態にて構成することが出来る。

本発明のステント、特に、その膨張可能な要素を形成するための材料は全体として２つの種類に分類することが出来る。その材料は、エラストマー的又は非エラストマー的なものとすることが出来る。エラストマー的材料の例としては、ばね鋼、ステンレス鋼、ニチール、エルジロイ、NP35Nとして公知の合金等がある。一般に非エラストマー的材料は可鍛性であると特徴づけることが出来る。

タンタル、チタニウム、銀、金及びここで説明したエラストマー的材料の焼鈍ししたものが含まれる。ポリエーテルサルホン、ポリイミド、ポリ炭酸エステル、ポロプロピレン、超高分子量ポリエチレン、炭素繊維、ゲルバー等のようなポリアーを使用しても良い。又、これらの材料には、泡の成長のため、多孔質又は繊維状表面等にて被覆し、又はパイロリティックカーボン、ヘパリン、ヒドロゲル、テフロン材料、シリコン、ポリウレタン等のような非凝塊形成性の材料を被覆することも可能である。ステントはそこから薬剤が浸出するように処理することも出来る。又、一部のステントは生物分解性の材料にて形成することも出来る。何れの場合でも、ステント材料は生物学的に適合性あることを要するのは勿論である。又、ステント材料のストランドは、ワイヤの場合に一般的であるように円形の断面形状とするか、又は、例えば、扁平または矩形の断面形状とすることが出来る。

第１３図乃至第１８図には、及びばね鋼のような弾性材料にて形成されたステントに特に適した埋め込み方法及び挿入システムが図示されている。狭窄又は病変６１が血管６２内に図示されている。ステント３１が全体として符号６３で示したバルーンカテーテル上に位置決めされる。導入管又はプランジャ６４、あるいは、同様のストッパ構造体がカテーテル管６５の外面に沿って位置決めされている。ステント３１は部材６４の末梢方向に位置決めされ、シーズ６６がステント３１を略圧縮状態に保持し、この間、ステント３１の膨張可能な部分は略折り畳まれているか又は閉じられている。第１３図には、さらに、カテーテルのバルーン６７が図示されており、このバルーン６７は病変に対し半径外方に向いた力を作用させ、該バルーン６７を拡張させて全体として第４図に示した広い開放部分を提供し、よって、病変の全体的寸法を小さくし、最初に治療した病変６１ａの全体的形状となるようにする。このとき、バルーン６７は収縮しており、カテーテル６３は末梢方向に動かし、収縮したステント３１が病変６１ａ内に略位置決めされるようにする。次いで、第１５図に図示するように、シーズ６６は略基端方向に動かすことにより引き抜き、ステント３１をシーズ６６から釈放させる。この釈放は略連続的な方法（全体として第１５図に図示）にてステントの隣接する円周方向部分が拡張し得るようにする。

この手順が完了したならば、ステント３１全体が反発し、全体として第１６図に図示された拡張病変６１ａに弾性的に係合する。その後、第１７図に図示するように、カテーテル６３は希望するならば、バルーン６７が拡張病変６１ａに再び略整合するまで略基端方向に動かす。次いで、バルーン６７に圧力を注入し、さらにステント３１を埋め込み、希望に応じて病変をさらに拡張して、第１８図に図示するようにカテーテル１８を除去した後に残る治療済みの病変６１ｂが形成されるようにすることが出来る。

第１９図乃至第２３図には、膨張可能な部分が可鍛性材料にて形成された非エラストマー的ステントに特に適した構造が図示されている。第１９図及び第２０図を参照すると、血管６２内の狭窄又は病変６１には、カテーテル７１の収縮したバルーン７２の上になるステント７１を有するバルーンカテーテル７１が経内腔的方法により到達する。次いで、バルーン７２を周知の方法にて膨張させ、その時点にてステント３１も又その膨張可能な部分を開放させることにより膨張される。中間の拡張位置は第２１図に図示されており、最初に拡張させた病変６１ａが図示されている。第２２図には、バルーン７２による追加的な拡張状態が図示されており、従って、治療済みの病変６１ｂも図示されている。この段階の達成後、バルーンカテーテル７１は第２３図に図示するように除去する。

ステント３１は全体として、第２３図に図示した位置に止まる。それは、可鍛性材料（又はこの場合にはエラストマー的材料）が膨張されて第２３図に図示した寸法になったとき、フープ応力を作用させ、治療済み病変及び血管壁等により提供

される半径方向中方の力により陥入することがないからである。換言すれば、膨張しされたステントのフープ応力はステントが埋め込まれる通路により作用されるフープ力よりも大きい。さらに、バルーンが収縮したステントを開放するのに必要な力はバルーンにより提供されるワープ力よりも小さい。換言すれば、収縮し、又は非伸長状態のステントに作用するフープ応力はカテーテルの加圧されたバルーンが提供するフープ応力よりも小さい。図示した型式の可鍛性ステントの有利なフープ応力の特性に寄与し得る1つの特徴は、拡張法を行うのに必要とされる以上、ステントを膨張させ得る能力を備えることである。例えば、典型的な拡張法及びステントの伸長法においては、挿入又は収縮時の径又は円周の約3倍の寸法にする。図示したような構造のステントの場合、伸長程度は各波状部分の長さ及び脚部間の距離いかんにより、2倍乃至10倍とすることが可能である。この特徴は、使用される特定の材料の可鍛性と相挨って、挿入又は収縮時の約3倍の大きさまでステントを膨張させるのに要するフープ力を軽減する傾向がある。

第24図及び第25図には、本発明に従って埋め込まれたステントを除去し又は移植するためのステント引き抜き方法及び係蹄カテーテルシステムが図示されている。係蹄カテーテルが全体として符号74で図示されている。細長い部材75がカテーテル本体76内に摺動可能に位置決めされている。この細長い部材75はその末梢端にフック部材77を備えている。このフック部材77はステント31内に伸長されたとき、ステント31の一部分を引っ掛ける。図示したプーラ組立体78のような適当な制御構造体を操作して、フック部材が基端方向に動き、その結果、ステントは巻きほどけ始め、開放して、血管62等内を通むことが出来るようになり、細長い部材75を基端方向に連続して動かすことにより、ステントは完全に身体外に出る。

説明の便宜上、典型的なステント31について、次の寸法を掲げる。一例としての可鍛性材料は公称径0.020インチの心金に巻き付けられた径0.005インチのタンタル線である。各脚部46の長さは約0.048インチ程度とし、一体形または能動的な隣接するヒンジ36間の中心間の距離は約0.010インチとする。かかるステントの収縮又は挿入時の典型的な外径は約0.085インチとし、その内径は約0.075インチとする。ステント31の全長は、病変等を治療するのに一般的に必要な値であるように選択し、ステントの全長が収縮又は伸長状態にあるか否かを問わず、略一定の値であるようにする。但し、外側円周方向部分32の脚部46はヒンジを屈曲させたときに、幾分中方に動き、ステントの全長が多少なりとも短くなるようにする。伸長時の典型的な外径は0.140インチとし、内径は0.130インチとする。この典型的な装置において、拡張比は約2.8とする。

上述した本発明の実施例は本発明の基本的原理の適用例の一部を示すものだけであり、当業者は本発明の精神及び範囲から逸脱することなく、幾多の変形例をなし得るものである。

4．〔図面の簡単な説明〕

第1図は本発明による体内補装具を製造する方法の初期の段階を示す斜視図、

第2図は第1図に示した後の段階を示す立面図、

第3図は本発明による完成した体内補装具を略図示する一方、第2図の後の製造段階を示す立面図、

第4図は第3図の線4－4に沿った断面図、

第5図は第3図に図示した体内補装具の一端の拡大部分詳細図、

第6図は別の実施例の体内補装具を製造する方法の初期の段階を示す斜視図、

第7図は円周方向に方向決めする前におけるこの体内補装具の一部分の形状を示す一方、第6図に示した後の段階を示す立面図、

第8図はさらに別の実施例による体内補装具を製造する方法における初期の段階を示す斜視図、

第9図は円周方向に方向決めする前にこの体内補装具の一部分の形状を示す一方、第8図の後の段階を示す立面図、

第１０図はさらに別の実施例の体内補装具の製造方法における初期の段階を示す立面図、

第１１図は第１０図に示した後の段階の立面図、

第１２図は心金上に略つる巻状に巻き付け、この実施例の体内補装具を形成するのに適した材料の長さを示す、第１１図に図示した後の製造段階を示す立面図、

第１３図は本発明による体内補装具を埋め込む方法（この方法は、ばね状の性質の体内補装具に特に適している）における初期の段階を示す断図、

第１４図は第１３図に図示した後の埋め込み方法を示す略断面図、

第１５図は第１４図に図示した後の埋め込み方法を示す略断面図、

第１６図は第１５図に図示した後の埋め込み方法を示す略断面図、

第１７図は第１６図に図示した後の埋め込み方法を示す略断面図、

第１８図は本発明による埋め込みステント又は体内補装具の略断面図、

第１９図は可鍛性材料にて形成された本発明による体内補装具に特に適した埋め込み方法用の体内補装具及びバルーンカテーテルの末梢端の立面図、

第２０図は血管内に位置決めされた体内補装具及びカテーテルの略断面図、

第２１図は第２０図に示した後の埋め込み段階を示す略断面図、

第２２図は第２１図に示した後の埋め込み段階を示す略断面図、

第２３図は本発明による埋め込まれたステント又は体内補装具の略断面図、

第２４図は本発明に従いステント又は体内補装具を移植する係路カテーテルの略断面図、及び

第２５図は第２４図に示した移植方法のさらに別の段階を示す略断面図である。

３１：体内補装具（ステント）

３２：円周方向部分

３４：膨張可能な部片

３５：脚部　　３６：能動的ヒンジ

３７：端部分　　３８：心金

３９：ストランド　　４１：心金

４２：円周方向部分　　４３：自由

４４：心金　　４５：波状体

４６：脚部　　４７：能動的ヒンジ

５１：レンズ形心金　　５３：小径の心金

５５：つる巻き体　　６１：狭窄（病変）

６２：血管　　６３：カテーテル

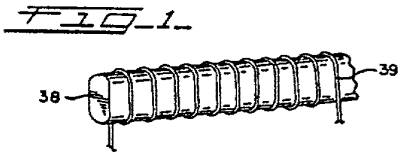
６５：カテーテル管　　６６：シーズ

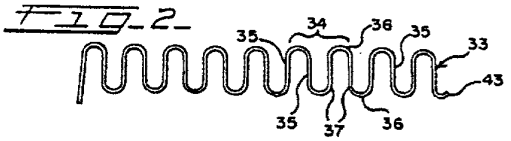
６７：バルーン　　７２：バルーン

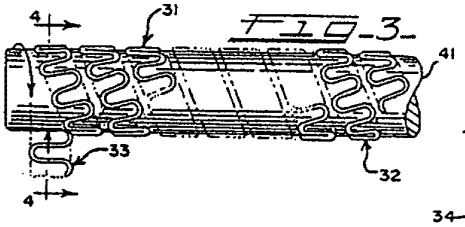
７４：係路カテーテル　　７５：細長い部材

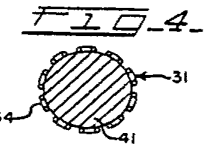
７６：カテーテル本体　　７７：フック部材

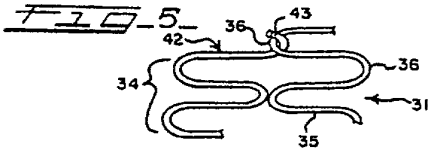
７８：プーラ組立体

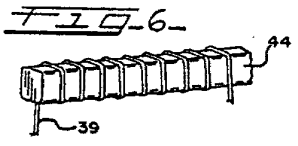


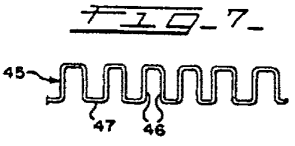












代理人　弁理士　湯浅恭三（外４名）

FIG_8_

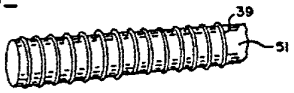


FIG_9_

FIG_10_

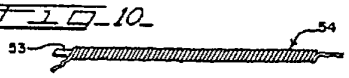


FIG_11_

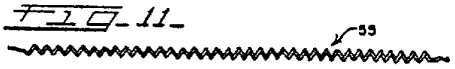


FIG_12_

FIG_13_

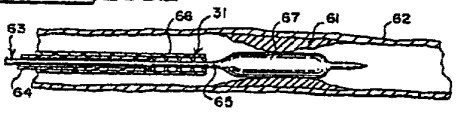


FIG_14_

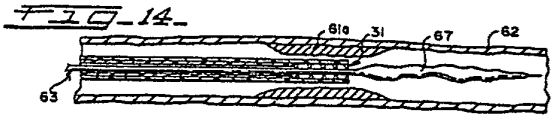


FIG_15_

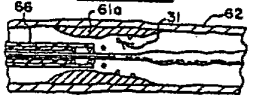


FIG_16_

FIG_17_

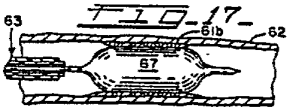
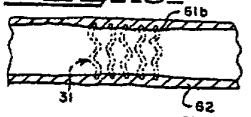
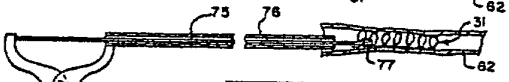


FIG_18_





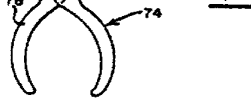


FIG_24_

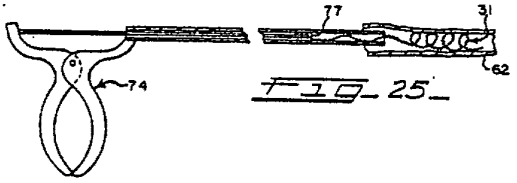


FIG_25_

FIG_19_

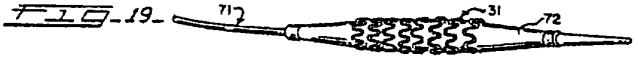


FIG_20_

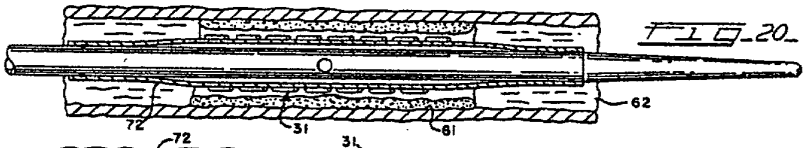


FIG_21_

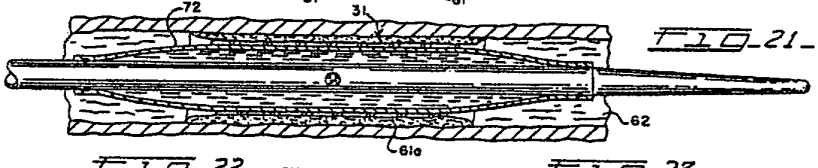


FIG_22_

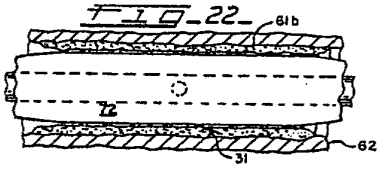
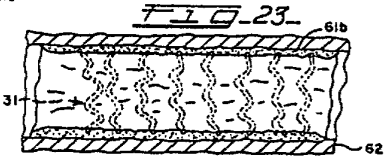


FIG_23_



Reference 1

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 357 003 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 89115943.6

(51) Int. Cl.[5]: A61F 2/00 , A61M 29/02

(22) Date of filing: 29.08.89

(30) Priority: 01.09.88 US 240000

(43) Date of publication of application:
07.03.90 Bulletin 90/10

(84) Designated Contracting States:
DE FR GB IT NL

(71) Applicant: CORVITA CORPORATION
8210 N.W. 27th Street
Miami Florida 33122(US)

(72) Inventor: Pinchuk, Leonard, Ph.D.
9722 S.W. 133rd Place
Miami Florida 33186(US)

(74) Representative: Weickmann, Heinrich, Dipl.-Ing. et al
Patentanwälte H. Weickmann, Dr. K. Fincke F.A. Weickmann, B. Huber Dr. H. Liska, Dr. J. Prechtel Möhlstrasse 22 Postfach 860 820
D-8000 München 86(DE)

(54) Radially expandable endoprothesis.

(57) Radially expandable endoprostheses or stents are provided, as well as their method of manufacture. These stents include a plurality of adjacent generally circumferential sections that are substantially axially positioned with respect to each other. At least one of the generally circumferential sections has a generally circumferentially disposed expandable segment that imparts circumferential and radial expandability to the stent.

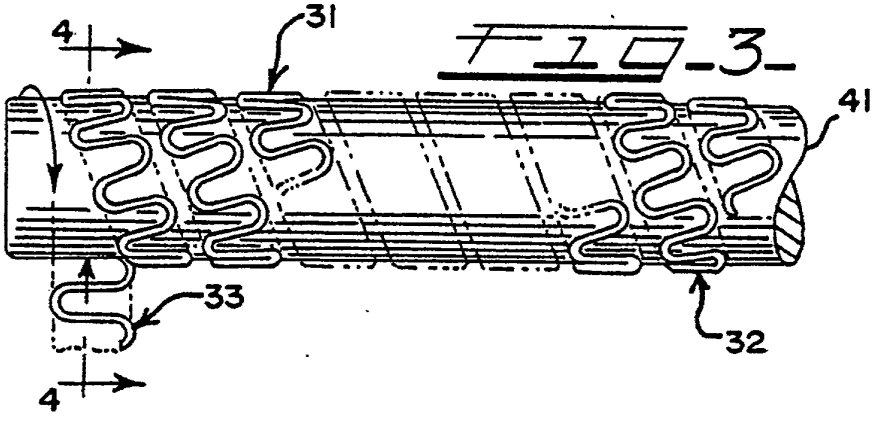


FIG-3

EP 0 357 003 A2

RADIALLY EXPANDABLE ENDOPROSTHESIS

Background and Description of the Invention

The present invention generally relates to endoprosthesis devices, to a procedure for making same, and to the use thereof. More particularly, the invention relates to a generally tubular endoprosthesis that is radially expandable between a generally unexpanded insertion circumference and an expanded implantation circumference which is greater than the unexpanded insertion circumference. Included are a plurality of generally circumferential sections, one or more of which includes one or more expandable segments that are bendable members which are generally collapsed when the endoprosthesis is in its generally unexpanded insertion orientation and which are generally opened when the endoprosthesis is in its expanded implantation orientation.

Endoprostheses are known for treating stenoses, aneurysm conditions and the like. An endoprosthesis device of this type, which is at times referred to as a stent, is typically placed or implanted by a mechanical transluminal procedure. Often a device of this type is percutaneously implanted within the vascular system to reinforce collapsing, partially occluded, weakened or abnormally dilated localized sections of a blood vessel or the like. When endoprostheses or stents are used to treat a stenosis condition, typically such is done in association with a dilation element such as an angioplasty balloon. In this instance, the dilation element or balloon device opens the constriction, and a stent or the like is positioned thereat in order to prevent or at least substantially slow re-formation of the stenosis.

One attribute of a stent is that it is radially compressible and expandable so that it will easily pass through a blood vessel or the like when collapsed and will expand to its implanted size after the stenosis, aneurysm or the like has been reached. It is also desirable that a stent be generally flexible throughout its length so that it is easily maneuverable through bends and curves of the blood vessel or the like. It is typically desirable that a stent or endoprosthesis have a substantial amount of open space so as to allow for endothelialization along its length and to minimize interference with collateral blood vessels and the like. While it is important that a stent or endoprosthesis lodge securely into place at the desired location, it can be advantageous to have a stent that is removable through a transluminal percutaneous procedure, should removal be needed.

Various currently known stent products have structures that are essentially coiled springs. When this type of spring stent is tightly coiled, its diameter is relatively small for insertion through a blood vessel or the like. When the coil is sprung or coiled more loosely, the stent assumes its expanded, implantation orientation. Maass et al U.S. Patent No. 4,553,545 is illustrative of this type of coiled spring stent or endoprosthesis. Multihelix or braided stents are also known, and they suffer from poor maneuverability. They are also difficult to remove once implanted, and they may exhibit numerous exposed, relatively sharp or jagged ends. Palmaz U.S. Patent No. 4,733,665 is representative of an expandable stent of this general type. Gianturco U.S. Patent No. 4,580,568 illustrates a percutaneous endovascular stent formed of stainless steel wire that is arranged in a closed zig-zag pattern somewhat in the nature of a bookbinder spring. Such a structure is somewhat unsymmetrical, and it may be subject to reocclusion due to the very large open space that is typically present between the wires of this type of device. Another type of stent is known as a Statz stent, and it includes a hypodermic tube with longitudinal slots etched into its body. While such a device has a high ratio of unexpanded to expanded diameter, it is a comparatively rigid device which is difficult to maneuver through a tortuous path and is not easily removed in a transluminal manner.

With many of these currently known stent structures, the axial length of the stent decreases as the circumference of the stent increases, which is typically a disadvantage. For example, any such length reduction must be taken into consideration in selecting proper stent sizing for a particular implantation procedure. Also, this attribute of many prior stents requires the passage through the blood vessel or the like of a stent which is longer than the length actually needed for the implantation procedure being performed. This is a particularly difficult problem for procedures in which the stent must be passed through a pathway having twists or turns, especially for a stent structure that is not easily bendable.

The present invention avoids the various deficiencies of these types of prior art structures and provides important and advantageous features of endoprostheses or stents and the use thereof. In summary, the endoprosthesis of this invention includes a plurality of generally circumferential sections that are generally adjacent to one another along their respective opposing generally circumferential edges. At least one of these generally circumferential sections has an expandable segment that imparts radial expandability to the generally circumferential section. The expandable seg-

ment is a bendable, elbow-like member that is bendable between a generally collapsed or closed orientation and a generally opened orientation and is capable of assuming bending orientations between one that is fully closed and one that is fully opened. By this structure, the endoprosthesis or stent has an unexpanded insertion circumference and an expanded implantation circumference, which is greater than the insertion circumference. In addition, this variation in circumference is achieved without substantially changing the axial length of the endoprosthesis or stent. The stent is made by a procedure that is relatively uncomplicated, and, generally speaking, the stent can be transluminally explanted if necessary.

It is a general object of the present invention to provide an improved radially expandable, axially extending endoprosthesis of the type that can be transluminally implanted.

Another object of the present invention is to provide an improved endoprosthesis or stent that can be constructed to have very large radial expansion capabilities.

Another object of this invention is to provide an improved radially expandable axially extending endoprosthesis that is extremely maneuverable and capable of moving through a tortuous path.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis that can, if desired, be transluminally explanted by means of, for example, a snare lead or catheter.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis which includes members that can be spaced apart in a manner that enhances lodging of the endoprosthesis at its implanted site.

Another object of the present invention is to provide an improved axially extending endoprosthesis that can be constructed in order to be radially expandable by an expanding member or balloon of a catheter device and/or can be radially expandable due to spring-like properties of the endoprosthesis.

Another object of this invention is to provide an improved procedure for making an axially extending and/or generally tubular endoprosthesis that is radially expandable.

Another object of the present invention is to provide an improved procedure and system for transluminally explanting an axially extending radially expandable endoprosthesis or stent.

Another object of the present invention is to provide an improved radially expandable endoprosthesis that substantially avoids the presentation of any frayed edges and that generally maintains its axial length throughout various radial expansion positions.

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description.

Brief Description of the Drawings

In the course of this description, reference will be made to the attached drawings, wherein:

Figure 1 is a perspective view illustrating an early step in the procedure of making an endoprosthesis according to the present invention;

Figure 2 is an elevational view illustrating a step subsequent to that shown in Figure 1;

Figure 3 is an elevational view showing a manufacturing step subsequent to that of Figure 2, while also illustrating a substantially completed endoprosthesis in accordance with the present invention;

Figure 4 is a cross-sectional view along the line 4-4 of Figure 3;

Figure 5 is an enlarged detail view of a portion of one end of the endoprosthesis shown in Figure 3;

Figure 6 is a perspective view illustrating an early step in the procedure of making another embodiment of the endoprosthesis;

Figure 7 is an elevational view illustrating a step subsequent to that shown in Figure 6, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

Figure 8 is a perspective view illustrating an early step in the procedure of making a further embodiment of the endoprosthesis;

Figure 9 is an elevational view illustrating a step subsequent to that shown in Figure 8, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

Figure 10 is an elevational view of an early step in the manufacturing procedure for still a further embodiment of the endoprosthesis;

Figure 11 is an elevational view of a step subsequent to that shown in Figure 10;

Figure 12 is an elevational view of a manufacturing step subsequent to that illustrated in Figure 11 and which shows a length of material suitable for winding on a mandrel in a generally helical manner in order to form the endoprosthesis of this embodiment;

Figure 13 is a generally cross-sectional view illustrating an early step in a procedure for implanting an endoprosthesis according to the present invention, this particular procedure being especially suitable for an endoprosthesis having spring-like

properties;

Figure 14 is a generally cross-sectional view illustrating an implantation step subsequent to that shown in Figure 13;

Figure 15 is a generally cross-sectional view illustrating an implantation step subsequent to that of Figure 14;

Figure 16 is a generally cross-sectional view illustrating an implantation step subsequent to that illustrated in Figure 15;

Figure 17 is a generally cross-sectional view of an implantation step subsequent to that illustrated in Figure 16;

Figure 18 is a generally cross-sectional view of an implanted stent or endoprosthesis in accordance with the present invention;

Figure 19 is an elevational view of an endoprosthesis and distal end of a balloon catheter for an implantation procedure that is especially suitable for an endoprosthesis according to the present invention that is constructed of a malleable-type of material;

Figure 20 is a generally cross-sectional illustration of the endoprosthesis and catheter of Figure 19 positioned within a blood vessel;

Figure 21 is a generally cross-sectional illustration of an implantation stage subsequent to that shown in Figure 20;

Figure 22 is a generally cross-sectional illustration of an implantation stage subsequent to that shown in Figure 21;

Figure 23 is a generally cross-sectional illustration of an implanted stent or endoprosthesis according to the present invention;

Figure 24 is a generally cross-sectional illustration of a snare catheter shown explanting a stent or endoprosthesis in accordance with the present invention; and

Figure 25 is a generally cross-sectional illustration showing a further stage of the explantation procedure illustrated in Figure 24.

Description of the Particular Embodiments

A radially expandable axially extending endoprosthesis or stent is generally designated as 31 in Figure 3, as well as in Figure 4. The stent includes a plurality of generally circumferential sections 32. In this illustrated embodiment, each of the circumferential sections 32 are formed from the same continuous, helically wrapped length, such as the undulating length 33 shown in Figure 2.

At least one of the circumferential sections 32 includes at least one expandable segment 34. Expandable segment 34 is a bendable member that typically includes one or more legs 35. Each leg 35 is bendably secured to the rest of the circumferential section 32 by a so-called living joint or hinge that is a unitary or integral component of the leg 35 and the adjacent portion of the circumferential section 32. For example, in the embodiment illustrated in Figures 1 through 5, each leg 35 is bendably joined to another leg 35 through an integral or living hinge 36 which has a generally arcuate shape. When the stent 31 expands, the integral hinge 36 permits end portions 37 of the legs 35 to move farther apart, thereby increasing the circumference and diameter of the stent 31. Of course, the circumference and diameter of the stent 31 can be reduced by forces which move these end portions 37 closer to each other.

An understanding of the manner in which the endoprostheses according to this invention, such as the stent 31, can be made will be obtained from a consideration of Figures 1, 2 and 3. Figure 1 shows a mandrel 38 that has a cross-sectional configuration that is somewhat oval in shape. Mandrel 38 can, for example, be a circular tube that has been flattened on two opposing longitudinal portions in order to provide a cross-section that is generally rectangular in shape, with two opposing end portions thereof being arcuate or rounded. A strand 39 of wire or other material, as generally discussed elsewhere herein, is generally tightly wound over the mandrel to the extent that the strand 39 takes on a cross-sectional shape along the lines of that of the mandrel 38. Preferably, this winding is done in a manner such that there is a substantial spacing between each individual wind of the strand 39. Generally speaking, the tighter the wind and the thinner the mandrel, the closer will be the spacing between the expandable segments 34 of the completed stent 31.

After this winding procedure has been completed, the mandrel 38 is removed from the wound strand 39. The wound strand 39 is then subjected to flattening forces so that the three-dimensional wound strand 39 is transformed into a generally planar shape such as that of the undulating length 33 shown in Figure 2. These forces may be applied by any suitable means. For example, the wound strand 39 can be compressed between two planar surfaces, during which procedure, portions of the wound strand 39 are twisted until the generally uniplanar undulating length 33 is formed. This length has a generally sinusoidal character.

In order to complete formation of the stent 31 illustrated in Figure 3, the undulating length 33 is then wound, in a generally helical manner, around a substantially cylindrical mandrel 41, as is generally illustrated in Figure 3. This generally helical wrapping procedure continues until the desired number of circumferential sections are formed in order to provide a stent 31 of a desired length.

With reference to Figure 5, this winding proce-

dure that is generally illustrated in Figure 3 includes proceeding in a manner so as to avoid the presentation of any loose ends in the completed stent 31. This is readily accomplished by forming the strand 39 and the undulating length 33 so that each end circumferential section 42 has a free end 43 that readily hooks onto an adjacent portion of the stent 31, such as an integral hinge 36 of the circumferential section 32 that is adjacent to and inwardly spaced from the end circumferential section 42. The free end 43 illustrated in Figure 5 is in the nature of a hook portion that readily loops or tucks into the integral hinge 36.

Regarding the embodiment shown in Figures 6 and 7, the mandrel around which the strand 39 is wound is a substantially rectangular mandrel 44. As a result, the generally planar structure that is subsequently formed is an undulating length 45 that includes a plurality of legs 46 joined by a unitary or integral hinge or living hinge 47 that is typically less arcuate than the integral hinge 36. This undulating length 45 is then formed into an endoprosthesis or stent by helically winding same on a structure such as the cylindrical mandrel 41.

Another embodiment of the endoprosthesis or stent is made in a manner generally illustrated in Figures 8 and 9. Here, the mandrel is a generally lens-shaped mandrel 51 which has a transverse cross-section that can be described as defining two convex surfaces positioned in back-to-back relationship with each other. Much in the same manner as the other embodiments, the elongated strand 39 is wound around the lens-shaped mandrel 51. The mandrel 51 is subsequently moved therefrom, and the wound strand 39 is rendered substantially uniplanar in order to form undulating length 52 that is suitable for forming into a stent by wrapping around the mandrel 41.

Another embodiment illustrating the manufacture of an endoprosthesis or stent in accordance with this invention is generally illustrated in Figures 10, 11 and 12. A strand is wound around a small-diameter mandrel 53. In this case, the strand is formed into a tightly wound helix 54. Thereafter, the mandrel 53 is removed, and the strand is formed into a more loosely wound helix 55. For example, the helix 55 can be elongated such that the pitch angle is less than approximately 60°. This helix 55 is then flattened generally in the manner previously discussed, for example to 15 tons in a pneumatic press, in order to form a generally uni-planar undulating length 56. If desired, the length 56 can be axially compressed in a contained mold to the desired pitch angle. Length 56 is suitable for winding around cylindrical mandrel 41 in order to thereby form an endoprosthesis or stent.

Stents illustrated herein are typically capable of moving through a tortuous path that may be encountered in vascular system implantation. Such stents can be easily axially bent over a relatively small radius without damage or high bending resistance.

It should be appreciated that in the illustrated embodiments, each circumferential section 32 is generally identical. It is also possible within the spirit of the invention to provide circumferential sections that are not this uniformly shaped. For example, the circumference of adjacent sections can differ in order to form a stent that is not strictly shaped in the nature of a right cylinder. For example, tapered, truncated cone-shaped stents or stepped stents can be provided. In addition, in some applications, it can be suitable to include circumferential sections that are not composed entirely of expandable segments, but instead could include non-expandable portions that are joined by expandable segments. It also may be possible to provide stents within the spirit of the present invention which include one or more circumferential sections that form a stent device without proceeding with helical winding around cylindrical mandrel 41 or the like. It is also possible to provide a stent that has a generally bifurcated structure for use in situations in which the stenosis, aneurysm or the like that is to be treated is at a branching location within the vascular system or the like. Such a bifurcated stent structure can be formed, for example, by joining portions of the opposing ends of two different unitary stents in order to provide a total structure that is bifurcated, Y-shaped or the like.

The materials out of which stents according to the present invention can be made, and especially the expandable segments thereof, fall into two general categories. The material can be either elastic or generally inelastic. Examples of elastic materials include spring steels, stainless steel, Nitinol, Elgiloy, an alloy known as NP36N, and the like. Generally inelastic materials can be characterized as being malleable. Included are tantalum, titanium, silver, gold, and annealed versions of the elastic materials described herein. Polymers may also be used, such as polyether sulfone, polyimide, polycarbonate, polypropylene, ultra high molecular weight polyethylene, carbon fiber, Kevlar, and the like. It is also possible to coat these materials with porous or textured surfaces for cellular ingrowth and the like or with non-thrombogenic agents such as pyrolytic carbon, heparin, hydrogels, Teflon materials, silicones, polyurethanes and the like. The stents can be treated so that drugs can be eluted therefrom. It is also possible that certain stents may be made of biodegradable materials. In any event, the stent material, of course, is to be biocompatible.

Figures 13 through 18 illustrate an implantation

procedure and an insertion system that is particularly suitable for stents that are constructed of an elastic material such as spring steel. A stenosis or lesion 61 is shown within a blood vessel 62. The stent 31 is positioned on a balloon catheter, generally designated as 63. An introducer tube or plunger 64, or a similar stop-providing structure, is positioned along the outside surface of the catheter tube 65. The stent 31 is located distally of the member 64, and a sheath 66 holds the stent 31 in a generally compressed state during which the expandable segments of the stent 31 are generally collapsed or closed. Figure 13 further shows the balloon 67 of the catheter in a mode in which it is exerting outwardly radially directed forces on the lesions in order to dilate same to provide a wider opening as generally illustrated in Figure 14 in order to thereby generally reduce the overall extent of the lesion 61a. At this time, the balloon 67 is collapsed, and the catheter 63 is moved in a distal direction so that the collapsed stent 31 is generally positioned within the lesion 61a. Next, as illustrated in Figure 15, the sheath 66 is withdrawn by moving same in a generally proximal direction, and the stent 31 is released from the sheath 66. This release can be such that adjacent circumferential sections of the stent expand in a generally sequential manner, which is generally illustrated in Figure 15.

After this procedure is completed, the entire stent 31 has been sprung, and it springingly engages the dilated lesion 61a, which is generally illustrated in Figure 16. Thereafter, as seen in Figure 17, the catheter 63 can be moved in a generally proximal direction until the balloon 67 is again generally aligned with the dilated lesion 61a, as desired. Then, the balloon 67 can be pressurized in order to further implant the stent 31 and in order to further dilate the lesion as desired so as to form a treated lesion 61b which remains after the catheter 63 is removed, as is generally shown in Figure 18.

Figures 19 through 23 show an arrangement that is especially suitable for non-elastic stents in which the expandable segments thereof are made of malleable material. With reference to Figures 19 and 20, a stenosis or lesion 61 within blood vessel 62 is transluminally reached by a balloon catheter 71 having a stent 31 overlying the collapsed balloon 72 of the catheter 71. The balloon 72 is then expanded in a well-known manner, at which time the stent 31 is also expanded by opening the expandable segments thereof. An intermediate dilation position is shown in Figure 21, and an initially dilated lesion 61a is shown therein. Figure 22 shows additional dilation by the balloon 72, and the thus treated lesion 61b is also shown. After this stage is achieved, the balloon catheter 71 is removed, as shown in Figure 23.

The stent 31 remains in place as generally illustrated in Figure 23 because the malleable material (or for that matter an elastic material) exerts a hoop stress when it is expanded to the size illustrated in Figure 23 such that it will not collapse by inwardly directed radial forces presented by the treated lesion and vessel wall or the like. In other words, the hoop stress of the expanded stent is greater than the hoop forces exerted by the passageway within which the stent is implanted. In addition, the force required to open the collapsed stent by the balloon is less than the hoop force provided by. the balloon. In other words, the hoop stress of the collapsed or unextended stent is less than that of the hoop force provided by the pressurized balloon of the catheter. One feature that can contribute to the advantageous hoop stress properties of the malleable stents of the type illustrated in the drawings is the ability of the stent to expand well beyond that needed to effect the dilation procedure. For example, a typical dilation procedure and stent extension is one in which the fully extended dilating diameter or circumference is approximately three times the insertion or collapsed diameter or circumference. With stent structures such as those illustrated in the drawings, the amount of possible expansion can be on the order of twelve times. This feature, together with the malleability of the particular material utilized, tends to reduce the hoop force that is needed to expand the stent to about three times its insertion or collapsed configuration.

Figures 24 and 25 illustrate a stent withdrawal procedure and a snare catheter system that can be used to remove or explant implanted stents according to the present invention. A snare catheter, generally designated as 74, is illustrated. An elongated member 75 is slidably positioned within a catheter body 76. Elongated member 75 includes a hook member 77 at its distal end. When extended into the stent 31, the hook member 77 snares a portion of the stent 31. A suitable control structure, such as the puller assembly 78 illustrated is manipulated in order that the hook member moves in a proximal direction, with the result that the stent begins to uncoil and is opened to such an extent that it can be passed through the blood vessel 62 or the like until it is totally removed from the body by continued movement of the elongated member 75 in the proximal direction.

For purposes of illustration, the following details are given regarding a typical stent 31. An exemplary malleable material is tantalum wire having a diameter of 0.005 inch wound on a mandrel having a nominal diameter of 0.020 inch. The length of each leg 46 is on the order of about 0.048 inch, and the center-to-center spacing between ad-

jacent integral or living hinges 36 is about 0.042 inch. A typical collapsed or insertion outer diameter for such a stent is about 0.085 inch, with the inner diameter thereof being about 0.070 inch. The overall length of the stent 31 is selected to be that generally needed to treat the lesion or the like inasmuch as the overall length of the stent will remain substantially the same whether it is collapsed or extended, except to the degree that the legs 46 of the exterior circumferential sections 32 move somewhat inwardly as the hinge is flexed, thereby somewhat nominally decreasing the overall length of the stent.

It will be understood that the embodiments of the present invention which have been described are illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

Claims

1. A radially expandable axially extending endoprosthesis, comprising:
a plurality of generally circumferential sections, said generally circumferential sections being substantially adjacent to one another and oriented with respect to each other in order to thereby define an axially extending endoprosthesis;
at least one of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference; and
said expandable segment of the generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability to the generally circumferential section.

2. The endoprosthesis according to claim 1, wherein said foldable member includes a generally elbow-like member.

3. The endoprosthesis according to claim 1, wherein said foldable member includes a living hinge unitarily connecting a pair of legs.

4. The endoprosthesis according to claim 1, wherein said generally circumferential sections form a substantially cylindrical endoprosthesis.

5. The endoprosthesis according to claim 1, wherein said generally circumferential sections form a continuous helix that defines the axially extending endoprosthesis.

6. The endoprosthesis according to claim 5, wherein an outside one of said generally circumferential sections has a free end having hook means for engaging an adjacent one of said generally circumferential sections.

7. The endoprosthesis according to claim 1, wherein said expandable segment is a generally foldable elastic spring-like member, and wherein the unexpanded insertion circumference of the endoprosthesis is maintained by an overlying sheath.

8. The endoprosthesis according to claim 1, wherein said expandable segment is a generally foldable malleable member, and wherein the expanded implantation circumference is achieved by radially directed forces from an expandable element of a catheter.

9. The endoprosthesis according to claim 1, wherein said generally foldable member is substantially U-shaped.

10. The endoprosthesis according to claim 5, wherein said continuous helix includes a plurality of said generally foldable members, each of which is substantially U-shaped, alternating ones of which are substantially oppositely oriented.

11. The endoprosthesis according to claim 1, wherein said generally foldable member is substantially V-shaped.

12. The endoprosthesis according to claim 5, wherein said continuous helix includes a plurality of said generally foldable members, each of which is substantially V-shaped, alternating ones of which are substantially oppositely oriented.

13. The endoprosthesis according to claim 1, wherein said endoprosthesis is generally tubular, and respective circumferential edges of respective generally circumferential sections are generally adjacent to each other.

14. The endoprosthesis according to claim 1, wherein said expandable segment of the generally circumferential section had been formed by winding a strand on a shaped mandrel to form a wound strand which was subsequently flattened to a generally uni-planar configuration.

15. A method for making a radially expandable axially extending endoprosthesis, comprising:
selecting a mandrel having a relatively small cross-sectional area in order to provide a narrow wrapping surface;
winding an elongated strand around said narrow wrapping surface and removing the strand from said small mandrel so as to form a wound strand having a plurality of turns therein, said turns being shaped to generally conform to the shape of said cross-sectional area;
subjecting said wound strand to flattening forces in order to form a generally uni-planar undulating strand length;
providing another mandrel having a cross-sectional area greater than that of said relatively small man-

drel; and
generally helically wrapping said undulating strand length around said another mandrel and removing said another mandrel to thereby provide a radially expandable axially extending endoprosthesis.

16. The method according to claim 15, further including hooking a free end of said undulating strand length onto an adjacent portion of said undulating strand length after said generally helically wrapping step has been initiated.

17. The method according to claim 15, wherein said providing step includes selecting the another mandrel to have a generally cylindrical outer surface.

18. The method according to claim 15, wherein said selecting step includes choosing the relatively small mandrel so that the wrapping surface is generally oval in shape.

19. The method according to claim 15, wherein said selecting step includes choosing the relatively small mandrel so that the wrapping surface is generally rectangular in shape.

20. The method according to claim 15, wherein said selecting step includes choosing the relatively small mandrel so that the wrapping surface is generally lens-shaped in shape.

21. The method according to claim 15, wherein said selecting step includes choosing the relatively small mandrel so that the wrapping surface is generally circular in shape.

22. A method for transluminally explanting an endoprosthesis implanted within a body, the method comprising:
percutaneously inserting an elongated member into a blood vessel or the like which has a radially expanded axially extending endoprosthesis implanted therewithin;
manipulating a proximal portion of the elongated member from a location exterior of the body until a distal end portion of the elongated member snares a portion of the implanted endoprosthesis;
thereafter sliding the elongated member in a proximal direction by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis,
continuing said sliding step in order to reduce the radial size of the endoprosthesis to an extent that it will pass through the blood vessel or the like; and
completely removing the elongated member from the body by generally reversing the percutaneous insertion step until the snared portion of the endoprosthesis has been explanted and withdrawing the endoprosthesis of reduced radial size.

23. The method according to claim 22, wherein said sliding step includes at least partially uncoiling the radially expanded endoprosthesis.

24. The method according to claim 22, wherein said continued sliding step reduces the radial size of the endoprosthesis until it is generally less than the radius of the blood vessel or the like.

25. A device for transluminally explanting an endoprosthesis implanted within a body, the device comprising:
an elongated member that is percutaneously insertable into a blood vessel or the like which has a radially expanded axially extending endoprosthesis implanted therewithin, said elongated member having a proximal portion exterior of the body;
snaring means at a distal end of the elongated member;
means for manipulating a proximal portion of the elongated member from a location exterior of the body, said manipulating means facilitating engagement of said snaring means with a portion of the implanted endoprosthesis;
puller means for sliding the elongated member in a proximal direction by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis;
said puller means further being for reducing the radial size of the endoprosthesis to an extent that it will pass through the blood vessel or the like; and
means for completely removing the elongated member from the body until the endoprosthesis of reduced radial size has been fully explanted.

26. The device according to claim 25, wherein said puller means is for uncoiling the endoprosthesis being explanted.

27. The device according to claim 25, further including a catheter body within which said elongated member is slidably mounted.

28. The device according to claim 25, wherein said snaring means includes a hook member.

29. An implantable and explantable endoprosthesis system, comprising a radially expandable axially extending endoprosthesis and a device for transluminally explanting the endoprosthesis;
said endoprosthesis includes:
a plurality of generally circumferential sections, said generally circumferential sections being substantially adjacent to one another and generally axially oriented with respect to each other in order to thereby generally define an endoprosthesis,
at least one of said generally circumferential sections includes an expandable segment that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference, and
said expandable segment of the generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a
generally opened orientation so as to impart radial expandability to the generally circumferential sec-

tion; and
said device for transluminally explanting the endoprosthesis includes:
an elongated member that is percutaneously insertable into a blood vessel or the like within which said endoprosthesis has been radially expanded and implanted, said elongated member having a proximal portion exterior of the body,
snaring means at a distal end of the elongated member,
means for manipulating a proximal portion of the elongated member from a location exterior of the body, said manipulating means facilitating engagement of said snaring means with one of said circumferential sections of the implanted endoprosthesis,
puller means for sliding the elongated member in a proximal direction by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis,
said puller means further being for reducing the radial size of the endoprosthesis to less than said expanded implantation circumference and such that it will pass through the blood vessel or the like, and
means for completely removing the elongated member from the body until the endoprosthesis of reduced radial size has been fully explanted.

30. The system according to claim 29, wherein said generally circumferential sections form a continuous helix that defines the axially extending endoprosthesis, and wherein said puller means is for at least partially uncoiling said helix.

31. The endoprosthesis according to claim 30, wherein said continuous helix includes a plurality of said generally foldable members, alternating ones of which are substantially oppositely oriented.

32. The system according to claim 29, wherein said foldable member of the endoprosthesis includes a generally elbow-like member.

33. The system according to claim 29, wherein said foldable member of the endoprosthesis includes a living hinge unitarily connecting a pair of legs.

34. The system according to claim 29, wherein said expandable segment of the generally circumferential section of the endoprosthesis had been formed by winding a strand on a shaped mandrel to form a wound strand, said wound strand having been subsequently flattened, and said circumferential section is defined by said flattened wound strand.

FIG 1

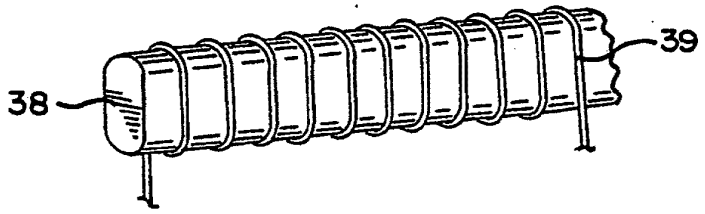


FIG 2

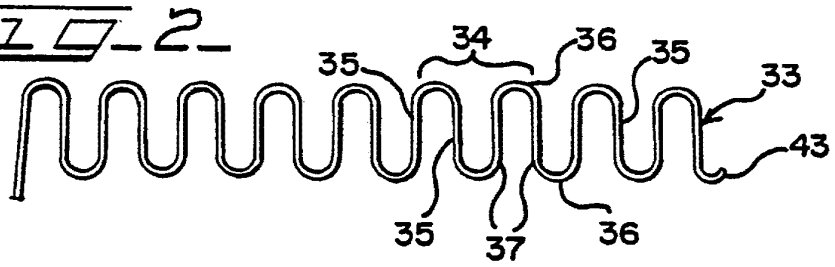


FIG 3

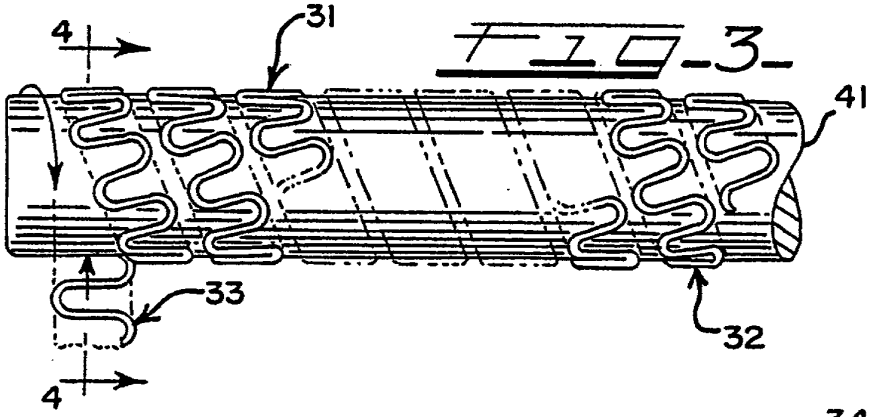


FIG 4

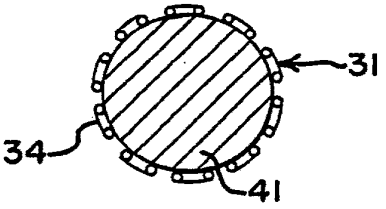


FIG 5

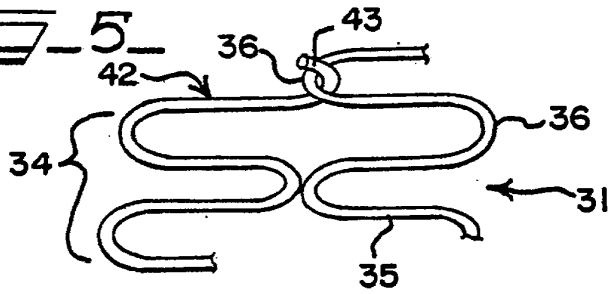


FIG 6

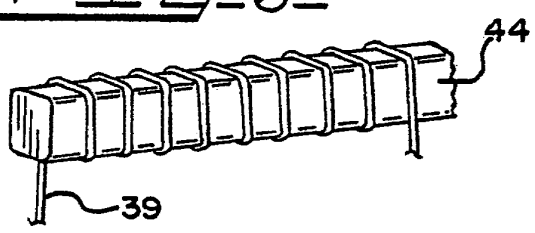
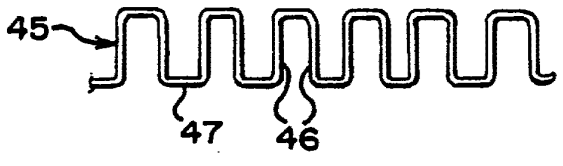


FIG 7



Neu eingereicht
Nouvellement déposé

FIG_8_

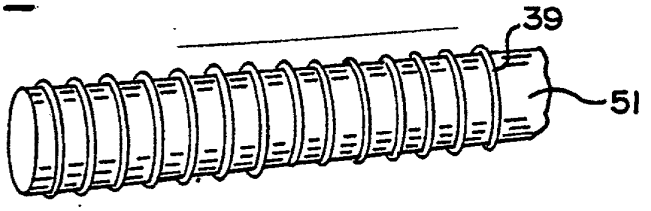


FIG_9_

FIG_10_

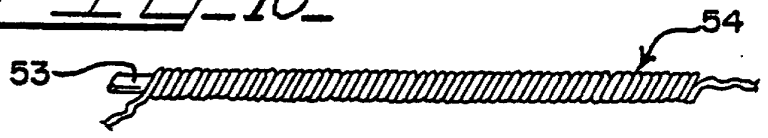


FIG_11_

FIG_12_

FIG_13_

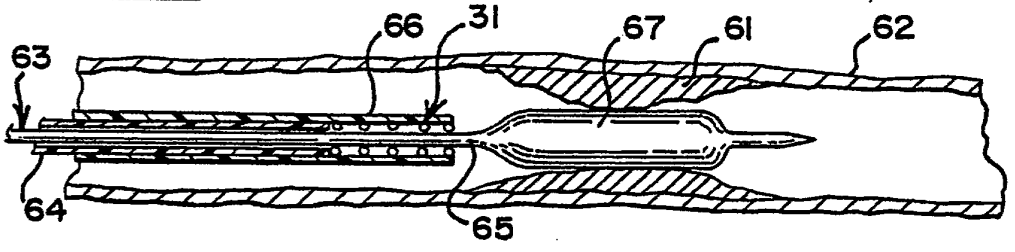


FIG_14_

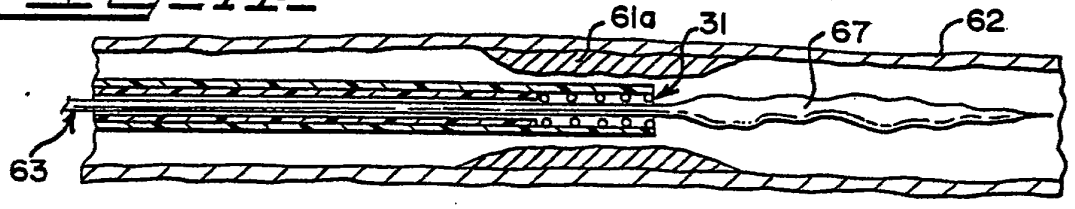


FIG_15_

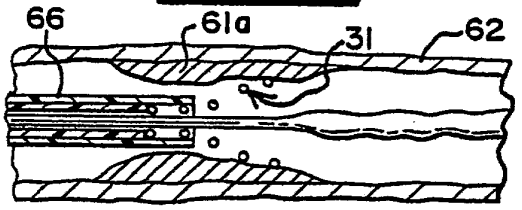


FIG_16_

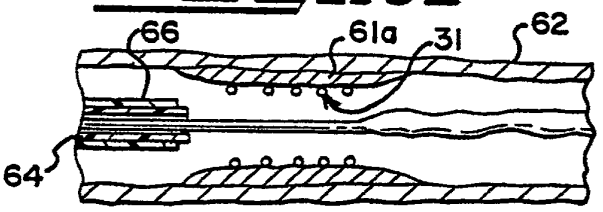


FIG_17_

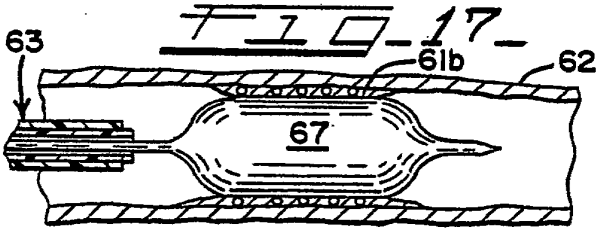
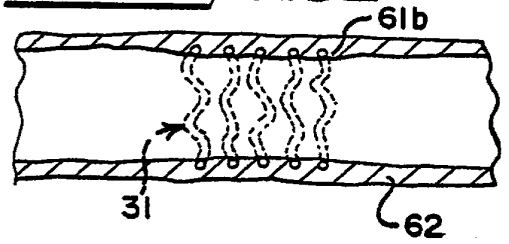


FIG_18_



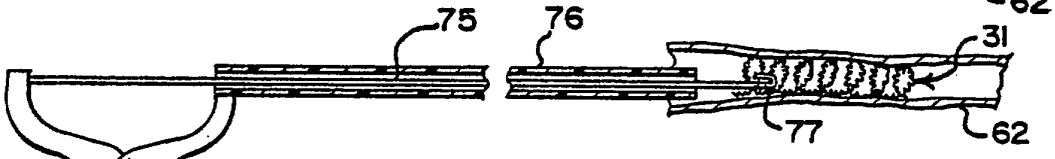
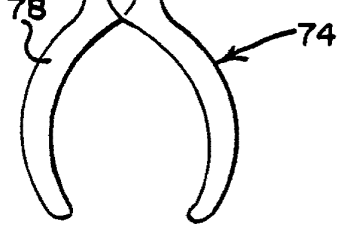
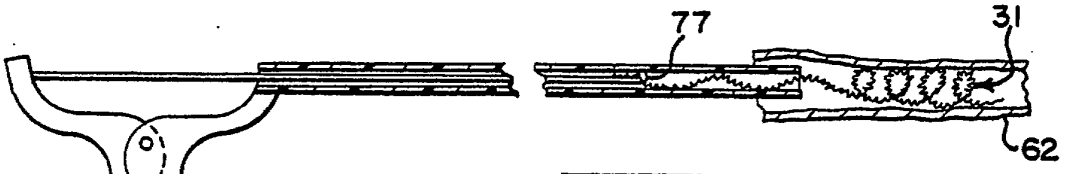


FIG_24_





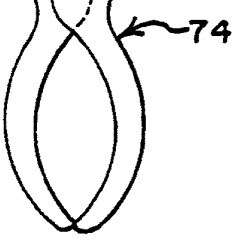


FIG_25_

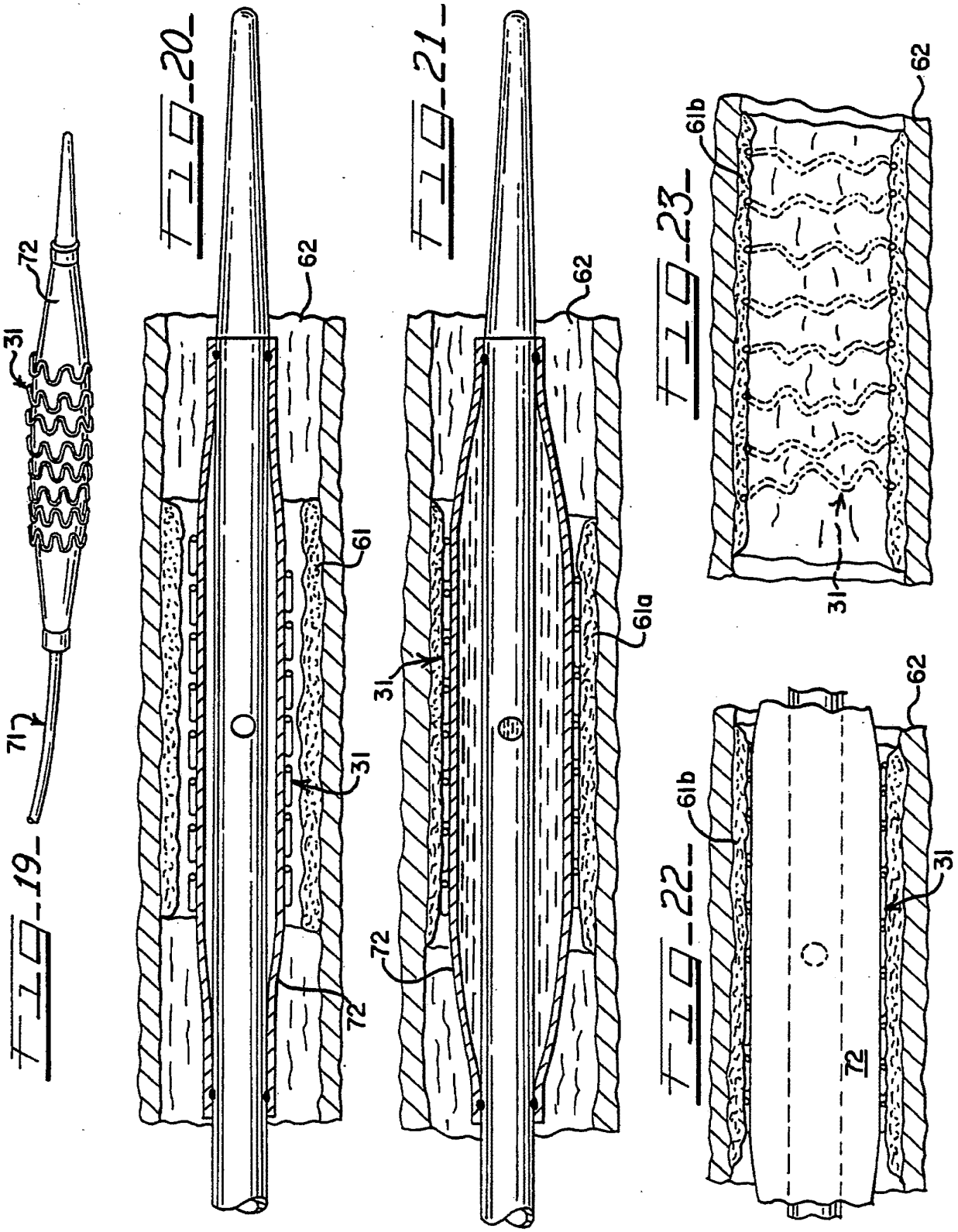


FIG-19

FIG-20

FIG-21

FIG-22

FIG-23

RCE IFW

PTO/SB/30 (04-05)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant **must** request non-entry of such amendment(s).
   - a. ☐ Previously submitted. If a final Office Action is outstanding, any amendments filed after the final Office Action may be considered as a submission even if this box is not checked.
     - i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____.
     - ii. ☐ Other _____.
   - b. ☒ Enclosed
     - i. ☒ Amendment/Reply
     - ii. ☐ Affidavit(s)/Declaration(s)
     - iii. ☐ Information Disclosure Statement (IDS)
     - iv. ☐ Other _____.

2. Miscellaneous
   - a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
   - b. ☐ Other _____.

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
   - a. ☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No. 18-0350. I have enclosed a duplicate copy of this sheet.
     - i. ☒ RCE fee required under 37 CFR 1.17(e).
     - ii. ☒ Extension of Time fee (37 CFR 1.136 and 1.17).
     - iii. ☐ Other _____.
   - b. ☐ Check in the amount of $ _____ is enclosed.
   - c. ☒ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	Joshua L. Cohen	Date	8/6/2007
Name (Print/Type)	Joshua L. Cohen	Registration No. (Attorney/Agent)	38,040

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	Denise Morgan		
Name (Print/Type)	Denise Morgan	Date	8/6/2007

This collection of information is required by 37 CFR 1.114. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

08/09/2007 TLUU11 00000015 09977826
01 FC:1801 790.00 DP

PTO/SB/21 (09-04) (AW 10/2004)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/Declaration(s)
- ☒ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (**Appeal Notice, Brief, Reply Brief**)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below): RCE transmittal (in dup); PTO-2038; post card receipt

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm Name	RatnerPrestia		
Signature	Joshua L. Cohen		
Printed Name	Joshua L. Cohen		
Date	8/6/07	*Registration No.*	38,040

CERTIFICATE OF TRANSMISSION / MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Denise Morgan		
Typed or Printed Name	Denise Morgan	*Date*	8/6/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, ALEXANDRIA, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/22 (10-04) (12-04)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2005** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818))*	Docket Number (Optional) BSI-010US4
Application Number 09/977,826	Filed 10/15/2001
For Endoluminal Stent	
Art Unit 3738	Examiner William H. Matthews

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☐ One month	(37 CFR 1.17(a)(1))	$120	$60	$_____
☐ Two months	(37 CFR 1.17(a)(2))	$450	$225	$_____
☒ Three months	(37 CFR 1.17(a)(3))	$1020	$510	$1020.00
☐ Four months	(37 CFR 1.17(a)(4))	$1590	$795	$_____
☐ Five months	(37 CFR 1.17(a)(5))	$2160	$1080	$_____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 18-0350. I have enclosed a duplicate copy of this sheet.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number: 38,040.

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

Joshua L. Cohen — *Signature*

August 6, 2007 — *Date*

Joshua L. Cohen — *Typed or Printed Name*

610-407-0700 — *Telephone Number*

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

08/09/2007 TLUU11 00000015 09977826

02 FC:1253 1020.00 OP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoechea
Filed:	October 15, 2001
Title:	ENDOLUMINAL STENT
TC/A.U.:	3738
Examiner:	Willaim H. Matthews
Confirmation No.:	4645
Docket No.:	BSI-010US4

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please amend the above-identified application as follows:

☐ **Amendments to the Specification** begin on page of this paper.

☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet(s).

☐ **Amendments to the Abstract** are on page of this paper. A clean version of the Abstract is on page of this paper.

☒ **Remarks/Arguments** begin on page 7 of this paper.

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1 - 19. (Cancelled)

20. (Previously Presented) A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

21. (Cancelled)

22. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

26. (Withdrawn) A stent as recited in claim 22 wherein said axially aligned segments are connected to one another by a tubular fabric element.

27. (Previously Presented) A stent as recited in claim 20 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment.

28. (Previously Presented) A stent as recited in claim 27 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment.

29. (Previously Presented) A stent as recited in claim 28 wherein at least one of said first and second additional stent segments is of frustoconical shape and is further

combined with a third an additional stent segment, one end of which includes a mating frustoconical shape.

30. (Previously Presented) A stent as recited in claim 29, wherein said mating frustoconical stent segments are adapted to be separately placed in a bifurcated artery and then, by expansion of one of said frustoconical stent segments, secured to one another.

31. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. (Previously Presented) An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

34. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

35. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a staple.

36. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is wire twisted into loop.

37. (Withdrawn) An endoluminal stent as claimed in claim 36 wherein said wire is nitinol.

38. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is bead of thermoplastic material.

39. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

40. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said stent is at least partially covered in fabric.

41. (Previously Presented) An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

42. (Cancelled)

43. (Previously Presented) An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is gold.

50-53. (Cancelled)

54. (Currently Amended) A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to an abutting ~~a~~ juxtaposed apex of a neighboring hoop.

55. (Previously Presented) A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. (Previously Presented) A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. (Previously Presented) A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

58. (Withdrawn) A method of reinforcing a body vessel using a tubular sheath disposed between an entry location in a body and an implantation location, said method comprising the steps of:

a. providing a stent as recited in claim 56;

b. compressing the stent into its compressed configuration;

c. inserting the compressed stent into the tubular sheath;

d. delivering the compressed stent through the tubular sheath to the implantation location; and

e. withdrawing the sheath while holding the stent at the implantation location within the vessel and expanding the stent within the implantation location as the sheath is withdrawn by permitting the self-expandable stent, as the constraint of the sheath is removed to return to said expanded configuration;

whereby the stent is securely disposed in the implanted state against said body vessel.

59. (Withdrawn) A method according to claim 58, wherein said stent is comprised of a shape memory material.

60. (Withdrawn) A method according to claim 59, wherein said shape memory material is nitinol and step (b) is performed at low temperature.

61. (Withdrawn) A method according to claim 58, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

62. (Withdrawn) A prosthesis for placement in a body lumen comprising a tubular graft supported and adapted to be retained in said lumen by a stent as recited in claim 56.

Remarks/Arguments:

The pending claims are 20, 22-25, 27-33, 39, 41, 43-49, 54-57. Claim 54 has been amended. No new matter is introduced therein.

In order to expedite prosecution, claim 54 has been amended to recite, in part:

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent . . . .
>
> * * * * * * *
>
> means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

Claim 54 has been alternately rejected as anticipated by Cragg (U.S. Patent No. 5,405,377) and Fontaine (U.S. Patent No. 5,370,683) under 35 U.S.C. § 102(e) and as anticipated by Wolff (U.S. Patent No. 5,104,404) and Furui (JP 4-25755) under 35 U.S.C. § 102(b).

As indicated above, claim 54 has been amended to recite, in part, "each of said hoops being non-helical." In Cragg and in Fontaine, each of the hoops is not non-helical. Claim 54 has also been amended to recite "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." In Wolff and Furui, there are no abutting apices.

Since claim 54 is not subject to rejection as anticipated by any of Cragg, Fontaine, Wolff, and Furui, Applicants respectfully request allowance of claim 54. For at least the same reasons, the claims that depend from claim 54 are also not anticipated.

Claim 56, rejected under § 112, first paragraph, recites, in part:

> the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Para. 6, p. 3 of the present Office Action states

> Claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" which is not disclosed in the specification. The specification only provides support for the phrase "substantially perpendicular." (emphasis in original)

Para. 2, p. 2 of the present Office Action also states that the specification

> does not provide support for the limitation "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis

> of the tubular member." The specification only provides support for "substantially perpendicular." (emphasis in original)

In connection with this rejection of claim 56, it is respectfully submitted that Applicants' specification clearly supports an embodiment in which each hoop is perpendicular. For example, page 68, lines 7-8 (Abstract) refers to "an endoluminal stent having perpendicular hoop members." (emphasis added) Also, page 44, lines 19-23 describes axially aligned stent segments

> each of the requests [sic] comprising one or more adjacent hoops, perpendicular to a common axis. . . . (emphasis added)

The specification therefore also has support for "perpendicular" without the term "substantially."

As indicated above, page 68, lines 7-8 refers to an embodiment of "an endoluminal stent having perpendicular hoop members." This phrase refers to "hoop members," rather than a single hoop member. Also, page 44, lines 19-23 describes an embodiment in which "each" of the stent segments comprises one or more adjacent hoops that are perpendicular to a common axis. Finally, figures of the application illustrate at least one embodiment in which all hoops are oriented in this manner. The application therefore has support for an embodiment in which "each" hoop has vertices that lie in a common plane perpendicular to the longitudinal axis.

In view of the foregoing, it is respectfully submitted that the rejection of claim 56 should be withdrawn and that claim 56 should be allowed. For at least these reasons, the claims that are dependent on claim 56 are also not anticipated.

Conclusion

It is respectfully submitted, in view of the amendments and remarks herein, that the claims are allowable over the references cited in the Office Action. Favorable reconsideration is respectfully requested.

Respectfully submitted,

Joshua L. Cohen

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicants

JLC/SW/dhm

Dated: August 6, 2007

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

August 6, 2007

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2001

Application or Docket Number
09977826
BSI-010US4

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	53	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	53 minus 20=	* 33
INDEPENDENT CLAIMS	11 minus 3 =	* 8
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	370.00	OR	BASIC FEE	740.00
X$ 9=		OR	X$18=	594
X42=		OR	X84=	672
+140=		OR	+280=	0
TOTAL		OR	TOTAL	2006

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 37	Minus	** 53	* —
Independent	* 3	Minus	*** 11	= —
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

6/26/06

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 37	Minus	** 53	* 0
Independent	* 3	Minus	*** 11	= 0
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

8/8/07

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 37	Minus	** 53	* —
Independent	* 3	Minus	*** 11	= —
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 8/01)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 08/22/2007

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-41,43-49 and 54-62* is/are pending in the application.

4a) Of the above claim(s) *26,34-38,40 and 58-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-25,27-33,39,41,43-49 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-16-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8-8-07 have been fully considered but they are not persuasive.

2. Regarding the rejection under 35 USC 112 of claims 56 and 57, Applicant contends support is provided at p68 lines 7-8, p 44 lines 19-23, and "figures of the application". Applicant did not specify which "figures", and Examiner is unaware of a figure providing support for claims 56 and 57. Examiner disagrees with Applicant's position because the specification only provides support for each hoop being "substantially perpendicular" in combination with hoops having vertices connected to vertices of an adjacent hoop. This is described in connection with figures 1-4 at page 23 lines 20-23, in the current abstract, as amended on 3-1-02, and in claim 18 as originally filed. Page 44, lines 19-23 describes figures 22-23 and only state that "one or more hoops" are perpendicular rather than each or all hoops.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected because independent claims 54 and 56 each recite vertices that abut which is not disclosed in the specification. The specification only disclose juxtaposed vertices. Juxtapose is defined by Merriam Webster's Collegiate Dictionary, 10th Ed. as: to place side by side and synonymous with "adjacent". Adjacent is described as: may or may not imply contact , but always implies absence of anything of the same kind in between.

6. Claims 20,22-25,27-33,39,41,43-49,54-55 are rejected because independent claim 54 recites "non-helical" in combination with each hoop being substantially perpendicular and having connected apices. The specification only disclose embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical "offset" feature.

7. Claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" in combination with axially abutting vertices of adjacent hoops, which is not disclosed in the specification. The specification do provide support for the phrase "substantially perpendicular" for the combination, and "perpendicular" for the straight stents of figures 22-23 but only for "one or more" rather than each or all hoops. This is also supported by original claim 18, the description of figures 1-4, and the amended abstract of 3-1-02.

8. With further regard to claim 56, Applicant's arguments regarding the subject matter of page 68 (abstract) are moot because that abstract was replaced on 3-1-02.

Furthermore, it is noted that in the parent application (08/312,881), the abstract did not contain the limitations Applicant relies on in the arguments (remarks, page 8). Because the specification fail to support the combination (perpendicular and connected abutting apices), the abstract as originally filed on page 68 of the current application appear to contain new matter as compared to the parent application, 08/312,881.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3738

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 2

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
/WM/		JP H02-167178	06/27/1990	Medtronic, Inc.		☐
		EP 0 346 564 A1	12/20/1989	Medtronic, Inc.		☐
		JP H04-500328	01/23/1992	Hugh Trout		☐
		WO 90/15582	12/27/1990	Hugh Trout		☐
		JP H06-7454	01/18/1994	Cook Incorporated		☐
		EP 0 565 251 A1	10/13/1993	Cook Incorporated		☐
		JP H05-509008	12/16/1993	Richard Stack		
		WO 91/17789	11/28/1991	Richard Stack		
		JP H02-68052	03/07/1990	Corvita Corporation		
		EP 0 357 003 A2	03/07/1990	Corvita Corporation		

Examiner Signature	/William Matthews/	Date Considered	08/19/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6]Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 2 of 2

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
/WM/		Notice of Reasons for Rejection of Japan Patent Application No. 2004-335171 dated April 24, 2007	☐
/WM/		Notice of Reasons for Rejection of Japan Patent Application No. 2006-104574 dated May 15, 2007	☐
/WM/		Notice of Reasons for Rejection of Japan Patent Application No. 2006-104577 dated May 15, 2007	☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

Examiner Signature	/William Matthews/	Date Considered	08/19/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

The collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Search Notes

Application/Control No.	Applicant(s)/Patent under Reexamination	
09/977,826	GOICOECHEA ET AL.	
Examiner	**Art Unit**	
William H. Matthews (Howie)	3738	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
updated prior search	8/16/2007	WHM

PTO/SB/21 (09-04) (AW 10/2004)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

ENCLOSURES *(Check all that apply)*

- ☒ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/Declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below): 1 pg. PTO/SB/08b; Federal Circuit Decision; PTO-2038; post card receipt

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm Name	RatnerPrestia		
Signature	Joshua L. Cohen		
Printed Name	Joshua L. Cohen		
Date	8/23/2007	*Registration No.*	38,040

CERTIFICATE OF TRANSMISSION / MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Denise Morgan		
Typed or Printed Name	Denise Morgan	*Date*	8/23/2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, ALEXANDRIA, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/17 (12-04v2) (AW 1/2005)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/04.
Pursuant to the Consolidated Appropriations Act. 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2007

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 180

Complete If Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Examiner Name	William H. Matthews
Art Unit	3738
Attorney Docket No.	BSI-010US4

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify):_____

☒ Deposit Account Deposit Account Number: **18-0350** Deposit Account Name: **RatnerPrestia**

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	____
Design	200	100	100	50	130	65	____
Plant	200	100	300	150	160	80	____
Reissue	300	150	500	250	600	300	____
Provisional	200	100	0	0	0	0	____

2. EXCESS CLAIM FEES

Fee Description	Small Entity Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)	Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	- 20 or HP =	_____	x	_____	=	_____	____	____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x	_____	=	_____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/ 50 =	_____	(round up to a whole number) x	____	=	____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	____
Other (e.g., late filing surcharge): Submission of IDS	180

SUBMITTED BY

Complete *(if applicable)*

Signature	Joshua Cohen	Registration No. Attorney/Agent)	38,040	Telephone	610-407-0700
Name (Print/Type)	Joshua L. Cohen			Date	8/23/2007

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

BSI-010US4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoecha et al.
Filed:	October 15, 2001
Title:	Endoluminal Stent
TC/A.U.:	3738
Examiner:	William H. Matthews

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the document listed on the PTO/SB/08b form submitted herewith. A copy of the document listed on the PTO/SB/08b form, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

With respect to Applicants' claim of priority, Applicants would like to direct the Examiner's attention to the following court decision:

- Decision of the United States Court of Appeals for the Federal Circuit in *Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc.*, No. 2006-1434, dated August 8, 2007 (affirming the Memorandum Opinion and Final Judgment of the United States District Court for the District of Columbia in *Scimed Life Systems, Inc. v. Medtronic Vascular, Inc. and Eric C. Martin*, Civil Case No. 01-2015 (RJL) dated March 31, 2006).

A copy of the decision is attached. The decision was an appeal from a decision (previously submitted) of the USPTO Board of Patent Appeals and Interferences ("Board") dated July 27, 2001 in Interference No. 104,192, which involved an application of Andrew H. Cragg and Michael D. Dake that is familialy related to the present application.

08/27/2007 RMEBRAHT 00000022 09977826
01 FC:1806 180.00 OP

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

STATEMENT UNDER 37 C.F.R. § 1.97(e)

The undersigned hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(e) more than three months prior to the filing of the Information Statement.

The required fee set forth in 37 C.F.R. § 1.17(p) is provided herewith.

Respectfully submitted,

Joshua L. Cohen

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicants

JLC/SW/dhm

Enclosures: PTO/SB/08b
Federal Circuit Decision
Fee Transmittal
Transmittal Form
Credit Card Payment Form

Dated: August 23, 2007

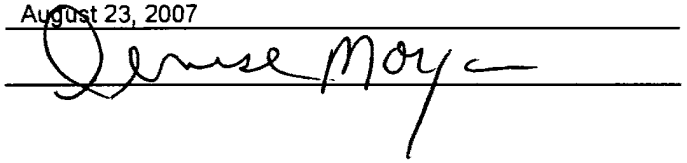
☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith..

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

August 23, 2007



PTO/SB/08b (08-03)
Approved for use through 6/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 1

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Decision from United States Court of Appeal for the Federal Circuit for Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc. and Eric C. Martin dated August 8, 2007	☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Coicoechea et al.
Filed:	October 15, 2001
Title:	ENDOLUMINAL STENT
TC/A.U.:	3738
Examiner:	William Matthews
Confirmation No.:	4645
Docket No.:	BSI-010US4

REQUEST FOR RECONSIDERATION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action dated August 22, 2007, please amend the above-identified application as follows:

☐ **Amendments to the Specification** begin on page of this paper.

☐ **Amendments to the Claims** are reflected in the listing of claims which begins on page of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet(s).

☐ **Amendments to the Abstract** are on page of this paper. A clean version of the Abstract is on page of this paper.

☒ **Remarks/Arguments** begin on page 2 of this paper.

Remarks/Arguments:

The pending claims are 20, 22-41, 43-49, 54-62. Claims 26, 34-38, 40, 58-62 have been withdrawn.

THE RESPONSE TO ARGUMENTS IN PARAGRAPH 2 OF THE OFFICE ACTION

Each of the points raised in paragraph 2 of the Office Action is addressed in this response.

THE GENERAL REJECTION IN PARAGRAPH 4 OF THE OFFICE ACTION

Paragraph 4 of the Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Paragraph 4 of the Office Action generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-8 of the Office Action provide more specific reasons for the rejections.

The rejections are traversed.

EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169. *Accord*, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the

claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should: (A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION IN PARAGRAPH 5 OF THE OFFICE ACTION

Paragraph 5 of the Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 because independent claims 54 and 56 each recites vertices that abut and, in the PTO's view, abutting apices are not disclosed in the specification. Instead, the PTO contends that the specification only discloses juxtaposed vertices. Applicants disagree.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Claim 56 recites, in part, "at least some of said vertices axially abut." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. The PTO has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

> Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. . . . (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The PTO has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that the above passages describe the stent embodiment selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show an embodiment in which juxtaposed apices of neighboring hoops abut. The PTO has not explained why a person skilled in the art would not recognize that the figures show abutting apices.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the PTO has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports the claims. Instead, paragraph 5 of the Office Action states only: "[t]he specification only disclose juxtaposed vertices." This single statement fails to evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

For all of the above reasons, Applicants request the PTO to withdraw the rejections of claims 54 and 56 stated in paragraph 5 of the Office Action.

THE REJECTION IN PARAGRAPH 6 OF THE OFFICE ACTION

Paragraph 6 of the Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-55. Claim 54 recites, in part,

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

The PTO has made the rejection "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the PTO's view, "[t]he specification only disclose embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical `offset' feature." Applicants disagree.

Applicants' specification expressly describes two alternative categories of embodiments of hoops, helical and substantially perpendicular. The specification states:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is not helical because the specification describes an alternative to a helical embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is non-helical.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

> Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention and Applicants therefore request the PTO to withdraw the rejection stated in paragraph 6 of the Office Action.

THE REJECTION IN PARAGRAPH 7 OF THE OFFICE ACTION

Claim 56 recites, in part

> vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Office Action has rejected claims 56 and 57 because, in the view of the PTO, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the PTO, the specification only supports a recitation that apices of "one or more" hoops lie in such a plane. The Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) The specification also discloses that its stents of the "perpendicular variety" "comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors." (page 10, lines 16-19). One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A). Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). These figures illustrate a stent embodiment that is an embodiment of the "perpendicular variety" having "juxtaposed apices 22 of neighboring hoops 20 are secured together. . .Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22." (page 25, lines 4-9). See also, page 23, ines 20-23 ("Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel 46.")

Fig. 22 illustrates another embodiment of a stent using the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a

proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of substantially perpendicular hoops or could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

For the above reasons, Applicants' disclosure supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." Applicants therefore request the PTO to withdraw the rejection stated in paragraph 7 of the Office Action.

THE COMMENTS REGARDING THE ORIGINALLY FILED ABSTRACT IN PARAGRAPH 8 OF THE OFFICE ACTION

In their Amendment filed on August 6, 2007, Applicants inadvertently relied upon the Abstract as originally filed. The Office Action has correctly pointed out that Applicants substituted a new Abstract for the originally filed Abstract in a Preliminary Amendment filed on March 1, 2002. Even though the original Abstract has been canceled, paragraph 8 of the Office Action states that the originally filed Abstract "appear[s] to contain new matter as compared to the parent application, 08/312,881" because, it contends, the specification "fail[s] to support the combination (perpendicular and connected abutting apices)." Applicants disagree. As explained above, these features are shown in Applicants' disclosure, which includes the specification and figures specifically cited above.

New matter is "[m]atter not in the original specification, claims, or drawings." MPEP §608.04(a). The existence of new matter is not determined by comparing only isolated parts of the disclosure. Accordingly, a determination of whether a new Abstract contains new

matter cannot be made only by comparing the new Abstract with the original Abstract. Instead, a new Abstract must be compared with the entire original disclosure comprising the specification, figures, and claims. The Office Action's determination of purported new matter is based solely upon a comparison of the originally filed Abstract with the Abstract filed in priority Application No. 312,881. Such a comparison is insufficient for purposes of determining the existence of new matter.

MPEP § 608.04 states that "[w]hen new matter is introduced into the specification, the amendment should be objected to under 35 U.S.C. 132 . . . and a requirement made to cancel the new matter." See also, MPEP § 2163.06 I., p. 2100-184. The Office Action did not object to the originally filed Abstract under § 132 and did not require Applicants to cancel it.

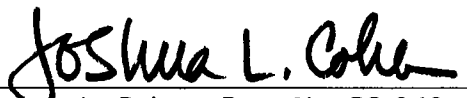
Accordingly, no response to paragraph 8 is required. Nevertheless, Applicants respectfully request the PTO to withdraw its incorrect suggestion that the originally filed Abstract contained new matter.

CONCLUSION

Applicants thank the Examiner for indicating inferentially that none of the pending claims are rejected over any prior art.

Since all of the pending claims have support in the specification, all of the pending claims are now in condition for allowance and Applicants request an early indication of allowance.

Respectfully submitted,



Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicants

JLC/SW/dhm

Dated: December 26, 2007

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

Electronic Patent Application Fee Transmittal

Application Number:	09977826
Filing Date:	15-Oct-2001
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Filer:	Joshua L. Cohen/Anne Pinto
Attorney Docket Number:	BSI-010US4

Filed as Large Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	120	120

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**120**

Electronic Acknowledgement Receipt

EFS ID:	2639951
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Joshua L. Cohen/Anne Pinto
Filer Authorized By:	Joshua L. Cohen
Attorney Docket Number:	BSI-010US4
Receipt Date:	26-DEC-2007
Filing Date:	15-OCT-2001
Time Stamp:	15:54:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$120

RAM confirmation Number	816
Deposit Account	180350
Authorized User	COHEN,JOSHUA L.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	bsi-010us4extoftime.pdf	52708 f901a86943059561bdf264dbf0dc2c525ba07e02	no	1
Warnings:					
Information:					
2	Amendment - After Non-Final Rejection	bsi-010us4resp.pdf	392878 8c31da5ae208a4262cd290c73fcc32476b1e85af	no	9
Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-info.pdf	8129 3d3fe906f83cba9c58a9bf043ae5fafbe50504d1	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	453715		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/22 (10-04) (12-04)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2005** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818))*	Docket Number (Optional) BSI-010US4
Application Number 09/977,826	Filed 10/15/2001
For Endoluminal Stent	
Art Unit 3738	Examiner William H. Matthews

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☒ One month	(37 CFR 1.17(a)(1))	$120	$60	$120
☐ Two months	(37 CFR 1.17(a)(2))	$450	$225	$_____
☐ Three months	(37 CFR 1.17(a)(3))	$1020	$510	$_____
☐ Four months	(37 CFR 1.17(a)(4))	$1590	$795	$_____
☐ Five months	(37 CFR 1.17(a)(5))	$2160	$1080	$_____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 18-0350.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number: 38,040.

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

Joshua L. Cohen — *Signature*

12/26/07 — *Date*

Joshua L. Cohen — *Typed or Printed Name*

610-407-0700 — *Telephone Number*

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 03/24/2008

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-41,43-49 and 54-62* is/are pending in the application.

4a) Of the above claim(s) *26,34-38,40 and 58-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-25,27-33,39,41,43-49 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-27-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12-26-07 have been fully considered but they are not persuasive.

2. Regarding the rejection under 35 USC 112 of claims 56 and 57, Examiner responds to each of Applicant's arguments below:

- Regarding the phrase "**abutting apices**", Applicant suggests the passage at page 10, lines 16-23 would lead one of ordinary skill in the art to recognize the specification expressly, implicitly, and inherently supports "abutting apices". Examiner disagrees because the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the question of how tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.
- Regarding the "**non-helical**" limitation in combination with each hoop being substantially perpendicular, Applicant points to page 9, lines 13-19 which references a helical configuration in EP-A-0556850, and a different novel configuration having substantially perpendicular hoops. Applicant suggests this passage describes a "helical" and "non-helical" configuration because the "novel" configuration is described as an alternative to the helical configuration. Examiner disagrees with this analysis because Figure 4A shows the "novel configuration" having substantially perpendicular hoops and a helical aspect

(i.e the longitudinal displacements described at page 23 lines 24-27) . The mere description of an alternative embodiment to a purely helical configuration does not require the alternative embodiment to be "non-helical" (which may be interpreted as lacking **any** helical features).

- Regarding claim 56 and the "**perpendicular**" limitation, Applicant suggests it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments (Remarks page 7, lines 7-10). Examiner disagrees with this analysis because the originally filed specification did not interrelate the embodiments in such a way that Applicant is entitled to combine various features from different embodiments. Furthermore, Examiner notes the "substantially perpendicular" embodiment of figures 1-4a is appropriate because of the longitudinal displacements described at page 23 lines 24-27. This feature is not present in the embodiment of figures 22-23 which is described as perpendicular.
- Regarding the originally filed **abstract**, Applicant notes an objection to the specification was not made under 35 USC 132. Examiner notes that the first action on the merits occurred after the abstract was replaced on 3-1-02 (and correspondingly deleted the issues Examiner noted in the previous office action at paragraph 8). Examiner maintains that future inclusion of the limitation at lines 8-13 with regard to "a bifurcated stent" in combination with "perpendicular hoop members" would raise the issue of new matter. The specification describe a substantially perpendicular embodiment (i.e figures 1-

4a which include the longitudinal displacement feature and are incapable of being considered ***perpendicular***), and a perpendicular embodiment (figures 22-23).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected because independent claims 54 and 56 recite vertices that abut which is not disclosed in the specification. The specification only discloses juxtaposed vertices. Juxtapose is defined by Merriam Webster's Collegiate Dictionary, 10th Ed. as: to place side by side and synonymous with "adjacent". Adjacent is described as: may or may not imply contact but always implies absence of anything of the same kind in between. Furthermore, the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply).

6. Claims 20,22-25,27-33,39,41,43-49,54-55 are rejected because independent claim 54 recites "non-helical" in combination with each hoop being substantially perpendicular and having connected apices. The specification only disclose embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical "offset" feature.

7. Claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" in combination with axially abutting vertices of adjacent hoops, which is not disclosed in the specification. The specification do provide support for the phrase "substantially perpendicular" for the combination, and "perpendicular" for the straight stents of figures 22-23, but the "perpendicular" embodiment is only for "one or more" rather than each or all hoops. This is also supported by original claim 18, the description of figures 1-4, and the amended abstract of 3-1-02.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774

PTO/SB/08b (08-03)
Approved for use through 6/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 1

Complete if Known	
Application Number	09/977,826
Filing Date	10/15/2001
First Named Inventor	George Goicoecha
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Decision from United States Court of Appeal for the Federal Circuit for Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc. and Eric C. Martin dated August 8, 2007	☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

Examiner Signature	/William Matthews/	Date Considered	03/15/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /WM/

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3774	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
updated prior search	3/14/2008	WHM

PTO/SB/31 (04-05)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional)
BSI-010US4

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____.

Typed or printed name _____

In re Application of

George Goicoechea et al.

Application Number	Filed
09/977,826	10/15/2001

For

ENDOLUMINAL STENT

Art Unit	Examiner
3774	William Matthews

Applicant hereby **appeals** to the Board of Patent Appeals and Interferences from the last decision of the Examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 510.00

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ _____

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 18-0350 . I have enclosed a duplicate copy of this sheet.

☐ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. Registration Number: 38,040

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34._____.

Joshua L. Cohen
Signature

Joshua L. Cohen
Typed or printed name

610-407-0700
Telephone Number

6/12/2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	09977826
Filing Date:	15-Oct-2001
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Filer:	Joshua L. Cohen/Denise Morgan
Attorney Docket Number:	BSI-010US4

Filed as Large Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of appeal	1401	1	510	510
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**510**

Electronic Acknowledgement Receipt

EFS ID:	3445688
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Joshua L. Cohen/denise morgan
Filer Authorized By:	Joshua L. Cohen
Attorney Docket Number:	BSI-010US4
Receipt Date:	12-JUN-2008
Filing Date:	15-OCT-2001
Time Stamp:	15:11:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$510

RAM confirmation Number	9403
Deposit Account	180350
Authorized User	COHEN,JOSHUA L.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of Appeal Filed	bsi010us4noa.PDF	58116 c4181044e2145ece6664f93d755ab9ae18bbe1b0	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8122 2786e0b0133ca434d95527ec9771139b9d380b06	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	66238		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoechea et al.
Filed:	October 15, 2001
Title:	ENDOLUMINAL STENT
TC/A.U.:	3774
Examiner:	William Matthews
Confirmation No.:	4645
Docket No.:	BSI-010US4
Notice of Appeal Filed:	June 12, 2008
Docket No.:	BSI-010US4

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated March 24, 2008 of claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken, within two months from the date of the Notice of Appeal, or within an extension of that time period.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, are provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Boston Scientific Scimed, Inc. by virtue of Articles of Merger of Boston Scientific Scimed, Inc. wth and ito Scimed Life Systems, Inc. dated December 22, 2004.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal, except as follows:

Interference No. 104,083. A copy of the Judgment of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 1. This Interference involved related Application Serial No. 08/461,402 of Andrew H. Cragg et al., filed June 5, 1995, titled BIFURCATED ENDOLUMINAL PROSTHESIS.

Interference No. 104,192. A copy of the Final Decision and Judgment of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 2. This Interference also involved related Application Serial No. 08/461,402.

Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL). This was an appeal from the Board's decision in Interference No. 104,192. The following interlocutory orders, and/or decisions, memorandum opinion, and final judgment were entered in that appeal, with copies included in the Related Proceedings Appendix (Section X) at the indicated Tabs:

DATE	ORDER OR OPINION	TAB
11/15/01	Order	3
12/21/01	Order	4
5/2/02	Order	5

8/30/03	Memorandum Opinion and Order	6
3/25/04	Stipulation and Order	7
9/12/04	Protective Order	8
12/14/04	Joint Stipulated Request To Extend Discovery	9
3/31/06	Memorandum Opinion	10
3/31/06	Final Judgment	11

Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), United States Court of Appeals for the Federal Circuit, No. 2006-1434. This was an appeal from the decision of the U.S. District Court for the District of Columbia. A copy of the decision of the Federal Circuit is provided in the Related Proceedings Appendix (Section X) at Tab 12.

III. STATUS OF CLAIMS

Claims 20, 22-41, 43-49 and 54-62 are pending. Claims 26, 34-38, 40, and 58-62 have been withdrawn from consideration. Claims 1-19, 21, 42, 50-53 have been canceled. Claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 stand rejected and are being appealed. A copy of the rejected claims is provided in the Claims Appendix (Section VIII).

To assist the Board in correlating dependent claims with their corresponding independent claims, appellants provide the following chart of the pending claims that have not been withdrawn:

20	Dependent on claim 54
22	Dependent on claim 20
23	Dependent on claim 20
24	Dependent on claim 20
25	Dependent on claim 20
27	Dependent on claim 20
28	Dependent on claim 27

29	Dependent on claim 28
30	Dependent on claim 29
31	Dependent on claim 54
32	Dependent on claim 54
33	Dependent on claim 32
39	Dependent on claim 54
41	Dependent on claim 31
43	Dependent on claim 54
44	Dependent on claim 43
45	Dependent on claim 44
46	Dependent on claim 44
47	Dependent on claim 43
48	Dependent on claim 47
49	Dependent on claim 47
54	Independent
55	Dependent on claim 20
56	Independent
57	Dependent on claim 56

IV. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 54

The invention recited in claim 54 is a stent including a plurality of hoops aligned along a common axis. Each of the hoops is non-helical and oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the stent. The stent also includes means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

For example, and for purposes of illustration only, one exemplary embodiment of the invention is shown as stent 10 in Fig. 1A (page 19, lines 5-7;

page 22, lines 17-18). Part of a stent such as stent 10 is also shown in Figs. 2A (page 19, lines 11-13; page 23, lines 11-12), 3 (page 19, lines 17-19; page 25, line 27-page 26, line 1), and 4A (page 19, lines 20-22; page 22, lines 17-18). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). Each hoop is non-helical and is oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent (page 9, lines 15-19, 13-19; page 10, lines 16-17).

Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices such as apices 22 (Fig. 2A, page 23, lines 11-20) that point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

The stent also has means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop (page 10, lines 16-23 and Figs. 1A, 1B, 2A, 4A-4F). This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following paragraphs set forth exemplary structures described in the specification as corresponding to the claimed function.

The securing means may comprise a loop element of a suture material, for example, to tie the abutting juxtaposed apices together. The loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol (page 10, lines 20-28). FIGS. 4B-4F are partial exploded views of embodiments of a stent illustrating exemplary means for securing juxtaposed apices of the stent (page 20, lines 1-4).

Referring to Fig. 4A, for example, abutting juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 which may be, for example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has an abutting juxtaposed apex of a neighboring hoop 20 is tied to the abutting

juxtaposed apex 22 in this embodiment. In other embodiments of the invention, only some of the juxtaposed apices 22 may be secured in this way (page 25, lines 4-11).

In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. 4B. The securing means may also comprise a bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in FIG. 4C. Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in FIGS. 4D, 4E, and 4F respectively (page 25, lines 12-21).

The foregoing, exemplary structures correspond to the function recited in claim 54 of securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop. Equivalent structures for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop are also within the literal scope of claim 54 under 35 U.S.C. § 112, sixth paragraph.

B. Claim 56

The invention recited in claim 56 is a stent including a tubular member that has a plurality of hoops aligned adjacent one another along the longitudinal axis of the tubular member. Each of the hoops has a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices that axially point in a direction along the longitudinal axis of the stent. At least some of the vertices axially abut and are individually connected to oppositely pointed veritices of elongate elements of an adjacent hoop. The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, a stent such as stent 10 includes a tubular member (page 8, lines 8-10). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). The exemplary hoops are aligned adjacent one another along the

longitudinal axis of the tubular member (Fig. 1A; page 9, lines 19-27; page 23, lines 24-27).

Each of the hoops includes a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices such as vertices 22 (Fig. 2A, page 23, lines 11-20) that axially point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

At least some of the vertices axially abut (Figs. 2A, 4A) and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop (Figs. 2A, 4A). For example, a loop element of a suture material connects oppositely pointed vertices of adjacent hoops (page 10, lines 18-23). Exemplary suture material is shown as element 99a in Fig. 4B (page 25, lines 13-15). Other materials for connecting oppositely pointed vertices of adjacent hoops are shown in Figs 4A and 4C to 4F (page 25, lines 4-21).

The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member (page 9, lines 15-19; page 10, lines 2-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are set forth in the Final Office Action dated March 24, 2008.

Claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 stand rejected under 35 U.S.C. § 112, first paragraph, the Final Office Action contending that the claims fail to comply with the written description requirement.

VII. ARGUMENT

Paragraph 4 of the Final Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. It generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-7 of the Final Office Action provide more specific reasons for the rejections. Paragraph 2 of the Final Office Action explains why the Examiner disagreed with Applicants' arguments regarding claims 56 and 57 in their December 26, 2007 Request for Reconsideration.

EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169. *Accord*, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION OF CLAIM 54 AND ITS DEPENDENT CLAIMS 20, 22-25, 27-33, 39, 41, 43-49, 55

Contrary To The Final Office Action's Contention, The Disclosure Does Support "Means For Securing An Apex Of One Hoop To An Abutting Juxtaposed Apex Of A Neighboring Hoop"

Paragraph 5 of the Final Office Action has rejected these claims because independent claim 54 recites vertices that abut which, in the Examiner's view, is not disclosed in the specification. Instead, the Examiner contends that the specification only discloses juxtaposed vertices, which, he contends, may or may not imply contact.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) implicitly and inherently supports these claim limitations. The Examiner, on the other hand, has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

> Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. . . . (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in

the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The Examiner has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that claim 54 finds clear support in stent embodiments such as those selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show embodiments having "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." The Examiner has not explained why a person skilled in the art would not recognize that the figures show this feature.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the Examiner has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports claim 54. Paragraph 5 of the Final Office Action states: "[t]he specification only discloses juxtaposed vertices." This statement fails to provide evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

Paragraph 5 of the Final Office Action also contends that "the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply)." The Examiner's contentions disregard not only page 10, lines 16-23 but also other significant aspects of Applicants' disclosure and fail to present required evidence demonstrating that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention.

Applicants' specification also states:

> [J]uxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 (see Figure 4(a)), which are, in this example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which

> has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22. (page 25, lines 4-9)
>
> In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in Fig. 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Fig. 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Fig. 4(d), 4(e), and 4(f) respectively. (page 25, lines 12-21).

These passages explain the relationship of juxtaposed apices that can be tied together or secured together as shown in Figures 4A through 4F, each of which also shows an embodiment having abutting apices. Taken together, the disclosure's statement that juxtaposed apices can be tied together or secured together, along with Figures 4A through 4F, combined with the explanation that "each hoop is supported by its neighbors" would inexorably lead one skilled in the art to conclude that the juxtaposed apices of at least some disclosed embodiments are abutting. The Examiner has not presented any evidence to the contrary.

For all of the above reasons, Applicants' specification discloses "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop."

Claim 54 also recites, in part,

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Paragraph 6 of the Final Office Action has rejected claim 54 and its dependent claims "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the Examiner's view, "[t]he specification only disclose [sic] embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical 'offset' feature."

Applicants' specification expressly describes two alternative categories of embodiments of hoops -- helical and substantially perpendicular. The specification states:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is not helical because the specification describes an alternative to a helical embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is non-helical.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

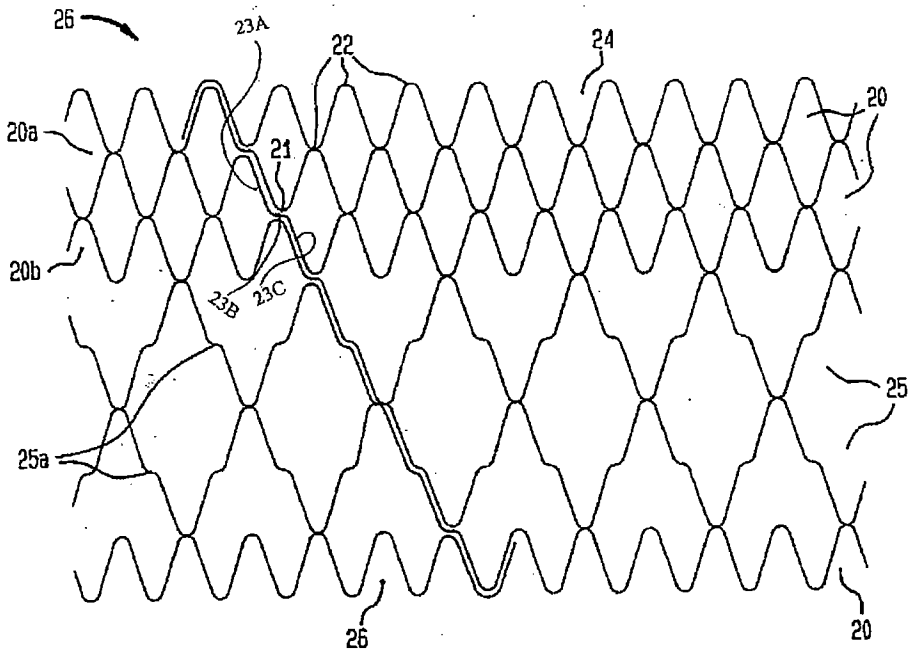
> Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

In paragraph 2, at the top of page 3[1], the Final Office Action indicates that it has interpreted "non-helical" to require that the claimed embodiment "lack[s] **any** helical features." Based upon this interpretation of "non-helical," the Examiner contends that Fig. 4A shows "a helical aspect (i.e. the longitudinal displacements described at page 23 lines 24-27)."

But page 23, lines 24-27 describes Figs. 2A and 2B, not Fig. 4A, and describes how hoops 20a and 20b in those figures are formed. Figs. 2A and 2B are reproduced below, with reference numbers 23A, 23B and 23C added to Fig. 2A for the Board's ease of reference.

FIG. 2A



[1] The opening sentence of paragraph 2 of the Final Office Action states that it only pertains to claims 56 and 57. Since claims 56-57 do not contain a "non-helical" recitation, the Examiner's contentions regarding "non-helical" must pertain to claim 54.

The referenced portion of the specification states:

> When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b.

Hoops 20a and 20b are shown in both figures.

Part of hoop 20a is formed by wire portion 23A. In order to form the adjoining hoop 20b, the point of winding of wire portion 23A is displaced longitudinally at wire portion 23B, and becomes wire portion 23C. Apparently, the Examiner contends that wire portion 23B precludes Applicants from reciting "hoops being non-helical." The Examiner is wrong.

The recitation at issue is: "**hoops** being non-helical." Figs. 1A, 1B, 2A, 3, 4A all show embodiments of non-helical **hoops**. Regardless of how the hoops are formed, and regardless of how one hoop flows into another hoop, the **hoops themselves** are non-helical. The disclosure therefore supports "**hoops** being non-helical."

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

THE REJECTION OF CLAIM 56 AND ITS DEPENDENT CLAIM 57

Contrary To The Final Office Action's Contention, The Disclosure Does Support "At Least Some Of Said Vertices Axially Abut"

Claim 56 recites, in part,

> at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop.

In addition to the contentions stated in paragraph 4 of the Final Office Action, the Examiner's reasoning is further explained in paragraph 2 of the Final Office Action, which contends that

> the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the question of how

tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.

As was the case regarding claim 54, even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. In addition, the Examiner has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

As Applicants argued above regarding the rejection of claim 54, the specification describes, and the figures illustrate, embodiments in which "each hoop is supported by its neighbors" (page 10, line 20), "vertices . . . are individually connected to oppositely pointed vertices" using various connecting elements (page 10, lines 23-29; page 25, lines 4-9, 12-21), and apices are tied together. See also, Figs. 1A, 1B, 2A, and 4A-4F.

Taken together, the specification and the figures demonstrate that "at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop."

The Final Office Action has disregarded the above-described teachings in the specification because, in its view, the teachings "are not equivalent to a connection created by adhesive or welding." This statement makes the unsupported assumption that any two things (including juxtaposed apices) can abut only if they are connected by adhesive or welding or only if they are connected by something that is equivalent to adhesive or welding. The Board must reject these contentions because the Examiner has not supported them with any evidence and because they are clearly wrong. For example, a pencil resting on a desk top abuts the desk top even though the pencil is not connected to the desk top at all or by adhesive, welding, or anything equivalent to adhesive or welding. Applicants' disclosure demonstrates embodiments in which apices abut, even though the disclosure does not expressly refer to adhesive or welding.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Claim 56 also recites, in part:

vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Final Office Action has rejected claims 56 and 57 because, in the view of the Examiner, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the Examiner, the specification only supports a recitation that for the perpendicular embodiment apices of "one or more" hoops lie in such a plane. The Final Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A). Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). "Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel." (page 23, lines 20-23)

Fig. 22 illustrates another embodiment of a stent using configurations such as the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents

may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

Page 3 of the Final Office Action has mischaracterized Applicants' arguments. Applicants have not suggested that "it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments." As explained above, Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). As stated above, therefore, since both stent embodiments may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops. Contrary to the belief of the Examiner, therefore, one skilled in the art would understand that the specification does interrelate at least Figs. 1-4 with at least Figs. 22 and 23. The Final Office Action fails to demonstrate that one skilled in the art would not have such an understanding.

For the above reasons, Applicants' disclosure fully supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member."

CONCLUSION

In view of the foregoing remarks, Applicants submit that the grounds for rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 are improper. Applicants respectfully request that the Board reverse the Examiner's rejection of all pending rejected claims.

Respectfully submitted,

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicant

Dated: October 14, 2008

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

VIII. CLAIMS APPENDIX

20. (Previously Presented) A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

22. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

27. (Previously Presented) A stent as recited in claim 20 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment.

28. (Previously Presented) A stent as recited in claim 27 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment.

29. (Previously Presented) A stent as recited in claim 28 wherein at least one of said first and second additional stent segments is of frustoconical shape and is further combined with a third an additional stent segment, one end of which includes a mating frustoconical shape.

30. (Previously Presented) A stent as recited in claim 29, wherein said mating frustoconical stent segments are adapted to be separately placed in a bifurcated artery and then, by expansion of one of said frustoconical stent segments, secured to one another.

31. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. (Previously Presented) An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

39. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

41. (Previously Presented) An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

43. (Previously Presented) An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is gold.

50-53. (Cancelled)

54. (Currently Amended) A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

55. (Previously Presented) A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. (Previously Presented) A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. (Previously Presented) A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

Electronic Patent Application Fee Transmittal

Application Number:	09977826
Filing Date:	15-Oct-2001
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Filer:	Joshua L. Cohen/Anne Pinto
Attorney Docket Number:	BSI-010US4

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Filing a brief in support of an appeal	1402	1	540	540
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	490	490
Miscellaneous:				
			Total in USD ($)	**1030**

Electronic Acknowledgement Receipt

EFS ID:	4113014
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Joshua L. Cohen/Anne Pinto
Filer Authorized By:	Joshua L. Cohen
Attorney Docket Number:	BSI-010US4
Receipt Date:	14-OCT-2008
Filing Date:	15-OCT-2001
Time Stamp:	17:57:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1030

RAM confirmation Number	3761
Deposit Account	180350
Authorized User	COHEN,JOSHUA L.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010us4tab1.PDF	121765 4e3095b3da327c2dadae35b22a6478d036dd5938	no	5
Warnings:					
Information:					
2	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010us4tab2.PDF	3153888 da5c5eb3b5f57a18d2fcc771681e599e72e24156	no	74
Warnings:					
Information:					
3	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010US4tab3.PDF	31419 6a1a966e2233991bdf2d382a5633103dc693ca46	no	2
Warnings:					
Information:					
4	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010us4tab4.PDF	52209 4b73ddd7a220bd2ab852525aebd43d4d08aa5c0c	no	3
Warnings:					
Information:					
5	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010US4tab5.PDF	87219 cc38626bb36a16aeac812c49724925fc4420b641	no	4
Warnings:					
Information:					
6	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010us4tab6.PDF	562769 d0d9e1b3f96e69c5607efd12b38a5c7e07b1a00d	no	16
Warnings:					
Information:					
7	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010us4tab7.PDF	295939 47f81c43d490d75cf7803642a6a7e261274afd02	no	9
Warnings:					
Information:					

8	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010us4tab8.PDF	779858 5e7bd9923627b713efcb8a7fc2f992312cebdff0	no	18
Warnings:					
Information:					
9	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010US4tab9.PDF	75701 026226b6adbc62228d7e9a96b5397fe2de657021	no	3
Warnings:					
Information:					
10	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010US4tab10.PDF	774435 9e311ea9d142b1a3b7f1c71cd6cf023fb8569b61	no	16
Warnings:					
Information:					
11	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010uS4tab11.PDF	56190 1c397329c9368623fab183735c347f80aeae6269	no	3
Warnings:					
Information:					
12	Affidavit/Dec/Exhibit after Notice of Appeal	BSI-010US4tab12.PDF	327292 c50da777dff23a9b55500f277a2975b5f5464cfa	no	9
Warnings:					
Information:					
13	Extension of Time	BSI-010us4extoftime.PDF	58092 d6441f561866c989d56ea221cfba3991dade0292	no	1
Warnings:					
Information:					
14	Appeal Brief Filed	BSI-010us4appealbrief.PDF	875988 8ce7428f46426aabf8b6ec1ac6a155aa7770385e	no	24
Warnings:					
Information:					
15	Fee Worksheet (PTO-06)	fee-info.pdf	32118 0416bac7749e66936cb9c5c8621ffb8f6dd4376a	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	7284882	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

TAB 1

BSI-944

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 33

Filed by: Trial Section Merits Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ERIC C. MARTIN,

Junior Party
(Patent No. 5,575,817)[1],

v.

ANDREW H. CRAGG, and MICHAEL D. DAKE

Senior Party
(Application 08/461,402)[2]

Patent Interference No. 104,083

Before McKelvey, Senior Administrative Patent Judge, Schafer, Lee and Torczon, Administrative patent Judges.

PER CURIAM

JUDGMENT

Junior party Martin has failed to serve its case-in-chief testimony on priority by the time such service was due, i.e.,

[1] Filed August 19, 1994.

[2] Assigned to Boston Scientific Technology, Inc. Accorded the benefit of European applications EP9440284.9, filed February 9, 1994, and EP94401306.9, filed June 10, 1994. Also accorded the benefit of U.S. applications 08/317,763, filed October 4, 1994, and 08/312,881, filed September 27, 1994.

March 1, 1999. Based on party Martin's failure to take testimony, party Cragg has filed a miscellaneous motion for judgment or a show cause order under 37 CFR § 1.652.

In a telephone conference conducted at 2:45 PM, March 8, 1999, between administrative patent judge Jameson Lee and counsel to the respective parties, Mr. Peter Davis, counsel to party Martin, indicated that the failure to serve its case-in-chief evidence was not inadvertent and that the junior party would have no objection to the Board's entering adverse judgment against party Martin on the basis that its case-in-chief evidence was not served. Accordingly, entry of judgment against party Martin is now appropriate.

It is **ORDERED** that judgment as to the subject matter of count 1 is entered against junior party Martin and awarded in favor of senior party Cragg.

It is **ORDERED** that Eric C. Martin is not entitled to a patent containing claim 1 of his involved patent, which corresponds to count 1.

It is **ORDERED** that on this record, Andrew H. Cragg and Michael D. Dake are entitled to a patent containing their application claim 89 which corresponds to the count.

It is **ORDERED** that upon return of party Cragg's involved application to the primary examiner, party Cragg shall inform the

examiner of the administrative patent judge's decision (Paper No. 20) granting party Cragg's motion to correct inventorship (Paper No. 16), and request that the correction, inclusive of the accompanying petition and amendment, be processed and entered in the official file of party Cragg's involved application.

It is **FURTHER ORDERED** that in light of this entry of judgment, party Cragg's motion for judgment or an order to show cause why judgment should not be entered against party Martin is dismissed as moot.

Fred E. Mckelvey, Senior)
Administrative Patent Judge)
)
)
Richard E. Schafer)
Administrative Patent Judge)
) BOARD OF PATENT
) APPEALS
) AND
Jameson Lee) INTERFERENCES
Administrative Patent Judge)
)
)
Richard Torczon)
Administrative Patent Judge)

Paul F. Prestia
Ratner & Prestia
Suite 301
One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, Pennsylvania 19482-0980

Robert J. Koch
Fulbright & Jaworski
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

TAB 2

The opinion in support of the decision being entered today is not binding precedent of the Board.

Filed by: Trial Section Merits Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

Paper No. 187

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

ANDREW H. CRAGG and MICHAEL D. DAKE,

Junior Party,
(Application 08/461,402),[1]

v.

ERIC C. MARTIN,

Junior Party,
(Application 5,575,817),[2]

v.

THOMAS J. FOGARTY, JAY A. LENKER, TIMOTHY J. RYAN and KIRSTEN FREISLINGER,

Senior Party,
(Application 08/463,836).[3]

Patent Interference No. 104,192

[1] Filed 06/05/95. Accorded the benefit of application 08/317,763, filed October 4, 1994, now Patent No. 5,609,627, and application 08/312,881, filed September 27, 1994. The real party in interest is Boston Scientific Technology, Inc.

[2] Based on application 08/293,541, filed August 19, 1994.

[3] Filed June 5, 1995. Accorded the benefit of application 08/255,681, filed June 8, 1994. The real party in interest is Medtronic Aneurx, Inc.

Interference No. 104,192
Cragg v. Martin v. Fogarty

Before McKELVEY, Senior Administrative Patent Judge, and SCHAFER, LEE and MEDLEY, Administrative Patent Judges.

LEE, Administrative Patent Judge.

FINAL DECISION AND JUDGMENT

Introduction

When this interference was declared on April 23, 1998, current junior party Cragg was then senior party Goicoechea. Because of the granting of a motion to correct inventorship in related Interference No. 104,083 for application 08/461,402, the same application that is involved in this interference, co-inventors George Goicoechea, John Hudson, and Claude Mialhe were deleted and the only remaining inventors in that application are Andrew H. Cragg and Michael D. Dake. Thus, party Goicoechea became party Cragg. Any reference to party Goicoechea should be understood as a reference to party Cragg.

A decision on the parties' preliminary motions was rendered on February 11, 2000 (Paper No. 108), after which party Fogarty filed a miscellaneous motion (Paper No. 112) for leave to file, out of time, a preliminary motion 12 to attack the benefit accorded party Cragg of European Applications EP94400284.9 and EP94401306.9. The motion for leave as well as the preliminary motion 12 (Paper No. 113) were granted by a panel consisting of administrative patent judges Schafer and Lee (Paper No. 130).

The decision on Fogarty's preliminary motion 12 was adhered to on reconsideration (Paper No. 138) by a panel consisting of Senior Administrative Patent Judge McKelvey, and Administrative Patent Judges Schafer and Lee. This interference was re-declared in Paper No. 131 to change the junior/senior status of parties Cragg and Fogarty, with Cragg now being junior party.

Junior party Martin did not file a preliminary statement. It has indicated to the administrative patent judge to which this case was assigned that it did not want to participate in this interference except to "ride along" for the possibility that (1) the only interference-in-fact is determined to be between parties Cragg and Martin (a Cragg contention), and (2) that party Cragg will be deprived of its accorded benefit date (a Fogarty contention) and cannot demonstrate a sufficiently early date to prevail over Martin.

Because junior party Cragg filed no case-in-chief during the priority phase of this proceeding, it was placed under an order to show cause why judgment should not be entered against Cragg. Party Cragg requested final hearing for review of the Board's decision on Cragg's preliminary motions 1 and 2 and on Fogarty's preliminary motion 12. According to party Cragg it should not have been made a junior party and thus need not have had to put on a priority case in the first instance. Party Fogarty

requested review of the Board's decision on its preliminary motions 8 and 10. Oral argument was made on February 28, 2001, before administrative patent judges Schafer, Lee and Medley.

Findings of Fact

The below-listed findings as well as those contained in the discussion portion of this opinion are supported by a preponderance of the evidence:

1. This interference was declared on April 23, 1998, between three parties, Martin, Fogarty, and Goicoechea (now Cragg).

2. The involved patent of Martin is Patent No. 5,575,817, based on application 08/293,541, filed August 19, 1994.

3. The involved application of Cragg is application 08/461,402, filed June 5, 1995.

4. The involved application of Fogarty is application 08/463,836, filed June 5, 1995.

5. At the time of declaration of this interference, the named inventors of Cragg's involved application 08/461,402 were George Goicoechea, John Hudson, Claude Mialhe, Andrew H. Cragg, and Michael D. Dake.

6. Cragg's application 08/461,402, was also involved in a related interference, Interference No. 104,083, between parties Cragg and Martin but not Fogarty, wherein a motion to correct

inventorship was granted, deleting George Goicoechea, John Hudson, and Claude Mialhe as co-inventors, and leaving only Andrew H. Cragg and Michael D. Dake.

7. This interference was re-declared on June 2, 1999 (Paper No. 106) to reflect that only Andrew H. Cragg and Michael D. Dake are named inventors in Cragg's involved application.

8. Independent claim 1 of Martin's involved patent reads identically as the count in related Interference No. 104,083, and judgment was entered against party Martin in that interference on March 10, 1999.

9. Claim 2 of Martin's involved patent depends from claim 1, and if re-written in independent form it would read the same as the count in this interference.

10. The count of this interference reads as follows (Paper No. 16):

> An apparatus for reinforcing a bifurcated lumen comprising:
>
> a first section, configured to be positioned within the lumen, comprising:
>
> an upper limb, configured to fit within the lumen upstream of the bifurcation;
>
> a first lower limb, configured to extend into a first leg of said bifurcation when said first section is positioned in the lumen, and

> a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,
>
> and further comprising
>
> a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

11. Cragg's preliminary statement identifies only Michael D. Dake as the inventor of the subject matter of the count.

12. After the rendering of the Board's decision on preliminary motions (Paper No. 108) and subsequent service of the preliminary statement of party Cragg, Cragg filed a miscellaneous motion to amend or correct its preliminary statement to identify Andrew H. Cragg and Michael D. Dake as co-inventors of the subject matter of the count. (Paper No. 117).

13. Cragg's motion to amend was denied. (Paper No. 130). A written opinion explaining the basis of that denial followed. (Paper No. 140). Cragg requested reconsideration. The original decision was adhered to on reconsideration. (Paper No. 146).

14. Cragg has not sought review of the Board's denial of Cragg's motion to amend or correct its preliminary statement to name both Andrew H. Cragg and Michael D. Dake as inventors.

15. Upon declaration of this interference, Cragg was accorded benefit of U.S. application 08/317,763, filed October 4, 1994, European application EP94400284.9, filed February 9, 1994, and European application EP94401306.9, filed June 10, 1994. The European applications did not identify any inventor and were filed by the entity MINTEC SARL.

16. Based on representations from individuals associated with party Cragg, party Fogarty regarded as true, until the service of party Cragg's preliminary statement, that European applications EP94400284.9 and EP94401306.9 were filed by MINTEC SARL on behalf of inventors Goicoechea, Hudson, Mialhe, and Cragg. (Fogarty Preliminary Motion 12, Fact No. 5 - not disputed by Cragg).

17. Michael D. Dake made an assignment of rights, including his interests in the invention covered by Cragg's involved application relating to a bifurcated stent-graft, to MinTec, Inc., for a one time payment of eight hundred thousand U.S. dollars (U.S. $800,000) and other considerations, on May 6, 1996, with a stated effective date of April 30, 1996. (Cragg Exhibit 1025, CE-1025). The date of assignment was nearly two years and three months from the date of filing of EP94400284.9 on February 9, 1994, and nearly two years from the date of filing of EP94401306.9 on June 10, 1994.

18. Parties Cragg and Fogarty evidently treat, without dispute, that MinTec, Inc. and MINTEC SARL are related entities such that an assignment of interest to the former means the latter is an "assign."

19. Andrew H. Cragg made an assignment of rights, including his interests in the invention covered by Cragg's involved application relating to a bifurcated endoluminal prosthesis, to MINTEC, INC. on August 22, 1994. (Cragg Exhibit 1021, CE-1021). The date of assignment was six months after the date of filing of EP94400284.9 on February 9, 1994, and two months after the date of filing of EP94401306.9 on June 10, 1994.

Discussion

A. Fogarty's Preliminary Motion 12

In the "Relief Requested" portion of Fogarty's preliminary motion 12, it is stated:

> Fogarty moves under 37 CFR § 1.633(g) to deny the senior party the benefit of EP94400284.9 and EP94401306.9 on the grounds that neither application was filed by (i) the individual now identified as the inventor or (ii) on his behalf by his legal representatives or assigns.

The statutory basis of Fogarty's preliminary motion 12 is 35 U.S.C. § 119, which states, in pertinent part:

> (a) An application for patent for an invention filed in this country by **any person who has, or whose legal representatives or assigns have,** previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; . . . . (Emphasis added.)

As the motion panel's decision on reconsideration (Paper No. 138) states on page 3, a statement with which we agree and adopt herein:

> We interpret the above-quoted "any person who has, or whose legal representatives or assigns have" language as meaning that the previously filed foreign application must have been filed by the person or one who was, at the time of filing of the previously filed foreign application, already a legal representative or assign of that person. This view is necessary to ensure a link between the presently involved application and the earlier filed foreign application with respect to the particular inventor. A contrary interpretation would cause entitlement to benefit to be negotiable as a commodity between unrelated entities. Note that if party Martin or party Fogarty now assigned its involved patent or application to MINTEC, that does not and should not mean party Martin or party Fogarty's involved case should suddenly be entitled to the benefit of the earlier filing dates of party Cragg's European applications, on the basis that the European applications were previously filed by MINTEC who is now the assignee of party Martin or party Fogarty's involved patent or application.

Our view is consistent with the opinion of the Court of Customs and Patent Appeals in Vogel v. Jones, 486 F.2d 1068, 1072, 179 USPQ 425, 428 (CCPA 1973), wherein the court determined that a foreign application made by the assignee of a U.S. applicant, on behalf of one other than the United States inventor, is irrelevant to the rights of priority of the U.S. inventor. The Vogel case concerns 35 U.S.C. § 119, not 35 U.S.C. § 116 or § 120. Contrary to a suggestion by party Cragg in its reply brief at final hearing, Vogel has not been made outdated by statutory amendments to 35 U.S.C. § 116 and § 120 in 1984. The inventive entity may not always be identical between a U.S. application as a whole and an ancestral corresponding application in a foreign application. E.g., Reitz v. Inoue, 39 USPQ2d 1838, 1840) (Bd. Pat. App. & Int. 1996)("the proposition that the inventive entity must be the same in both the foreign and the corresponding U.S. application in order to obtain benefit can no longer be accepted, if it ever was, as a hard and fast rule in view of the liberalization of the requirements for filing a U.S. application as joint inventors wrought by the 1984 amendment of 35 U.S.C. § 116."). But with regard to any particular invention at issue or involved in an interference, 35 U.S.C. § 119 still includes the language concerning filing in a foreign country by

assigns or legal representatives of the one who files for that invention in the United States.

We have reviewed Schmitt v. Babcock, 377 F.2d 994, 153 USPQ 719 (CCPA 1967), a case mentioned by Cragg during oral argument at final hearing as somehow being in support of its position, but it does not help Cragg's position. The Schmitt case, from a pre-1984 era, relates to an inconsistency or disagreement in inventorship between the U.S. application and the foreign application and a resolution of that disagreement prior to accordance of benefit. Here, inconsistency or disagreement in inventorship is not the issue. Nothing in Schmitt purports to not recognize the filing by assigns requirement of 35 U.S.C. § 119. Even if it does, that would be contrary to the Vogel case which is later in time and thus takes precedent over Schmitt.

It is not in dispute that the assignment from Michael D. Dake to Mintec, Inc. occurred subsequent to the filing of the two European applications. In its request for reconsideration (Paper No. 137) of the granting of Fogarty's preliminary motion 12, on pages 4-5, Cragg stated:

> Mintec, the applicant in the EP applications in question, was the assignee of both Dr. Cragg and Dr. Dake, albeit the assignment by Dr. Cragg came several months after those applications had been filed and the assignment by Dr. Dake came more than a year after they had been filed.

Note Cragg's exhibit CE-1025, an assignment document from Mr. Michael D. Dake to MinTec, Inc., which was executed on May 6, 1996, more than two years after the filing of EP94400284.9, and nearly two years after the filing of EP94401306.9.

Cragg's brief at final hearing does not appear to argue that under 35 U.S.C. § 119, a subsequent assignment puts an assignee in the same position as if it were a "legal representative" or "assign" of the inventor at a previous time when a foreign application for the same invention was filed by that assignee. In any event, that argument, if made, would be rejected because it ignores plain statutory language to the contrary. Cragg has not set forth evidence of legislative history which clearly indicates that the statute does not mean what it plainly says.

Two new arguments have been raised for the first time by party Cragg in its reply brief at final hearing, which should have been raised, if at all, in its opposition to Fogarty's preliminary motion 12. The first new argument is this: That the two European applications were filed by MINTEC SARL for an invention "actually made" by Michael D. Dake and Andrew H. Cragg, regardless of assignment, and that this should satisfy the filing by assign or legal representative requirement of 35 U.S.C. § 119. The second new argument is raised by the last sentence on page 10 of Cragg's reply brief, which reads: "There is no requirement

either in Section 119 or in case law that the assignment must have been perfected before the EP applications were filed in order to rely on those applications for priority purposes." The statement implies that somehow there was at least an obligation of assignment which only was not perfected or formalized until after the filing of the European applications, and that this should satisfy 35 U.S.C. § 119.

The two new arguments were not in Cragg's opposition to Fogarty's preliminary motion 12, and still not in Cragg's request for reconsideration of the motion panel's decision on Fogarty's preliminary motion 12. They further still do not appear to be contained in Cragg's principal brief at final hearing.[4] These arguments do not involve mere statutory construction, but are also fact determinative. If the new arguments were timely raised in Cragg's opposition to Fogarty's preliminary motion 12,

---

[4] In its principal brief at final hearing on page 24, Cragg states: "Michael Dake had assigned his invention to Mintec and his collaboration with Andrew Cragg on the claimed invention prior to the filing of the EP applications is acknowledged. CE1025-1." This cannot be reasonably construed as an argument that the European applications filed by MINTEC SARL were for an invention actually made by Michael D. Dake and that that would satisfy the filing by assigns requirement of 35 U.S.C. § 119. In any event, raising such an argument for the first time in the principal brief at final hearing would nonetheless be untimely. Exhibit CE1025 also does not speak of any "collaboration" in the sense of there being a common goal, but mere discussion, consultation, and communication between Michael D. Dake and one or more of Messr. Goicoechea, Cragg, and Hudson on a topic and "whatever contributions Dr. Dake may have made" (Emphasis added).

pertinent facts could have been presented by both parties and Fogarty would have had an opportunity to explore and possibly discredit Cragg's assertions. We decline to entertain new arguments which were not presented in Cragg's opposition to Fogarty's preliminary motion 12.

Accordingly, we address only those arguments of Cragg which were raised in its opposition to Fogarty's preliminary motion 12.

Cragg argues that Fogarty's preliminary motion 12 was based on the representation in Cragg's preliminary statement that Michael D. Dake was the inventor for the subject matter of the count, and yet applicable precedent indicates that preliminary statements can only be used as an effective admission of the earliest or limiting date of invention provable by the party. Cragg's argument overlooks the 1984 changes to 35 U.S.C. § 116 and a corresponding change to 37 CFR § 1.622 regarding the content of preliminary statements. Cragg's argument is rejected.

There are many precedents, including the one cited by Cragg, Dewey v. Lawton, 347 F.2d 629, 631, 146 USPQ 187, 188 (CCPA 1965), which set forth the law that the date alleged in a party's preliminary statement only constitutes a limiting date. Thus, although a party may prove a date of invention that is earlier or later than the alleged date, it cannot be entitled to a date that is prior to the alleged date. Those cases all focus on

the assertion of a date of invention and are not concerned with any identification of inventorship in the preliminary statement. Identification of inventorship did not become a requirement for preliminary statements until an amendment was made to 37 CFR § 1.622 in 1984 when Title 35, United States Code, was amended to provide that not every named inventor has to have made a contribution to every claim in a patent application. In pertinent part, 35 U.S.C. § 116 now states:

> § 116 Inventors
>
> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Thus, when an application is filed which names multiple inventors, it is not known which inventor(s) contributed to the subject matter of which claims, or to the count in an interference, even though that information may be relevant to the requirements for accordance of benefit in an interference. Rule 1.622, as amended in 1984, partially addresses that problem by requiring in a preliminary statement identification of the inventors of the subject matter of the count. It reads, in pertinent part:

> (a) A party's preliminary statement must identify the inventor who made the invention defined by each count and must state on behalf of the inventor the facts required by paragraph (a) of §§ 1.623, 1.624, and 1.625 as may be appropriate. . . .

Thus, the established precedent focusing on the effect of assertions of invention dates and not concerned with identification of inventorship are not apposite.

Cragg argues:

> Rule 629, entitled "Effect of preliminary statement," is the only rule that addresses the consequences for allegations made in a preliminary statement, such consequences being limited to dates and issues of proving priority. Importantly, Rule 629 was amended at the same time Rule 622 was amended (in 1984) to require identification of inventors in a preliminary statement, but the amendment did not create an admission as to inventorship. Rule 629(a) states:
>
> > A party shall be held to <u>any date alleged</u> in the preliminary statement. Doubts as to definiteness or sufficiency of <u>any allegation</u> in a preliminary statement . . . will be resolved against the party filing the statement by restricting the party to its <u>effective date</u> or the <u>latest date</u> of a period alleged in the preliminary statement. (Emphasis in original).

But again, this rule focuses on the effect of assertions as to a date of invention. It is concerned with ambiguities or indefiniteness in the assertion of a date of invention, and is not concerned with anything about the naming of inventors. The rule gives notice of something not so plain and obvious, i.e., that if a range of dates is asserted, then the party making the

assertion is limited to the latest of such dates. For instance, if a party asserts that its invention was made in a period from January through March of a certain year, then the earliest date of invention the party is entitled would be March 31st.

There need not be a rule to state that which is plainly so, e.g., that what a party represents to an administrative tribunal or an opposing party can be used against the party if the representation is relevant to an adjudication of the party's own rights or the rights between the parties. Party Cragg is not charged with a crime and is not being interrogated in a criminal investigation such that it must be "mirandized" -- warned that anything it says can and will be used against it in a court of law -- before it makes a usable statement. What is important is that party Cragg be given an opportunity to explain or correct any misstatement it might have made and which has been relied upon by either the tribunal or the opposing party. There was ample such opportunity in this case.

Concurrently with the filing of its opposition to Fogarty's preliminary motion 12, Cragg filed a motion under 37 CFR § 1.628 to amend or correct its preliminary statement, to name not just Michael D. Dake as the only inventor of the subject matter of the count, but Andrew H. Cragg and Michael D. Dake as co-inventors. That was a full opportunity for party Cragg to present all the

evidence it wanted to present on the issue, to demonstrate that it had made an error in only naming Michael D. Dake as the inventor of the subject matter of the count. That motion was denied on April 7, 2000, in Paper No. 130. Party Cragg requested reconsideration of that decision. The original decision was adhered to in a reconsideration decision on June 27, 2000, in Paper No. 146. Party Cragg has not sought review of that decision at final hearing.

Party Cragg further argues that the outcome here is unfair because as the original senior party it need not have filed a preliminary statement, and if it did not file a preliminary statement, then none of this would have ensued. The argument is rejected. If Cragg had not filed a preliminary statement, it would not have revealed information which ultimately led to its being deprived of benefit to the earlier filing dates of foreign applications. But this result is not unfair if, as it is here, all pertinent information were known, Cragg would not be entitled, under the law, to those earlier filing dates. Cragg had ample opportunity to show that the information it had first given was a mistake but failed to make a successful showing.

When 35 U.S.C. § 116 was amended in 1984 to permit co-inventors to be jointly listed as inventors without all of them having contributed to each and every claim in an application, a

corresponding change was made in 35 U.S.C. § 120 (relating to benefit to the earlier filing date of previously filed United States applications) to require not identity but merely an overlap of inventor(s) between the application seeking benefit and the earlier filed application. The change to 35 U.S.C. § 120 was necessary because additional or non-overlapping inventors may be present due to the inclusion of claims drawn to different subject matter. No such change was necessary, however, with respect to the requirement of 35 U.S.C. § 119 that the person who has filed for a patent on an invention (here the invention of the count) must have previously regularly filed for a patent on the same invention in a foreign country, whether it is through legal representatives or assigns. Indeed, no change was made. The contexts and requirements of 35 U.S.C. § 119 and 35 U.S.C. § 120 are different. That Michael D. Dake being a sole inventor for the subject matter of the count is not a problem under 35 U.S.C. § 120 with respect to earlier filed United States applications does not mean Cragg can expect that it should also not be a problem insofar as benefit to foreign applications are concerned. Satisfaction of requirements under 35 U.S.C. § 120 entitles a party only to the earlier filing date of a previously filed United States application, not a foreign application.

Alternatively, even assuming that Cragg's identification of Michael D. Dake as the only inventor for the subject matter of the count is a mistake and that Cragg has been allowed to amend its preliminary statement to identify both Andrew H. Cragg and Michael D. Dake as co-inventors of the subject matter of the count, that still does not help party Cragg in any meaningful way. Like Michael D. Dake, Andrew H. Cragg also did not assign his rights to MinTec, Inc. until after European application EP94400284.9 was filed on February 9, 1994, and European application EP94401306.9 was filed on June 10, 1994.

Cragg's Exhibit CE1021 is an assignment from Andrew Cragg, Claude Mialhe, George Goicoechea, and John Hudson to MINTEC, INC. It was executed by Andrew H. Cragg on August 22, 1994. Accordingly, MINTEC SARL was not an assign of either Michael D. Dake nor Andrew H. Cragg when it filed European applications EP94400284.9 and EP94401306.9. In that connection, we vacate the Board's previous finding in paragraph no. 7 of Paper No. 130 which stated: "The European applications EP94400284.9 and EP94401306.9 were filed by the assignee MINTEC SARL on behalf of inventors Andrew H. Cragg, George Goicoechea, John Hudson, and Claude Mialhe." That finding was made when the question of when Andrew H. Cragg assigned his rights was not an issue and also prior to party Cragg's representation to the Board in its request

for reconsideration of the Board's granting of Fogarty's preliminary motion 12 that Andrew H. Cragg did not assign his rights to Mintec until several months after the European applications were filed. It lacks adequate basis in the record.[5]

Cragg still further argues that because it has been accorded benefit to the September 27, 1994 filing date of application 08/312,881 (granting of Cragg's preliminary motion 7) and because that application claims foreign priority to EP94400284.9 and EP94401306.9, which claim was granted by an examiner and not challenged in this interference, it still should have benefit of the filing dates of EP94400284.9 and EP94401306.9. The argument is without merit.

As the Board's decision on reconsideration (Paper No, 138) has stated on page 6:

> Benefit to the two European applications cannot be obtained indirectly through the intermediate application 08/312,881, where the required overlap in inventor/filer is missing between the involved application and the European applications. This is not the same issue as satisfying the "filing within one year requirement of § 119" through an intermediary United States parent application.

---

[5] Our authority and discretion to vacate the previous finding does not depend on whether Fogarty has asked the Board to reconsider the finding or when the request by Fogarty was made. We dismiss Cragg's argument that Fogarty was late in asking the Board to reconsider the previous finding.

Cragg has offered no reason why the above-quoted analysis is erroneous. Here, we add the following observations.

Having benefit to the 9/27/94 filing date of application 08/312,881 means Cragg's involved application is deemed to have been filed not on the actual filing date of June 5, 1995, but on September 27, 1994. That brings Cragg's involved application much closer in time, by approximately 8 months, to any foreign application with respect to which it desires to be accorded benefit. With that shortening of the time gap, it is easier to satisfy the "within twelve months" time requirement of 35 U.S.C. § 119. It does not mean Cragg's involved application stands in the shoes or otherwise takes the place of the earlier filed domestic application. Benefit is still considered from the perspective of the claims or counts at issue in Cragg's involved application. Whether application 08/312,881 is entitled to benefit with respect to any claim contained therein is irrelevant, not at issue, and has not been determined in this proceeding. We are concerned with the claims of Cragg's involved application and the count in this interference. Fogarty is also correct in stating (Opp. Brief at 8):

> Cragg's further argument on page 24 that 35 USC § 119 priority "has not been challenged" for Serial No. 08/312,881 also is irrelevant. In the context of an interference, rights under 35 USC § 119 and § 120 arise with respect to an embodiment within the count in a

> benefit application. Hunt v. Treppschuh, 523 F.2d 1386, 187 USPQ 426 (CCPA 1975). It is thus inaccurate to speak of priority between applications without reference to claims and/or a count. (Emphasis in original.)

For the foregoing reasons, Cragg has shown no error in the motion panel's granting of Fogarty's preliminary motion 12.

B. Fogarty's Preliminary Motions 8 and 10

In a decision mailed February 11, 2000 (Paper No. 108), the motions panel denied Fogarty's preliminary motion 8 under 37 CFR § 1.633(e)(1) which sought to declare another interference between proposed new claim 62 of an uninvolved application 08/684,508 of Fogarty and claim 89 of Cragg's involved application 08/461,402, and claim 1 of Martin's involved Patent No. 5,575,817. The decision gave two grounds for denying the preliminary motion:

> (1) that the proposed new interference is barred by 35 U.S.C. § 135(b) because no claim which is the same or substantially the same as Martin's supposedly interfering patent claim 1 had been made by Fogarty within the critical one year period of 35 U.S.C. § 135(b); and
>
> (2) that Fogarty failed to demonstrate that there is interference-in-fact between the allegedly interfering claims.

Fogarty argues, first, that we misapplied the requirements of 35 U.S.C. § 135(b) and that if correctly applied, the requirements of 35 U.S.C. § 135(b) are met. Fogarty further

argues that there is no requirement in 37 CFR § 1.637 or otherwise, in connection with a preliminary motion to declare an additional interference, that the moving party has to demonstrate the existence of an interference-in-fact between the allegedly interfering claims.

1. Interference-In-Fact

According to Fogarty, it can find nothing in the interference rules which requires that in order for a preliminary motion to declare an additional interference to be granted, the preliminary motion must establish or demonstrate that an interference-in-fact exists between the claims sought to be involved in the additional interference. While there may be no express requirement, the decision on preliminary motions (Paper No. 108) on page 53, lines 18-22, states that the requirement is an implicit one:

> Secondly, it is implicit that to demonstrate entitlement to the declaration of an additional interference as is requested in Fogarty's motion, Fogarty must demonstrate that there is interference-in-fact between Goicoechea's [Cragg after deleting Goicoechea as a co-inventor] application claim 89 and claim 62 of Fogarty's uninvolved application 08/684,508. (Emphasis added.)

Party Fogarty's brief at final hearing does not explain why it is not an implicit requirement that a motion to have an

interference declared must demonstrate that the claims said to interfere with each other actually interfere with each other, i.e., that there is interference-in-fact between the allegedly interfering claims. Moreover, the very first sentence of 37 CFR § 1.637(a) is this: "A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion." (Emphasis added).

We decline to simply take a moving party's word that one of its claims interferes with one or more claims of other parties. We reiterate our holding in the decision on preliminary motions that it is an implicit requirement for a preliminary motion to have another interference declared that the motion must demonstrate that there is interference-in-fact between the allegedly interfering claims. Fogarty's brief at final hearing does not address the point of "implicit" requirement and thus has not shown that the motion panel was erroneous.

Fogarty also asserts that in any event the Board's two-way interference-in-fact analysis follows the Trial Section's precedential decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999), but that was not the criteria in October 1998 when preliminary motions were filed in this proceeding. We suppose that what Fogarty is arguing is that had it known of the two-way analysis requirement at the time it filed its preliminary

motion 8, it could have tried to demonstrate satisfaction of the two-way requirement. That is true, but as was explained in our initial decision, Fogarty has failed to explain why there is interference-in-fact, in either direction, e.g., neither from Martin's claim 1 or Cragg's claim 89 to Fogarty's claim 62, nor from Fogarty's claim 62 to Martin's claim 1 or Cragg's claim 89.[6] Note also that the declaration of an interference is a discretionary matter. See Ewing v. Fowler Car Co., 244 U.S. 1, 10-11 (1917) (explicitly rejecting the assertion of an applicant's right to declaration of an interference). It is not an abuse of discretion to not declare an interference where the moving party has not demonstrated that there is a conflict or interference-in-fact between opposing claims, regardless of whether the interference rules expressly require a demonstration of conflicting subject matter or interference-in-fact.

---

[6] The motion panel's decision observed that Fogarty's position that Cragg's claim 89 and Martin's claim 1 are unpatentable over prior art while Fogarty's claim 62 is patentable over that same prior art is contrary to the position that Fogarty's claim 62 defines the same patentable invention as Cragg's claim 89 and Martin's claim 1. Fogarty's brief at final hearing points out that the motion panel rejected Fogarty's prior art argument and that Cragg has not sought review of that issue. But at best the circumstance pointed out by Cragg only eliminates an apparent inconsistency. It does not demonstrate affirmatively that the claims define the same patentable invention.

2. 35 U.S.C. § 135(b) Bar

There is no dispute that Fogarty's amendment in its uninvolved application 08/684,508, proposing to add claim 62 to provoke an interference with claim 89 of Cragg's application 08/461,402 and claim 1 of Martin's Patent No. 5,575,817, is filed more than one year after the date of issuance of Martin's Patent No. 5,575,817. The question at issue is whether Fogarty had another claim, drawn to the same or substantially the same invention as Martin's claim 1, that was pending within one year subsequent to the date of issuance of the Martin patent. If so, claim 62 is not barred. If not, then claim 62 is barred.

In pertinent part, 35 U.S.C. § 135(b) states:

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Even though the new interference proposed by Fogarty involves claim 1 of Martin's patent, Fogarty attempted to demonstrate that it had a claim drawn to substantially the same subject matter as Martin's claim 1 by showing that it was claiming, within the critical one year period, the same invention as Martin's claim 2. Martin's claim 2 depends from claim 1 and in independent form represents the count of this interference.

In the motion panel's initial decision (Paper No. 108, pages 52-53), it was stated:

> There is no indication anywhere by any party that Fogarty's uninvolved application 08/684,508 had a claim drawn to substantially the same subject matter as Martin's claim 2. While Fogarty's involved application [08/463,836] in this interference include claims which correspond to the count which is Martin's claim 2, that does not mean Fogarty's uninvolved application 08/684,508 has at any time included a claim drawn to substantially the same subject matter as Martin's claim 2.

In its brief for final hearing, Fogarty argues that so long as it was claiming the required subject matter in some earlier application within one year of the issuance of the Martin patent, it passes muster under 35 U.S.C. § 135(b). Fogarty cites two decisions of the Court of Customs and Patent Appeals, In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981) and Corbett v. Chisholm, 568 F.2d 759, 196 USPQ 337 (CCPA 1977), two decisions of the Board of Patent Interferences, Tezuka v. Wilson, 224 USPQ 1030, 1036 (Bd. Pat. Int. 1984), Olin v. Duerr, 175 USPQ 707 (Bd. Pat. Int. 1972), and one decision of the Board of Patent Appeals and Interferences, Bowen v. Bihlmaier, 231 USPQ 662 (Bd. Pat. App. & Int. 1986), in support of its view. Fogarty points out that its uninvolved application 08/684,508 is a file wrapper continuation of application 08/255,681, to which it has been

accorded benefit in this interference and with respect to which Fogarty's involved application is a divisional application.

Cragg's opposition brief does not take up and address the issue as noted above. We find Fogarty's presentation persuasive at least in the circumstances of this case. Consequently, we no longer rely on the above-quoted portion of the motion panel's decision to deny Fogarty's preliminary motion 8.

Another issue, however, nonetheless undermines and precludes the granting of Fogarty's preliminary motion 8. As was explained in the motion panel's decision on page 53:

> [W]e disagree with Fogarty's contention that if a claim the same as Martin's claim 2 is made in an application, then a claim the same as Martin's claim 1 is also necessarily made, simply because Martin's claim 2 depends from Martin's claim 1 and thus includes all features of Martin's claim 1. The case cited by Fogarty, In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981), does not hold that so long as every feature of a claim is present in another claim then substantially the same subject matter is being claimed. In Schutte, no other difference between two claims is at issue, except for the one which the Court regarded as different in language but same in substance.

Fogarty's view leads to the erroneous result that a claim directed to patentably distinct and separately patentable subject matter as that of another claim can be regarded, at the same time, as claiming the same or substantially the same invention as that other claim. Party Cragg should note that Martin's claim 2 can be separately patentable and patentably distinct from

Martin's claim 1 even though it depends from claim 1 and undoubtedly includes every limitation of claim 1.

Because it is important that we fully address Fogarty's arguments, we reproduce portions of Fogarty's brief below (Br. at 7-8):

> Fogarty responded to Cragg's assertion of noncompliance with 35 USC § 135(b) by noting that the determination under the statute is:
>
> > [W]hether the claim which was pending had *all the material limitations* of the patent claim. *In re Schutte*, 244 F.2d 323, 113 USPQ 537 (CCPA 1981). If the pending claims had all the material limitations there is compliance with the statute even if different language is employed. [Fogarty Reply, p. 5, original italics]
>
> This principle of law has been applied for at least half a century, as is apparent from the authorities cited in the last two paragraphs on page 5 of Fogarty's Reply, i.e., *Ex parte Bowen*, 80 USPQ 106 (Bd. App. 1947), *Stalego v. Heymes*, *supra*, *Olin v. Duerr*, *supra*, and *In re Schutte*, *supra*.
>
> The decision adopted Cragg's argument but with one possible exception did not address (nor acknowledge) the precedents cited by Fogarty.
>
> The test in each of *Bowen*, *Stalego*, *Olin* and *Schutte* for determining compliance with 35 USC § 135(b) is straight forward: is a limitation of the patent claim material and if so, is it claimed by the applicant, expressly or inherently? [Footnote omitted] Application of this test to different fact patterns is seen in a comparison of the results in, for example, (i) *Corbett v. Chisholm*, *supra*, where there was no compliance because a limitation was material but was neither disclosed nor inherent, (ii) *Bowen v.*

Bihlmaier, supra where compliance was found because the material limitation was substantially claimed albeit in different language, (iii) *Connin v. Andrews*, 223 USPQ 243 (Bd. Pat. Int'f. 1984) where the limitation, while material and undisclosed, was inherent, and (iv) *Pizzurro v. Pfund*, 1 USPQ2d 1056 (Bd. Pat. Int'f. 1984) where a limitation was material and claimed.

In our view, none of the authorities Fogarty cites sets forth the principle that so long as every material limitation of a patent claim is included in an applicant's claim, then the applicant has claimed substantially the same invention as the patent claim regardless of whether the applicant's claim includes additional features which may render the applicant's claim patentably distinct or separately patentable from the patent claim.

Except for In re Tanke, 213 F.2d 551, 102 USPQ 83 (CCPA 1954), Stalego v. Heymes, 263 F.2d 334, 120 USPQ 473 (CCPA 1959), Wetmore v. Miller, 477 F.2d 960, 177 USPQ 699 (CCPA 1973), and Corbett v. Chisholm, 568 F.2d 759, 196 USPQ 337 (CCPA 1977), none of the other cases cited by Fogarty[7] for determining whether substantially the same invention was being claimed by an

---

[7] Not Rieser v. Williams, 255 F.2d 419, 118 USPQ 96 (CCPA 1958); not In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981); not Ex parte Bowen, 80 USPQ 106 (Bd. App. 1947); not Olin v. Duerr, 175 USPQ 707 (Bd. Pat. Int. 1972); not Connin v. Andrews, 223 USPQ 243 (Bd. Pat. Int. 1984); not Pizzurro v. Pfund, 1 USPQ2d 1056 (Bd. Pat. Int. 1984); not Bowen v. Bihlmaier, 231 USPQ 662 (Bd. Pat. App. & Int. 1986).

applicant discussed as an issue whether the applicant's claim contained additional features which made the application claim not substantially the same as the patent claim. Fogarty too strictly applied the principle that if every material feature of the patent claim is present in the application claim then substantially the same invention is being claimed by the applicant. The mistake lies in not recognizing that the applicant's claim may include material features that render the applicant's claim patentably distinct and separately patentable from the patent claim.

In Stalego v. Heymes, 263 F.2d 334, 335, 120 USPQ 473, 475 (CCPA 1959), the Court of Customs and Patent Appeals stated:

> Those decisions [citing to precedents] hold, in effect, that claims are not for substantially the same subject matter if one of them contains one or more material limitations which are not found in the other. Accordingly, the ultimate question to be decided in such cases is generally whether specific differences between claims are material; and that is a question which must be decided largely on the basis of the particular circumstances of each case.

In Stalego, the Court reviewed the additional features of the reissue applicant's claim and stated that it did not regard any of those limitations as important. In analyzing the additional features claimed by the reissue applicant, the Court in Stalego, 263 F.2d at 338, 120 USPQ at 477, referred to one feature as not having criticality and another as adding nothing of consequence.

The key is that the limitations of the applicant's claim at issue must be examined and are relevant too for materiality, not just the features of the patent claim. In Wetmore v. Miller, 477 F.2d 960, 177 USPQ 699, 701 (CCPA 1973), the Court of Customs and Patent Appeals cited to Rieser v. Williams, 255 F.2d 419, 118 USPQ 96 (1958) and Stalego v. Heymes, 263 F.2d 334, 120 USPQ 473 (1959), as setting forth the criterion that has been adopted by the CCPA for determining the applicability of section 135(b).

We do not regard Wetmore v. Miller as making any change to the criterion set forth in Stalego v. Heymes. Evidently, neither does Fogarty. In Wetmore, in light of the additional "fusible" limitation contained in the applicant's claim, the Court stated that the Board made too much emphasis on the fact that the patent claim applies to multiple embodiments and gave insufficient weight to embodiments in the patent using a heat fusible member. Note that the patent claim utilized means-plus-function features under 35 U.S.C. § 112, sixth paragraph. Clearly, the Court considered the technical significance of features in the applicant's claim in a comparison with the claim of the patentee.

In Corbett v. Chisholm, supra, and as Fogarty itself has noted, (Reply at 6, lines 19-25), in response to a restriction requirement the applicant elected to prosecute apparatus claims instead of method claims as the patentee had claimed and the

patentee's method could be practiced with apparatus materially different from that which the applicant elected. On that basis, the Court held that the applicant's claim and the patentee's claim defined patentably distinct inventions. Thus, the applicant was not claiming substantially the same invention as the patentee. What this suggests is that the features claimed by the applicant, over and above that which is claimed by the patentee, are important and cannot be ignored.[8]

As for In re Tanke, 213 F.2d 551, 102 USPQ 83 (CCPA 1954), it does not hold, as Fogarty argues on page 8 of its reply, that "a mere distinction in breadth or scope" does not define a separate invention. The language of In re Tanke must be read in context. What it actually conveys is that where the subject matter of the differently claimed inventions has already been determined as being directed to substantially the same invention, the specific variations are a mere distinction in breadth or scope within the same or substantially the same subject matter and thus do not define separate inventions or inventions which are not substantially the same. Note that In re Tanke states, 213 F.2d at 555, 102 USPQ at 85:

---

[8] Note also that other claims of the applicant did not include one or more material features of the patentee's claim.

> Furthermore, it should be noted that the terms "draft structure" defined by appellants' original claims 6 and 14, and the terms such as "drawbar-receiving member" and "bail-receiving member" in the appealed claims seem to be merely different expressions for essentially the same apparatus both structurally and functionally.
>
> The final conclusion of the board in this case holding that the recitation of the draft structure in the appealed claims "to be different in scope from that recited in claim 14" does not appear to legally establish that such claims are not for substantially the same subject matter.
>
> In dealing with competing claims, one group of which was drawn to a spring which assisted in both lifting and lowering certain plow beams therein defined, and another group which merely defined the function of the spring as assisting in the lifting of said beams, the Supreme Court held that **both groups of claims were for the same combination;** . . . and that such [one group of] claims should they consist of nothing more than a mere distinction in breadth or scope when compared to the [other group of] patented claims, do not define a separate invention or subject matter which is not substantially the same. Miller v. Eagle Manufacturing Co., 151 U.S. 186 [citations omitted]. (Empahsis added.)

Fogarty's claim 27, the same as original claim 27 in Fogarty's parent application 08/255,681 filed on June 8, 1994, was made within the one-year of November 19, 1996, the date of issuance of Martin's Patent No. 5,575,817. Even assuming that claim 27 includes every feature of Martin's dependent claim 2, and therefor it must include every feature of Martin's independent claim 1, that does not mean Fogarty had claimed substantially the same invention as Martin's claim 1. Martin's

independent claim 1 formed the basis of the count in related Interference No. 104,083. Martin's dependent claim 2 forms the basis of the count in this interference (See Paper No. 16). Martin's claim 2 adds a feature which is not present in Martin's claim 1. Fogarty had notice that the examiner regarded Martin's claim 2 as patentably distinct from Martin's claim 1. On page 3 of the examiner's Rule 1.609(b) submission, it is stated:

> **Distinction between Counts 1 and 2.**
>
> The important feature of count 1 [the count in Interference 104,083] is that the bifurcated prosthesis has two limbs but only one limb extends across the bifurcation and into the lumen of the vessel. Count 2 [the count in this interference] requires an additional stent to be added to the short limb, thus making a two piece graft that extends into both branches of the vessel. The count 2 is patentably distinct from count 1 for this reason.

Moreover, on page 9 of Fogarty's preliminary motion 8, Fogarty expressly recognized that the USPTO has regarded the counts of Interference No. 104,083 and this interference, represented by Martin's claims 1 and 2, as being directed to separately patentable inventions. Fogarty did not challenge that position. Instead, Fogarty stated that "[t]he same would apply to the Count of the present interference and proposed Count F-2 [for the additional interference]."

In summary, according to Fogarty, because its claim 27 was pending within the critical one-year period of 35 U.S.C. § 135(b)

and because claim 27 includes every feature of Martin's dependent claim 2, and therefore Martin's independent claim 1, Fogarty was claiming substantially the same invention as Martin's claim 1 within the critical one-year period of 35 U.S.C. § 135(b). We reject Fogarty's argument, because it regards as irrelevant whether the additional feature added by Martin's dependent claim 2 renders Martin's claim 2 patentably distinct and separaetly patentable from Martin's claim 1. If it is, as it apparently is so based on the examiner's Rule 1.609(b) submission, a position Fogarty has not disputed and in fact urged as similarly true with the count in this interference as compared to the proposed count (see Fogarty's preliminary motion 8, Section 7 on page 9), then Fogarty cannot be deemed as claiming substantially the same invention as Martin's claim 1 by way of having a claim the same as Martin's claim 2.[9] Fogarty has failed to demonstrate that it had been claiming substantially the same invention as Martin's claim 1 within the one-year period of 35 U.S.C. § 135(b).

3. Cragg's Assertion that claim 62 of Fogarty's uninvolved application is unpatentable under 35 U.S.C. § 112, first and second paragraphs

---

[9] This is in contrast with the applicant's claiming the same patentable invention as the patentee but merely adds features which are of no criticality or significance. See Stalego v. Heymes, 263 F.2d at 338, 120 USPQ at 477.

In opposing Fogarty's preliminary motion 8, Cragg never asserted that any claim of Fogarty was unpatentable for indefiniteness under 35 U.S.C. § 112, second paragraph. The brief for final hearing is not an occasion to be raising such issues for the first time. Accordingly, we decline to entertain Cragg's argument that claim 62 of Fogarty's uninvolved application is unpatentable under 35 U.S.C. § 112, second paragraph.

The motion panel's decision on preliminary motions (Paper No. 108) stated that it was manifestly apparent based on the entirety of the pleadings that claim 62 and not claim 63 of Fogarty's uninvolved application was the claim at issue in connection with Fogarty's motion to have an additional interference declared. It further found that parties Cragg and Martin would not be prejudiced by a recognition that Fogarty's motion concerned claim 62 of Fogarty's uninvolved application. While opposing Fogarty's motion, Cragg asserted that Fogarty's claims 62 and 63 are unpatentable under 35 U.S.C. § 112, first paragraph, but meaningfully discussed only the features of Fogarty's claim 63. Because nothing meaningful was presented with regard to Fogarty's claim 62, the decision on preliminary motions did not discuss Cragg's mere conclusion that Fogarty's claim 62 is unpatentable under 35 U.S.C. § 112, first paragraph.

In its opposition brief at final hearing, Cragg asserts that claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph, and makes a detailed analysis, for the first time, as to why the assertion has merit. This substantive analysis directed to Fogarty's claim 62 was not previously provided in Cragg's opposition to Fogarty's preliminary motion 8. Accordingly, such analysis will not be entertained for the first time at final hearing.

We will not compare Fogarty's claims 62 and 63 and attempt to figure out which features are common therebetween such that when Cragg discussed a certain feature of claim 63 when opposing Fogarty's preliminary motion 8 it was the same as if it were discussing a corresponding feature in Fogarty's claim 62. It was incumbent upon Cragg when opposing Fogarty's motion to clearly set forth why Fogarty's claim 62 is unpatentable under 35 U.S.C. § 112, first paragraph. It is not the role of the Board to act as an advocate for either party by making arguments, presentations, or comparisons which should have been made by the parties themselves.

Because no meaningful argument was presented by Cragg in its opposition to Fogarty's preliminary motion 8 as to why claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph, we reject Cragg's

argument at final hearing that claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph.

Alternatively, even if we do consider the substantive arguments made for the first time by Cragg in its opposition brief at final hearing concerning claim 62 of Fogarty's uninvolved application 08/684,508, the arguments are without merit and do not make out a prima facie case that claim 62 of Fogarty's application 08/684,508 is without written description support in the specification.

According to Cragg, the features (1) a first leg joined to said anchor section, and (2) means for joining a second leg to said anchor section, of claim 62 of Fogarty's uninvolved application 08/684,508 are without support in the specification of application 08/684,508. Cragg contends that "Fogarty's first leg is never joined to an anchor section." Cragg explains that Fogarty's first leg is positioned within a fiber fabric liner at a location spaced below the anchor section. According to Cragg, Fogarty's second leg is also not joined to the anchor section, evidently for the same reason, and thus there can be no description for a "means for joining a second leg to said anchor section." Cragg's arguments assume that there must be direct contact between the first leg and the anchor section and between

the second leg and the anchor section. We see no reason, however, to construe claim 62 of Fogarty's uninvolved application 08/684,508 so narrowly as to require direct or immediate contact between the first and second legs and the anchor section.

Cragg does not contend that Fogarty's application 08/684,508 sets forth a special definition for the word "join" that is different from the ordinary meaning of the term. We understand the word "join" as sufficiently broad to encompass an indirect connection through an intermediate member. See, for example, Merriam-Webster's Collegiate Dictionary, Tenth Edition, Copyright © 1999, which defines "join" as follows:

> 1 a: to put or bring together so as to form a unit . . . . b: to connect (as points) by a line c: ADJOIN 2: to put or bring into close association or relationship . . . 3: to engage in (battle) 4 a: to come into the company of . . . b: to associate oneself with . . .

If the first and second legs in Fogarty's application 08/684,508 are connected to the anchor section by way of a fiber fabric liner, as Cragg apparently indicates, that does not mean the first and the second legs are not joined to the anchor section. Cragg argues that the tubular liner means cannot also be the means for joining because if it is then that would render meaningless the tubular liner means element of claim 62. The argument is without merit, because the recitation of a tubular liner means in claim 62 further specifies that the liner

structure defines a continuous flow path from the anchor section to the first leg and an opening disposed toward the second branch lumen. We note further that nothing precludes the same disclosed physical element from being the corresponding structure of two or more means-plus-function elements in a claim, provided that the structure performs the recited functions of those means-plus-function clauses.

4. Fogarty's argument that notwithstanding any 35 U.S.C. § 135(b) bar relative to patentee Martin, Fogarty is not precluded from having an interference with Cragg is without merit

Fogarty points out that in related Interference No. 104,083 involving only Martin and Cragg, specifically Cragg claim 89 and Martin claim 1, judgment has been entered against patentee Martin and thus claim 1 of Martin is as good as cancelled. According to Fogarty, the time bar under 35 U.S.C. § 135(b) is for protecting patentees from perpetually under threat of an interference proceeding initiated by applicants. Thus, Fogarty argues that because judgment has been entered against Martin's patent claim 1 in Interference No. 104,083, protection for Martin under 35 U.S.C. § 135(b) insofar as Martin's claim 1 is concerned is moot and unnecessary. Fogarty's view is that in this circumstance, application of the bar under 35 U.S.C. § 135(b) only protects another applicant, i.e., party Cragg, whose claim 89 would be shielded from a priority determination relative to Fogarty.

While 35 U.S.C. § 135(b) was primarily enacted to protect patentees, the language of the statute is not such that only a patentee may benefit from the bar. The statutory section is written in terms of a bar on the presentation of a claim, not as a bar on having an interference with a patentee. If an applicant is time-barred by 35 U.S.C. § 135(b) from presenting a certain claim, then it follows that the barred claim cannot serve as the basis of an interference with respect to another applicant whose claim for the same patentable invention is not subject to the bar. Thus, if applicable, the bar under 35 U.S.C. § 135(b) yields an incidental benefit to potentially opposing applicants. The statutory section does not restrict or limit who may benefit from application of the bar, as it only precludes the presentation of a claim. Note that 35 U.S.C. § 135(b) has been upheld as an applicable ground of rejection in ex parte prosecution before the USPTO. In re McGrew, 120 F.3d 1236, 43 USPQ2d 1632 (Fed. Cir. 1997).

Fogarty would have us read into 35 U.S.C. § 135(b) language that is not there, to turn it into a bar against having certain types of interferences instead of simply a bar on the presentation of certain claims as it so plainly reads. We decline to so distort or add to the statutory language. In our

view, if Fogarty cannot present a claim, then it cannot have an interference based on that claim with another party, whether that other party is an applicant or a patentee.

Fogarty's claim 62 was presumed by the parties as being for substantially the same invention as Martin's patent claim 1. Because it was presented outside of the one year period from the date of issuance of the Martin patent, and because Fogarty can demonstrate no other claim which was pending prior to the one year period and which was directed to substantially the same invention as Martin's claim 1, Fogarty's claim 62 is barred.

The fact that Martin's patent claim 1 has been determined unpatentable to Martin because of an adverse judgment in Interference No. 104,083 does not help Fogarty. The language of 35 U.S.C. § 135(b) refers to a claim for the same or substantially the same subject matter as "a claim of an issued patent" and does not purport to add the qualifications that such a claim must remain valid, non-canceled, patentable, non-disclaimed, and/or enforceable. We decline to read into 35 U.S.C. § 135(b) these conditions in the absence of a showing by Fogarty of a clear legislative intent to that effect. The operative word is "issued," similar to the word "born." Just as a baby cannot be un-born, an issued claim cannot become non-issued whatever its status becomes subsequent to issuance.

The public's interest is not harmed by applying 35 U.S.C. § 135(b) the way it is written and enacted by Congress. Fogarty is also under a mistaken belief that it is prejudiced by its not being successful with preliminary motion 8 to get into an interference with Cragg who has a dominating claim. Fogarty's predicament arises from its not having established, in connection with a proposed new interference involving Cragg's claim 89, interference-in-fact with respect to a Fogarty claim that is not time barred under 35 U.S.C. § 135(b). Alternatively, if Fogarty believes that Cragg's dominating claim 89 and any Fogarty claim involved in this interference define the same patentable subject matter, Fogarty could have moved to broaden out the count in this interference to the scope of Cragg's claim 89 and to have Cragg's claim 89 designated as corresponding to the revised new count. Fogarty did not take such action in this case. On these circumstances, that Cragg has a dominating claim not involved in this interference or a new interference with Fogarty does not mean Fogarty has been subjected to prejudice. A dominating claim is not necessarily a claim drawn to the same patentable invention as a dominated claim. In either case, however, with regard to Cragg's allegedly dominating claim 89 Fogarty has shown no prejudice by the denial of its preliminary motion 8.

5. Fogarty's preliminary motion 10

Fogarty's preliminary motion 10 sought to be accorded benefit of the earlier filing date of application 08/255,681, with respect to the count proposed in connection with Fogarty's preliminary motion 8. Consequently, preliminary motion 10 is contingent upon the granting of preliminary motion 8. Because Fogarty's preliminary motion 8 was properly denied, Fogarty's preliminary motion 10 was correctly dismissed as moot.

6. Cragg's Motion to Suppress

Cragg has filed a motion to suppress five exhibits FE-3001, FE-3002, FE-3004, FE-3005, and CE-1019. These are exhibits identified by party Fogarty, prior to submission of its brief at final hearing, as those which Fogarty intended to rely upon at final hearing in connection with its seeking review of the motion panel's decision of Fogarty's preliminary motion 8. According to Cragg, Fogarty may not rely on these exhibits at final hearing because Fogarty did not rely on these exhibits when filing its preliminary motion 8.

Cragg has not pointed out, and it is not immediately apparent, where in Fogarty's briefs at final hearing are references made to exhibits FE-3001, FE-3002, FE-3004, FE-3005, and CE-1019, or how the substance of these exhibits have been relied upon by Fogarty in meaningful furtherance of any argument.

Thus, with regard to these exhibits, Cragg has failed to make out a prima facie case of why the motion to suppress should be granted. Alternatively, even without suppressing these exhibits, Fogarty's arguments concerning its preliminary motions 8 and 10 have not been shown to have merit. Accordingly, Cragg's motion to suppress is denied and alternatively dismissed as moot.

C. Cragg's Preliminary Motion 1

In Cragg's preliminary motion 1, it is alleged that Fogarty's claims 41-69, not all of Fogarty's claims corresponding to the count, are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description in the specification. Fogarty's claims 42-69 depend either directly or indirectly from claim 41. Cragg's preliminary motion 1 (Paper No. 39, pp. 6-7) specifically identified the following feature of Fogarty's method claim 41 as that which is without written description:

> [I]ntroducing into a patient's vasculature an anchor section and first tubular graft of the vascular graft so that the anchor section is disposed within the primary artery and the first tubular graft is disposed within the first branch artery to form a first continuous flow path from the primary artery to the first branch artery.

According to Cragg's preliminary motion 1, the above-quoted feature of Fogarty's method claim 41 requires the anchor section and the first tubular graft to be introduced in a single step, not sequentially as is disclosed in Fogarty's specification. We

reproduce the following paragraph from page 10 of Cragg's preliminary motion 1, which clearly reveals Cragg's position:

> The Fogarty Application fails to suggest introducing an anchor section and first tubular graft in a single step. Instead, the Fogarty Application teaches (1) first introducing the bifurcated base structure so that the anchor section is positioned within a primary vessel; (2) *after the bifurcated base structure is anchored,* the first tubular graft is introduced into the first connector leg and anchored between the leg and the first branch artery; and (3) the second tubular graft is *then* inserted into the second connector section and anchored between the described second connector and the second branch artery. See Fogarty Application at Page 6, lines 1-9. (Emphasis in original).

The decision on preliminary motions rejected Cragg's argument, stating (Paper No. 108, p. 10):

> We reject Goicoechea's [Cragg's] argument because we do not read or interpret the above-quoted language of claim 41 as requiring that the anchor section and the first tubular graft be introduced "in a single step" or simulataneously. The words "in a single step" do not appear in claim 41, nor do the words "simulataneously," "concurrently," "unison," or any other term which means the same. The language is simply broadly recited and imposes no particular order for the insertion of the anchor section and the first tubular graft.

In its principal brief at final hearing, Cragg does not continue to argue that Fogarty's claim 41 requires that the anchor section and the first tubular graft be introduced in a single step or simultaneously. Rather, a new argument is made through the back door that the claim is so broad that the full

scope of what is claimed is not described in the specification. Specifically, on page 20 of its brief, in a section entitled "CRAGG MOTION 1 SHOULD BE GRANTED," Cragg states:

> If the Board adheres to its broad construction of claim 41 [that no specific sequence of introduction is required], then the Fogarty specification lacks written description for claim 41 because as discussed it only describes the sequential introduction of the anchor section and the first tubular graft but not the introduction of the anchor section and first tubular graft as a unitary structure. There is nothing in the Fogarty application to convey to those skilled in the art that Fogarty was in possession of that aspect of the invention of claim 41, if claim 41 is broadly construed as proposed.

We have again reviewed Cragg's preliminary motion 1 (Paper No. 39). Nothing therein can reasonably be considered as an alternative or contingent argument that if the Board is not persuaded by Cragg's primary argument that Fogarty's claim 41 requires the introduction of the anchor section and the first tubular graft in a single step then the claim is nonetheless not described in the specification because of undue breadth. In the case of Cragg's preliminary motion 1, the one argument actually made is the only argument made. Consequently, the issue now raised by Cragg at final hearing was neither developed and briefed by the parties during the preliminary motions stage of this interference, nor considered by the motions panel when preliminary motions were decided.

In short, Cragg wants the board to now hold Fogarty's claims 41-69 as being without written description in the specification for a reason other than that articulated and set forth by Cragg in its preliminary motion 1. We decline to consider this new argument at the final hearing stage of the proceeding. Final hearing under the interference rules is not a place to begin preliminary motions afresh. Rather, we are here to review the decision by a three-member motions panel on preliminary motions made by the parties, on the evidence and arguments which formed the basis of the decision on preliminary motions.

A new reason for granting a motion should not be considered at final hearing if it was not included in the original motion and not supported by a showing of good cause why the argument was not earlier presented. Fredkin v. Irasek, 397 F.2d 342, 346, 158 USPQ 280, 284 (CCPA 1968); Koch v. Lieber, 141 F.2d 518, 520, 61 USPQ 127, 129 (CCPA 1944); Bayles v. Elbe, 16 USPQ2d 1389, 1391 (Bd. Pat. & Int. 1990)("It has been a longstanding practice that a party whose motion was denied cannot present at final hearing grounds not included in the original motion."). It is inappropriate for a party to present arguments in its brief which were not a part of the motion or opposition. Lawson v. Enloe, 26 USPQ2d 1594 (Bd. Pat. App. & Int. 1992).

All reasons for granting a party's desired relief should be advanced in the party's motion. A piecemeal presentation in which a party may start over with new arguments after an adverse decision has been rendered would make an orderly proceeding next to impossible to conduct. Cragg's brief offered no excuse for raising the issue of undue breadth issue so late, more than two years after the filing of Cragg's preliminary motion 1 on October 16, 1998, and ten months after the decision on preliminary motions has been rendered.

Cragg cannot credibly assert that it had no idea that Fogarty's claim 41 can possibly be construed so as to not require the introduction of the anchor section and the first tubular graft in a single step or simultaneously. As the moving party, Cragg was attempting to persuade the Board to adopt a narrow interpretation of Fogarty's claim 41, i.e., that the claim required the introduction of the anchor section and the first tubular graft in a single step or simultaneously. The mere filing of Cragg's motion reflects an awareness that the claim may not be so construed. Cragg was very much on notice that the Board may not adopt the narrow interpretation urged by Cragg. Cragg may not credibly claim to have been blind-sided by the Board's not adopting its position.

An interference is an inter partes proceeding. The Board may not suitably act as an advocate for either party, either to fill in gaps left open in either party's presentation, or to offer an alternate rationale and to try to fit the facts to that rationale, all on its own, particularly when the considerations are complex and the parties may well differ in their views. In presenting a preliminary motion for judgment, a party may not simply plead a statutory section, e.g., 35 U.S.C. § 112, first paragraph, and then rely on the Board to propose different ways in which the opponent's claims may possibly be attacked as being without written description in the specification. With regard to Cragg's preliminary motion 1, our decision on preliminary motions addressed the arguments made by Cragg. The new argument now presented by Cragg is not entitled to consideration.

For the foregoing reasons, the motions panel properly denied Cragg's preliminary motion 1.

D. Cragg's Preliminary Motion 2

We adopt in its entirety the discussion in our decision on preliminary motions (Paper No. 108), which is reproduced below, and then add a few more comments to address Cragg's brief at final hearing:

By this motion, Goicoechea [Cragg] alleges that there is no interference-in-fact between its involved application 08/461,402 and Fogarty's involved application 08/463,836. As is stated in 37 CFR § 1.601(j):

> An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

In that regard, 37 CFR § 1.601(n) states:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". (Emphasis in original.)

Resolution of an interference-in-fact issue involves a two-way patentability analysis. For there to be an interference-in-fact, the parties must each have at least one claim which collectively satisfy the following: The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must

anticipate or render obvious the claimed invention of Party A.

For a showing of no-interference-in-fact, the burden is on Goicoechea as the movant, see, e.g., 37 CFR § 1.637(a), to demonstrate that all of Goicoechea's claims 55, 59, 62-65, 88 and 90 which correspond to the count do not define the same patentable invention as any one of Fogarty's claims 27-69, or that all of Fogarty's claims 21-69 do not define the same patentable invention as any one of Goicoechea's claims 55, 59, 62-65, 88 and 90. Goicoechea has attempted to show that all of its claims 55, 59, 62-65, 88 and 90 define an invention process which is neither anticipated nor obvious over any one of Fogarty's claims 27-69.

Goicoechea argues that all of its claims include a "long-leg, short-leg" concept which is absent from and not suggested by any one of Fogarty's claims corresponding to the count. Also, apparently referring to the count, the motion on page 10 explains the subject matter "supposedly" in conflict as follows:

> The invention that is the subject of this Interference relates to a two-section apparatus comprising (1) a first section configured to be positioned within a

> bifurcated lumen and (2) a second section configured to be positioned separately in a branch of the bifurcated lumen and to extend into the bifurcated lumen. A first lower limb of the first section is configured so that it extends into a first leg of the bifurcation when the first section is positioned in the lumen. A second lower limb of the first section, which is shorter than the first lower limb, is configured so that it does not extend into a second leg of the bifurcation. Accordingly, the first section defines a "long-leg, short-leg" concept. Joining two components (the first and second sections) completes the apparatus. (Emphasis in original).

Of all Goicoechea claims which correspond to the count, claims 55, 59 and 90 are independent claims. Claim 90 is identical to the count. Claim 55 embodies the "long-leg, short-leg" idea by including step (a) -- disposing said proximal portion of said bifurcated prosthesis in said blood vessel such that said first distal portion of said bifurcated prosthesis extends into said first branched vessel [long-leg], and step (c) -- attaching said second prosthesis to said extension portion of said bifurcated prosthesis such that said second prosthesis extends into said second branched vessel [short-leg]. But claim 59 is broad and does not do the same. In that regard, claim 59 is reproduced below:

> 59. A bifurcated prosthesis for use with an angeological bifurcation of a blood vessel into two branched vessels comprising a bifurcated proximal portion adapted to be disposed within said blood vessel, a distal portion adapted to extend across the bifurcation into one of the branched vessels, and a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel.

Goicoechea has not shown that claim 59 requires that whenever the proximal portion is placed within the blood vessel, the first distal portion is already attached to the proximal portion and extending from the blood vessel into a branched vessel and the second distal segment is not yet joined to the proximal portion. Indeed, claim 59 is broad enough to cover the case of two short-legs, i.e., the proximal portion is introduced into the blood vessel first, and then the first distal portion and the second distal segment are introduced in sequence, each extending into a respective branched blood vessel.

For the foregoing reasons, the patentable distinction argued by Goicoechea does not exist with respect to at least Goicoechea's independent claim 59. That alone is sufficient ground to reject Goicoechea's motion for no interference-in-fact. Additionally, with

respect to Fogarty's claims 41-69, Goicoechea is improperly reading into those claims a specific embodiment from Fogarty's disclosure rather than focusing on the language of the claims themselves. As we discussed in the context of Goicoechea's preliminary motion 1, Fogarty's independent claim 41 is broadly recited and imposes no particular manner for the insertion of the anchor section and the first tabular graft.

Given Fogarty's claim 41, it is left to the discretion of one with ordinary skill in the art just how to introduce the anchor section and the first tubular graft. One with ordinary skill in the art possesses a certain basic level of skill. See, e.g., In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) ([Applicant's] argument presumes stupidity rather than skill). A conclusion of obviousness also may be made based on the common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 163 USPQ 545, 549 (CCPA 1969). It cannot be reasonably argued that one with ordinary skill in the art is so devoid of skill and

common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined in situ, or inserted as a unitary whole. Those are the only two possibilities with regard to the insertion of the anchor section and the first tubular graft. In our view, selecting one of the two readily apparent choices would have been well within the basic level of skill and common sense possessed by one with ordinary skill in the art. Moreover, it is incumbent upon Goicoechea as the movant to establish why, given Fogarty's independent claim 41, one with ordinary skill in the art would not have known that the anchor section and the first tabular graft can be inserted as one or separately. Goicoechea set forth no persuasive reasons in that regard.

For the foregoing reasons, Goicoechea has failed to demonstrate that all of its claims 55, 59, 62-65, 88 and 90 do not define the same patentable invention as any one of Fogarty's claims 27-69. Goicoechea's preliminary motion 2 insofar as it seeks a judgment based on no interference-in-fact is denied.

As for Goicoechea's assertion that Fogarty's claims 27-69, all of Fogarty's claims which have been designated as corresponding to the count in the declaration of this interference, do not correspond to the count, Goicoechea has to satisfy the requirements set forth in 37 CFR § 1.637(c)(4). Goicoechea has to show that each of Fogarty's claims 27-69 does not define the same patentable invention as any of Goicoechea's claims and Martin's claims whose correspondence to the count Goicoechea does not dispute.

As is already discussed above in connection with Goicoechea's assertion of no interference-in-fact, Goicoechea has not established patentable distinction between Fogarty's claims 41-69 and at least Goicoechea's claim 55 and claim 90, and also between Fogarty's claims 27-69 and at least Goicoechea's claim 59. Goicoechea's preliminary motion 2 to designate Fogarty's claims 27-69 as not corresponding to the count is denied.

Nothing presented by Cragg in its brief at final hearing demonstrates that our above-quoted analysis was in error. Fogarty is correct that Cragg continues to attempt an

inappropriate reading of extraneous limitations from the specification into the claims. Although the specification is useful in interpreting claim language, as the Court of Appeals for the Federal Circuit has nonetheless stated, "the name of the game is the claim." In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). See also Giles Sutherland Rich, Extent of Protection and Interpretation of Claims--American Perspectives, 21 Int' Rev. Indus. Prop. & Copyright L, 497, 499 (1990)("The U.S. is strictly an examination country and the main purpose of the examination, to which every application is subjected, is to try to make sure that what each claim defines is patentable. To coin a phrase, the name of the game is the claims."). Reading into the claims an extraneous limitation from the specification is simply improper. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988). In E.I. de Pont, 849 F.2d at 1433, 7 USPQ2d at 1131, the Federal Circuit stated:

> It is entirely proper to use the specification to interpret what the Patentee meant by a word or phrase in the claim. See, e.g., Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir. 1985). But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By "extraneous," we mean a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.

In interpreting its own claims, Cragg in its brief at final hearing begins with a section discussing its disclosure, entitled "Cragg Discloses A *Unitary* Bifurcated Long Leg/Short Leg Prosthesis" (Emphasis in original). That section ends with this one sentence paragraph:

> The specification supports that Cragg's claims require a unitary bifurcated long leg/short leg structure, where "unitary" requires a securing means connecting the portions of the structure.

By the time Cragg made the above-quoted conclusion, it has not yet recited, reproduced, or even referred to any actual language in its claims. That Cragg's specification has a description for a certain embodiment does not necessarily mean that all of Cragg's claims must include the elements of that embodiment. If the claims do not require a unitary structure in the sense that there is a securing means which connects all the parts together, these are extraneous limitations which should not be read into the claims from the specification. Moreover, even Cragg's own specification contains no reference to the term "unitary" on which Cragg now places so much emphasis. Neither does Cragg's own specification contain any reference to words which are generally synonymous with the word "unitary," such as "integral"

or "one-piece." Thus, what Cragg is arguing in this part is many steps removed from the actual language of the claims.

The bifurcated prosthesis according to Cragg's claim 59 requires (1) a proximal portion, (2) a distal portion, and (3) a separate distal segment. Unlike Cragg's claim 55, Cragg's claim 59 does not require disposing the proximal portion in the blood vessel such that the distal portion extends into a first branched vessel. That means claim 59 is sufficiently broad to have the proximal portion put in place without regard to whether the distal portion is also placed in working position.

Cragg argues that because the word "portion" means part of a whole, the proximal portion and the distal portion must be part of a unitary structure in which the proximal portion and the distal portion is unitary or connected together by some securing means before being introduced into the blood vessel. We are not persuaded by Cragg's argument.

While the word "portion" may indeed mean part of a whole or part of something, Cragg has not submitted any evidence that the so called parts of a whole must be physically attached to each other at all times. In that regard, note that a jig-saw puzzle has many parts or portions but the many pieces don't have to be connected to each other before properly being referred to as portions of the same puzzle. Cragg has not made any meaningful

showing that the word "portion" as is ordinarily used in the English language requires an actual physical attachment. Nor has Cragg argued that its specification has specially defined the word "portion" in a manner different from its ordinary usage in the English language. Indeed, Cragg even cites to Merriam Webster's Collegiate Dictionary, 10th Ed. (1994) in its brief at final hearing for the meaning of "portion," which states: "part of something." Note that "part of something" can be conceptual and does not necessarily require a physical connection at all times. Moreover, we note that even Cragg's so called "portions" are not physically connected at all times; indisputably, they have to be preassembled prior to introduction into the patient.

Alternatively, our decision on preliminary motion held that even assuming that the "unitary" feature argued by Cragg is included in all of Cragg's claims corresponding to the count, Fogarty's claim 41 still would have rendered obvious Cragg's claimed invention such as Cragg's claim 59.

Cragg argues (Br. at 18):

> The Board states that insertion of the anchor section and the first tubular graft as a unitary whole is only one of two possibilities with regard to the insertion of the Fogarty structure. Paper No. 108, p.15. There is a third possibility ignored by the Board, namely, inserting the anchor section and both tubular grafts at the same time.

The argument is without merit. We stated (Paper No. 108, at 15) that there are "only two possibilities with regard to **the insertion of the anchor section and the first tubular graft**" (emphasis added). In that context, the second tubular graft is uninvolved, and how it is introduced is irrelevant.

We adopt and reiterate herein the following portion of our decision on preliminary motions concerning Cragg's preliminary motion 2 (Paper No. 108, pp. 14-16):

> Additionally, with respect to Fogarty's claims 41-69, Goicoechea is improperly reading into those claims a specific embodiment from Fogarty's disclosure rather than focusing on the language of the claims themselves. As we discussed in the context of Goicoechea's preliminary motion 1, Fogarty's independent claim 41 is broadly recited and imposes no particular manner for the insertion of the anchor section and the first tabular graft.
>
> Given Fogarty's claim 41, it is left to the discretion of one with ordinary skill in the art just how to introduce the anchor section and the first tubular graft. One with ordinary skill in the art possesses a certain basic level of skill. See, e.g., In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) ([Applicant's] argument presumes stupidity rather than skill). A conclusion of obviousness also may be made based on the common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 163 USPQ 545, 549 (CCPA 1969). It cannot be reasonably argued that one with ordinary skill in the art is so devoid of skill and common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined in situ, or inserted as a unitary whole.

> Those are the only two possibilities with regard to the insertion of the anchor section and the first tubular graft. In our view, selecting one of the two readily apparent choices would have been well within the basic level of skill and common sense possessed by one with ordinary skill in the art. Moreover, it is incumbent upon Goicoechea as the movant to establish why, given Fogarty's independent claim 41, one with ordinary skill in the art would not have known that the anchor section and the first tabular graft can be inserted as one or separately. Goicoechea set forth no persuasive reasons in that regard.

Cragg dismisses our citation to In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) and In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969), by arguing that "[b]oth Bozek and Sovish required a disclosure in the prior art references to render the claims obvious."). It appears that Cragg completely misses the point for which we cited to those cases, i.e., that one with ordinary skill in the art is presumed to possess some logic and skill that is independent of what is disclosed in an item of prior art. Here, the starting point is Fogarty's claim 41. In that sense, Fogarty's claim 41 is the disclosure with which one with ordinary skill in the art is presented, in determining whether claims such as Cragg's claim 59 would have been obvious over Fogarty's claim 41. We agree entirely with the following two paragraphs in Fogarty's opposition brief at pages 14-15:

> Second, while Cragg would argue that *Sovish* and *Bozek* are somehow anomalous, the principle for which

> they were actually cited in the Decision has been repeatedly followed by this Board; e.g., Ex parte Research and Manufacturing Co., 10 USPQ2d 1657, 1664 (Bd. Pat. App. & Intf. 1989)(skill is presumed on the part of the artisan rather than the converse); Ex parte George, 21 USPQ2d 1058, 1060 n.1 (Bd. Pat. App. & Int. 1991) (the ability of one having ordinary skill in the art should not be underestimated); Ex parte Nesbit, 25 USPQ2d 1817, 1823 (Bd. Pat. App. & Intf. 1992)(the law presumes skill on the part of the artisan rather than the converse); Ex parte GPAC Inc., 29 USPQ2d 1401, 1405 (Bd. Pat. App. & Intf. 1993)(the skill of the art must be presumed, not the contrary).
>
> The Board thus found that the worker is not so devoid of skill or common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined *in situ*, or inserted as a unitary whole. (Emphasis in original).

Cragg's citation to Al-Site Corp. v. VSI Intern., Inc., 174 F.3d 1308, 1323, 50 USPQ2d 1161 (Fed. Cir. 1999) is inapposite. The Al-Site case does not stand for the proposition that Fogarty's claim 41 must be combined with another prior art reference in order to render obvious a Cragg claim which corresponds to the count. In contrast, the case supports the position that the perspective from which a prior art reference is viewed is that of a person with ordinary skill in the art.

Cragg further argues that the Board has not explained how, if Fogarty's anchor section and first tubular graft are inserted as one piece, a skilled worker would successfully position that device. According to Cragg, because the first tubular graft of

Fogarty is within the fabric liner leg 28, one ends up with an anchor section-fabric liner-tubular graft assembly that is not rigid and is not supported. The argument is misdirected and in any event unpersuasive. Here, the starting point for the obviousness analysis is not some embodiment disclosed in Fogarty's specification, but Fogarty's claim 41 which does not require placing the first tubular graft in a fabric liner leg. Moreover, in any event Cragg has submitted no meaningful evidence in the form of declaration or affidavit testimony from anyone to establish that one with ordinary skill in the art would not have known how to introduce the anchor section together with the first tubular graft. As Fogarty has pointed out in its opposition brief, attorney argument cannot take the place of evidence lacking in the record. See, e.g., Knorr v. Pearson, 671 F.2d 1368, 1373, 213 USPQ 196, 200 (CCPA 1982); Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA), cert. denied, 434 U.S. 854, 195 USPQ 465 (1977); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972).

Cragg's preliminary motion 2 further seeks to have all of Fogarty's claims corresponding to the count, i.e., claims 27-69, designated as not corresponding to the count. We ruled in the decision on preliminary motions that per 37 CFR § 1.637(c)(4), the motion is without merit because it failed to demonstrate that

each of Fogarty's claims 27-69 does not define the same patentable invention as any of Cragg's claims and Martin claims whose correspondence to the count is not disputed by Cragg.

Cragg's arguments with regard to designating Fogarty's claims as not corresponding to the count is merely a reference to its arguments alleging no interference-in-fact between Cragg's claims and Fogarty's claims. Cragg evidently is of the view that if it has demonstrated no interference-in-fact between its claims and Martin's claims on the one hand and Fogarty's claims on the other hand, then the case has been made that Fogarty's claims corresponding to the count should be designated as not corresponding to the count. But Cragg has failed to demonstrate no interference-in-fact between its claims and Martin's claims on the one hand and Fogarty's claims on the other hand. Thus, no reason has been shown to designate Fogarty's claims 27-69 as not corresponding to the count. Note also that even if there was no interference-in-fact with respect to any Fogarty claim, Fogarty's application would become uninvolved and there would be no need to designate any of its claims as not corresponding to the count.

For the foregoing reasons, Cragg has shown no error in the denial of Cragg's preliminary motion 2.

Judgment

It is

ORDERED that judgment as to the subject matter of the count is herein entered against junior party ERIC C. MARTIN and also against junior party ANDREW H. CRAGG and MICHAEL D. DAKE;

FURTHER ORDERED that the junior party ERIC C. MARTIN is not entitled to his patent claims 2-17 which correspond to the count;

FURTHER ORDERED that junior party ANDREW H. CRAGG and MICHAEL D. DAKE are not entitled to their application claims 55, 59, 62-65, 88 and 90 which correspond to the count; and

FURTHER ORDERED that a copy of this paper shall be given a paper number and filed in the respective involved application/patent of the parties.[10]

---

[10] Failure to file a copy of any agreement regarding the termination of this proceeding may render the agreement and any resulting patent unenforceable. See section 35 U.S.C. § 135(c) and 37 CFR § 1.661.

FMcK

Fred E. McKelvey, Senior
Administrative Patent Judge

Richard E. Schafer
Administrative Patent Judge

Jameson Lee
Administrative Patent Judge

Sally C. Medley
Administrative Patent Judge

BOARD OF PATENT
APPEALS
AND
INTERFERENCES

Interference No. 104,192
Cragg v. Martin v. Fogarty

By Federal Express

Attorney for party Cragg:

Paul F. Prestia
RATHER & PRESTIA
Suite 301
One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, Pennsylvania 19482-0980

Attorney for party Fogarty:

Bruce M. Collins
MATHEWS, COLLINS, SHEPHERD & GOULD, P.A.
100 Thanet Circle, Suite 306
Princeton, New Jersey 08540-3674

Attorney for party Martin:

Robert J. Koch
FULBRIGHT & JAWORSKI
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Merriam-Webster's Collegiate® Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

John \'jän\ *n* [fr. *John*] (1856) 1 : TOILET 2 : a prostitute's client

John \'jän\ *n* [LL *Johannes*, fr. Gk *Iōannēs*, fr. Heb *Yōḥānān*] 1 : an Old Testament Jewish prophet who according to Gospel accounts foretold Jesus's messianic ministry and baptized him — called also *John the Baptist* 2 : an apostle who according to various Christian traditions wrote the Fourth Gospel, the three Johannine Epistles, and the Book of Revelation 3 : the fourth Gospel in the New Testament — see BIBLE table 4 *pl* : any of three short didactic letters addressed to early Christians and included in the New Testament — see BIBLE table 5

John Barleycorn *n* (ca. 1620) : alcoholic liquor personified

John-boat \'jän-ˌbōt\ *n* [fr. the name *John*] (1905) : a narrow flat-bottomed square-ended boat usu. propelled by a pole or paddle and used on inland waterways

John Bull \-'bůl\ *n* [*John Bull*, character typifying the English nation in *The History of John Bull* (1712) by John Arbuthnot] (1778) 1 : the English nation personified : the English people 2 : a typical Englishman — **John Bull-ish** \-'bů-lish\ *adj* — **John Bull-ish-ness** *n* — **John Bull-ism** \-li-zəm\ *n*

John Doe \-'dō\ *n* (ca. 1659) 1 : a party to legal proceedings whose true name is unknown 2 : an average man

John Do-ry \-'dōr-ē, -'dȯr-\ *n, pl* **John Dories** [earlier *dory*, fr. ME *dorre*, fr. MF *doree*, lit., gilded one] (1754) : a common yellow to olive food fish (*Zeus faber*) of Europe and Africa with an oval compressed body, long dorsal spines, and a dark spot on each side; *also* : a closely related and possibly identical fish (*Z. capensis*) widely distributed in southern seas

Joh-ne's disease \'yō-nəz-\ *n* [Heinrich A. *Johne* †1910 Ger. bacteriologist] (1907) : a chronic often fatal contagious enteritis of ruminants and esp. of cattle that is caused by a bacterium (*Mycobacterium paratuberculosis*) and is characterized by persistent diarrhea and gradual emaciation

John Han-cock \'jän-'han-ˌkäk\ *n* [*John Hancock*; fr. the prominence of his signature on the Declaration of Independence] (1903) : an autograph signature

John Hen-ry \-'hen-rē\ *n* [fr. the name *John Henry*, fr. confusion with *John Hancock*] (1914) : an autograph signature

John Mark *n* : MARK 1a

John-ny \'jä-nē\ *n, pl* **johnnies** [fr. the name *Johnny*] (1673) 1 *often cap* : FELLOW, GUY 2 : a short-sleeved collarless gown that is open in the back and is worn by persons (as hospital patients) undergoing medical examination or treatment

johnny-cake \'jä-nē-ˌkāk\ *n* [prob. fr. the name *Johnny*] (1739) : a bread made with cornmeal

Johnny-come-lately \'jä-nē-(ˌ)kəm-'lāt-lē\ *n, pl* **Johnny-come-latelies** *or* **Johnnies-come-lately** (1839) 1 : a late or recent arrival : NEWCOMER 2 : UPSTART 〈established families tend to hold themselves above the *Johnny-come-latelies* —William Zeckendorf †1976〉

Johnny-jump-up \ˌjä-nē-'jəmp-ˌəp\ *n* (1842) 1 : a common and long-cultivated European viola (*Viola tricolor*) which has short-spurred flowers usu. blue or purple mixed with white and yellow and from which most of the garden pansies are derived; *broadly* : any of various small-flowered cultivated pansies 2 : any of various American violets

Johnny-on-the-spot \'jä-nē-ˌȯn-thə-'spät, -ˌän-\ *n* (1896) : a person who is on hand and ready to perform a service or respond to an emergency

Johnny Reb \-'reb\ *n* [fr. the name *Johnny* + *reb* rebel] (1865) : a Confederate soldier

John-son-ese \ˌjän(t)-sə-'nēz, -'nēs\ *n* [Samuel *Johnson*] (1843) : a literary style characterized by balanced phraseology and Latinate diction

johnson grass \'jän(t)-sən-ˌgras\ *n, often cap* [William *Johnston* †1859 Am. agriculturist] (1884) : a tall perennial sorghum (*Sorghum halepense*) orig. of the Mediterranean region that is widely used for forage in warm areas and often becomes naturalized

joie de vivre \ˌzhwä-də-'vēvr\ *n* [F, lit., joy of living] (1889) : keen or buoyant enjoyment of life

[1]join \'jöin\ *vb* [ME, fr. OF *joindre*, fr. L *jungere* — more at YOKE] *vt* (13c) 1 a : to put or bring together so as to form a unit 〈~ two blocks of wood with glue〉 b : to connect (as points) by a line c : ADJOIN 2 : to put or bring into close association or relationship 〈~*ed* in marriage〉 3 : to engage in (battle) 4 a : to come into the company of 〈~*ed* us for lunch〉 b : to associate oneself with 〈~*ed* the church〉 ~ *vi* 1 a : to come together so as to be connected 〈nouns ~ to form compounds〉 b : ADJOIN 〈the two estates ~〉 2 : to come into close association or relationship: as a : to form an alliance b : to become a member of a group c : to take part in a collective activity 〈~ in singing〉 — **join-able** \'jöi-nə-bəl\ *adj*

syn JOIN, COMBINE, UNITE, CONNECT, LINK, ASSOCIATE, RELATE mean to bring or come together into some manner of union. JOIN implies a bringing into contact or conjunction of any degree of closeness 〈*joined* forces in an effort to win〉. COMBINE implies some merging or mingling with corresponding loss of identity of each unit 〈*combined* jazz and rock to create a new music〉. UNITE implies somewhat greater loss of separate identity (the colonies *united* to form a republic). CONNECT suggests a loose or external attachment with little or no loss of identity 〈a mutual defense treaty *connected* the two nations〉. LINK may imply strong connection or inseparability of elements still retaining identity 〈a name forever *linked* with liberty〉. ASSOCIATE stresses the mere fact of frequent occurrence or existence together in space or in logical relation 〈opera is popularly *associated* with high society〉. RELATE suggests the existence of a real or presumed logical connection 〈*related* what he observed to what he already knew〉.

[2]join *n* (1825) 1 : JOINT 2 : UNION 2d

join-der \'jöin-dər\ *n* [F *joindre* to join, fr. OF] (1601) 1 : CONJUNCTION 1 2 a (1) : a joining of parties as plaintiffs or defendants in a suit (2) : a joining of causes of action or defense b : acceptance of an issue tendered

join-er \'jöi-nər\ *n* (14c) : one that joins: as a : a person whose occupation is to construct articles by joining pieces of wood b : a gregarious or civic-minded person who joins many organizations

join-ery \'jöi-nə-rē, [2]jöin-rē\ *n* (1678) 1 : the art or trade of a joiner 2 : work done by a joiner

join-ing \'jöi-niŋ\ *n* (14c) 1 : the act or an instance of joining one thing to another : JUNCTURE 2 a : the place or manner of being joined together b : something that joins two things together

[1]joint \'jöint\ *n* [ME *jointe*, fr. OF, fr. *jointdre*] (13c) 1 a (1) : the point of contact between elements of an animal skeleton with the parts that surround and support it (2) : NODE 5b b : a part or space included between two articulations, knots, or nodes c : a large piece of meat for roasting 2 a : a place where two things or parts are joined b : a space between the adjacent surfaces of two bodies joined and held together (as by cement or mortar) c : a fracture or crack in rock not accompanied by dislocation d : the flexing part of a cover along either backbone edge of a book e : the junction of two or more members of a framed structure f : a union formed by two abutting rails in a track including the elements (as bars and bolts) necessary to hold the abutting rails together g : an area at which two ends, surfaces, or edges are attached. 3 a : a shabby or disreputable place of entertainment b : PLACE, ESTABLISHMENT c *slang* : PRISON 2 4 : a marijuana cigarette — **joint-ed** \'jöin-təd\ *adj* — **joint-ed-ly** *adv* — **joint-ed-ness** *n* — **out of joint** 1 a *of a bone* : having the head slipped from its socket b : at variance 2 a : DISORDERED 2a b : being out of humor : DISSATISFIED

[2]joint *adj* [ME, fr. MF, fr. pp. of *joindre*, fr. OF] (14c) 1 : UNITED, COMBINED 〈the ~ influences of culture and climate〉 2 : common to two or more: as a (1) : involving the united activity of two or more 〈a ~ effort〉 (2) : constituting an activity, operation, or organization in which elements of more than one armed service participate 〈~ maneuvers〉 (3) : constituting an action or expression of two or more governments 〈~ peace talks〉 b : shared by or affecting two or more 〈a ~ fine〉 3 : united, joined, or sharing with another (as in a right or status) 〈~ heirs〉 4 : being a function of or involving two or more variables and esp. random variables — **joint-ly** *adv*

[3]joint *vb* [[2]*joint*] *vt* (1530) 1 : to separate the joints of (as meat) 2 a : to unite by a joint : fit together b : to provide with a joint : ARTICULATE c : to prepare (as a board) for joining by planing the edge ~ *vi* 1 : to fit as if by joints 〈the stones ~ neatly〉 2 : to form joints as a stage in growth — used esp. of small grains

Joint Chiefs of Staff (1946) : a military advisory group composed of the chiefs of staff of the army and air force, the chief of naval operations, and sometimes the commandant of the marine corps

joint-er \'jöin-tər\ *n* (1678) : one that joints; *esp* : any of various tools used in making joints

joint grass *n* (1835) : a coarse creeping grass (*Paspalum distichum*) with jointed stems that is used for fodder and for erosion control

joint resolution *n* (1838) : a resolution passed by both houses of a legislative body that has the force of law when signed by or passed over the veto of the executive

joint-ress \'jöin-trəs\ *n* (1602) : a woman having a legal jointure

joint-stock company *n* (1776) : a company or association consisting of individuals organized to conduct a business for gain and having a joint stock of capital represented by shares owned individually by the members and transferable without the consent of the group

join-ture \'jöin-chər\ *n* (14c) 1 a : an act of joining : the state of being joined b : JOINT 2 2 a : an estate settled on a wife to be taken by her in lieu of dower b : a settlement on the wife of a freehold estate for her lifetime

joint-worm \'jöint-ˌwərm\ *n* (1851) : the larva of any of several small chalcid wasps (genus *Harmolita*) that attacks the stems of grain and causes swellings like galls at or just above the first joint

joist \'jöist\ *n* [ME *joiste*, fr. MF *giste* fr. (assumed) VL *jacitum*, fr. L *jacēre* to lie — more at ADJACENT] (13c) : any of the small timbers or metal beams ranged parallel from wall to wall in a structure to support a floor or ceiling

jo-jo-ba \hō-'hō-bə\ *n* [MexSp] (1923) : a shrub or small tree (*Simmondsia chinensis* syn. *S. californica*) of the box family of southwestern No. America with edible seeds that yield a valuable liquid wax

[1]joke \'jōk\ *n* [L *jocus*; perh. akin to OHG *gehan* to say, Skt *yācati* he asks] (1670) 1 a : something said or done to provoke laughter; *esp* : a brief oral narrative with a climactic humorous twist b (1) : the humorous or ridiculous element in something (2) : an instance of jesting : KIDDING 〈can't take a ~〉 c : PRACTICAL JOKE d : LAUGHINGSTOCK 2 : something not to be taken seriously : a trifling matter 〈consider his skiing a ~ —Harold Callender〉 — often used in negative construction 〈it is no ~ to be lost in the desert〉

[2]joke *vb* **joked; jok-ing** (1670) : to make jokes : JEST ~ *vt* : to make the object of a joke : KID — **jok-ing-ly** \'jō-kiŋ-lē\ *adv*

jok-er \'jō-kər\ *n* (1729) 1 a : a person given to joking : WAG b : FELLOW, GUY; *esp* : an insignificant, obnoxious, or incompetent person 〈a shame to let a ~ like this win —Harold Robbins〉 2 : a playing card added to a pack as a wild card or as the highest-ranking card 3 a (1) : an ambiguous or apparently immaterial clause inserted in a legislative bill to make it inoperative or uncertain in some respect (2) : an unsuspected, misleading, or misunderstood clause, phrase, or word in a document that nullifies or greatly alters it b : something (as an expedient or stratagem) held in reserve to gain an end or escape from a predicament c : an unsuspected or not readily apparent fact, factor, or condition that thwarts or nullifies a seeming advantage

joke-ster \'jōk-stər\ *n* (1877) : JOKER 1

jok-ey *also* **joky** \'jō-kē\ *adj* **jok-i-er; -est** (ca. 1825) 1 : given to joking 2 : HUMOROUS, COMICAL 3 : amusingly ridiculous : LAUGHABLE — **jok-i-ly** \-kə-lē\ *adv* — **jok-i-ness** \-kē-nəs\ *n*

jol-li-fi-ca-tion \ˌjä-li-fə-'kā-shən\ *n* (1809) : FESTIVITY, MERRYMAKING

jol-li-ty \'jä-lə-tē\ *n, pl* **-ties** (14c) 1 : the quality or state of being jolly : MERRIMENT 2 *Brit* : a festive gathering

[1]jol-ly \'jä-lē\ *adj* **jol-li-er; -est** [ME *joli*, fr. OF] (14c) 1 a (1) : full of high spirits : JOYOUS (2) : given to conviviality : JOVIAL b : expressing, suggesting, or inspiring gaiety : CHEERFUL 2 : extremely pleasant or agreeable : SPLENDID *syn* see MERRY

TAB 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BOSTON SCIENTIFIC TECHNOLOGY, INC.,	
Plaintiff,	**Case No.** 1:01CV02015
v.	Judge: Gladys Kessler
MEDTRONIC ANEURX, INC. and ERIC C. MARTIN,	FILED
Defendants.	NOV 15 2001
	NANCY MAYER WHITTINGTON, CLERK U.S DISTRICT COURT

~~[PROPOSED]~~ ORDER EXTENDING TIME TO RESPOND TO COMPLAINT

Defendant Medtronic Aneurx, Inc. has moved to extend to Monday, December 17, 2001 the time in which they may answer, move or otherwise respond to the Complaint of plaintiff, Boston Scientific Technology, Inc. Plaintiff does not oppose this motion.

Accordingly, upon motion of the defendant and for good cause shown, the motion is GRANTED.

Dated: November 15, 2001

Gladys Kessler
United States District Judge

TAB 4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff,

CASE NO. 1:01CV 2015 (GK)

v.

MEDTRONIC AVE, INC.
and ERIC C. MARTIN,

Defendants.

~~[PROPOSED]~~ ORDER ALLOWING FILING OF SECOND AMENDED COMPLAINT

Plaintiff Scimed Life Systems, Inc. ("Scimed") has moved to file a Second Amended Complaint pursuant to Rule 15(a), Fed.R.Civ.P. and Local Rule 7.1. Defendant Medtronic AVE, Inc. ("Medtronic AVE") and defendant Eric C. Martin ("Martin") have consented in writing to this motion.

Accordingly, upon motion of plaintiff, the motion is GRANTED.

Dated: December 14, 2001

Honorable Gladys Kessler
United States District Judge for the
District of Columbia

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the

(1) STIPULATED JOINT MOTION TO FILE SECOND AMENDED COMPLAINT,

(2) SECOND AMENDED COMPLAINT, and

(3) [PROPOSED] ORDER ALLOWING FILING OF SECOND AMENDED COMPLAINT

were served this _____ day of December, 2001 by Hand, on the attorneys for defendants as follows:

Charles R. Work, Esq.
Donna M. Tanguay, Esq.
Mark G. Davis, Esq.
John R. Fuisz, Esq.
McDermott, Will & Emery
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096

Counsel for Medtronic AVE, Inc.

and

Robert J. Koch, Esq.
Fulbright and Jaworski
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Counsel for Eric C. Martin

_____

TAB 5

F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff and Counterclaim-Defendant,

v.

MEDTRONIC AVE, INC.,

Defendant and Counterclaimant,

and ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

CASE NO. 1:01CV 2015 (RJL)

[PROPOSED] ORDER GRANTING SCIMED'S MOTION TO FILE UNDER SEAL SCIMED'S OPPOSITION BRIEF AND THE DECLARATION OF GIDON D. STERN IN SUPPORT OF SCIMED'S OPPOSITION TO MEDTRONIC'S REQUEST FOR ENTRY OF DEFAULT JUDGMENT AS TO SCIMED

The matter having come before the Court on plaintiff Scimed Life Systems, Inc. ("Scimed") Motion To File Under Seal (1) SCIMED'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MEDTRONIC'S MOTION FOR ENTRY OF DEFAULT JUDGMENT AS TO SCIMED ("Scimed's Opposition Memorandum) and (2) the DECLARATION OF GIDON D. STERN in support of Scimed's Opposition Memorandum and attached exhibits to be filed under seal pursuant to Local Rule 5.1(j), and the Court having fully considered the arguments in support of and in opposition to that motion:

IT IS HEREBY ORDERED THAT:

The aforementioned motion is GRANTED.

Scimed's Memorandum of Points and Authorities in Opposition to Metronic's Motion for Entry of Default Judgment As to Scimed ("Scimed's Opposition Memorandum) and the

19

DECLARATION OF GIDON D. STERN in support of Scimed's Opposition Memorandum and attached exhibits shall be filed under seal, with the exception that the memorandum, declarations and exhibits thereof shall be available to defendant, Medtronic AVE, Inc. and defendant, Eric C. Martin.

SO ORDERED.

Dated: May 1st, 2002

Honorable Richard J. Leon

United States District Judge for the
District of Columbia

LIST OF PERSONS TO BE NOTIFIED
OF ENTRY OF ORDER

Marcia H. Sundeen, Esq.
PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
Tel: (202) 496-4400
Fax: (202) 496-4444

Gidon D. Stern, Esq.
Thomas E. Friebel, Esq.
Alexandra N. Haner, Esq.
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036
Tel: (212) 790-9090
Fax: (212) 869-9741

Paul F. Prestia, Esq.
Joshua L. Cohen, Esq.
RATNER & PRESTIA
Suite 301, One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, PA 19482-0908
Tel: (610) 407-0700
Fax: (610) 407-0701

Charles R. Work, Esq.
Donna M. Tanguay, Esq.
Mark G. Davis, Esq.
John R. Fuisz, Esq.
McDERMOTT, WILL & EMERY
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
Tel: (202) 756-8029
Fax: (202) 756-8087

Robert J. Koch, Esq.
FULLBRIGHT & JAWORSKI
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Tel: (202) 662-4765
Fax: (202) 662-4643

TAB 6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	**Case Number 01-2015 (RJL)**
	)	
	)	
MEDTRONIC AVE INC.,	)	
	)	
Defendant and Counterclaimant,	)	
	)	
and ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant	)	

MEMORANDUM OPINION AND ORDER
(August 30, 2003) (# 17, 22, 29, 34)

Three motions are now pending before the Court in the above captioned case. The first is the motion for default judgment by defendant and counterclaimant Medtronic AVE, Inc. ("Medtronic") against defendant and counterclaim-defendant Eric C. Martin and plaintiff and counterclaim-defendant Scimed Life Systems, Inc. ("Scimed"). Second is Scimed's motion to dismiss Medtronic's counterclaim for lack of subject matter jurisdiction. Finally, Medtronic has filed a Rule 11 motion for sanctions against Scimed, arguing that Scimed's case is a "sham," and that Scimed's papers contain material

(2)

#45

misrepresentations of fact.

For the reasons set forth below the Court hereby grants Medtronic's motion for entry of default judgment against Martin, but reserves ruling on the relief to which Medtronic is entitled. The Court denies Medtronic's motion for default judgment as to Scimed and denies Scimed's motion to dismiss Medtronic's counterclaim. Finally, the Court also denies Medtronic's Rule 11 motion for sanctions.

I. BACKGROUND

Plaintiff and counterclaim-defendant Scimed brought the instant action pursuant to 35 U.S.C. § 146 to contest the decision of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("USPTO") regarding certain patent applications for an apparatus for reinforcing a bifurcated lumen. Plaintiff Scimed and defendant and counterclaimant Medtronic each are assignees of record of two, different patent applications for a bifurcated lumen invention;[1] defendant and

---

[1] Andrew Cragg and Michael Dake filed an application with the USPTO regarding the bifurcated lumen apparartus on June 5, 1995. The application was assigned the serial number 08/461,402 (the "'402 application"). Cragg and Dake assigned all rights in the '402 application to Boston Scientific Technology, Inc., which merged into plaintiff Scimed. Scimed is now the present legal owner of the '402 application. Defendant and counterclaimant Medtronic was assigned its rights in a patent application for the invention by Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively referred to as party "Fogarty" in the underlying proceedings at the USPTO). That application was filed with the USPTO on June 5, 1995, and assigned the serial number 08/463,836 (the "'836 application"). Fogarty assigned its rights in the '836 application to Medtronic Aneurx, Inc., which merged into Medtronic AVE, Inc. Defendant Medtronic is now the

counterclaim-defendant Eric C. Martin was awarded a patent for the same apparatus. The USPTO declared an interference on April 23, 1998, between Scimed's patent application (the "Cragg" or "'402 application"), Medtronic's patent application (the "Fogarty" or "'836 application") and Martin's patent (the "Martin" or "'817 patent"). This interference proceeding was assigned Interference No. 104,192, and is referred to as the "'192 interference." Shortly thereafter, on September 20, 1998, Martin and Scimed entered into an option and license agreement under which Scimed had an exclusive option to purchase the rights to Martin's '817 patent. Neither Scimed nor Martin disclosed the existence of this agreement to Medtronic or the Board before the Board rendered its decision in the '192 interference.[2]

The Board yielded its decisions pertaining to the '192 interference on July 27, 2001. Scimed filed a complaint in this Court on September 25, 2001, challenging the Board's decisions that were adverse to its interests in the '402 application. Subsequently, Scimed filed an amended complaint on November 9, 2001, and a second amended complaint on December 21, 2001. Defendant Medtronic filed its answer to the second amended complaint and its counterclaim on January 2, 2002. In turn, Scimed filed its

---

legal owner of the '836 application.

[2] Scimed disclosed the existence of the agreement with Martin on March 21, 2002; Medtronic maintains that the disclosure was untimely and in violation of the pertinent regulations contained in 37 C.F.R. § 1.602. *See* Medtronic Mot. for Default Judgment at 3-4. Scimed contends that the disclosure was timely and proper. As this issue is irrelevant to the Court's resolution of the motions now before it, the Court will not consider the parties' arguments on this issue at this time.

answer to Medtronic's counterclaim on January 18, 2002, and then separately filed a motion to dismiss the counterclaim almost five months later, on May 17, 2002, arguing that this Court lacks subject matter jurisdiction to hear Medtronic's claims.

As defendant and counterclaim-defendant Martin never filed an answer to Medtronic's counterclaim, Medtronic filed a motion for default judgment against Martin on April 23, 2002.[3] In its motion for default judgment, Medtronic asked this Court not only to grant default judgment as to Martin, but also as to Scimed for Martin's failure to answer the counterclaim. According to Medtronic, because Scimed is the owner of an exclusive license to Martin's '817 patent, it has a duty under that license to litigate all claims stemming from the patent. Under Medtronic's theory, default as to Martin is default as to Scimed, even though Scimed filed a timely answer to the counterclaim.

Additionally, Medtronic brings a Rule 11 motion for sanctions against Scimed, coincidentally filed on the same day as Scimed's motion to dismiss Medtronic's counterclaim. Medtronic argues that Scimed has materially misrepresented its relationship with Martin as to whether Scimed or Martin owns all right, title, and interest in the '817 patent. Due to these alleged misrepresentations, Medtronic asks the Court to dismiss this case "as sanction for Scimed's conduct and Martin's collusion in that conduct." Medtronic Mot. for Sanctions at 10.

---

[3] The Clerk of Courts made an entry of default against Martin on the same day.

II. ANALYSIS

A. Scimed's Rule 12(b)(1) Motion to Dismiss Medtronic's Counterclaim for Lack of Subject Matter Jurisdiction is Denied

Scimed asks this Court to dismiss Medtronic's counterclaim against it and against Martin pursuant to Federal Rule of Civil Procedure 12(b)(1), claiming that the Court lacks subject matter jurisdiction under 35 U.S.C. § 146 to hear Medtronic's claim.[4] The Court disagrees, and denies Scimed's motion to dismiss.

In its counterclaim against Scimed and Martin, Medtronic asks this Court, in essence, to affirm the Board's decisions that were favorable to Medtronic, reverse those that were not, and to adjudge that Medtronic is entitled to a Letters Patent of the United States for the bifurcated lumen invention. *See* Medtronic Counterclaim at 10. At issue for purposes of Scimed's motion to dismiss are three preliminary motions filed by Fogarty — who assigned its rights in the patent application to Medtronic — with the Board. In Preliminary Motion No. 1, Fogarty argued that the claims contained in the Cragg/Scimed patent application were not patentable. Additionally, in Preliminary Motion No. 3, Fogarty challenged any benefit awarded to the Cragg/Scimed patent application due to an earlier filing date of a European patent application. Finally, Fogarty alleged in

---

[4] Section 146 provides, in relevant part, that "Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days . . . ."

Preliminary Motion No. 4 that certain claims in Martin's patent and in the Cragg/Scimed patent application were unpatentable.

The Board denied each of these motions on February 11, 2000. Six months later on August 14, 2000, the Board asked Fogarty "to file a paper identifying all [previous] motion decisions adverse to party Fogarty which Fogarty believes still must be considered at final hearing even if all issues raised by Party Cragg [Scimed] for final hearing are decided against party Cragg." Scimed Mot. to Dismiss at 2. In response, Fogarty submitted to the Board that Preliminary Motion Nos. 1, 3, 4, among others, "would become moot and need not be considered in the event judgment is entered against Cragg. (While the motions thus need not be reviewed, reference to Cragg's position and/or the Board's rulings with respect to certain of these may still be required.)." At the final hearing before the Board on the '192 interference, Preliminary Motions 1, 3 and 4 were neither discussed by Cragg or Fogarty nor briefed by the parties as part of the proceeding. When the Board rendered its decision on July 27, 2001 awarding priority of invention to the '836 or Fogarty/Medtronic application over the '402 or Cragg/Scimed application, the judgment did not address any of the issues raised in Fogarty's Preliminary Motions 1, 3 and 4. *See* Medtronic Mot. for Default Judgment, Exh. A (Board's Op. in the '192 interference).

Despite the fact that the issues were never briefed by the parties nor discussed by the Board during the final hearing proceedings on the '192 interference, Medtronic now

asks this Court to reverse the Board's rejection of Fogarty Preliminary Motions 1, 3 and 4. Both Medtronic and Scimed primarily cite the same cases as support for their arguments regarding this Court's subject matter jurisdiction to hear Medtronic's counterclaim: *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 9Fed. Cir. 1994) and *General Instrument Corp. v. Scientific-Atlanta*, 995 F.2d 209, 214 (Fed. Cir. 1993).

While the cases provide some guidance, they are not factually analogous to the situation presently before the Court. In *Conservolite*, the party bringing a Section 146 action in district court asked the court to consider an issue that the party did not raise either by preliminary motion or at the final hearing. The Federal Circuit in *Conservolite* held that a party's failure to raise the issue in a preliminary motion not only precluded it not from raising the matter at the final hearing, but also precluded district court review. *See Conservolite*, 21 F.3d at 1101. Here, the situation before the Court is different. Unlike the party that brought a Section 146 action in *Conservolite*, Medtronic raised in Preliminary Motions 1, 3, and 4 the same issues it now brings in its counterclaim, although those issues were not addressed at the final hearing.

The Court must therefore determine whether failure to introduce an issue during a final hearing on an interference — even if the issue was raised by preliminary motion — prevents a district court from considering the issue during a Section 146 action. While *Conservolite* states that "an action under § 146 is essentially a proceeding to review the action of the Board," *id.*, the Court cannot conclude that it stands for the proposition that

Scimed advances: that district courts lack subject matter jurisdiction over issues raised in preliminary motions but not addressed at a final hearing. *See* Scimed Reply at 4 (arguing that "[i]f an issue is not raised at final hearing or considered in the Board's final decision, it cannot be raised in a Section 146 action."). The Federal Circuit's opinion in *Conservolite* recognizes as much when it states that "[i]n order for an issue to have been raised adequately so that it qualifies for consideration in a Section 146 proceeding, the issue should have been raised as specified in the PTO's interference rules, for example, *through preliminary motions*, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or opposition to these motions." *Id.* at 1102 (emphasis added). Medtronic complied with that requirement by bringing Preliminary Motions 1, 3, and 4. *See* Scimed Reply at 5. Neither *Conservolite*, nor the pertinent statute and regulation, require more. *See* 35 U.S.C. § 146; 37 C.F.R. § 1.658.

Furthermore, the Court does not believe that allowing Medtronic to raise issues here that were not specifically briefed or raised during the final hearing to be inconsistent with the general principle that administrative remedies must be exhausted before seeking district court review. This is especially true because the Board itself limited the issues to be considered at the final hearing when it asked Medtronic to list only those issues Medtronic believed "still must be considered at final hearing *even if all issues raised by Party Cragg [Scimed] for final hearing are decided against party Cragg*." Scimed Mot. to Dismiss at 2. Medtronic's answer to that question was a qualified one: only if all issues

were decided against Cragg were Medtronic's preliminary motions moot. As the Board limited the issues to be considered, and because Fogarty/Medtronic raised the issues in preliminary motions which were denied by the Board, the Court concludes that permitting Medtronic to bring them here in its counterclaim is "not wasteful of administrative and judicial resources." *Conservolite*, 21 F.3d at 1102. Moreover, the Court does not find Medtronic waived its claims for the same reasons it finds that Medtronic sufficiently exhausted its administrative remedies.

For the reasons set forth above, the Court denies Scimed's motion to dismiss Medtronic's counterclaim.

B. Medtronic's Motion for Default Judgment Against Scimed is Denied

Medtronic has moved for default judgment against Scimed under the theory that Scimed was the true party-in-interest to Martin's patent, and had a duty to defend Martin in all litigation arising from that patent. Default against Martin, under the defendant's theory, is also default against the plaintiff, Scimed.

The standard in this court for granting a motion for default judgment is set forth in *Jackson v. Beech*, 636 F.2d 831 (D.C. Cir. 1980), as well as Rule 55 of the Federal Rules of Civil Procedure. In *Jackson*, the Circuit Court specifically explained that default judgment is disfavored when it stated that "modern federal procedure favors a trial on the merits over a default judgment," and that default judgment is normally reserved for a

"totally unresponsive party." *Id.* at 835. Scimed, in this case, has not been a totally unresponsive party. It has filed its opposition to the motion for default judgment and the motion for sanctions in a timely manner. It cannot be said that Scimed is being unresponsive or otherwise dilatory in defending its interests.

This Court has been unable to find support in the law for entering default judgment against a party because that party has a duty to defend a second party, who is truly in default for failing to appear or is totally responsive, under a licensing agreement. Those cases where a duty to defend has resulted in default judgment have been limited to cases between an insured and an insurer — where there has been privity in contract between those parties, and the insured, rather than a third party, sought to enforce the contract and the insurer's duty to defend. *See, e.g., Weiss v. St. Paul Fire and Marine Ins. Co.* 283 F.3d 790 (6th Cir. 2002); *Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co.*, 219 F.3d 895 (9th Cir. 2000). The Court does not find support for a third party - like Medtronic - seeking to enforce a contractual duty to defend between two other parties in order to obtain default judgment.

In any event, Medtronic has not satisfied the test set for granting default judgment set forth by this Circuit in *Combs v. Nick Garin Trucking*, 825 F.2d 437 (D.C. Cir 1987). The Court in *Combs* listed three factors to consider when setting aside default judgment, which is relevant to this Court's determination as to whether default judgment is appropriate in the first place: whether the default was willful, whether denying default

judgment would prejudice the moving party, and whether the alleged defense - here, the plaintiff's claim - is meritorious. As mentioned previously, the Court does not find willful default in this case. Scimed has been responsive to every pleading and motion. The court also does not find that denying default judgment would prejudice Medtronic at this early stage in the proceedings.

Given this Circuit's disfavor toward default judgment and strong preference for adjudication of claims on their merits, if Medtronic's position is as truly meritorious as it claims in its papers, a motion for summary judgment would be the proper procedure for addressing which party is the true party at interest in the Martin patent. A motion for default judgment should not be used as a motion in limine to prevent a party from presenting proofs or making claims.

For those reasons set forth above, Medtronic's motion for default judgment against Scimed is denied.

C. Medtronic's Motion for Default Judgment Against Defendant and Counterclaim Defendant Martin is Granted

Although the Court denies Medtronic's motion for default judgment against Scimed, the Court grants its motion for entry of default judgment as to Martin, but reserves ruling on what relief should be granted.

Applying the *Combs* test, discussed above, the Court finds that Medtronic has satisfied the first requirement by showing that Martin's default is willful. Martin has been

served with copies of the pleadings and motions filed in this case. He has not responded to Scimed's complaint, Medtronic's counterclaim, or Medtronic's motion for default judgment. However, Martin has retained counsel and filed a declaration included as Exhibit 5 to Scimed's opposition to Medtronic's motion for entry of default judgment. Given that he has retained counsel, has received copies of all pleadings and motions filed in this case, and has been a "totally unresponsive party" to this filings, *Jackson*, 636 F.2d at 836, the Court can only conclude that Martin's default is willful, rather than the result of negligence on his or his attorney's part.

As Martin has neither opposed the entry of default judgment against him nor suggested he may have a meritorious defense to Medtronic's counterclaim, the Court need not consider the remaining two prongs of the *Combs* test. Although Martin has willfully defaulted, the question of the relief to which Medtronic is entitled due to his default is a complicated one. In its motion for default judgment, Medtronic, in essence, asks this Court to reverse the Board's decisions that are adverse to Medtronic's interest in the '836 patent application, and affirm those that are favorable.[5] Entering a judgment against

---

[5] Specifically, Medtronic asks this Court to grant the following relief:

(1) Reversing the Patent Board's decision concerning Fogarty's Preliminary Motion No. 4;
(2) Reversing those portions of the Patent Board's decision of July 27, 2001 with regard to the '192 interference that are adverse to Fogarty; and
(3) Adjudging that Medtronic is entitled to a Letters Patent of the United States for the invention disclosed in the '836 Application

Martin for this relief, however, necessarily gives Medtronic the relief it seeks against Scimed as well — relief the Court denied to Medtronic when it rejected its motion for default judgment against Scimed. The Court cannot see how it is possible to enter default judgment against Martin without also simultaneously, and inadvertently, entering judgment against Scimed on the underlying issues of Medtronic's counterclaim.

While finding that Martin is in default, the Court will therefore reserve entering judgment against Martin until Medtronic's counterclaim is adjudicated on the merits.

D. Medtronic's Rule 11 Motion for Sanctions Against Scimed is Denied

Medtronic charges that Scimed has made misrepresentations to the Court that "go to the core of the dispute between the parties," Medtronic Mot. for Sanctions at 1, and requests that this Court sanction Scimed for this alleged misconduct by dismissing its complaint. The Court declines to do so.

The charges made in Medtronic's motion for sanctions and Scimed's opposition go, as Medtronic notes, to the heart of this case: which party is entitled to the rights for the bifurcated lumen patent. To resolve the motion for sanctions either in Scimed's or Medtronic's favor, the Court must necessarily resolve the merits of the underlying dispute without the benefit of discovery. To do so at this stage in the litigation would not be fair

---

Medtronic Mot. for Default Judgment at 5.

to either side. Therefore, without ruling one way or the other as to the factual allegations contained in Medtronic's motion and Scimed's opposition, the Court denies Medtronic's motion for sanctions.

III. CONCLUSION

For the reasons set forth above, the Court hereby:

GRANTS Medtronic's motion for entry of default judgment against Martin (#17), but reserves ruling on the relief to which Medtronic is entitled;

DENIES Medtronic's motion for default judgment as to Scimed (#17);

DENIES Scimed's motion to dismiss Medtronic's counterclaim (#22); and

DENIES Medtronic's motion for sanctions (#23).

In addition the Court also:

GRANTS Scimed's motion for Gideon Stern to appear *pro hac vice* for Scimed (#29); and

GRANTS Scimed's motion for leave to file the Patent Office's Decision to Pending Motions (#34).

SO ORDERED.

RICHARD J. LEON
UNITED STATES DISTRICT JUDGE

TAB 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff and Counterclaim-Defendant,

v.

MEDTRONIC AVE, INC.,

Defendant and Counterclaimant,

and

ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

Civil Action No. 1:01 CV 02015 (RJL)

STIPULATION AND ORDER

WHEREAS on July 27, 2001 the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office issued a Final Decision and Judgment ("July 27, 2001 Final Decision") in Interference No. 104,192 involving a single count and the following applications and patent of the parties:

Fogarty *et al.* United States Patent Application Serial No. 08/463,836 owned by Medtronic AVE, Inc., now known as Medtronic Vascular, Inc. ("Medtronic");

Cragg *et al.* United States Patent Application Serial No. 08/461,402 owned by Scimed Life Systems, Inc. ("Scimed"); and

Martin United States Patent No. 5,575,817 owned by Eric. C. Martin ("Martin").

WHEREAS the July 27, 2001 Final Decision awarded priority of invention to Fogarty *et al.* (Medtronic) for the subject matter of the single count;

WHEREAS on December 17, 2001 Scimed filed a Second Amended Complaint requesting review of certain rulings in the July 27, 2001 Final Decision, including the award of priority of invention to Fogarty *et al.* (Medtronic);

WHEREAS on January 2, 2002, Medtronic filed an Answer, Counterclaim and Cross-Claim requesting review of certain rulings in the July 27, 2001 Final Decision;

WHEREAS Martin did not respond to Scimed's Second Amended Complaint or to Medtronic's Answer and Cross-Claim; and

WHEREAS the Court ruled Martin in default for failure to respond to Medtronic's Cross-Claim.

NOW THEREFORE Medtronic and Scimed desire to limit and expedite the remaining issues in dispute between them and therefore agree as follows:

1. Scimed agrees that in this action it will not rely on Martin's alleged date of invention to prove a date of invention for the inventors of Scimed's Cragg *et al.* Application Serial No. 08/461,402. Medtronic and Scimed reserve all rights against Martin.

2. Medtronic agrees to withdraw, with prejudice, the Complaint in *Medtronic Vascular Inc. v. James E. Rogan and Nicholas P. Goldici*, Case No. 1:03 CV 02466, filed on November 24, 2003 in the United States District Court for the District of Columbia.

3. Medtronic and Scimed agree to limit the issues in this case to the following:

(a) Whether the Board erroneously affirmed its grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application No. 94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192;[1]

(b) If the answer to issue (a) is yes and the Court elects to determine the issue of priority, then whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192; and

(c) If the answer to issue (a) is yes and the Court elects not to determine the issue of priority, then the case may be remanded to the Board of Patent Appeals and Interferences for determination of whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192.

4. Medtronic and Scimed further agree that if the answer to issue (a) is no, then Fogarty *et al.* (Medtronic) is entitled to an award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be affirmed.

5. Medtronic and Scimed further agree that if the answer to (a) is yes and the Court determines that the answer to (b) is no, then Cragg *et al.* (Scimed) is entitled to an

[1] The applicable burdens of proof are not intended to be modified by this Agreement.

award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be reversed.

6. Medtronic and Scimed further agree that if the answer to (a) is yes and the Court determines that the answer to (b) is yes, then Fogarty *et al.* (Medtronic) is entitled to an award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be affirmed.

7. If either party is dissatisfied with the final judgment of the Court or the final decision of the Board of Patent Appeals and Interferences upon remand, the dissatisfied party may pursue appropriate review.

8. Medtronic and Scimed agree that amended pleadings will be filed in this case reflecting this agreement to limit the issues.

IT IS AGREED TO AND ORDERED THAT:

1. Pleadings filed in this case hereafter shall bear the following caption:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff and Counterclaim-Defendant, v. MEDTRONIC VASCULAR, INC., Defendant and Counterclaimant, and ERIC C. MARTIN, Defendant and Counterclaim-Defendant.	Civil Action No. 1:01 CV 02015 (RJL)

2. Medtronic is directed to withdraw, with prejudice, its Complaint in *Medtronic Vascular Inc. v. James E. Rogan and Nicholas P. Goldici*, Case No. 1:03 CV 02466, filed on November 24, 2003 in the United States District Court for the District of Columbia within 14 days of entry of this Order.

3. The issues as between Scimed and Medtronic in this action are limited to the following:

(a) Whether the Board erroneously affirmed its grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application

No. 94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192;

(b) If the answer to issue (a) is yes and the Court elects to determine the issue of priority, then whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192; and

(c) If the answer to issue (a) is yes and the Court elects not to determine the issue of priority, then the case may be remanded to the Board of Patent Appeals and Interferences for determination of whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192.

4. Scimed is directed to file a Third Amended Complaint consistent with the above statement within 14 days of entry of this Order. Medtronic is directed to file an Amended Answer and Counterclaim that is consistent with the above statements within 14 days of service of the Third Amended Complaint.

STIPULATED AND AGREED TO BY

Gidon D. Stern Thomas E. Friebel (D.C. Bar No. 290627) Cathy J. Chin Max Bachrach (D.C. Bar No. 477267) JONES DAY 222 East 41st Street New York, New York 10017 Attorneys for Scimed Life Systems, Inc.	Donna M. Tanguay (D.C. Bar No. 4496) Mark G. Davis (D.C. Bar No. 412228) John R. Fuisz (D.C. Bar No. 439698) McDERMOTT, WILL & EMERY 600 13th St., N.W. Washington, D.C. 20005-3096 Attorneys for Medtronic Vascular, Inc.

SO ORDERED

3/25/04

Honorable Richard J. Leon
UNITED STATES DISTRICT JUDGE

WDC99 853493-4.052734.0050

NYJD: 1490229.3

CERTIFICATE OF SERVICE

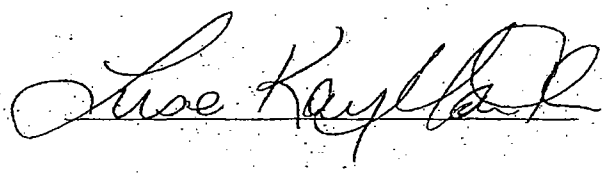
The undersigned hereby certifies that a true copy of the STIPULATION AND ORDER was served this 18th day of February, 2004, as follows:

Gidon D. Stern (Via Federal Express)
Thomas E. Friebel
Jones Day
222 East 41st Street
New York, NY 10017

Counsel for Plaintiff Scimed Life Systems, Inc.

Robert J. Koch (Via Hand Delivery)
Fulbright & Jaworski
801 Pennsylvania Ave., N.W.
Washington, DC 20004

Attorney for Defendant Eric C. Martin



WDC99 539970-1.052734.0050

TAB 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff,

v.

MEDTRONIC VASCULAR, INC.,

Defendant and Counterclaimant,

and ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

CASE NO. 1:01CV2015 (RJL)

PROTECTIVE ORDER

WHEREAS, Medtronic Vascular, Inc. ("Medtronic") and Scimed Life Systems, Inc. ("Scimed") each may seek discovery or documents, information or other materials which may contain or relate to, *inter alia*, valuable research, development, commercial, financial and technical proprietary data, or other information that another party or a nonparty regards as confidential, proprietary or trade secret information of another party or of a nonparty in the above-captioned action (the "Action");

IT IS HEREBY ORDERED that the following Protective Order be entered in this Action:

1. This Protective Order shall cover all information, documents, or tangible items disclosed and/or produced in connection with any discovery taken in the above-captioned action pursuant to the Federal Rules of Civil Procedure and Local Rules of Civil Practice and Procedure of the United States District Court for the District of Columbia or disclosed and/or produced in connection with any hearings or other proceedings in the above-captioned action. All

information, documents, or tangible items covered by this Protective Order shall be used only for the purposes of this litigation and shall not be used for any purpose outside of this litigation.

2. The following classification shall apply:

a. "Confidential Information" shall mean and include any document (whether in hard copy or electronic or computer readable form), thing, deposition testimony, interrogatory answers, responses to requests for admissions and/or production, or other information provided in discovery in this Action ("Discovery Material"), which contains non-public, confidential or proprietary information, whether personal or business-related, including but not limited to information that constitutes, reflects, or concerns trade secrets, know-how or proprietary data, business, financial or commercial information, the disclosure of which is likely to cause harm to the competitive position of the party making the confidential designations on Discovery Material ("the Designating Party").

b. All such Confidential designations shall be made in good faith by the Designating Party and made at the time of disclosure, production, or tender to the party receiving the same ("Receiving Party"), or at such other time as permitted by this Protective Order, provided that the inadvertent failure to so designate does not constitute a waiver of such claim, and a party may so designate Discovery Material after such Discovery Material has been produced, with the effect that such Discovery Material is thereafter subject to the protections of this Protective Order in accordance with such designation.

c. When the Designating Party produces files, records or materials for inspection, no marking need be made in advance of the inspection. All files, records, and materials subject to inspection shall be treated as "Confidential." Upon selection of files,

records, or materials for copying, the witness or producing party shall mark the copies with the appropriate classification prior to production to the inspecting party.

d. A Confidential Designation shall constitute a representation that such Discovery Material has been reviewed by an attorney for the Designating Party and that there is a valid basis for such designation.

3. The designation of Discovery Material as Confidential in the form of documents, responses to requests for admission and interrogatories, or other tangible materials (including, without limitation, CD-ROMs and tapes) other than depositions or other pretrial testimony shall be made by the Designating Party in the following manner:

a. Documents designated "Confidential" shall be so marked by conspicuously affixing the legend "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" on each page containing any Confidential Information (or in the case of computer medium on the medium and its label and/or cover) to which the designation applies. Such designated Discovery Material shall be identified by Bates number. To the extent practical, the Confidential legend shall be placed near the Bates number;

4. Confidential Information shall not include any Discovery Materials which:

a. Have been or become lawfully in the possession of the Receiving Party through communications other than production or disclosure in this Action, or in other litigation, for example, as a result of legitimate business dealings between the parties, unless those documents are covered by a separate non-disclosure or confidentiality agreement, in which case the Receiving Party may continue to use such documents in the course of its business subject to those agreements; or

b. Have been or become part of the public domain by publication or otherwise and not due to any unauthorized act or omission on the part of the Receiving Party or any of its authorized representatives or designees under this Protective Order. Nothing herein shall impose any restriction on the use or disclosure by a party or nonparty of its own documents or information.

5. Subject to paragraph 6 of this Protective Order, "Qualified Persons" having access to Discovery Material designated "Confidential Information" under this Protective Order, in this Action are:

a. McDermott, Will & Emery LLP, attorneys of record for Medtronic, their stenographic, clerical and paralegal employees whose duties and responsibilities require access to such materials;

b. Jones Day, attorneys of record for Scimed, their stenographic, clerical and paralegal employees whose duties and responsibilities require access to such materials;

c. For each party, a total of three (3) in-house counsel or patent agents (collectively "in-house counsel") whose names are listed below and who have responsibility for maintaining, defending or evaluating this litigation. The approved in-house counsel are as follows:

	Medtronic, Inc.	Scimed Life Systems, Inc.
Name Title	Sue R. Halverson Vice President, Assistant General Counsel, Litigation	Luke R. Dohmen Vice President and Chief Patent Counsel, Scimed Life Systems, Inc.
Name Title	Michael J. Jaro Chief Patent Counsel	Peter J. Gafner Director and Managing Counsel for Cardiology Litigation, Scimed Life Systems, Inc.

	Medtronic, Inc.	Scimed Life Systems, Inc.
Name		Steven A. McAuley
Title		Patent Counsel, Scimed Life Systems, Inc.

The parties may identify additional in-house counsel who meet[s] the above criteria for inclusion on this list following execution of this Protective Order by providing written notice of the names of the additional in-house counsel to the other parties pursuant to Paragraph 7. The parties to this Action may substitute in-house counsel who meet the above criteria for good cause shown;

d. Retained independent consultants or experts, for purposes of this Action only (as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials) who are not current employees of any party to this litigation, or any direct competitor of any party to this litigation;

e. The Court, Court personnel, and stenographic and video reporters engaged in proceedings incident to this Action;

f. Outside document copying services, document coding or computerization services, trial graphics consultants, jury and trial consultants, and other entities retained by counsel of record to aid in the preparation of or in the trial of this action. The class of persons identified in this subsection does not include any independent consultants or experts as set forth in subsection (d) above. Notwithstanding any other provision of this Protective Order, access to Confidential documents shall be permitted to the entities listed in this subsection (f), without need for the completion of Exhibit A or the execution of Exhibit B. The outside counsel providing Confidential documents to an entity listed in this subsection shall be responsible for that entity's compliance with the provisions of this Protective Order.

6. Qualified Persons defined in paragraph 5(d) shall be allowed access to Confidential Information only after complying with the following procedure:

a. A Receiving Party who desires to give access to Discovery Materials designated by another party or witness as Confidential Information to a person described in paragraph 5(d) shall first provide written notice to the Designating Party of the proposed person to receive such materials. The written notice shall include a written list, in a form similar to Exhibit A hereto, setting forth the name of the person, his or her occupation, and business address, a curriculum vitae and disclosure of any past or current relationship with any party in this Action. The Designating Party shall have seven (7) business days after receipt of the written notice to object in writing to the disclosure of Confidential Information to the proposed expert or consultant. If the parties are unable to resolve that objection, the objecting party shall, no later than five (5) business days after objection, move the Court for an order prohibiting the disclosure at issue. The objecting party shall have the burden of persuasion that disclosure should not be made. A failure by the Designating Party to timely serve an objection or file a motion shall be deemed to constitute approval of disclosure to the proposed person. If a written objection and a timely motion to prohibit disclosure has been made, no Confidential Information shall be made available to the proposed expert or consultant unless and until the Court rules that disclosure can be made. This objection procedure does not apply to the approved individuals already listed in paragraph 5(c);

b. Before receiving any Confidential Information, the person shall be furnished with a copy of this Protective Order and shall acknowledge, by executing the acknowledgment form attached hereto as Exhibit B, that he or she has read this Protective Order, understands it, and agrees to be bound by it, and also expressly consents to the jurisdiction of this

Court in connection with any proceeding or hearing relating to the enforcement of this Protective Order. In-house attorneys authorized to receive Confidential Information shall not be required to execute the acknowledgment form, but shall otherwise be bound by its terms;

c. Outside counsel for each Receiving Party shall retain a copy of each such written list (Exhibit A) and acknowledgment form (Exhibit B), and shall serve opposing counsel with a copy of these documents upon request and thereafter upon revision of such documents.

7. Confidential Information and the substance or content thereof, including any notes, memoranda or other similar documents relating thereto, shall be used by a Receiving Party and its authorized representative or designees under this Protective Order solely for the purpose of this Action and any appeals therefrom, and shall not be made available, or disclosed, or summarized to any persons, including the parties, other than as permitted by paragraphs 5-6 of this Protective Order. Confidential Information shall be maintained by the Receiving Party under the overall supervision of outside counsel.

8. Any person in possession of Confidential Information shall exercise care with regard to the storage, custody or use of such Confidential Information in order to ensure that the Confidential nature of the same is maintained.

9. If Confidential Information is disclosed to anyone other than in a manner authorized by this Protective Order, the party responsible for such disclosure must: (a) immediately bring all pertinent facts relating to such disclosure (including to whom the disclosure was made and the specific documents or information disclosed) to the attention of the Designating Party of the Confidential Information; (b) retrieve such information, or, where the information is not retrievable, certify that it has been lost or destroyed and that no copies are within the possession, custody or control of unauthorized recipients of the information,

documents, or materials; and (c) request that the person to whom the information was disclosed sign an acknowledgement in the form of Exhibit B; and (d) prevent further disclosure.

10. When Confidential Information is discussed, quoted or referred to in any deposition, the disclosing party shall ensure that only persons permitted by paragraph 5 of this Protective Order to have access to such Information are present. During any hearing or trial persons not authorized to have access to confidential information shall be asked to leave the courtroom when such Confidential Information is being published. The confidentiality of evidence not published in open court during any hearing or trial is not waived.

11. During the course of preparing for a deposition or testimony, a fact deponent/witness may be shown Confidential Information from another party's documents strictly limited to those documents which on their face reveal that they were authored or received in the normal course of business by the deponent/witness. Use of Confidential Information during a deposition shall be subject to compliance with this Order.

12. Any deposition transcript containing Confidential Information shall be marked on the cover as "Confidential Pursuant To Protective Order," and shall indicate as appropriate within the transcript what information has been so designated. Whenever possible, the stenographic reporter shall be requested prior to the deposition (where the attorneys have reason to believe the testimony will contain Confidential Information) or when the Confidential Information is disclosed (when not previously anticipated) to separate those portions of the transcript containing Confidential Information and separately bind it from the non-confidential portions. However, a party may designate any portion or all (if appropriate) of the transcript as containing Confidential Information by so advising, with reasonable precision as to the affected testimony, the deposition reporter, who shall accordingly indicate in the deposition transcript

what portion(s) of the testimony (or exhibits thereto) were so designated, or by so advising all other parties in writing, and with page and line designations, within ten (10) business days after receipt of the transcript. Until ten (10) business days have passed after the receipt of any transcript, that entire transcript shall be deemed to be Confidential. In the event of disagreement about the confidential status of a deposition transcript, it shall continue to be treated as Confidential until the Court rules otherwise.

13. Any Designating Party may redact from the documents and things it produces (1) sensitive matter not relevant to the subject matter of this litigation, and (2) matter that the Designating Party claims is subject to attorney-client privilege, work product immunity, a legal prohibition against disclosure, private patient medical data, or other privilege or immunity. The Designating Party shall mark each document or thing where matter has been redacted with a legend stating "REDACTED FOR RELEVANCE" or "REDACTED FOR PRIVILEGE" as appropriate, or a comparable notice. Where a document consists of more than one page, at least the first page and each page on which information has been redacted shall be so marked. The Designating Party shall preserve an unredacted version of each such document. This provision shall not affect any obligation to provide a log of information redacted or otherwise withheld on the basis of attorney-client privilege, work product immunity, a legal prohibition against disclosure, or other privilege or immunity.

14. Any pleading, paper or other document filed in this action which contains or discloses Confidential Information shall be filed under seal and shall be maintained under seal according to the terms of this Protective Order or as otherwise determined by the Court. When filing pleadings, motions, briefs, discovery materials, and other papers, which contain Confidential Information, the party so filing shall designate the following on the first page of

filed documents: "Filed Under Seal - Subject To Protective Order - Contains Confidential Material - May Only Be Opened by Order of the Court" and shall otherwise comply with the Court's order on the subject.

15. Entering into, agreeing to and/or producing or receiving Confidential Information or otherwise complying with the terms of this Protective Order shall not:

a. Operate as an admission by any party that any Discovery Material designated as Confidential Information contains or reflects trade secrets or any other type of confidential or proprietary information entitled to protection under applicable law;

b. Prejudice in any way the rights of any party to object to the production of documents it considers not subject to discovery, or operate as an admission by any party that the restrictions and procedures set forth herein constitute adequate protection for any particular information deemed by any party to be Confidential Information;

c. Prejudice in any way the rights of any party to object to the authenticity or admissibility into evidence of any document, testimony or the evidence subject to this Protective Order;

d. Prejudice in any way the rights of any party to seek a determination by the Court whether any Discovery Material or Confidential Information should be subject to the terms of this Protective Order;

e. Prejudice in any way the rights of any party to petition the Court for a further protective order, or modification or amendment of this order, relating to any purportedly Confidential Information;

f. Prejudice in any way the rights of any party to petition the Court for permission to disclose or use particular Confidential Information more broadly than would otherwise be permitted by the terms of this Protective Order; or

g. Prevent any Designating Party from agreeing to alter or waive the provisions or protections provided for herein with respect to any particular Discovery Material designated as Confidential Information by that party.

16. If a party disagrees with any designation of Confidential Information, such party shall first make its objection known to the producing party and request a change of designation. The parties shall first try to resolve such dispute in good faith on an informal basis. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court no sooner than five (5) days following the service of a written notice of disagreement. The burden of proving that information has been properly designated as Confidential is on the party making such designation. Until a determination by the Court, the information in issue shall be treated as originally designated by the producing party. Any failure to object to any material being designated as Confidential shall not be construed as an admission by any non-designating party that the material constitutes or contains a trade secret or other confidential information.

17. All provisions of this Protective Order restricting the use of information obtained during discovery shall continue to be binding on the parties and all persons who have received information under this Protective Order, after the conclusion of this action, including all appeals, until further Order of the Court, unless the parties agree otherwise in writing. Upon conclusion of this matter, outside experts and consultants shall return or destroy all Confidential Information in their possession, including notes or other documents prepared relating to such information. Any and all originals and copies of Discovery Materials designated Confidential (including all

originals or copies in the possession of any outside experts or consultants, and any notes or other documents prepared by such persons relating to any Confidential Materials) shall, at the request of the producing party, be returned to the party within sixty (60) days after a final judgment herein or settlement of this Action, or, at the option of the producing party, destroyed in that time frame, except that outside counsel for each party may maintain in its files one copy of each pleading filed with the Court, each deposition transcript together with the exhibits marked at the deposition, and documents constituting work product which were internally generated based upon or which include Confidential Information. In the event that outside counsel maintains such documents, it shall not disclose material containing any type of Confidential Information to another party absent subpoena or court order. In the event that documents are returned to or destroyed at the request of the producing party, the other party or its outside counsel shall certify in writing that all such documents have been returned or destroyed, as the case may be.

18. By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Protective Order who becomes subject to a motion to disclose another party's information designated Confidential Information pursuant to this Protective Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed. If any Receiving Party is subpoenaed in another action, served with a demand in another action to which it is a party, or served with any other legal process by one not a party to this action seeking information which was produced or designated as Confidential by someone other than the receiving party, the receiving party shall transmit a copy of such subpoena, demand, or legal process, by hand or facsimile transmission, within three

business days of receipt of such subpoena, demand, or legal process, to the producing party and prepare timely objections to production of the Confidential Information. Should the person seeking access to the Confidential Information take action against the receiving party or anyone else covered by this Protective Order to enforce such a subpoena, demand, or other legal process, the receiving party shall respond by setting forth the existence of this Protective Order. Nothing herein shall be construed as requiring the receiving party or anyone else covered by this Protective Order to challenge or appeal any order requiring production of information covered by this Protective Order, subject itself to any penalties for noncompliance with any legal process or order, or seek any relief from this Court.

19. The inadvertent production in discovery of any privileged or otherwise protected or exempted information, as well as the inadvertent production in discovery of information without an appropriate designation of confidentiality, shall not be deemed a waiver or impairment of any claim or privilege or protection including but not limited to the attorney-client privilege, the protection afforded to work-product materials or the subject matter thereof, or the confidential nature of any such information, provided that the producing party shall immediately notify the Receiving Party in writing when inadvertent production is discovered. Upon receiving written notice from the producing party that privileged information or work-product material has been inadvertently produced, all such information, and all copies thereof, shall be returned to the producing party, and the Receiving Party and counsel shall not use such information for any purpose. Any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information shall immediately be destroyed.

20. Any violation of the terms of this Protective Order shall be punishable by money damages, interim or final injunctive or other equitable relief, sanctions, contempt of court

citation, or such other or additional relief as deemed appropriate by the Court. The foregoing remedies shall be in addition to any other common law or statutory relief available for violation of the terms of this Protective Order.

21. Discovery Material produced by third parties may be designated by them as Confidential Information pursuant to the terms of this Protective Order and, when so designated, shall be treated by the parties in conformance with this Protective Order.

22. The Court retains jurisdiction subsequent to settlement or entry of judgment to enforce the terms of this Protective Order.

AGREED:

OF COUNSEL:

Donna M. Tanguay (D.C. Bar No. 414496)
John R. Fuisz (D.C. Bar No. 439698)
Stephen K. Shahida (D.C. Bar No. 454970)
McDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8000

Attorneys for Defendant and Counterclaimant
Medtronic Vascular, Inc.

Sep. 9, 2004

OF COUNSEL:

Gidon D. Stern
Thomas E. Friebel (D.C. Bar No. 290627)
Catharina J. Chin Eng
JONES DAY
222 East 41st Street
New York, NY 10017

Max Bachrach (D.C. Bar No. 477267)
JONES DAY
51 Louisiana Avenue N.W.
Washington, D.C. 20001-2113
(202) 496-4456

Attorneys for Plaintiff
Scimed Life Systems, Inc.

Sept 8, 2004

The parties, having entered into the above stipulation, and having shown good cause herein, it is SO ORDERED:

Leon, J.

9/12/04

EXHIBIT A

LIST OF QUALIFIED PERSONS, paragraphs 5(c) and 5(d)

NAME	BUSINESS ADDRESS	OCCUPATION/ TITLE	GOVERNING PARAGRAPH	DATE IDENTIFIED

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff, v. MEDTRONIC VASCULAR, INC., Defendant and Counterclaimant, and ERIC C. MARTIN, Defendant and Counterclaim-Defendant.	CASE NO. 1:01CV2015 (RJL)

I hereby certify (i) my understanding that Discovery Material and/or Confidential Information are being provided to me pursuant to the terms and restrictions of the Protective Order (the "Order") entered by the United States District Court for the District of Columbia (the "District Court") in this Action, and (ii) that I have read the Order. I understand the terms of the Order, I agree to be fully bound by the Order, and I hereby submit to the jurisdiction of the District Court for purposes of enforcement of the Order. I understand that violation of the Order may be punishable by contempt of court, or other sanction, penalty, injunction, or damages available at law or equity.

Dated: _____ Signature: _____

Name: _____

Address: _____

_____

_____

TAB 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff v. MEDTRONIC VASCULAR, INC., and ERIC C. MARTIN Defendants	Case No. 1:01 CV 02015 RJL

JOINT STIPULATED REQUEST TO EXTEND DISCOVERY

Plaintiff Scimed Life Systems, Inc. and Defendant Medtronic Vascular, Inc. jointly and respectfully request this Court to extend the discovery deadline and all subsequent dates in this case by two months.

The parties have engaged in written discovery with all deliberate speed. In order to avoid any duplication of efforts, however, depositions have not taken place pending the completion of all document production. Given the number of witnesses located in and outside the United States and the fast approaching holiday season, the parties jointly propose the following extensions of the dates set forth in the Court's Scheduling Order:

Close of factual discovery	February 1, 2005
Deadline for filing discovery motions	February 15, 2005
Service of expert reports on those issues as to which a party has the burden of proof	March 14, 2005

(N)

Service of expert reports on those issues to which opposing party has the burden of proof	April 15, 2005
Completion of expert depositions	May 25, 2005
Deadline for filing summary judgment motions	June 22, 2005

(The parties are not precluded from filing summary judgment motions prior to this date.)

Opposition to summary judgment motions	21 days after filing of motion
Reply memorandum in support of summary judgment motions	14 days after filing of opposition
Hearing on summary judgment motions	To be scheduled by Court
The pretrial conference	On or after July 25, 2005

Respectfully submitted,

Friebel / SKS

Gidon D. Stern
Thomas E. Friebel (D.C. Bar No. 290627)
Catharina J. Chin Eng
JONES DAY
222 East 41st Street
New York, NY
Attorneys for Plaintiff
Scimed Life Systems, Inc.

Donna M. Tanguay (D.C. Bar No. 414496)
John R. Fuisz (D.C. Bar No. 439698)
Stephen K Shahida (D.C. Bar No. 454970)
McDERMOTT, WILL & EMERY
600 13th St., N.W.
Washington, D.C. 20005-3096
Attorneys for Defendant
Medtronic Vascular, Inc.

It is so ORDERED

Dated November 2, 2004

Honorable Richard J. Leon
United States District Judge

WDC99 999766-1.052734.0050

TAB 10

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim-Defendant,	)	
	)	
v.	)	
	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
	)	**Civil Case No. 01-2015 (RJL)**
Defendant and Counterclaim-Plaintiff,	)	
	)	
	)	
and	)	
	)	
ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant.	)	

MEMORANDUM OPINION
(March 31, 2006) [# 76, 100, 102, 103]

Plaintiff, Scimed Life Systems, Inc. ("Scimed"), brought this action against defendants, Medtronic Vascular, Inc. ("Medtronic") and Eric C. Martin, under Title 35 of the United States Code Section 146, challenging the Final Decision and Judgment of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("USPTO") regarding Patent Interference No. 104,192 between certain patent applications for an apparatus for reinforcing a bifurcated lumen. Presently before the Court are Medtronic's Motion for Summary Judgment, Scimed's First and Second Motions for Summary Judgment, and Medtronic's Motion to Compel Production of Documents and

Things. After due consideration of the parties' submissions, the relevant law and the entire record herein, the Court finds that the Board did not erroneously affirm its Grant of the Fogarty *et al.* United States Patent Application Serial No. 08/463,836 (now owned by Medtronic) Motion 12 in its July 27, 2001 Final Decision and Judgment. Accordingly, this Court affirms the Board's Final Decision and Judgment and, therefore, GRANTS Medtronic's Motion for Summary Judgment, DENIES Scimed's First and Second Motions for Summary Judgment, and DENIES AS MOOT Medtronic's Motion to Compel Production of Documents and Things.

I. BACKGROUND

Plaintiff Scimed and defendant/counterclaimant Medtronic are each assignees of record of two different patent applications for a bifurcated lumen invention.[1] Andrew Cragg and Michael Dake (collectively referred to as party "Cragg" in the underlying proceedings at the USPTO) filed an application with the USPTO regarding the bifurcated lumen apparatus on June 5, 1995. The application was assigned the serial number 08/461,402 (the "'402 application"). Cragg and Dake assigned all rights in the '402 application to Boston Scientific Technology, Inc., which later merged into plaintiff Scimed. Scimed is now the present legal owner of the '402 application. Medtronic was assigned its rights in a patent application for the same invention by Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively referred to as party "Fogarty" in the underlying proceedings at the

[1] The "Background" section of this Memorandum Opinion has been partially adapted from this Court's earlier Memorandum Opinion in *Scimed Life Systems, Inc. v. Medtronic Ave Inc.*, 297 F. Supp. 2d 4 (D.D.C. 2003).

USPTO). That application was also filed with the USPTO on June 5, 1995, and assigned the serial number 08/463,836 (the "'836 application"). Party Fogarty assigned its rights in the '836 application to Medtronic Aneurx, Inc., which merged into Medtronic AVE, Inc. which later became the defendant/counterclaimant Medtronic. Medtronic is now the legal owner of the '836 application. Defendant/counterclaim-defendant Eric Martin owns patent No. 5,575,817 (the "Martin" or "'817 patent"), based on application 08/293,541, filed on August 19, 2004.

On April 23, 1998, the USPTO Board declared an interference between Scimed's patent application (the "Cragg" or "'402 application"), Medtronic's patent application (the "Fogarty" or "'836 application") and the Martin patent. This interference proceeding was assigned Interference No. 104,192, and is referred to as the "'192 interference."[2] On July 2, 1998, the Board set the following as the sole "count"[3]:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:
> an upper limb, configured to fit within the lumen upstream of the bifurcation;
> a first lower limb, configured to extend into the first leg of said bifurcation when said first section is positioned in the lumen, and

---

2 "The purpose of an interference proceeding is to resolve the question of priority of invention when more than one applicant seeks a patent on substantially the same invention." 3A-10 Donald S. Chisum, Chisum on Patents § 10.09[1][a] (2006). This action was brought in federal Court pursuant to 35 U.S.C. § 146, which allows a party dissatisfied with the decision of the Board in an interference to bring a civil action as long as the Board's decision is not being appealed to the United States Court of Appeals for the Federal Circuit "and such appeal is pending or has been decided." *See* 35 U.S.C. § 146.

3 "A count defines the interfering subject matter. In *In re Van Geuns* (1993), the Federal Circuit noted that (1) '[a]lthough claims of one or more of the parties may be identical to the count of an interference, the count is not a claim to an invention,' and (2) '[t]he count of an interference is merely the vehicle for contesting the priority of invention and determining what evidence is relevant to the issue of priority.'" 3A-10 Donald S. Chisum, Chisum on Patents § 10.09[3] (2006).

a second lower limb, shorter that said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,
and further comprising
a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

Cragg et al. v. Martin v. Fogarty et al., Patent Interference No. 104,192, Paper No. 187, Final Decision and Judgment at 5-6 (United States Patent and Trademark Office, Board of Patent Appeals and Inferences July 21, 2001)("Board's Final Judgment"). The purpose of the '192 Interference was for the Board to determine who among the three parties had priority of inventorship, and was, therefore, entitled to the invention defined by the count.

At the time of declaration of the interference, party Cragg was accorded by the USPTO the benefit of the filing dates of two European patent applications (i.e. February 9 and June 10, 1994), which had been filed by a French Company known as Mintec SARL. At the time of declaration of the interference, party Fogarty, on the other hand, was accorded by the USPTO the benefit of the earlier filing date of U.S. patent application 08/255,681: i.e. on June 8, 1994. Thus, at the start of the interference, party Cragg was designated the "senior party,"[4] on the basis of the accorded benefit date of February 9, 1994. On March 13, 2000, party Fogarty filed a preliminary motion attacking the benefit accorded party Cragg to

[4] "In an interference proceeding, the first party to file is designated as the 'senior party' and all other parties as 'junior.' The junior party bears the burden of going forward with evidence as to actual reduction to practice prior to the senior party's filing date or conception prior to the senior party's filing date plus continuous and reasonable diligence during the critical period. If the senior party desires to show a date of conception or reduction to practice prior to his filing date, he bears the burden of going forward with evidence." 3A-10 Donald S. Chisum, Chisum on Patents § 10.03[1][c][ii] (2006).

the filing dates of the two European applications and sought to be made the senior party in the interference. On April 7, 2000, the Board granted party Fogarty's preliminary motion 12, declaring party Fogarty the senior party in the interference and party Cragg and party Martin as junior parties in the interference. *Cragg et al. v. Martin v. Fogarty et al.*, Patent Interference No. 104,192, Paper No. 130, Decision on Party Cragg's Motion to Correct the Preliminary Statement and on Party Fogarty's Preliminary Motion No. 12 at 7 (United States Patent and Trademark Office, Board of Patent Appeals and Inferences April 24, 2000)("Decision on Preliminary Motion No. 12"). In that same opinion, the Board denied party Cragg's motion to amend its preliminary statement to name Michael D. Dake and Andrew H. Cragg as co-inventors of the party Cragg invention. *Id.* at 7. Party Cragg requested reconsideration of that decision claiming that the Board had erred in its ruling and claimed that Mintec filed the European applications as assignees of both Dake and Cragg, the co-inventors of the subject matter of the patent application.

On April 24, 2000, the Board issued a Decision on Reconsideration denying the request for reconsideration on the basis that Dake's assignment of his rights in the patent application came after the filing of the European application and that 35 U.S.C. § 119 could not be interpreted to allow Mintec the benefit of priority with this subsequent assignment of rights. *Cragg et al. v. Martin v. Fogarty et al.*, Patent Interference No. 104,192, Paper No. 138, Decision on Reconsideration (United States Patent and Trademark Office, Board of Patent Appeals and Inferences April 24, 2000)("Board's Decision on Reconsideration"). In

its decision, the Board interpreted Title 35 of the United States Code Section 119 to require that "the previously filed foreign application must have been filed by the person or one who was, at the time of filing of the previously filed foreign application, already a legal representative or assign of that person." *Id.* at 3. The Board went on to state that their interpretation of Section 119 "is necessary to ensure a link between the presently involved application and the earlier filed foreign application with respect to the particular inventor. A contrary interpretation would cause entitlement to benefit to be negotiable as a commodity between unrelated entities." *Id.* In essence, the Board rejected party Cragg's position on the assignment of rights to the patent and stated:

> We are unpersuaded that an assignment of ownership rights changes on whose behalf an application was previously already filed. It would appear that only filings subsequent to the assignment of rights from Michael D. Dake can be deemed as being executed or performed on his behalf.

Id. at 5. Party Cragg requested a final hearing for review of the Board's decision claiming that the Board had erroneously interpreted Section 119 and that Dake and Cragg were co-inventors and that Mintec SARL was the assignee of both Dake and Cragg for the subject matter invention even though the assignments occurred after the European patent applications were filed. *See id* at 11-23. On July 27, 2001, the Board issued its Final Decision and Judgment. *See* Board's Final Judgment.

In its Final Judgment, the Board adopted its earlier interpretation of 35 U.S.C.§ 119. *Id.* at 9. The Board cited *Vogel v. Jones*, 486 F.2d 1068, 1072 (C.C.P.A. 1973), for the proposition that "a foreign application made by the assignee of a U.S. applicant, on behalf

of one other that the United States inventor, is irrelevant to the rights of priority of the U.S. inventor." *Id.* at 10. The Board stated that the "plain statutory language" of Section 119 does not put "an assignee in the same position as if it were a 'legal representative' or 'assign' of the inventor at a previous time when a foreign application for the same invention was filed by that assignee." *Id.* at 12. The Board found that Dake assigned his invention to Mintec, Inc. more than two years *after* the filing of the two European patent applications. *Id.* at 11-12. The Board went on to state, that even assuming that party Cragg's preliminary statement identified both Cragg and Dake as co-inventors of the subject matter of the count, that fact would not help party Cragg as "Cragg also did not assign his rights to Mintec, Inc. until after" the two European patent applications were filed. *Id.* at 20. The Board found that "MINTEC SARL was not an assign of either Michael D. Dake nor Andrew H. Cragg when it filed European applications EP944oo284.9 and EP94401306.9." *Id.* For those reasons, and others, the Board found that there was no error in the granting of party Fogarty's preliminary motion 12. *Id.* at 23.

On September 25, 2001, Scimed filed this appeal under Title 35 of the United States Code Section 146, seeking this Court's review of the Board's Final Decision and Judgment in the '192 Interference. The parties to this action entered into a stipulation and order limiting the issues in this case. The stipulated issue to be resolved is:

> Whether the Board erroneously affirmed its Grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application No.

94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192.

(*See* Stipulation and Order entered March 25, 2004, Dkt. 50.) On July 22, 2005, both parties moved for summary judgment on this remaining issue and provided the Court with exhibits supporting their positions.

II. STANDARD OF REVIEW

Summary Judgment is appropriate when the pleadings and the record demonstrate that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a Court must look to the substantive law on which each claims rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248. Additionally, to be a genuine issue of fact, it must be supported by sufficient admissible evidence such that a reasonable trier of fact could find for the nonmovant. *See Laningham v. United States Navy*, 813 F.2d 1236, 1242-43 (D.C. Cir. 1987).

The moving party bears the initial burden of "identifying those portions of the 'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrates the absence of a genuine issue of material fact." *See Celotex*, 477 U.S. at 323. In order to prevail on its motion for summary judgment,

the movant must show that the nonmovant "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322.

In opposing summary judgment, the "nonmoving party [must] go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and 'admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324. The Court must view the facts in the light most favorable to the nonmovant, giving the nonmovant the benefit of all justifiable inferences derived from the evidence in the record. *Anderson*, 477 U.S. at 255 (1986). The nonmovant, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252.

In order for Scimed to prevail on summary judgment, Scimed must put forth evidence and legal support that meets the standard of proof this Court is required to apply when reviewing decisions of the Board of Patent Appeals and Interferences of the USPTO. In determining whether or not the Board erroneously affirmed its Grant of party Fogarty's preliminary motion 12 and, therefore, erroneously awarded priority for the subject matter of the single count in the '192 Interference to Medtronic, this Court will apply the standard of proof set forth in *Morgan v. Daniels*, in that when a decision has been made by the Patent Office in an action contesting priority of invention, "the decision there made must be accepted as controlling upon that question of fact in any subsequent suit between the same parties, unless the contrary is established by testimony which in character and amount *carries*

thorough conviction." *Morgan*, 153 U.S. 120, 125 (1894) (emphasis added) (determining the standard of review for a Patent Office decision when no additional evidence was put forth to the Circuit Court). Our Circuit Court, in *United States v. Szuecs*, 240 F.2d 886 (D.C. Cir. 1957), upheld the *Morgan* standard of proof that must be applied by a District Court when reviewing a decision of the Patent Office pursuant to 35 U.S.C. § 146. "To reach a conclusion contrary to that of the Patent Office," the *Morgan* standard requires the evidence to carry "'thorough conviction.'" *Szuecs*, 240 F.2d at 887 (citing *Morgan*, 153 U.S. at 125) (reversing and remanding the case to the District Court to apply the correct standard of proof).

Another District Court Judge of this Court reaffirmed the application of *Morgan* in reviewing Patent Office cases under 35 U.S.C. § 146. *Anderson v. Anderson*, 403 F. Supp. 834, 844-45 (D.D.C. 1975) (affirming the decision of the Board of Patent Interferences after reviewing the full administrative record and hearing additional oral testimony), *aff'd*, 543 F.2d 1389 (D.C. Cir. Nov. 11, 1976). In *Anderson*, Judge John H. Pratt found that the "Patent Office is entitled to a presumption of correctness and regularity." *Id.* at 844 (citing *Vogel v. Jones*, 346 F. Supp. 1005 (D.D.C. 1972). Judge Pratt went on to reiterate that the District Court could not overturn the Board's decision unless the evidence put forth by the movant carried "thorough conviction," and "[t]he 'thorough conviction' standard imposes a heavy burden on plaintiffs in an action under 35 U.S.C. § 146," and that "[a] mere preponderance of the evidence is not enough to justify reversing the Patent Office." *Id.* at

845. For the following reasons, the Court finds that the plaintiff has failed to meet its heavy burden, and concludes that the Board did not err in its interpretation of Section 119.

III. ANALYSIS

A. *Interpretation of 35 U.S.C. § 119*

In the Board's Final Judgment, it reaffirmed its earlier decision that the "plain statutory language" of Section 119 requires that the person who filed the foreign patent application must have been a legal representative or assign of the person who filed the patent application in the United States at the time that the foreign patent application was filed.[5] Board's Final Judgment 9-10. The pertinent part of Section 119 reads:

> (a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country.

35 U.S.C. § 119(a). The Board's interpretation of Section 119 is supported by *Vogel v. Jones*, 486 F.2d 1068 (C.C.P.A. 1973). *See* Board's Final Decision 10-11. In *Vogel*, the Court of Customs and Patent Appeal, the predecessor to the current Court of Appeals for the Federal Circuit, read Section 119 to mean "that an applicant for a United States patent can rely for priority on the 'first filed' application by an assignee on his behalf." 486 F.2d at

---

[5] While counsel for Scimed is quick to point out its own grammatical analysis of Section 119 without citing to any grammar reference guide, the Court notes that it is quite capable of reading the statute, interpreting the language of the statute, researching the case law pertaining to the statute and applying that law to the present action.

1072. In order for the foreign patent application to be filed on behalf of the United States applicant, the person filing the foreign application must be an assignee or legal representative *at the time* that the foreign application was filed. *Id.* If the foreign applicant was allowed to become the legal representative or assign of the United States applicant *after* the foreign application was filed, it would be impossible for the foreign application to have been filed *on the behalf* of the United States applicant. If the Board or this Court held otherwise, the right of priority could be, as the Board noted, traded or sold as a commodity to the highest bidder. *See* Board's Decision on Reconsideration 3; Board's Final Decision 9. Therefore, this Court does not find that the Board erred in its interpretation of Section 119 and Scimed has neither cited any precedent or legislative history that would warrant interpreting the statute otherwise.[6]

---

[6] Scimed argues that the Board's construction of Section 119 is inconsistent with the Paris Convention for the Protection of Industrial Property, *opened for signature* Mar. 20, 1883, as amended at Stockholm, July 14, 1967, 21 U.S.T. 1630, 828 U.N.T.S. 305 ("Paris Convention"), and asks this Court to find that the Board's erroneously construed Section 119 as the Board's construction is inconsistent with and violates Article 4 of the Paris Convention. While Section 119, and its predecessor R.S. 4887, were enacted in order to implement Article 4 of the Paris Convention, *Vogel*, 486 F.2d at 1072, the Board's construction of Section 119, which this Court finds correct, does not violate and is not inconsistent with the Paris Convention. The Paris Convention is not self-executing and, therefore, the U.S. was free to implement the Paris Convention in the manner and form that Congress deemed appropriate. *In re Dr. Matthais Rath*, 402 F.3d 1207, 1209-10 (Fed. Cir. 2005). Congress executed Article 4 of the Paris Convention first with R.S. 4887, and then with Section 119, and Section 119 requires that in order to claim a right of priority in a foreign application, the foreign application must have been filed by the U.S. applicant or a person or entity who was a legal representative or assign of the U.S. applicant at the time that the foreign application was filed. The concern expressed by Scimed that upholding the Board's construction of Section 119 would have in foreign countries is conjecture and "based on pure speculation." *See Kawai v. Metlestics*, 480 F.2d 880, 889 (C.C.P.A. 1973).

B. *Review of Board's Decision*

Having found that the Board did not err in its reading and interpretation of Section 119, the question remains whether the Board erred in granting Medtronic's preliminary motion 12 seeking to deny Scimed the benefit of the filing date of its European patent applications. It did not. While a review by this Court of a Board's Final Decision is a "hybrid of an appeal and a trial de novo" because the Court considers evidence before the Board "as well as evidence that was not before the Board," *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (quoting *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997)), it nonetheless must treat the Board's decision as controlling "unless the contrary is established by testimony which in character and amount carries thorough conviction." *Morgan*, 153 U.S. at 125.

Scimed argues that the '284 European application was either filed on Dake's behalf "pursuant to the constructive trust imposed upon that application" when Mintec SARL filed the application, or a theory of an equitable assignment to party Cragg. (Scimed's Mem. of P&A in Opp'n to Medtronic's Mot. For Summ. J. 29, 35-36 ("Scimed's Opp'n"); Mem. of P&A in Supp. of Scimed's Second Mot. For Summ J. That Scimed is Entitled to the Priority of Its EP '284 Application Even Under the Board's Construction of 35 U.S.C. § 119(a)) 31-33 ("Scimed's Second Mot. For Summ. J.".) As this Court earlier recognized, "[t]he Federal Circuit in *Conservolite* [*Inc., v. Widmayer*] held that a party's failure to raise the issue in a preliminary motion not only precluded it not from raising the matter at the final hearing, but

also precluded district Court review." *Scimed Life Systems, Inc. v. Medtronic AVE, Inc.*, 297 F. Supp. 2d 4, 8 (D.D.C. 2003) (citing *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994)). The Federal Circuit has stated that "[i]n order for an issue to have been raised adequately so that it qualifies for consideration in a § 146 proceeding, the issue should have been raised as specified in the PTO's interference rules, for example, through preliminary motions, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or oppositions to these motions." *Conservolite*, 21 F.3d at 1102. Therefore, Scimed is precluded from arguing that the Board erred in denying priority to Scimed either under the newfound constructive trust or equitable assignment theories advanced before this Court.

Thus, applying the *Morgan* standard of proof to this review and not having conducted a *de novo* review as in *Winner*, the Court finds that Scimed has not presented sufficient evidence that Mintec SARL was either the legal representative or assign of Dake or Cragg *at* the time that the relevant European patent applications were filed. Accordingly, party Cragg and Scimed cannot claim the benefit of priority of the European patent applications. Therefore, this Court finds that the Board did not err in its granting of party Fogarty's (Medtonic's) motion No. 12 which denied Cragg *et al.* (Scimed) the benefit of the earlier filing date of European application No. 94400284.9 and affirms the Board's award of priority to Fogarty *et al.* (Medtronic) in its July 27, 2001 Final Decision and Judgment.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS defendant and counterclaim-plaintiff Medtronic's Motion for Summary Judgment [#100]; DENIES Plaintiff and counterclaim-defendant Scimed's First Motion for Summary Judgment [#102]; DENIES Plaintiff and counterclaim-defendant Scimed's Second Motion for Summary Judgment [#103]; and DENIES AS MOOT defendant and counterclaim-plaintiff Medtronic's Motion to Compel Production of Documents and Things [#76]. An order consistent with this decision accompanies this Memorandum Opinion.

RICHARD J. LEON
United States District Judge

TAB 11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim-Defendant,	)	
	)	
v.	)	
	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
	)	**Civil Case No. 01-2015 (RJL)**
Defendant and Counterclaim-Plaintiff,	)	
	)	
	)	
and	)	
	)	
ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant.	)	

FINAL JUDGMENT

For the reasons set forth in the Memorandum Opinion entered this date, it is, this 31st day of March 2006, hereby

ORDERED that defendant and counterclaim defendant Medtronic Vascular, Inc's ("Medtronic") Motion to Compel Motion to Compel Production of Documents and Things [#76] is **DENIED AS MOOT**; and it is further

ORDERED that Medtronic's Motion for Summary Judgment [#100] is **GRANTED**; and it is further

ORDERED that Scimed Life Systems, Inc.'s ("Scimed") First Motion for Summary Judgment [#102] is **DENIED**; and it is further

ORDERED that Scimed Life Systems, Inc.'s ("Scimed") Second Motion for Summary Judgment [#103] is **DENIED**; and it is further

ORDERED that judgment is entered in favor of defendant and counterclaim defendant Medtronic, that the Board of Patent Appeals and Interferences Final Decision and Judgment issued on July 27, 2001, is affirmed, and that the case is dismissed with prejudice.

SO ORDERED.

RICHARD J. LEON
United States District Judge

TAB 12

United States Court of Appeals for the Federal Circuit

2006-1434

BOSTON SCIENTIFIC SCIMED, INC.
(formerly known as Scimed Life Systems, Inc.),

Plaintiff-Appellant,

v.

MEDTRONIC VASCULAR, Inc.
(also known as Medtronic AVE, Inc.),

Defendant-Appellee,

and

ERIC C. MARTIN,

Defendant.

Gregory A. Castanias, Jones Day, of Washington, DC, argued for the plaintiff-appellant. With him on the brief were Gidon D. Stern, Thomas E. Friebel, Catharina J. Chin Eng, and Brent P. Ray, of New York, New York.

Brian E. Ferguson, McDermott Will & Emery LLP, of Washington, DC, argued for the defendant-appellee. On the brief were Paul Devinsky, John R. Fuisz, Stephen K. Shahida, and Natalia V. Blinkova. Of counsel were Joel M. Freed and Amanda E. Koenig.

Appealed from: United States District Court for the District of Columbia

Judge Richard J. Leon

United States Court of Appeals for the Federal Circuit

2006-1434

BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiff-Appellant,

v.

MEDTRONIC VASCULAR, Inc. (also known as Medtronic AVE, Inc.),

Defendant-Appellee,

and

ERIC C. MARTIN,

Defendant.

DECIDED: August 8, 2007

Before MAYER, BRYSON and PROST, Circuit Judges.

MAYER, Circuit Judge.

Boston Scientific Scimed, Inc. ("Scimed")* appeals the district court's grant of summary judgment affirming the Board of Patent Appeals and Interferences' final decision, which denied Scimed the priority benefit of an earlier-filed European patent application for the subject matter at issue in Patent Interference Number 104,192 ("the

---

* Plaintiff-appellant Boston Scientific Scimed, Inc., was formerly known as Scimed Life Systems, Inc., and will be referred to throughout this opinion as "Scimed."

'192 interference"). Scimed Life Sys., Inc. v. Medtronic Vascular, Inc., 486 F. Supp. 2d 60 (D.D.C. 2006). We affirm.

Background

This appeal stems from an interference proceeding before the United States Patent and Trademark Office Board of Patent Appeals and Interferences. Scimed and Medtronic Vascular, Inc. ("Medtronic") are each assignees of different United States patent applications covering the same invention. Andrew Cragg and Michael Dake (collectively "Cragg") filed patent application 08/461,402 ("the '402 application") for the invention in question on June 5, 1995. Cragg then assigned all rights in the '402 application to Boston Scientific Technology, Inc., which later merged into Scimed, the plaintiff-appellant and current legal owner of the '402 application. Also on June 5, 1995, Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively "Fogarty") filed patent application 08/463,836 ("the '836 application") for the same invention. Fogarty assigned their rights in the '836 application to a company that eventually became Medtronic, the defendant-appellee and current legal owner of the '836 application. Eric Martin, a third-party to the instant appeal, owns U.S. Patent No. 5,575,817 (the "Martin patent" or "'817 patent"), which resulted from an application filed on August 19, 1994.

On April 23, 1998, the board declared an interference between Scimed's '402 application, Medtronic's '836 application, and Martin's '817 patent. The purpose of the interference was to determine which party had priority of inventorship, thereby entitling it to the invention as set forth in the sole count of the interference:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:

an upper limb, configured to fit within the lumen upstream of the bifurcation;

a first lower limb, configured to extend into the first leg of said bifurcation when said first section is positioned in the lumen, and

a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation, and further comprising

a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

Cragg v. Martin v. Fogarty, Patent Interference No. 104,192, Paper No. 187, 2001 WL 1339890 at *2-3 (B.P.A.I. July 21, 2001) ("Final Interference Decision").

The board initially gave Cragg the benefit of the filing dates of two European patent applications filed by MinTec SARL ("MinTec"), a French company. The earlier of these dates was February 9, 1994. At the time these European applications were filed, no legal relationship existed between MinTec and Cragg, nor was MinTec acting on behalf of Cragg. Fogerty was granted the benefit of the filing date of U.S. patent application 08/255,681, which was June 8, 1994. Martin was accorded benefit of the application that led to the '817 patent, which was filed on August 19, 1994. Accordingly, the PTO initially designated Cragg as the senior party in the interference.

Fogarty responded by filing a motion attacking the priority benefit granted to Cragg. The board granted the motion, declaring Fogarty the senior party in the interference. After Cragg protested this decision, the board issued a final decision denying his request to be declared the senior party. The board ruled that Cragg was not entitled to priority benefit under 35 U.S.C. § 119 because neither Cragg nor Dake had assigned their rights to MinTec until after it had filed the European applications. Final Interference Decision, 2001 WL 1339890, at *5.

Scimed, the assignee of Cragg's U.S. patent application, then brought an action in the United States District Court for the District of Columbia challenging the board's final decision in the '192 interference. The district court affirmed the board's final decision, Scimed, 486 F. Supp. 2d at 61, and Scimed filed this appeal. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

Discussion

We review a district court's grant of summary judgment de novo. Monsanto Co. v. Scruggs, 459 F.3d 1328, 1344 (Fed. Cir. 2006). We also apply a de novo standard when reviewing questions of law, including a trial court's interpretation of statutory language. Pitsker v. Office of Pers. Mgmt., 234 F.3d 1378, 1381 (Fed. Cir. 2000).

At issue here is whether 35 U.S.C. § 119(a)** permits an applicant for a United States patent to benefit from the priority of a foreign application previously filed by an entity that was not acting on behalf of the U.S. applicant at the time of filing. We hold that it does not.

A similar issue was addressed by the Court of Customs and Patent Appeals in Vogel v. Jones, 486 F.2d 1068 (CCPA 1973), which, to the extent relevant here, is binding upon us, South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982)

** 35 U.S.C. § 119(a) reads in relevant part:

> An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed . . . .

(en banc). According to Vogel, "§ 119 gives rise to a right of priority that is personal to the United States applicant." 486 F.2d at 1072. Due to the personal nature of this right, an applicant for a U.S. patent may only benefit from the priority of a foreign application if it was filed by the U.S. applicant or "on his behalf." Id.

Scimed argues that Vogel does not require the foreign applicant to have been acting on behalf of the U.S. applicant at the time the foreign application was filed. It points to the following passage in support:

> This practice [of allowing a U.S. applicant to claim priority from a foreign application filed by someone else] arose because it was recognized that in many foreign countries, unlike in the United States, the actual applicant for a patent can be other than the inventor, e.g., an assignee. In light of this, we regard the language in § 119 referring to legal representatives and assigns to merely represent a codification of the actual practice under [the predecessor statute to § 119]. Since under United States law an application for patent must be made by the inventor, that practice was based on the requirement that the foreign application, regardless of the identity of the applicant, must have been filed for an invention actually made by the inventive entity seeking to rely upon it for priority purposes. We think § 119 must be construed to the same end.

Id. (footnote omitted). Scimed attempts to construe this language as permitting a U.S. applicant to benefit from a foreign application's earlier filing date whenever "the invention described in the foreign application [is the same] one actually made by the U.S. applicant," "'regardless of the identity of the applicant' of the foreign application." According to its interpretation, "the Vogel court did not hold that the foreign application must have been filed by a person who was an assignee or legal representative of the U.S. inventor at the time the foreign application was filed, or that the foreign application must have been filed on his behalf in order for there to be priority benefit." We disagree.

Vogel clearly held that the above-quoted passage "means that an applicant for a United States patent can rely for priority on the 'first filed' application by an assignee on his behalf." Id. (emphasis added). Moreover, "the existence of an application made by [the inventor's] assignee in a foreign country on behalf of one other than the United States inventor is irrelevant to his right of priority based on applications made on his behalf." Id. In other words, while the foreign application must obviously be for the same invention and may be filed by someone other than the inventor, section 119(a) also requires that a nexus exist between the inventor and the foreign applicant at the time the foreign application was filed. Indeed, as a matter of pure logic, an entity could not have filed a foreign application "on behalf of" an inventor without the inventor's knowledge or consent; that the foreign application may have been filed in accordance with the laws of the country in which it was filed has no bearing here. Therefore, to the extent that there may have been any uncertainty or ambiguity in Vogel, we now explicitly hold that a foreign application may only form the basis for priority under section 119(a) if that application was filed by either the U.S. applicant himself, or by someone acting on his behalf at the time the foreign application was filed.

Scimed also contends that the district court erred by precluding it from presenting evidence relating to theories of constructive trust and equitable assignment. A party may present new evidence to the trial court when appealing a board decision in an interference proceeding. Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994). A party may not, however, advance new legal theories at the trial court level, even if the overarching legal issue was presented below. See id. ("[A]n action under [35 U.S.C.] § 146 is essentially a proceeding to review the action of the Board. . . . [T]he

parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources."). Failure to advance legal theories before the board constitutes a failure to "make a complete presentation of the issues," and permitting a party to raise those theories for the first time before the trial court would be both inefficient and "wasteful of administrative and judicial resources." The parties stipulated that the only issue to be resolved by the district court was whether the board correctly ruled on Fogarty's motion attacking the priority benefit initially granted to Cragg, Scimed, 486 F. Supp. 2d at 64, and Scimed did not raise either of these theories before the board, see Final Interference Decision, 2001 WL 1339890, at *3-10. The district court therefore did not err by precluding Scimed from presenting evidence to support these new legal theories.

Conclusion

Accordingly, the judgment of the United States District Court for the District of Columbia is affirmed.

AFFIRMED

PTO/SB/22 (08-08)
Approved for use through 09/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2008** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818))*	Docket Number (Optional) BSI-010US4
Application Number 09/977,826	Filed October 15, 2001
For ENDOLUMINAL STENT	
Art Unit 3774	Examiner Wiliam H. Matthews

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☐ One month	(37 CFR 1.17(a)(1))	$130	$65	$_____
☒ Two months	(37 CFR 1.17(a)(2))	$490	$245	$490
☐ Three months	(37 CFR 1.17(a)(3))	$1110	$555	$_____
☐ Four months	(37 CFR 1.17(a)(4))	$1730	$865	$_____
☐ Five months	(37 CFR 1.17(a)(5))	$2350	$1175	$_____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card. Form PTO-2038 is attached. (Electronically Filed)

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 18-0350. I have enclosed a duplicate copy of this sheet.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number: 38,040.

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

Joshua L. Cohen
Signature

October 14, 2008
Date

Joshua L. Cohen
Typed or Printed Name

(610) 407-0700
Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 01/05/2009

EXAMINER

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

ART UNIT	PAPER NUMBER

DATE MAILED: 01/05/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 09/977,826	Applicant(s) GOICOECHEA ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3774	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *14 October 2008* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☒ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☒ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☐ Other (including any explanation in support of the above items):

_____.

/William H. Matthews/
Primary Examiner
Art Unit: 3774

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoechea et al.
Filed:	October 15, 2001
Title:	ENDOLUMINAL STENT
TC/A.U.:	3774
Examiner:	William Matthews
Confirmation No.:	4645
Docket No.:	BSI-010US4
Notice of Appeal Filed:	June 12, 2008
Docket No.:	BSI-010US4

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated March 24, 2008 of claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken, within two months from the date of the Notice of Appeal, or within an extension of that time period.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, are provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Boston Scientific Scimed, Inc. by virtue of Articles of Merger of Boston Scientific Scimed, Inc. wth and ito Scimed Life Systems, Inc. dated December 22, 2004.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal, except as follows:

Interference No. 104,083. A copy of the Judgment of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 1. This Interference involved related Application Serial No. 08/461,402 of Andrew H. Cragg et al., filed June 5, 1995, titled BIFURCATED ENDOLUMINAL PROSTHESIS.

Interference No. 104,192. A copy of the Final Decision and Judgment of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 2. This Interference also involved related Application Serial No. 08/461,402.

Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL). This was an appeal from the Board's decision in Interference No. 104,192. The following interlocutory orders, and/or decisions, memorandum opinion, and final judgment were entered in that appeal, with copies included in the Related Proceedings Appendix (Section X) at the indicated Tabs:

DATE	ORDER OR OPINION	TAB
11/15/01	Order	3
12/21/01	Order	4
5/2/02	Order	5
8/30/03	Memorandum Opinion and Order	6
3/25/04	Stipulation and Order	7
9/12/04	Protective Order	8
12/14/04	Joint Stipulated Request To Extend Discovery	9
3/31/06	Memorandum Opinion	10
3/31/06	Final Judgment	11

Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), United States Court of Appeals for the Federal Circuit, No. 2006-1434. This was an appeal from the decision of the U.S. District Court for the District of Columbia. A copy of the decision of the Federal Circuit is provided in the Related Proceedings Appendix (Section X) at Tab 12.

III. STATUS OF CLAIMS

Claims 20, 22-41, 43-49 and 54-62 are pending. Claims 26, 34-38, 40, and 58-62 have been withdrawn from consideration. Claims 1-19, 21, 42, 50-53 have been canceled. Claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 stand rejected and are being appealed. A copy of the rejected claims is provided in the Claims Appendix (Section VIII).

To assist the Board in correlating dependent claims with their corresponding independent claims, appellants provide the following chart of the pending claims that have not been withdrawn:

20	Dependent on claim 54
22	Dependent on claim 20
23	Dependent on claim 20
24	Dependent on claim 20
25	Dependent on claim 20
27	Dependent on claim 20
28	Dependent on claim 27
29	Dependent on claim 28
30	Dependent on claim 29
31	Dependent on claim 54
32	Dependent on claim 54
33	Dependent on claim 32
39	Dependent on claim 54
41	Dependent on claim 31
43	Dependent on claim 54
44	Dependent on claim 43
45	Dependent on claim 44
46	Dependent on claim 44
47	Dependent on claim 43
48	Dependent on claim 47
49	Dependent on claim 47
54	Independent
55	Dependent on claim 20

56	Independent
57	Dependent on claim 56

IV. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 54

The invention recited in claim 54 is a stent including a plurality of hoops aligned along a common axis. Each of the hoops is non-helical and oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the stent. The stent also includes means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

For example, and for purposes of illustration only, one exemplary embodiment of the invention is shown as stent 10 in Fig. 1A (page 19, lines 5-7; page 22, lines 17-18). Part of a stent such as stent 10 is also shown in Figs. 2A (page 19, lines 11-13; page 23, lines 11-12), 3 (page 19, lines 17-19; page 25, line 27-page 26, line 1), and 4A (page 19, lines 20-22; page 22, lines 17-18). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). Each hoop is non-helical and is oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent (page 9, lines 15-19, 13-19; page 10, lines 16-17).

Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices such as apices 22 (Fig. 2A, page 23, lines 11-20) that point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

The stent also has means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop (page 10, lines 16-23 and Figs. 1A, 1B, 2A, 4A-4F). This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following

paragraphs set forth exemplary structures described in the specification as corresponding to the claimed function.

The securing means may comprise a loop element of a suture material, for example, to tie the abutting juxtaposed apices together. The loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol (page 10, lines 20-28). FIGS. 4B-4F are partial exploded views of embodiments of a stent illustrating exemplary means for securing juxtaposed apices of the stent (page 20, lines 1-4).

Referring to Fig. 4A, for example, abutting juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 which may be, for example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has an abutting juxtaposed apex of a neighboring hoop 20 is tied to the abutting juxtaposed apex 22 in this embodiment. In other embodiments of the invention, only some of the juxtaposed apices 22 may be secured in this way (page 25, lines 4-11).

In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. 4B. The securing means may also comprise a bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in FIG. 4C. Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in FIGS. 4D, 4E, and 4F respectively (page 25, lines 12-21).

The foregoing, exemplary structures correspond to the function recited in claim 54 of securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop. Equivalent structures for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop are also within the literal scope of claim 54 under 35 U.S.C. § 112, sixth paragraph.

B. Claim 56

The invention recited in claim 56 is a stent including a tubular member that has a plurality of hoops aligned adjacent one another along the

longitudinal axis of the tubular member. Each of the hoops has a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices that axially point in a direction along the longitudinal axis of the stent. At least some of the vertices axially abut and are individually connected to oppositely pointed veritices of elongate elements of an adjacent hoop. The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, a stent such as stent 10 includes a tubular member (page 8, lines 8-10). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). The exemplary hoops are aligned adjacent one another along the longitudinal axis of the tubular member (Fig. 1A; page 9, lines 19-27; page 23, lines 24-27).

Each of the hoops includes a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices such as vertices 22 (Fig. 2A, page 23, lines 11-20) that axially point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

At least some of the vertices axially abut (Figs. 2A, 4A) and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop (Figs. 2A, 4A). For example, a loop element of a suture material connects oppositely pointed vertices of adjacent hoops (page 10, lines 18-23). Exemplary suture material is shown as element 99a in Fig. 4B (page 25, lines 13-15). Other materials for connecting oppositely pointed vertices of adjacent hoops are shown in Figs 4A and 4C to 4F (page 25, lines 4-21).

The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member (page 9, lines 15-19; page 10, lines 2-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following provides a concise statement of each ground of rejection presented for review:

Whether claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, as set forth in the Final Office Action.

VII. ARGUMENT

Paragraph 4 of the Final Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. It generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-7 of the Final Office Action provide more specific reasons for the rejections. Paragraph 2 of the Final Office Action explains why the Examiner disagreed with Applicants' arguments regarding claims 56 and 57 in their December 26, 2007 Request for Reconsideration.

EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169.

Accord, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION OF CLAIM 54 AND ITS DEPENDENT CLAIMS 20, 22-25, 27-33, 39, 41, 43-49, 55

Contrary To The Final Office Action's Contention, The Disclosure Does Support "Means For Securing An Apex Of One Hoop To An Abutting Juxtaposed Apex Of A Neighboring Hoop"

Paragraph 5 of the Final Office Action has rejected these claims because independent claim 54 recites vertices that abut which, in the Examiner's view, is not disclosed in the specification. Instead, the Examiner contends that the specification only discloses juxtaposed vertices, which, he contends, may or may not imply contact.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) implicitly and inherently supports these claim limitations. The Examiner, on the other hand, has not established a *prima facie* case, with reasons, explaining why a person skilled in

the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

> Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. . . . (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The Examiner has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that claim 54 finds clear support in stent embodiments such as those selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show embodiments having "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." The Examiner has not explained why a person skilled in the art would not recognize that the figures show this feature.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the Examiner has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports

claim 54. Paragraph 5 of the Final Office Action states: "[t]he specification only discloses juxtaposed vertices." This statement fails to provide evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

Paragraph 5 of the Final Office Action also contends that "the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply)." The Examiner's contentions disregard not only page 10, lines 16-23 but also other significant aspects of Applicants' disclosure and fail to present required evidence demonstrating that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention.

Applicants' specification also states:

> [J]uxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 (see Figure 4(a)), which are, in this example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22. (page 25, lines 4-9)
>
> In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in Fig. 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Fig. 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Fig. 4(d), 4(e), and 4(f) respectively. (page 25, lines 12-21).

These passages explain the relationship of juxtaposed apices that can be tied together or secured together as shown in Figures 4A through 4F, each of which also shows an embodiment having abutting apices. Taken together, the disclosure's statement that juxtaposed apices can be tied together or secured together, along with Figures 4A through 4F, combined with the explanation that "each hoop is supported by its neighbors" would inexorably lead one skilled in the art to conclude

that the juxtaposed apices of at least some disclosed embodiments are abutting. The Examiner has not presented any evidence to the contrary.

For all of the above reasons, Applicants' specification discloses "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop."

Claim 54 also recites, in part,

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Paragraph 6 of the Final Office Action has rejected claim 54 and its dependent claims "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the Examiner's view, "[t]he specification only disclose [sic] embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical 'offset' feature."

Applicants' specification expressly describes two alternative categories of embodiments of hoops -- helical and substantially perpendicular. The specification states:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is <u>not helical</u> because the specification describes an <u>alternative</u> to a <u>helical</u> embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is <u>non-helical</u>.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this

invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

> Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

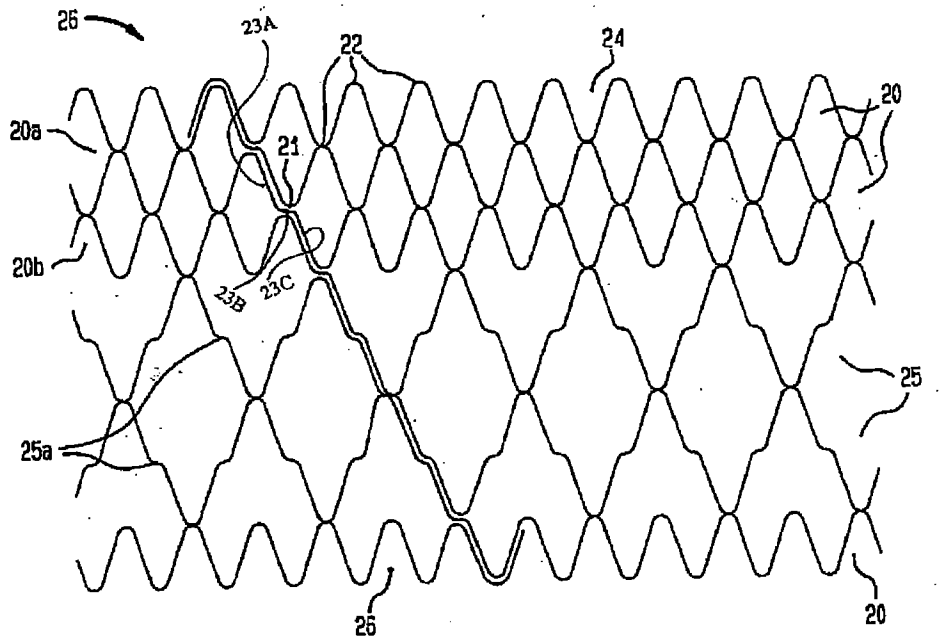
In paragraph 2, at the top of page 3[1], the Final Office Action indicates that it has interpreted "non-helical" to require that the claimed embodiment "lack[s] **any** helical features." Based upon this interpretation of "non-helical," the Examiner contends that Fig. 4A shows "a helical aspect (i.e. the longitudinal displacements described at page 23 lines 24-27)."

But page 23, lines 24-27 describes Figs. 2A and 2B, not Fig. 4A, and describes how hoops 20a and 20b in those figures are formed. Figs. 2A and 2B are reproduced below, with reference numbers 23A, 23B and 23C added to Fig. 2A for the Board's ease of reference.

---

[1] The opening sentence of paragraph 2 of the Final Office Action states that it only pertains to claims 56 and 57. Since claims 56-57 do not contain a "non-helical" recitation, the Examiner's contentions regarding "non-helical" must pertain to claim 54.

FIG. 2A



The referenced portion of the specification states:

> When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b.

Hoops 20a and 20b are shown in both figures.

Part of hoop 20a is formed by wire portion 23A. In order to form the adjoining hoop 20b, the point of winding of wire portion 23A is displaced longitudinally at wire portion 23B, and becomes wire portion 23C. Apparently, the Examiner contends that wire portion 23B precludes Applicants from reciting "hoops being non-helical." The Examiner is wrong.

The recitation at issue is: "**hoops** being non-helical." Figs. 1A, 1B, 2A, 3, 4A all show embodiments of non-helical **hoops**. Regardless of how the hoops are formed, and regardless of how one hoop flows into another hoop, the **hoops themselves** are non-helical. The disclosure therefore supports "**hoops** being non-helical."

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

THE REJECTION OF CLAIM 56 AND ITS DEPENDENT CLAIM 57

Contrary To The Final Office Action's Contention, The Disclosure Does Support "At Least Some Of Said Vertices Axially Abut"

Claim 56 recites, in part,

> at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop.

In addition to the contentions stated in paragraph 4 of the Final Office Action, the Examiner's reasoning is further explained in paragraph 2 of the Final Office Action, which contends that

> the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the question of how tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.

As was the case regarding claim 54, even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. In addition, the Examiner has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

As Applicants argued above regarding the rejection of claim 54, the specification describes, and the figures illustrate, embodiments in which "each hoop is supported by its neighbors" (page 10, line 20), "vertices . . . are individually connected to oppositely pointed vertices" using various connecting elements (page 10, lines 23-29; page 25, lines 4-9, 12-21), and apices are tied together. See also, Figs. 1A, 1B, 2A, and 4A-4F.

Taken together, the specification and the figures demonstrate that "at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop."

The Final Office Action has disregarded the above-described teachings in the specification because, in its view, the teachings "are not equivalent to a connection created by adhesive or welding." This statement makes the unsupported assumption that any two things (including juxtaposed apices) can abut only if they are connected by adhesive or welding or only if they are connected by something that is equivalent to adhesive or welding. The Board must reject these contentions because the Examiner has not supported them with any evidence and because they are clearly wrong. For example, a pencil resting on a desk top abuts the desk top even though the pencil is not connected to the desk top at all or by adhesive, welding, or anything equivalent to adhesive or welding. Applicants' disclosure demonstrates embodiments in which apices abut, even though the disclosure does not expressly refer to adhesive or welding.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Claim 56 also recites, in part:

> vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Final Office Action has rejected claims 56 and 57 because, in the view of the Examiner, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the Examiner, the specification only supports a recitation that for the perpendicular embodiment apices of "one or more" hoops lie in such a plane. The Final Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A). Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). "Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel." (page 23, lines 20-23)

Fig. 22 illustrates another embodiment of a stent using configurations such as the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

Page 3 of the Final Office Action has mischaracterized Applicants' arguments. Applicants have not suggested that "it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments." As explained above, Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). As stated above, therefore, since both stent embodiments may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops. Contrary to the belief of the Examiner, therefore, one skilled

in the art would understand that the specification does interrelate at least Figs. 1-4 with at least Figs. 22 and 23. The Final Office Action fails to demonstrate that one skilled in the art would not have such an understanding.

For the above reasons, Applicants' disclosure fully supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member."

CONCLUSION

In view of the foregoing remarks, Applicants submit that the grounds for rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 are improper. Applicants respectfully request that the Board reverse the Examiner's rejection of all pending rejected claims.

Respectfully submitted,

Joshua L. Cohen

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicant

Dated: February 5, 2009

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

VIII. CLAIMS APPENDIX

1-19 (Canceled)

20. (Previously Presented) A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

21. (Canceled)

22. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

26. (Withdrawn) A stent as recited in claim 22 wherein said axially aligned segments are connected to one another by a tubular fabric element.

27. (Previously Presented) A stent as recited in claim 20 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment.

28. (Previously Presented) A stent as recited in claim 27 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment.

29. (Previously Presented) A stent as recited in claim 28 wherein at least one of said first and second additional stent segments is of frustoconical shape

and is further combined with a third an additional stent segment, one end of which includes a mating frustoconical shape.

30. (Previously Presented) A stent as recited in claim 29, wherein said mating frustoconical stent segments are adapted to be separately placed in a bifurcated artery and then, by expansion of one of said frustoconical stent segments, secured to one another.

31. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. (Previously Presented) An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

34. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

35. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a staple.

36. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is wire twisted into loop.

37. (Withdrawn) An endoluminal stent as claimed in claim 36 wherein said wire is nitinol.

38. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is bead of thermoplastic material.

39. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

40. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said stent is at least partially covered in fabric.

41. (Previously Presented) An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

42. (Canceled)

43. (Previously Presented) An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is gold.

50-53. (Cancelled)

54. (Previously Presented) A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

55. (Previously Presented) A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. (Previously Presented) A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. (Previously Presented) A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

58. (Withdrawn) A method of reinforcing a body vessel using a tubular sheath disposed between an entry location in a body and an implantation location, said method comprising the steps of:

a. providing a stent as recited in claim 56;

b. compressing the stent into its compressed configuration;

c. inserting the compressed stent into the tubular sheath;

d. delivering the compressed stent through the tubular sheath to the implantation location; and

e. withdrawing the sheath while holding the stent at the implantation location within the vessel and expanding the stent within the implantation location as the sheath is withdrawn by permitting the self-expandable stent, as the constraint of the sheath is removed to return to said expanded configuration;

whereby the stent is securely disposed in the implanted state against said body vessel.

59. (Withdrawn) A method according to claim 58, wherein said stent is comprised of a shape memory material.

60. (Withdrawn) A method according to claim 59, wherein said shape memory material is nitinol and step (b) is performed at low temperature.

61. (Withdrawn) A method according to claim 58, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

62. (Withdrawn) A prosthesis for placement in a body lumen comprising a tubular graft supported and adapted to be retained in said lumen by a stent as recited in claim 56.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

TAB 1

BSI-944

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 33

Filed by: Trial Section Merits Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ERIC C. MARTIN,

Junior Party
(Patent No. 5,575,817)[1],

v.

ANDREW H. CRAGG, and MICHAEL D. DAKE

Senior Party
(Application 08/461,402)[2]

Patent Interference No. 104,083

Before McKelvey, Senior Administrative Patent Judge, Schafer, Lee and Torczon, Administrative patent Judges.

PER CURIAM

JUDGMENT

Junior party Martin has failed to serve its case-in-chief testimony on priority by the time such service was due, i.e.,

[1] Filed August 19, 1994.

[2] Assigned to Boston Scientific Technology, Inc. Accorded the benefit of European applications EP9440284.9, filed February 9, 1994, and EP94401306.9, filed June 10, 1994. Also accorded the benefit of U.S. applications 08/317,763, filed October 4, 1994, and 08/312,881, filed September 27, 1994.

March 1, 1999. Based on party Martin's failure to take testimony, party Cragg has filed a miscellaneous motion for judgment or a show cause order under 37 CFR § 1.652.

In a telephone conference conducted at 2:45 PM, March 8, 1999, between administrative patent judge Jameson Lee and counsel to the respective parties, Mr. Peter Davis, counsel to party Martin, indicated that the failure to serve its case-in-chief evidence was not inadvertent and that the junior party would have no objection to the Board's entering adverse judgment against party Martin on the basis that its case-in-chief evidence was not served. Accordingly, entry of judgment against party Martin is now appropriate.

It is **ORDERED** that judgment as to the subject matter of count 1 is entered against junior party Martin and awarded in favor of senior party Cragg.

It is **ORDERED** that Eric C. Martin is not entitled to a patent containing claim 1 of his involved patent, which corresponds to count 1.

It is **ORDERED** that on this record, Andrew H. Cragg and Michael D. Dake are entitled to a patent containing their application claim 89 which corresponds to the count.

It is **ORDERED** that upon return of party Cragg's involved application to the primary examiner, party Cragg shall inform the

examiner of the administrative patent judge's decision (Paper No. 20) granting party Cragg's motion to correct inventorship (Paper No. 16), and request that the correction, inclusive of the accompanying petition and amendment, be processed and entered in the official file of party Cragg's involved application.

It is **FURTHER ORDERED** that in light of this entry of judgment, party Cragg's motion for judgment or an order to show cause why judgment should not be entered against party Martin is dismissed as moot.

Fred McKelvey
Fred E. Mckelvey, Senior)
Administrative Patent Judge)
)
)
Richard E Schafer)
Richard E. Schafer)
Administrative Patent Judge)
) BOARD OF PATENT
) APPEALS
) AND
Jameson Lee) INTERFERENCES
Jameson Lee)
Administrative Patent Judge)
)
)
Richard Torczon)
Richard Torczon)
Administrative Patent Judge)

Paul F. Prestia
Ratner & Prestia
Suite 301
One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, Pennsylvania 19482-0980

Robert J. Koch
Fulbright & Jaworski
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

TAB 2

The opinion in support of the decision being entered today is not binding precedent of the Board.

Filed by: Trial Section Merits Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

Paper No. 187

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

ANDREW H. CRAGG and MICHAEL D. DAKE,

Junior Party,
(Application 08/461,402),[1]

v.

ERIC C. MARTIN,

Junior Party,
(Application 5,575,817),[2]

v.

THOMAS J. FOGARTY, JAY A. LENKER, TIMOTHY J. RYAN and KIRSTEN FREISLINGER,

Senior Party,
(Application 08/463,836).[3]

Patent Interference No. 104,192

[1] Filed 06/05/95. Accorded the benefit of application 08/317,763, filed October 4, 1994, now Patent No. 5,609,627, and application 08/312,881, filed September 27, 1994. The real party in interest is Boston Scientific Technology, Inc.

[2] Based on application 08/293,541, filed August 19, 1994.

[3] Filed June 5, 1995. Accorded the benefit of application 08/255,681, filed June 8, 1994. The real party in interest is Medtronic Aneurx, Inc.

Interference No. 104,192
Cragg v. Martin v. Fogarty

Before McKELVEY, Senior Administrative Patent Judge, and SCHAFER, LEE and MEDLEY, Administrative Patent Judges.

LEE, Administrative Patent Judge.

FINAL DECISION AND JUDGMENT

Introduction

When this interference was declared on April 23, 1998, current junior party Cragg was then senior party Goicoechea. Because of the granting of a motion to correct inventorship in related Interference No. 104,083 for application 08/461,402, the same application that is involved in this interference, co-inventors George Goicoechea, John Hudson, and Claude Mialhe were deleted and the only remaining inventors in that application are Andrew H. Cragg and Michael D. Dake. Thus, party Goicoechea became party Cragg. Any reference to party Goicoechea should be understood as a reference to party Cragg.

A decision on the parties' preliminary motions was rendered on February 11, 2000 (Paper No. 108), after which party Fogarty filed a miscellaneous motion (Paper No. 112) for leave to file, out of time, a preliminary motion 12 to attack the benefit accorded party Cragg of European Applications EP94400284.9 and EP94401306.9. The motion for leave as well as the preliminary motion 12 (Paper No. 113) were granted by a panel consisting of administrative patent judges Schafer and Lee (Paper No. 130).

The decision on Fogarty's preliminary motion 12 was adhered to on reconsideration (Paper No. 138) by a panel consisting of Senior Administrative Patent Judge McKelvey, and Administrative Patent Judges Schafer and Lee. This interference was re-declared in Paper No. 131 to change the junior/senior status of parties Cragg and Fogarty, with Cragg now being junior party.

Junior party Martin did not file a preliminary statement. It has indicated to the administrative patent judge to which this case was assigned that it did not want to participate in this interference except to "ride along" for the possibility that (1) the only interference-in-fact is determined to be between parties Cragg and Martin (a Cragg contention), and (2) that party Cragg will be deprived of its accorded benefit date (a Fogarty contention) and cannot demonstrate a sufficiently early date to prevail over Martin.

Because junior party Cragg filed no case-in-chief during the priority phase of this proceeding, it was placed under an order to show cause why judgment should not be entered against Cragg. Party Cragg requested final hearing for review of the Board's decision on Cragg's preliminary motions 1 and 2 and on Fogarty's preliminary motion 12. According to party Cragg it should not have been made a junior party and thus need not have had to put on a priority case in the first instance. Party Fogarty

requested review of the Board's decision on its preliminary motions 8 and 10. Oral argument was made on February 28, 2001, before administrative patent judges Schafer, Lee and Medley.

Findings of Fact

The below-listed findings as well as those contained in the discussion portion of this opinion are supported by a preponderance of the evidence:

1. This interference was declared on April 23, 1998, between three parties, Martin, Fogarty, and Goicoechea (now Cragg).

2. The involved patent of Martin is Patent No. 5,575,817, based on application 08/293,541, filed August 19, 1994.

3. The involved application of Cragg is application 08/461,402, filed June 5, 1995.

4. The involved application of Fogarty is application 08/463,836, filed June 5, 1995.

5. At the time of declaration of this interference, the named inventors of Cragg's involved application 08/461,402 were George Goicoechea, John Hudson, Claude Mialhe, Andrew H. Cragg, and Michael D. Dake.

6. Cragg's application 08/461,402, was also involved in a related interference, Interference No. 104,083, between parties Cragg and Martin but not Fogarty, wherein a motion to correct

inventorship was granted, deleting George Goicoechea, John Hudson, and Claude Mialhe as co-inventors, and leaving only Andrew H. Cragg and Michael D. Dake.

7. This interference was re-declared on June 2, 1999 (Paper No. 106) to reflect that only Andrew H. Cragg and Michael D. Dake are named inventors in Cragg's involved application.

8. Independent claim 1 of Martin's involved patent reads identically as the count in related Interference No. 104,083, and judgment was entered against party Martin in that interference on March 10, 1999.

9. Claim 2 of Martin's involved patent depends from claim 1, and if re-written in independent form it would read the same as the count in this interference.

10. The count of this interference reads as follows (Paper No. 16):

> An apparatus for reinforcing a bifurcated lumen comprising:
>
> a first section, configured to be positioned within the lumen, comprising:
>
> an upper limb, configured to fit within the lumen upstream of the bifurcation;
>
> a first lower limb, configured to extend into a first leg of said bifurcation when said first section is positioned in the lumen, and

> a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,
>
> and further comprising
>
> a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

11. Cragg's preliminary statement identifies only Michael D. Dake as the inventor of the subject matter of the count.

12. After the rendering of the Board's decision on preliminary motions (Paper No. 108) and subsequent service of the preliminary statement of party Cragg, Cragg filed a miscellaneous motion to amend or correct its preliminary statement to identify Andrew H. Cragg and Michael D. Dake as co-inventors of the subject matter of the count. (Paper No. 117).

13. Cragg's motion to amend was denied. (Paper No. 130). A written opinion explaining the basis of that denial followed. (Paper No. 140). Cragg requested reconsideration. The original decision was adhered to on reconsideration. (Paper No. 146).

14. Cragg has not sought review of the Board's denial of Cragg's motion to amend or correct its preliminary statement to name both Andrew H. Cragg and Michael D. Dake as inventors.

15. Upon declaration of this interference, Cragg was accorded benefit of U.S. application 08/317,763, filed October 4, 1994, European application EP94400284.9, filed February 9, 1994, and European application EP94401306.9, filed June 10, 1994. The European applications did not identify any inventor and were filed by the entity MINTEC SARL.

16. Based on representations from individuals associated with party Cragg, party Fogarty regarded as true, until the service of party Cragg's preliminary statement, that European applications EP94400284.9 and EP94401306.9 were filed by MINTEC SARL on behalf of inventors Goicoechea, Hudson, Mialhe, and Cragg. (Fogarty Preliminary Motion 12, Fact No. 5 - not disputed by Cragg).

17. Michael D. Dake made an assignment of rights, including his interests in the invention covered by Cragg's involved application relating to a bifurcated stent-graft, to MinTec, Inc., for a one time payment of eight hundred thousand U.S. dollars (U.S. $800,000) and other considerations, on May 6, 1996, with a stated effective date of April 30, 1996. (Cragg Exhibit 1025, CE-1025). The date of assignment was nearly two years and three months from the date of filing of EP94400284.9 on February 9, 1994, and nearly two years from the date of filing of EP94401306.9 on June 10, 1994.

18. Parties Cragg and Fogarty evidently treat, without dispute, that MinTec, Inc. and MINTEC SARL are related entities such that an assignment of interest to the former means the latter is an "assign."

19. Andrew H. Cragg made an assignment of rights, including his interests in the invention covered by Cragg's involved application relating to a bifurcated endoluminal prosthesis, to MINTEC, INC. on August 22, 1994. (Cragg Exhibit 1021, CE-1021). The date of assignment was six months after the date of filing of EP94400284.9 on February 9, 1994, and two months after the date of filing of EP94401306.9 on June 10, 1994.

Discussion

A. Fogarty's Preliminary Motion 12

In the "Relief Requested" portion of Fogarty's preliminary motion 12, it is stated:

> Fogarty moves under 37 CFR § 1.633(g) to deny the senior party the benefit of EP94400284.9 and EP94401306.9 on the grounds that neither application was filed by (i) the individual now identified as the inventor or (ii) on his behalf by his legal representatives or assigns.

The statutory basis of Fogarty's preliminary motion 12 is 35 U.S.C. § 119, which states, in pertinent part:

> (a) An application for patent for an invention filed in this country by **any person who has, or whose legal representatives or assigns have,** previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; . . . . (Emphasis added.)

As the motion panel's decision on reconsideration (Paper No. 138) states on page 3, a statement with which we agree and adopt herein:

> We interpret the above-quoted "any person who has, or whose legal representatives or assigns have" language as meaning that the previously filed foreign application must have been filed by the person or one who was, at the time of filing of the previously filed foreign application, already a legal representative or assign of that person. This view is necessary to ensure a link between the presently involved application and the earlier filed foreign application with respect to the particular inventor. A contrary interpretation would cause entitlement to benefit to be negotiable as a commodity between unrelated entities. Note that if party Martin or party Fogarty now assigned its involved patent or application to MINTEC, that does not and should not mean party Martin or party Fogarty's involved case should suddenly be entitled to the benefit of the earlier filing dates of party Cragg's European applications, on the basis that the European applications were previously filed by MINTEC who is now the assignee of party Martin or party Fogarty's involved patent or application.

Our view is consistent with the opinion of the Court of Customs and Patent Appeals in Vogel v. Jones, 486 F.2d 1068, 1072, 179 USPQ 425, 428 (CCPA 1973), wherein the court determined that a foreign application made by the assignee of a U.S. applicant, on behalf of one other than the United States inventor, is irrelevant to the rights of priority of the U.S. inventor. The Vogel case concerns 35 U.S.C. § 119, not 35 U.S.C. § 116 or § 120. Contrary to a suggestion by party Cragg in its reply brief at final hearing, Vogel has not been made outdated by statutory amendments to 35 U.S.C. § 116 and § 120 in 1984. The inventive entity may not always be identical between a U.S. application as a whole and an ancestral corresponding application in a foreign application. E.g., Reitz v. Inoue, 39 USPQ2d 1838, 1840 (Bd. Pat. App. & Int. 1996) ("the proposition that the inventive entity must be the same in both the foreign and the corresponding U.S. application in order to obtain benefit can no longer be accepted, if it ever was, as a hard and fast rule in view of the liberalization of the requirements for filing a U.S. application as joint inventors wrought by the 1984 amendment of 35 U.S.C. § 116."). But with regard to any particular invention at issue or involved in an interference, 35 U.S.C. § 119 still includes the language concerning filing in a foreign country by

assigns or legal representatives of the one who files for that invention in the United States.

We have reviewed Schmitt v. Babcock, 377 F.2d 994, 153 USPQ 719 (CCPA 1967), a case mentioned by Cragg during oral argument at final hearing as somehow being in support of its position, but it does not help Cragg's position. The Schmitt case, from a pre-1984 era, relates to an inconsistency or disagreement in inventorship between the U.S. application and the foreign application and a resolution of that disagreement prior to accordance of benefit. Here, inconsistency or disagreement in inventorship is not the issue. Nothing in Schmitt purports to not recognize the filing by assigns requirement of 35 U.S.C. § 119. Even if it does, that would be contrary to the Vogel case which is later in time and thus takes precedent over Schmitt.

It is not in dispute that the assignment from Michael D. Dake to Mintec, Inc. occurred subsequent to the filing of the two European applications. In its request for reconsideration (Paper No. 137) of the granting of Fogarty's preliminary motion 12, on pages 4-5, Cragg stated:

> Mintec, the applicant in the EP applications in question, was the assignee of both Dr. Cragg and Dr. Dake, albeit the assignment by Dr. Cragg came several months after those applications had been filed and the assignment by Dr. Dake came more than a year after they had been filed.

Note Cragg's exhibit CE-1025, an assignment document from Mr. Michael D. Dake to MinTec, Inc., which was executed on May 6, 1996, more than two years after the filing of EP94400284.9, and nearly two years after the filing of EP94401306.9.

Cragg's brief at final hearing does not appear to argue that under 35 U.S.C. § 119, a subsequent assignment puts an assignee in the same position as if it were a "legal representative" or "assign" of the inventor at a previous time when a foreign application for the same invention was filed by that assignee. In any event, that argument, if made, would be rejected because it ignores plain statutory language to the contrary. Cragg has not set forth evidence of legislative history which clearly indicates that the statute does not mean what it plainly says.

Two new arguments have been raised for the first time by party Cragg in its reply brief at final hearing, which should have been raised, if at all, in its opposition to Fogarty's preliminary motion 12. The first new argument is this: That the two European applications were filed by MINTEC SARL for an invention "actually made" by Michael D. Dake and Andrew H. Cragg, regardless of assignment, and that this should satisfy the filing by assign or legal representative requirement of 35 U.S.C. § 119. The second new argument is raised by the last sentence on page 10 of Cragg's reply brief, which reads: "There is no requirement

either in Section 119 or in case law that the assignment must have been perfected before the EP applications were filed in order to rely on those applications for priority purposes." The statement implies that somehow there was at least an obligation of assignment which only was not perfected or formalized until after the filing of the European applications, and that this should satisfy 35 U.S.C. § 119.

The two new arguments were not in Cragg's opposition to Fogarty's preliminary motion 12, and still not in Cragg's request for reconsideration of the motion panel's decision on Fogarty's preliminary motion 12. They further still do not appear to be contained in Cragg's principal brief at final hearing.[4] These arguments do not involve mere statutory construction, but are also fact determinative. If the new arguments were timely raised in Cragg's opposition to Fogarty's preliminary motion 12,

---

[4] In its principal brief at final hearing on page 24, Cragg states: "Michael Dake had assigned his invention to Mintec and his collaboration with Andrew Cragg on the claimed invention prior to the filing of the EP applications is acknowledged. CE1025-1." This cannot be reasonably construed as an argument that the European applications filed by MINTEC SARL were for an invention actually made by Michael D. Dake and that that would satisfy the filing by assigns requirement of 35 U.S.C. § 119. In any event, raising such an argument for the first time in the principal brief at final hearing would nonetheless be untimely. Exhibit CE1025 also does not speak of any "collaboration" in the sense of there being a common goal, but mere discussion, consultation, and communication between Michael D. Dake and one or more of Messr. Goicoechea, Cragg, and Hudson on a topic and "whatever contributions Dr. Dake may have made" (Emphasis added).

pertinent facts could have been presented by both parties and Fogarty would have had an opportunity to explore and possibly discredit Cragg's assertions. We decline to entertain new arguments which were not presented in Cragg's opposition to Fogarty's preliminary motion 12.

Accordingly, we address only those arguments of Cragg which were raised in its opposition to Fogarty's preliminary motion 12.

Cragg argues that Fogarty's preliminary motion 12 was based on the representation in Cragg's preliminary statement that Michael D. Dake was the inventor for the subject matter of the count, and yet applicable precedent indicates that preliminary statements can only be used as an effective admission of the earliest or limiting date of invention provable by the party. Cragg's argument overlooks the 1984 changes to 35 U.S.C. § 116 and a corresponding change to 37 CFR § 1.622 regarding the content of preliminary statements. Cragg's argument is rejected.

There are many precedents, including the one cited by Cragg, Dewey v. Lawton, 347 F.2d 629, 631, 146 USPQ 187, 188 (CCPA 1965), which set forth the law that the date alleged in a party's preliminary statement only constitutes a limiting date. Thus, although a party may prove a date of invention that is earlier or later than the alleged date, it cannot be entitled to a date that is prior to the alleged date. Those cases all focus on

the assertion of a date of invention and are not concerned with any identification of inventorship in the preliminary statement. Identification of inventorship did not become a requirement for preliminary statements until an amendment was made to 37 CFR § 1.622 in 1984 when Title 35, United States Code, was amended to provide that not every named inventor has to have made a contribution to every claim in a patent application. In pertinent part, 35 U.S.C. § 116 now states:

> § 116 Inventors
>
> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Thus, when an application is filed which names multiple inventors, it is not known which inventor(s) contributed to the subject matter of which claims, or to the count in an interference, even though that information may be relevant to the requirements for accordance of benefit in an interference. Rule 1.622, as amended in 1984, partially addresses that problem by requiring in a preliminary statement identification of the inventors of the subject matter of the count. It reads, in pertinent part:

> (a) A party's preliminary statement must identify the inventor who made the invention defined by each count and must state on behalf of the inventor the facts required by paragraph (a) of §§ 1.623, 1.624, and 1.625 as may be appropriate. . . .

Thus, the established precedent focusing on the effect of assertions of invention dates and not concerned with identification of inventorship are not apposite.

Cragg argues:

> Rule 629, entitled "Effect of preliminary statement," is the only rule that addresses the consequences for allegations made in a preliminary statement, such consequences being limited to dates and issues of proving priority. Importantly, Rule 629 was amended at the same time Rule 622 was amended (in 1984) to require identification of inventors in a preliminary statement, but the amendment did not create an admission as to inventorship. Rule 629(a) states:
>
> > A party shall be held to <u>any date alleged</u> in the preliminary statement. Doubts as to definiteness or sufficiency of <u>any allegation</u> in a preliminary statement . . . will be resolved against the party filing the statement by restricting the party to its <u>effective date</u> or the <u>latest date</u> of a period alleged in the preliminary statement. (Emphasis in original).

But again, this rule focuses on the effect of assertions as to a date of invention. It is concerned with ambiguities or indefiniteness in the assertion of a date of invention, and is not concerned with anything about the naming of inventors. The rule gives notice of something not so plain and obvious, i.e., that if a range of dates is asserted, then the party making the

assertion is limited to the latest of such dates. For instance, if a party asserts that its invention was made in a period from January through March of a certain year, then the earliest date of invention the party is entitled would be March 31st.

There need not be a rule to state that which is plainly so, e.g., that what a party represents to an administrative tribunal or an opposing party can be used against the party if the representation is relevant to an adjudication of the party's own rights or the rights between the parties. Party Cragg is not charged with a crime and is not being interrogated in a criminal investigation such that it must be "mirandized" -- warned that anything it says can and will be used against it in a court of law -- before it makes a usable statement. What is important is that party Cragg be given an opportunity to explain or correct any misstatement it might have made and which has been relied upon by either the tribunal or the opposing party. There was ample such opportunity in this case.

Concurrently with the filing of its opposition to Fogarty's preliminary motion 12, Cragg filed a motion under 37 CFR § 1.628 to amend or correct its preliminary statement, to name not just Michael D. Dake as the only inventor of the subject matter of the count, but Andrew H. Cragg and Michael D. Dake as co-inventors. That was a full opportunity for party Cragg to present all the

evidence it wanted to present on the issue, to demonstrate that it had made an error in only naming Michael D. Dake as the inventor of the subject matter of the count. That motion was denied on April 7, 2000, in Paper No. 130. Party Cragg requested reconsideration of that decision. The original decision was adhered to in a reconsideration decision on June 27, 2000, in Paper No. 146. Party Cragg has not sought review of that decision at final hearing.

Party Cragg further argues that the outcome here is unfair because as the original senior party it need not have filed a preliminary statement, and if it did not file a preliminary statement, then none of this would have ensued. The argument is rejected. If Cragg had not filed a preliminary statement, it would not have revealed information which ultimately led to its being deprived of benefit to the earlier filing dates of foreign applications. But this result is not unfair if, as it is here, all pertinent information were known, Cragg would not be entitled, under the law, to those earlier filing dates. Cragg had ample opportunity to show that the information it had first given was a mistake but failed to make a successful showing.

When 35 U.S.C. § 116 was amended in 1984 to permit co-inventors to be jointly listed as inventors without all of them having contributed to each and every claim in an application, a

corresponding change was made in 35 U.S.C. § 120 (relating to benefit to the earlier filing date of previously filed United States applications) to require not identity but merely an overlap of inventor(s) between the application seeking benefit and the earlier filed application. The change to 35 U.S.C. § 120 was necessary because additional or non-overlapping inventors may be present due to the inclusion of claims drawn to different subject matter. No such change was necessary, however, with respect to the requirement of 35 U.S.C. § 119 that the person who has filed for a patent on an invention (here the invention of the count) must have previously regularly filed for a patent on the same invention in a foreign country, whether it is through legal representatives or assigns. Indeed, no change was made. The contexts and requirements of 35 U.S.C. § 119 and 35 U.S.C. § 120 are different. That Michael D. Dake being a sole inventor for the subject matter of the count is not a problem under 35 U.S.C. § 120 with respect to earlier filed United States applications does not mean Cragg can expect that it should also not be a problem insofar as benefit to foreign applications are concerned. Satisfaction of requirements under 35 U.S.C. § 120 entitles a party only to the earlier filing date of a previously filed United States application, not a foreign application.

Alternatively, even assuming that Cragg's identification of Michael D. Dake as the only inventor for the subject matter of the count is a mistake and that Cragg has been allowed to amend its preliminary statement to identify both Andrew H. Cragg and Michael D. Dake as co-inventors of the subject matter of the count, that still does not help party Cragg in any meaningful way. Like Michael D. Dake, Andrew H. Cragg also did not assign his rights to MinTec, Inc. until after European application EP94400284.9 was filed on February 9, 1994, and European application EP94401306.9 was filed on June 10, 1994.

Cragg's Exhibit CE1021 is an assignment from Andrew Cragg, Claude Mialhe, George Goicoechea, and John Hudson to MINTEC, INC. It was executed by Andrew H. Cragg on August 22, 1994. Accordingly, MINTEC SARL was not an assign of either Michael D. Dake nor Andrew H. Cragg when it filed European applications EP94400284.9 and EP94401306.9. In that connection, we vacate the Board's previous finding in paragraph no. 7 of Paper No. 130 which stated: "The European applications EP94400284.9 and EP94401306.9 were filed by the assignee MINTEC SARL on behalf of inventors Andrew H. Cragg, George Goicoechea, John Hudson, and Claude Mialhe." That finding was made when the question of when Andrew H. Cragg assigned his rights was not an issue and also prior to party Cragg's representation to the Board in its request

for reconsideration of the Board's granting of Fogarty's preliminary motion 12 that Andrew H. Cragg did not assign his rights to Mintec until several months after the European applications were filed. It lacks adequate basis in the record.[5]

Cragg still further argues that because it has been accorded benefit to the September 27, 1994 filing date of application 08/312,881 (granting of Cragg's preliminary motion 7) and because that application claims foreign priority to EP94400284.9 and EP94401306.9, which claim was granted by an examiner and not challenged in this interference, it still should have benefit of the filing dates of EP94400284.9 and EP94401306.9. The argument is without merit.

As the Board's decision on reconsideration (Paper No, 138) has stated on page 6:

> Benefit to the two European applications cannot be obtained indirectly through the intermediate application 08/312,881, where the required overlap in inventor/filer is missing between the involved application and the European applications. This is not the same issue as satisfying the "filing within one year requirement of § 119" through an intermediary United States parent application.

---

[5] Our authority and discretion to vacate the previous finding does not depend on whether Fogarty has asked the Board to reconsider the finding or when the request by Fogarty was made. We dismiss Cragg's argument that Fogarty was late in asking the Board to reconsider the previous finding.

Cragg has offered no reason why the above-quoted analysis is erroneous. Here, we add the following observations.

Having benefit to the 9/27/94 filing date of application 08/312,881 means Cragg's involved application is deemed to have been filed not on the actual filing date of June 5, 1995, but on September 27, 1994. That brings Cragg's involved application much closer in time, by approximately 8 months, to any foreign application with respect to which it desires to be accorded benefit. With that shortening of the time gap, it is easier to satisfy the "within twelve months" time requirement of 35 U.S.C. § 119. It does not mean Cragg's involved application stands in the shoes or otherwise takes the place of the earlier filed domestic application. Benefit is still considered from the perspective of the claims or counts at issue in Cragg's involved application. Whether application 08/312,881 is entitled to benefit with respect to any claim contained therein is irrelevant, not at issue, and has not been determined in this proceeding. We are concerned with the claims of Cragg's involved application and the count in this interference. Fogarty is also correct in stating (Opp. Brief at 8):

> Cragg's further argument on page 24 that 35 USC § 119 priority "has not been challenged" for Serial No. 08/312,881 also is irrelevant. In the context of an interference, rights under 35 USC § 119 and § 120 arise with respect to an embodiment within the count in a

benefit application. Hunt v. Treppschuh, 523 F.2d 1386, 187 USPQ 426 (CCPA 1975). It is thus inaccurate to speak of priority between applications without reference to claims and/or a count. (Emphasis in original.)

For the foregoing reasons, Cragg has shown no error in the motion panel's granting of Fogarty's preliminary motion 12.

B. Fogarty's Preliminary Motions 8 and 10

In a decision mailed February 11, 2000 (Paper No. 108), the motions panel denied Fogarty's preliminary motion 8 under 37 CFR § 1.633(e)(1) which sought to declare another interference between proposed new claim 62 of an uninvolved application 08/684,508 of Fogarty and claim 89 of Cragg's involved application 08/461,402, and claim 1 of Martin's involved Patent No. 5,575,817. The decision gave two grounds for denying the preliminary motion:

> (1) that the proposed new interference is barred by 35 U.S.C. § 135(b) because no claim which is the same or substantially the same as Martin's supposedly interfering patent claim 1 had been made by Fogarty within the critical one year period of 35 U.S.C. § 135(b); and
>
> (2) that Fogarty failed to demonstrate that there is interference-in-fact between the allegedly interfering claims.

Fogarty argues, first, that we misapplied the requirements of 35 U.S.C. § 135(b) and that if correctly applied, the requirements of 35 U.S.C. § 135(b) are met. Fogarty further

argues that there is no requirement in 37 CFR § 1.637 or otherwise, in connection with a preliminary motion to declare an additional interference, that the moving party has to demonstrate the existence of an interference-in-fact between the allegedly interfering claims.

1. Interference-In-Fact

According to Fogarty, it can find nothing in the interference rules which requires that in order for a preliminary motion to declare an additional interference to be granted, the preliminary motion must establish or demonstrate that an interference-in-fact exists between the claims sought to be involved in the additional interference. While there may be no express requirement, the decision on preliminary motions (Paper No. 108) on page 53, lines 18-22, states that the requirement is an implicit one:

> Secondly, it is implicit that to demonstrate entitlement to the declaration of an additional interference as is requested in Fogarty's motion, Fogarty must demonstrate that there is interference-in-fact between Goicoechea's [Cragg after deleting Goicoechea as a co-inventor] application claim 89 and claim 62 of Fogarty's uninvolved application 08/684,508. (Emphasis added.)

Party Fogarty's brief at final hearing does not explain why it is not an implicit requirement that a motion to have an

interference declared must demonstrate that the claims said to interfere with each other actually interfere with each other, i.e., that there is interference-in-fact between the allegedly interfering claims. Moreover, the very first sentence of 37 CFR § 1.637(a) is this: "A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion." (Emphasis added).

We decline to simply take a moving party's word that one of its claims interferes with one or more claims of other parties. We reiterate our holding in the decision on preliminary motions that it is an implicit requirement for a preliminary motion to have another interference declared that the motion must demonstrate that there is interference-in-fact between the allegedly interfering claims. Fogarty's brief at final hearing does not address the point of "implicit" requirement and thus has not shown that the motion panel was erroneous.

Fogarty also asserts that in any event the Board's two-way interference-in-fact analysis follows the Trial Section's precedential decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999), but that was not the criteria in October 1998 when preliminary motions were filed in this proceeding. We suppose that what Fogarty is arguing is that had it known of the two-way analysis requirement at the time it filed its preliminary

motion 8, it could have tried to demonstrate satisfaction of the two-way requirement. That is true, but as was explained in our initial decision, Fogarty has failed to explain why there is interference-in-fact, in either direction, e.g., neither from Martin's claim 1 or Cragg's claim 89 to Fogarty's claim 62, nor from Fogarty's claim 62 to Martin's claim 1 or Cragg's claim 89.[6] Note also that the declaration of an interference is a discretionary matter. See Ewing v. Fowler Car Co., 244 U.S. 1, 10-11 (1917) (explicitly rejecting the assertion of an applicant's right to declaration of an interference). It is not an abuse of discretion to not declare an interference where the moving party has not demonstrated that there is a conflict or interference-in-fact between opposing claims, regardless of whether the interference rules expressly require a demonstration of conflicting subject matter or interference-in-fact.

---

[6] The motion panel's decision observed that Fogarty's position that Cragg's claim 89 and Martin's claim 1 are unpatentable over prior art while Fogarty's claim 62 is patentable over that same prior art is contrary to the position that Fogarty's claim 62 defines the same patentable invention as Cragg's claim 89 and Martin's claim 1. Fogarty's brief at final hearing points out that the motion panel rejected Fogarty's prior art argument and that Cragg has not sought review of that issue. But at best the circumstance pointed out by Cragg only eliminates an apparent inconsistency. It does not demonstrate affirmatively that the claims define the same patentable invention.

2. 35 U.S.C. § 135(b) Bar

There is no dispute that Fogarty's amendment in its uninvolved application 08/684,508, proposing to add claim 62 to provoke an interference with claim 89 of Cragg's application 08/461,402 and claim 1 of Martin's Patent No. 5,575,817, is filed more than one year after the date of issuance of Martin's Patent No. 5,575,817. The question at issue is whether Fogarty had another claim, drawn to the same or substantially the same invention as Martin's claim 1, that was pending within one year subsequent to the date of issuance of the Martin patent. If so, claim 62 is not barred. If not, then claim 62 is barred.

In pertinent part, 35 U.S.C. § 135(b) states:

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Even though the new interference proposed by Fogarty involves claim 1 of Martin's patent, Fogarty attempted to demonstrate that it had a claim drawn to substantially the same subject matter as Martin's claim 1 by showing that it was claiming, within the critical one year period, the same invention as Martin's claim 2. Martin's claim 2 depends from claim 1 and in independent form represents the count of this interference.

In the motion panel's initial decision (Paper No. 108, pages 52-53), it was stated:

> There is no indication anywhere by any party that Fogarty's uninvolved application 08/684,508 had a claim drawn to substantially the same subject matter as Martin's claim 2. While Fogarty's involved application [08/463,836] in this interference include claims which correspond to the count which is Martin's claim 2, that does not mean Fogarty's uninvolved application 08/684,508 has at any time included a claim drawn to substantially the same subject matter as Martin's claim 2.

In its brief for final hearing, Fogarty argues that so long as it was claiming the required subject matter in some earlier application within one year of the issuance of the Martin patent, it passes muster under 35 U.S.C. § 135(b). Fogarty cites two decisions of the Court of Customs and Patent Appeals, In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981) and Corbett v. Chisholm, 568 F.2d 759, 196 USPQ 337 (CCPA 1977), two decisions of the Board of Patent Interferences, Tezuka v. Wilson, 224 USPQ 1030, 1036 (Bd. Pat. Int. 1984), Olin v. Duerr, 175 USPQ 707 (Bd. Pat. Int. 1972), and one decision of the Board of Patent Appeals and Interferences, Bowen v. Bihlmaier, 231 USPQ 662 (Bd. Pat. App. & Int. 1986), in support of its view. Fogarty points out that its uninvolved application 08/684,508 is a file wrapper continuation of application 08/255,681, to which it has been

accorded benefit in this interference and with respect to which Fogarty's involved application is a divisional application.

Cragg's opposition brief does not take up and address the issue as noted above. We find Fogarty's presentation persuasive at least in the circumstances of this case. Consequently, we no longer rely on the above-quoted portion of the motion panel's decision to deny Fogarty's preliminary motion 8.

Another issue, however, nonetheless undermines and precludes the granting of Fogarty's preliminary motion 8. As was explained in the motion panel's decision on page 53:

> [W]e disagree with Fogarty's contention that if a claim the same as Martin's claim 2 is made in an application, then a claim the same as Martin's claim 1 is also necessarily made, simply because Martin's claim 2 depends from Martin's claim 1 and thus includes all features of Martin's claim 1. The case cited by Fogarty, In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981), does not hold that so long as every feature of a claim is present in another claim then substantially the same subject matter is being claimed. In Schutte, no other difference between two claims is at issue, except for the one which the Court regarded as different in language but same in substance.

Fogarty's view leads to the erroneous result that a claim directed to patentably distinct and separately patentable subject matter as that of another claim can be regarded, at the same time, as claiming the same or substantially the same invention as that other claim. Party Cragg should note that Martin's claim 2 can be separately patentable and patentably distinct from

Martin's claim 1 even though it depends from claim 1 and undoubtedly includes every limitation of claim 1.

Because it is important that we fully address Fogarty's arguments, we reproduce portions of Fogarty's brief below (Br. at 7-8):

> Fogarty responded to Cragg's assertion of noncompliance with 35 USC § 135(b) by noting that the determination under the statute is:
>
> > [W]hether the claim which was pending had *all the material limitations* of the patent claim. *In re Schutte*, 244 F.2d 323, 113 USPQ 537 (CCPA 1981). If the pending claims had all the material limitations there is compliance with the statute even if different language is employed. [Fogarty Reply, p. 5, original italics]
>
> This principle of law has been applied for at least half a century, as is apparent from the authorities cited in the last two paragraphs on page 5 of Fogarty's Reply, i.e., *Ex parte Bowen*, 80 USPQ 106 (Bd. App. 1947), *Stalego v. Heymes*, *supra*, *Olin v. Duerr*, *supra*, and *In re Schutte*, *supra*.
>
> The decision adopted Cragg's argument but with one possible exception did not address (nor acknowledge) the precedents cited by Fogarty.
>
> The test in each of *Bowen*, *Stalego*, *Olin* and *Schutte* for determining compliance with 35 USC § 135(b) is straight forward: is a limitation of the patent claim material and if so, is it claimed by the applicant, expressly or inherently? [Footnote omitted] Application of this test to different fact patterns is seen in a comparison of the results in, for example, (i) *Corbett v. Chisholm*, *supra*, where there was no compliance because a limitation was material but was neither disclosed nor inherent, (ii) *Bowen v.*

> *Bihlmaier, supra* where compliance was found because the material limitation was substantially claimed albeit in different language, (iii) *Connin v. Andrews*, 223 USPQ 243 (Bd. Pat. Int'f. 1984) where the limitation, while material and undisclosed, was inherent, and (iv) *Pizzurro v. Pfund*, 1 USPQ2d 1056 (Bd. Pat. Int'f. 1984) where a limitation was material and claimed.

In our view, none of the authorities Fogarty cites sets forth the principle that so long as every material limitation of a patent claim is included in an applicant's claim, then the applicant has claimed substantially the same invention as the patent claim regardless of whether the applicant's claim includes additional features which may render the applicant's claim patentably distinct or separately patentable from the patent claim.

Except for In re Tanke, 213 F.2d 551, 102 USPQ 83 (CCPA 1954), Stalego v. Heymes, 263 F.2d 334, 120 USPQ 473 (CCPA 1959), Wetmore v. Miller, 477 F.2d 960, 177 USPQ 699 (CCPA 1973), and Corbett v. Chisholm, 568 F.2d 759, 196 USPQ 337 (CCPA 1977), none of the other cases cited by Fogarty[7] for determining whether substantially the same invention was being claimed by an

---

[7] Not Rieser v. Williams, 255 F.2d 419, 118 USPQ 96 (CCPA 1958); not In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981); not Ex parte Bowen, 80 USPQ 106 (Bd. App. 1947); not Olin v. Duerr, 175 USPQ 707 (Bd. Pat. Int. 1972); not Connin v. Andrews, 223 USPQ 243 (Bd. Pat. Int. 1984); not Pizzurro v. Pfund, 1 USPQ2d 1056 (Bd. Pat. Int. 1984); not Bowen v. Bihlmaier, 231 USPQ 662 (Bd. Pat. App. & Int. 1986).

applicant discussed as an issue whether the applicant's claim contained additional features which made the application claim not substantially the same as the patent claim. Fogarty too strictly applied the principle that if every material feature of the patent claim is present in the application claim then substantially the same invention is being claimed by the applicant. The mistake lies in not recognizing that the applicant's claim may include material features that render the applicant's claim patentably distinct and separately patentable from the patent claim.

In Stalego v. Heymes, 263 F.2d 334, 335, 120 USPQ 473, 475 (CCPA 1959), the Court of Customs and Patent Appeals stated:

> Those decisions [citing to precedents] hold, in effect, that claims are not for substantially the same subject matter if one of them contains one or more material limitations which are not found in the other. Accordingly, the ultimate question to be decided in such cases is generally whether specific differences between claims are material; and that is a question which must be decided largely on the basis of the particular circumstances of each case.

In Stalego, the Court reviewed the additional features of the reissue applicant's claim and stated that it did not regard any of those limitations as important. In analyzing the additional features claimed by the reissue applicant, the Court in Stalego, 263 F.2d at 338, 120 USPQ at 477, referred to one feature as not having criticality and another as adding nothing of consequence.

The key is that the limitations of the applicant's claim at issue must be examined and are relevant too for materiality, not just the features of the patent claim. In Wetmore v. Miller, 477 F.2d 960, 177 USPQ 699, 701 (CCPA 1973), the Court of Customs and Patent Appeals cited to Rieser v. Williams, 255 F.2d 419, 118 USPQ 96 (1958) and Stalego v. Heymes, 263 F.2d 334, 120 USPQ 473 (1959), as setting forth the criterion that has been adopted by the CCPA for determining the applicability of section 135(b).

We do not regard Wetmore v. Miller as making any change to the criterion set forth in Stalego v. Heymes. Evidently, neither does Fogarty. In Wetmore, in light of the additional "fusible" limitation contained in the applicant's claim, the Court stated that the Board made too much emphasis on the fact that the patent claim applies to multiple embodiments and gave insufficient weight to embodiments in the patent using a heat fusible member. Note that the patent claim utilized means-plus-function features under 35 U.S.C. § 112, sixth paragraph. Clearly, the Court considered the technical significance of features in the applicant's claim in a comparison with the claim of the patentee.

In Corbett v. Chisholm, supra, and as Fogarty itself has noted, (Reply at 6, lines 19-25), in response to a restriction requirement the applicant elected to prosecute apparatus claims instead of method claims as the patentee had claimed and the

patentee's method could be practiced with apparatus materially different from that which the applicant elected. On that basis, the Court held that the applicant's claim and the patentee's claim defined patentably distinct inventions. Thus, the applicant was not claiming substantially the same invention as the patentee. What this suggests is that the features claimed by the applicant, over and above that which is claimed by the patentee, are important and cannot be ignored.[8]

As for In re Tanke, 213 F.2d 551, 102 USPQ 83 (CCPA 1954), it does not hold, as Fogarty argues on page 8 of its reply, that "a mere distinction in breadth or scope" does not define a separate invention. The language of In re Tanke must be read in context. What it actually conveys is that where the subject matter of the differently claimed inventions has already been determined as being directed to substantially the same invention, the specific variations are a mere distinction in breadth or scope within the same or substantially the same subject matter and thus do not define separate inventions or inventions which are not substantially the same. Note that In re Tanke states, 213 F.2d at 555, 102 USPQ at 85:

---

[8] Note also that other claims of the applicant did not include one or more material features of the patentee's claim.

> Furthermore, it should be noted that the terms "draft structure" defined by appellants' original claims 6 and 14, and the terms such as "drawbar-receiving member" and "bail-receiving member" in the appealed claims seem to be merely different expressions for essentially the same apparatus both structurally and functionally.
>
> The final conclusion of the board in this case holding that the recitation of the draft structure in the appealed claims "to be different in scope from that recited in claim 14" does not appear to legally establish that such claims are not for substantially the same subject matter.
>
> In dealing with competing claims, one group of which was drawn to a spring which assisted in both lifting and lowering certain plow beams therein defined, and another group which merely defined the function of the spring as assisting in the lifting of said beams, the Supreme Court held that **both groups of claims were for the same combination; . . .** and that such [one group of] claims should they consist of nothing more than a mere distinction in breadth or scope when compared to the [other group of] patented claims, do not define a separate invention or subject matter which is not substantially the same. Miller v. Eagle Manufacturing Co., 151 U.S. 186 [citations omitted]. (Empahsis added.)

Fogarty's claim 27, the same as original claim 27 in Fogarty's parent application 08/255,681 filed on June 8, 1994, was made within the one-year of November 19, 1996, the date of issuance of Martin's Patent No. 5,575,817. Even assuming that claim 27 includes every feature of Martin's dependent claim 2, and therefor it must include every feature of Martin's independent claim 1, that does not mean Fogarty had claimed substantially the same invention as Martin's claim 1. Martin's

independent claim 1 formed the basis of the count in related Interference No. 104,083. Martin's dependent claim 2 forms the basis of the count in this interference (See Paper No. 16). Martin's claim 2 adds a feature which is not present in Martin's claim 1. Fogarty had notice that the examiner regarded Martin's claim 2 as patentably distinct from Martin's claim 1. On page 3 of the examiner's Rule 1.609(b) submission, it is stated:

> **Distinction between Counts 1 and 2.**
>
> The important feature of count 1 [the count in Interference 104,083] is that the bifurcated prosthesis has two limbs but only one limb extends across the bifurcation and into the lumen of the vessel. Count 2 [the count in this interference] requires an additional stent to be added to the short limb, thus making a two piece graft that extends into both branches of the vessel. The count 2 is patentably distinct from count 1 for this reason.

Moreover, on page 9 of Fogarty's preliminary motion 8, Fogarty expressly recognized that the USPTO has regarded the counts of Interference No. 104,083 and this interference, represented by Martin's claims 1 and 2, as being directed to separately patentable inventions. Fogarty did not challenge that position. Instead, Fogarty stated that "[t]he same would apply to the Count of the present interference and proposed Count F-2 [for the additional interference]."

In summary, according to Fogarty, because its claim 27 was pending within the critical one-year period of 35 U.S.C. § 135(b)

and because claim 27 includes every feature of Martin's dependent claim 2, and therefore Martin's independent claim 1, Fogarty was claiming substantially the same invention as Martin's claim 1 within the critical one-year period of 35 U.S.C. § 135(b). We reject Fogarty's argument, because it regards as irrelevant whether the additional feature added by Martin's dependent claim 2 renders Martin's claim 2 patentably distinct and separaetly patentable from Martin's claim 1. If it is, as it apparently is so based on the examiner's Rule 1.609(b) submission, a position Fogarty has not disputed and in fact urged as similarly true with the count in this interference as compared to the proposed count (see Fogarty's preliminary motion 8, Section 7 on page 9), then Fogarty cannot be deemed as claiming substantially the same invention as Martin's claim 1 by way of having a claim the same as Martin's claim 2.[9] Fogarty has failed to demonstrate that it had been claiming substantially the same invention as Martin's claim 1 within the one-year period of 35 U.S.C. § 135(b).

3. Cragg's Assertion that claim 62 of Fogarty's uninvolved application is unpatentable under 35 U.S.C. § 112, first and second paragraphs

---

[9] This is in contrast with the applicant's claiming the same patentable invention as the patentee but merely adds features which are of no criticality or significance. See Stalego v. Heymes, 263 F.2d at 338, 120 USPQ at 477.

In opposing Fogarty's preliminary motion 8, Cragg never asserted that any claim of Fogarty was unpatentable for indefiniteness under 35 U.S.C. § 112, second paragraph. The brief for final hearing is not an occasion to be raising such issues for the first time. Accordingly, we decline to entertain Cragg's argument that claim 62 of Fogarty's uninvolved application is unpatentable under 35 U.S.C. § 112, second paragraph.

The motion panel's decision on preliminary motions (Paper No. 108) stated that it was manifestly apparent based on the entirety of the pleadings that claim 62 and not claim 63 of Fogarty's uninvolved application was the claim at issue in connection with Fogarty's motion to have an additional interference declared. It further found that parties Cragg and Martin would not be prejudiced by a recognition that Fogarty's motion concerned claim 62 of Fogarty's uninvolved application. While opposing Fogarty's motion, Cragg asserted that Fogarty's claims 62 and 63 are unpatentable under 35 U.S.C. § 112, first paragraph, but meaningfully discussed only the features of Fogarty's claim 63. Because nothing meaningful was presented with regard to Fogarty's claim 62, the decision on preliminary motions did not discuss Cragg's mere conclusion that Fogarty's claim 62 is unpatentable under 35 U.S.C. § 112, first paragraph.

In its opposition brief at final hearing, Cragg asserts that claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph, and makes a detailed analysis, for the first time, as to why the assertion has merit. This substantive analysis directed to Fogarty's claim 62 was not previously provided in Cragg's opposition to Fogarty's preliminary motion 8. Accordingly, such analysis will not be entertained for the first time at final hearing.

We will not compare Fogarty's claims 62 and 63 and attempt to figure out which features are common therebetween such that when Cragg discussed a certain feature of claim 63 when opposing Fogarty's preliminary motion 8 it was the same as if it were discussing a corresponding feature in Fogarty's claim 62. It was incumbent upon Cragg when opposing Fogarty's motion to clearly set forth why Fogarty's claim 62 is unpatentable under 35 U.S.C. § 112, first paragraph. It is not the role of the Board to act as an advocate for either party by making arguments, presentations, or comparisons which should have been made by the parties themselves.

Because no meaningful argument was presented by Cragg in its opposition to Fogarty's preliminary motion 8 as to why claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph, we reject Cragg's

argument at final hearing that claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph.

Alternatively, even if we do consider the substantive arguments made for the first time by Cragg in its opposition brief at final hearing concerning claim 62 of Fogarty's uninvolved application 08/684,508, the arguments are without merit and do not make out a prima facie case that claim 62 of Fogarty's application 08/684,508 is without written description support in the specification.

According to Cragg, the features (1) a first leg joined to said anchor section, and (2) means for joining a second leg to said anchor section, of claim 62 of Fogarty's uninvolved application 08/684,508 are without support in the specification of application 08/684,508. Cragg contends that "Fogarty's first leg is never joined to an anchor section." Cragg explains that Fogarty's first leg is positioned within a fiber fabric liner at a location spaced below the anchor section. According to Cragg, Fogarty's second leg is also not joined to the anchor section, evidently for the same reason, and thus there can be no description for a "means for joining a second leg to said anchor section." Cragg's arguments assume that there must be direct contact between the first leg and the anchor section and between

the second leg and the anchor section. We see no reason, however, to construe claim 62 of Fogarty's uninvolved application 08/684,508 so narrowly as to require direct or immediate contact between the first and second legs and the anchor section.

Cragg does not contend that Fogarty's application 08/684,508 sets forth a special definition for the word "join" that is different from the ordinary meaning of the term. We understand the word "join" as sufficiently broad to encompass an indirect connection through an intermediate member. See, for example, Merriam-Webster's Collegiate Dictionary, Tenth Edition, Copyright © 1999, which defines "join" as follows:

> 1 a: to put or bring together so as to form a unit . . . . b: to connect (as points) by a line c: ADJOIN 2: to put or bring into close association or relationship . . . 3: to engage in (battle) 4 a: to come into the company of . . . b: to associate oneself with . . .

If the first and second legs in Fogarty's application 08/684,508 are connected to the anchor section by way of a fiber fabric liner, as Cragg apparently indicates, that does not mean the first and the second legs are not joined to the anchor section. Cragg argues that the tubular liner means cannot also be the means for joining because if it is then that would render meaningless the tubular liner means element of claim 62. The argument is without merit, because the recitation of a tubular liner means in claim 62 further specifies that the liner

structure defines a continuous flow path from the anchor section to the first leg and an opening disposed toward the second branch lumen. We note further that nothing precludes the same disclosed physical element from being the corresponding structure of two or more means-plus-function elements in a claim, provided that the structure performs the recited functions of those means-plus-function clauses.

4. Fogarty's argument that notwithstanding any 35 U.S.C. § 135(b) bar relative to patentee Martin, Fogarty is not precluded from having an interference with Cragg is without merit

Fogarty points out that in related Interference No. 104,083 involving only Martin and Cragg, specifically Cragg claim 89 and Martin claim 1, judgment has been entered against patentee Martin and thus claim 1 of Martin is as good as cancelled. According to Fogarty, the time bar under 35 U.S.C. § 135(b) is for protecting patentees from perpetually under threat of an interference proceeding initiated by applicants. Thus, Fogarty argues that because judgment has been entered against Martin's patent claim 1 in Interference No. 104,083, protection for Martin under 35 U.S.C. § 135(b) insofar as Martin's claim 1 is concerned is moot and unnecessary. Fogarty's view is that in this circumstance, application of the bar under 35 U.S.C. § 135(b) only protects another applicant, i.e., party Cragg, whose claim 89 would be shielded from a priority determination relative to Fogarty.

While 35 U.S.C. § 135(b) was primarily enacted to protect patentees, the language of the statute is not such that only a patentee may benefit from the bar. The statutory section is written in terms of a bar on the presentation of a claim, not as a bar on having an interference with a patentee. If an applicant is time-barred by 35 U.S.C. § 135(b) from presenting a certain claim, then it follows that the barred claim cannot serve as the basis of an interference with respect to another applicant whose claim for the same patentable invention is not subject to the bar. Thus, if applicable, the bar under 35 U.S.C. § 135(b) yields an incidental benefit to potentially opposing applicants. The statutory section does not restrict or limit who may benefit from application of the bar, as it only precludes the presentation of a claim. Note that 35 U.S.C. § 135(b) has been upheld as an applicable ground of rejection in ex parte prosecution before the USPTO. In re McGrew, 120 F.3d 1236, 43 USPQ2d 1632 (Fed. Cir. 1997).

Fogarty would have us read into 35 U.S.C. § 135(b) language that is not there, to turn it into a bar against having certain types of interferences instead of simply a bar on the presentation of certain claims as it so plainly reads. We decline to so distort or add to the statutory language. In our

view, if Fogarty cannot present a claim, then it cannot have an interference based on that claim with another party, whether that other party is an applicant or a patentee.

Fogarty's claim 62 was presumed by the parties as being for substantially the same invention as Martin's patent claim 1. Because it was presented outside of the one year period from the date of issuance of the Martin patent, and because Fogarty can demonstrate no other claim which was pending prior to the one year period and which was directed to substantially the same invention as Martin's claim 1, Fogarty's claim 62 is barred.

The fact that Martin's patent claim 1 has been determined unpatentable to Martin because of an adverse judgment in Interference No. 104,083 does not help Fogarty. The language of 35 U.S.C. § 135(b) refers to a claim for the same or substantially the same subject matter as "a claim of an issued patent" and does not purport to add the qualifications that such a claim must remain valid, non-canceled, patentable, non-disclaimed, and/or enforceable. We decline to read into 35 U.S.C. § 135(b) these conditions in the absence of a showing by Fogarty of a clear legislative intent to that effect. The operative word is "issued," similar to the word "born." Just as a baby cannot be un-born, an issued claim cannot become non-issued whatever its status becomes subsequent to issuance.

The public's interest is not harmed by applying 35 U.S.C. § 135(b) the way it is written and enacted by Congress. Fogarty is also under a mistaken belief that it is prejudiced by its not being successful with preliminary motion 8 to get into an interference with Cragg who has a dominating claim. Fogarty's predicament arises from its not having established, in connection with a proposed new interference involving Cragg's claim 89, interference-in-fact with respect to a Fogarty claim that is not time barred under 35 U.S.C. § 135(b). Alternatively, if Fogarty believes that Cragg's dominating claim 89 and any Fogarty claim involved in this interference define the same patentable subject matter, Fogarty could have moved to broaden out the count in this interference to the scope of Cragg's claim 89 and to have Cragg's claim 89 designated as corresponding to the revised new count. Fogarty did not take such action in this case. On these circumstances, that Cragg has a dominating claim not involved in this interference or a new interference with Fogarty does not mean Fogarty has been subjected to prejudice. A dominating claim is not necessarily a claim drawn to the same patentable invention as a dominated claim. In either case, however, with regard to Cragg's allegedly dominating claim 89 Fogarty has shown no prejudice by the denial of its preliminary motion 8.

5. Fogarty's preliminary motion 10

Fogarty's preliminary motion 10 sought to be accorded benefit of the earlier filing date of application 08/255,681, with respect to the count proposed in connection with Fogarty's preliminary motion 8. Consequently, preliminary motion 10 is contingent upon the granting of preliminary motion 8. Because Fogarty's preliminary motion 8 was properly denied, Fogarty's preliminary motion 10 was correctly dismissed as moot.

6. Cragg's Motion to Suppress

Cragg has filed a motion to suppress five exhibits FE-3001, FE-3002, FE-3004, FE-3005, and CE-1019. These are exhibits identified by party Fogarty, prior to submission of its brief at final hearing, as those which Fogarty intended to rely upon at final hearing in connection with its seeking review of the motion panel's decision of Fogarty's preliminary motion 8. According to Cragg, Fogarty may not rely on these exhibits at final hearing because Fogarty did not rely on these exhibits when filing its preliminary motion 8.

Cragg has not pointed out, and it is not immediately apparent, where in Fogarty's briefs at final hearing are references made to exhibits FE-3001, FE-3002, FE-3004, FE-3005, and CE-1019, or how the substance of these exhibits have been relied upon by Fogarty in meaningful furtherance of any argument.

Thus, with regard to these exhibits, Cragg has failed to make out a prima facie case of why the motion to suppress should be granted. Alternatively, even without suppressing these exhibits, Fogarty's arguments concerning its preliminary motions 8 and 10 have not been shown to have merit. Accordingly, Cragg's motion to suppress is denied and alternatively dismissed as moot.

C. Cragg's Preliminary Motion 1

In Cragg's preliminary motion 1, it is alleged that Fogarty's claims 41-69, not all of Fogarty's claims corresponding to the count, are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description in the specification. Fogarty's claims 42-69 depend either directly or indirectly from claim 41. Cragg's preliminary motion 1 (Paper No. 39, pp. 6-7) specifically identified the following feature of Fogarty's method claim 41 as that which is without written description:

> [I]ntroducing into a patient's vasculature an anchor section and first tubular graft of the vascular graft so that the anchor section is disposed within the primary artery and the first tubular graft is disposed within the first branch artery to form a first continuous flow path from the primary artery to the first branch artery.

According to Cragg's preliminary motion 1, the above-quoted feature of Fogarty's method claim 41 requires the anchor section and the first tubular graft to be introduced in a single step, not sequentially as is disclosed in Fogarty's specification. We

reproduce the following paragraph from page 10 of Cragg's preliminary motion 1, which clearly reveals Cragg's position:

> The Fogarty Application fails to suggest introducing an anchor section and first tubular graft in a single step. Instead, the Fogarty Application teaches (1) first introducing the bifurcated base structure so that the anchor section is positioned within a primary vessel; (2) *after the bifurcated base structure is anchored,* the first tubular graft is introduced into the first connector leg and anchored between the leg and the first branch artery; and (3) the second tubular graft is *then* inserted into the second connector section and anchored between the described second connector and the second branch artery. See Fogarty Application at Page 6, lines 1-9. (Emphasis in original).

The decision on preliminary motions rejected Cragg's argument, stating (Paper No. 108, p. 10):

> We reject Goicoechea's [Cragg's] argument because we do not read or interpret the above-quoted language of claim 41 as requiring that the anchor section and the first tubular graft be introduced "in a single step" or simulataneously. The words "in a single step" do not appear in claim 41, nor do the words "simulataneously," "concurrently," "unison," or any other term which means the same. The language is simply broadly recited and imposes no particular order for the insertion of the anchor section and the first tubular graft.

In its principal brief at final hearing, Cragg does not continue to argue that Fogarty's claim 41 requires that the anchor section and the first tubular graft be introduced in a single step or simultaneously. Rather, a new argument is made through the back door that the claim is so broad that the full

scope of what is claimed is not described in the specification. Specifically, on page 20 of its brief, in a section entitled "CRAGG MOTION 1 SHOULD BE GRANTED," Cragg states:

> If the Board adheres to its broad construction of claim 41 [that no specific sequence of introduction is required], then the Fogarty specification lacks written description for claim 41 because as discussed it only describes the sequential introduction of the anchor section and the first tubular graft but not the introduction of the anchor section and first tubular graft as a unitary structure. There is nothing in the Fogarty application to convey to those skilled in the art that Fogarty was in possession of that aspect of the invention of claim 41, if claim 41 is broadly construed as proposed.

We have again reviewed Cragg's preliminary motion 1 (Paper No. 39). Nothing therein can reasonably be considered as an alternative or contingent argument that if the Board is not persuaded by Cragg's primary argument that Fogarty's claim 41 requires the introduction of the anchor section and the first tubular graft in a single step then the claim is nonetheless not described in the specification because of undue breadth. In the case of Cragg's preliminary motion 1, the one argument actually made is the only argument made. Consequently, the issue now raised by Cragg at final hearing was neither developed and briefed by the parties during the preliminary motions stage of this interference, nor considered by the motions panel when preliminary motions were decided.

In short, Cragg wants the board to now hold Fogarty's claims 41-69 as being without written description in the specification for a reason other than that articulated and set forth by Cragg in its preliminary motion 1. We decline to consider this new argument at the final hearing stage of the proceeding. Final hearing under the interference rules is not a place to begin preliminary motions afresh. Rather, we are here to review the decision by a three-member motions panel on preliminary motions made by the parties, on the evidence and arguments which formed the basis of the decision on preliminary motions.

A new reason for granting a motion should not be considered at final hearing if it was not included in the original motion and not supported by a showing of good cause why the argument was not earlier presented. Fredkin v. Irasek, 397 F.2d 342, 346, 158 USPQ 280, 284 (CCPA 1968); Koch v. Lieber, 141 F.2d 518, 520, 61 USPQ 127, 129 (CCPA 1944); Bayles v. Elbe, 16 USPQ2d 1389, 1391 (Bd. Pat. & Int. 1990) ("It has been a longstanding practice that a party whose motion was denied cannot present at final hearing grounds not included in the original motion."). It is inappropriate for a party to present arguments in its brief which were not a part of the motion or opposition. Lawson v. Enloe, 26 USPQ2d 1594 (Bd. Pat. App. & Int. 1992).

All reasons for granting a party's desired relief should be advanced in the party's motion. A piecemeal presentation in which a party may start over with new arguments after an adverse decision has been rendered would make an orderly proceeding next to impossible to conduct. Cragg's brief offered no excuse for raising the issue of undue breadth issue so late, more than two years after the filing of Cragg's preliminary motion 1 on October 16, 1998, and ten months after the decision on preliminary motions has been rendered.

Cragg cannot credibly assert that it had no idea that Fogarty's claim 41 can possibly be construed so as to not require the introduction of the anchor section and the first tubular graft in a single step or simultaneously. As the moving party, Cragg was attempting to persuade the Board to adopt a narrow interpretation of Fogarty's claim 41, i.e., that the claim required the introduction of the anchor section and the first tubular graft in a single step or simultaneously. The mere filing of Cragg's motion reflects an awareness that the claim may not be so construed. Cragg was very much on notice that the Board may not adopt the narrow interpretation urged by Cragg. Cragg may not credibly claim to have been blind-sided by the Board's not adopting its position.

An interference is an inter partes proceeding. The Board may not suitably act as an advocate for either party, either to fill in gaps left open in either party's presentation, or to offer an alternate rationale and to try to fit the facts to that rationale, all on its own, particularly when the considerations are complex and the parties may well differ in their views. In presenting a preliminary motion for judgment, a party may not simply plead a statutory section, e.g., 35 U.S.C. § 112, first paragraph, and then rely on the Board to propose different ways in which the opponent's claims may possibly be attacked as being without written description in the specification. With regard to Cragg's preliminary motion 1, our decision on preliminary motions addressed the arguments made by Cragg. The new argument now presented by Cragg is not entitled to consideration.

For the foregoing reasons, the motions panel properly denied Cragg's preliminary motion 1.

D. Cragg's Preliminary Motion 2

We adopt in its entirety the discussion in our decision on preliminary motions (Paper No. 108), which is reproduced below, and then add a few more comments to address Cragg's brief at final hearing:

By this motion, Goicoechea [Cragg] alleges that there is no interference-in-fact between its involved application 08/461,402 and Fogarty's involved application 08/463,836. As is stated in 37 CFR § 1.601(j):

> An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

In that regard, 37 CFR § 1.601(n) states:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". (Emphasis in original.)

Resolution of an interference-in-fact issue involves a two-way patentability analysis. For there to be an interference-in-fact, the parties must each have at least one claim which collectively satisfy the following: The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must

anticipate or render obvious the claimed invention of Party A.

For a showing of no-interference-in-fact, the burden is on Goicoechea as the movant, see, e.g., 37 CFR § 1.637(a), to demonstrate that all of Goicoechea's claims 55, 59, 62-65, 88 and 90 which correspond to the count do not define the same patentable invention as any one of Fogarty's claims 27-69, or that all of Fogarty's claims 21-69 do not define the same patentable invention as any one of Goicoechea's claims 55, 59, 62-65, 88 and 90. Goicoechea has attempted to show that all of its claims 55, 59, 62-65, 88 and 90 define an invention process which is neither anticipated nor obvious over any one of Fogarty's claims 27-69.

Goicoechea argues that all of its claims include a "long-leg, short-leg" concept which is absent from and not suggested by any one of Fogarty's claims corresponding to the count. Also, apparently referring to the count, the motion on page 10 explains the subject matter "supposedly" in conflict as follows:

> The invention that is the subject of this Interference relates to a two-section apparatus comprising (1) a first section configured to be positioned within a

> bifurcated lumen and (2) a second section configured to be positioned separately in a branch of the bifurcated lumen and to extend into the bifurcated lumen. A first lower limb of the first section is configured so that it extends into a first leg of the bifurcation when the first section is positioned in the lumen. A second lower limb of the first section, which is shorter than the first lower limb, is configured so that it does not extend into a second leg of the bifurcation. Accordingly, the first section defines a "long-leg, short-leg" concept. Joining two components (the first and second sections) completes the apparatus. (Emphasis in original).

Of all Goicoechea claims which correspond to the count, claims 55, 59 and 90 are independent claims. Claim 90 is identical to the count. Claim 55 embodies the "long-leg, short-leg" idea by including step (a) -- disposing said proximal portion of said bifurcated prosthesis in said blood vessel such that said first distal portion of said bifurcated prosthesis extends into said first branched vessel [long-leg], and step (c) -- attaching said second prosthesis to said extension portion of said bifurcated prosthesis such that said second prosthesis extends into said second branched vessel [short-leg]. But claim 59 is broad and does not do the same. In that regard, claim 59 is reproduced below:

> 59. A bifurcated prosthesis for use with an angeological bifurcation of a blood vessel into two branched vessels comprising a bifurcated proximal portion adapted to be disposed within said blood vessel, a distal portion adapted to extend across the bifurcation into one of the branched vessels, and a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel.

Goicoechea has not shown that claim 59 requires that whenever the proximal portion is placed within the blood vessel, the first distal portion is already attached to the proximal portion and extending from the blood vessel into a branched vessel and the second distal segment is not yet joined to the proximal portion. Indeed, claim 59 is broad enough to cover the case of two short-legs, i.e., the proximal portion is introduced into the blood vessel first, and then the first distal portion and the second distal segment are introduced in sequence, each extending into a respective branched blood vessel.

For the foregoing reasons, the patentable distinction argued by Goicoechea does not exist with respect to at least Goicoechea's independent claim 59. That alone is sufficient ground to reject Goicoechea's motion for no interference-in-fact. Additionally, with

respect to Fogarty's claims 41-69, Goicoechea is improperly reading into those claims a specific embodiment from Fogarty's disclosure rather than focusing on the language of the claims themselves. As we discussed in the context of Goicoechea's preliminary motion 1, Fogarty's independent claim 41 is broadly recited and imposes no particular manner for the insertion of the anchor section and the first tabular graft.

Given Fogarty's claim 41, it is left to the discretion of one with ordinary skill in the art just how to introduce the anchor section and the first tubular graft. One with ordinary skill in the art possesses a certain basic level of skill. See, e.g., In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) ([Applicant's] argument presumes stupidity rather than skill). A conclusion of obviousness also may be made based on the common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 163 USPQ 545, 549 (CCPA 1969). It cannot be reasonably argued that one with ordinary skill in the art is so devoid of skill and

common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined in situ, or inserted as a unitary whole. Those are the only two possibilities with regard to the insertion of the anchor section and the first tubular graft. In our view, selecting one of the two readily apparent choices would have been well within the basic level of skill and common sense possessed by one with ordinary skill in the art. Moreover, it is incumbent upon Goicoechea as the movant to establish why, given Fogarty's independent claim 41, one with ordinary skill in the art would not have known that the anchor section and the first tabular graft can be inserted as one or separately. Goicoechea set forth no persuasive reasons in that regard.

For the foregoing reasons, Goicoechea has failed to demonstrate that all of its claims 55, 59, 62-65, 88 and 90 do not define the same patentable invention as any one of Fogarty's claims 27-69. Goicoechea's preliminary motion 2 insofar as it seeks a judgment based on no interference-in-fact is denied.

As for Goicoechea's assertion that Fogarty's claims 27-69, all of Fogarty's claims which have been designated as corresponding to the count in the declaration of this interference, do not correspond to the count, Goicoechea has to satisfy the requirements set forth in 37 CFR § 1.637(c)(4). Goicoechea has to show that each of Fogarty's claims 27-69 does not define the same patentable invention as any of Goicoechea's claims and Martin's claims whose correspondence to the count Goicoechea does not dispute.

As is already discussed above in connection with Goicoechea's assertion of no interference-in-fact, Goicoechea has not established patentable distinction between Fogarty's claims 41-69 and at least Goicoechea's claim 55 and claim 90, and also between Fogarty's claims 27-69 and at least Goicoechea's claim 59. Goicoechea's preliminary motion 2 to designate Fogarty's claims 27-69 as not corresponding to the count is denied.

Nothing presented by Cragg in its brief at final hearing demonstrates that our above-quoted analysis was in error. Fogarty is correct that Cragg continues to attempt an

inappropriate reading of extraneous limitations from the specification into the claims. Although the specification is useful in interpreting claim language, as the Court of Appeals for the Federal Circuit has nonetheless stated, "the name of the game is the claim." In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). See also Giles Sutherland Rich, Extent of Protection and Interpretation of Claims--American Perspectives, 21 Int' Rev. Indus. Prop. & Copyright L, 497, 499 (1990)("The U.S. is strictly an examination country and the main purpose of the examination, to which every application is subjected, is to try to make sure that what each claim defines is patentable. To coin a phrase, the name of the game is the claims."). Reading into the claims an extraneous limitation from the specification is simply improper. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988). In E.I. de Pont, 849 F.2d at 1433, 7 USPQ2d at 1131, the Federal Circuit stated:

> It is entirely proper to use the specification to interpret what the Patentee meant by a word or phrase in the claim. See, e.g., Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir. 1985). But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By "extraneous," we mean a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.

In interpreting its own claims, Cragg in its brief at final hearing begins with a section discussing its disclosure, entitled "Cragg Discloses A *Unitary* Bifurcated Long Leg/Short Leg Prosthesis" (Emphasis in original). That section ends with this one sentence paragraph:

> The specification supports that Cragg's claims require a unitary bifurcated long leg/short leg structure, where "unitary" requires a securing means connecting the portions of the structure.

By the time Cragg made the above-quoted conclusion, it has not yet recited, reproduced, or even referred to any actual language in its claims. That Cragg's specification has a description for a certain embodiment does not necessarily mean that all of Cragg's claims must include the elements of that embodiment. If the claims do not require a unitary structure in the sense that there is a securing means which connects all the parts together, these are extraneous limitations which should not be read into the claims from the specification. Moreover, even Cragg's own specification contains no reference to the term "unitary" on which Cragg now places so much emphasis. Neither does Cragg's own specification contain any reference to words which are generally synonymous with the word "unitary," such as "integral"

or "one-piece." Thus, what Cragg is arguing in this part is many steps removed from the actual language of the claims.

The bifurcated prosthesis according to Cragg's claim 59 requires (1) a proximal portion, (2) a distal portion, and (3) a separate distal segment. Unlike Cragg's claim 55, Cragg's claim 59 does not require disposing the proximal portion in the blood vessel such that the distal portion extends into a first branched vessel. That means claim 59 is sufficiently broad to have the proximal portion put in place without regard to whether the distal portion is also placed in working position.

Cragg argues that because the word "portion" means part of a whole, the proximal portion and the distal portion must be part of a unitary structure in which the proximal portion and the distal portion is unitary or connected together by some securing means before being introduced into the blood vessel. We are not persuaded by Cragg's argument.

While the word "portion" may indeed mean part of a whole or part of something, Cragg has not submitted any evidence that the so called parts of a whole must be physically attached to each other at all times. In that regard, note that a jig-saw puzzle has many parts or portions but the many pieces don't have to be connected to each other before properly being referred to as portions of the same puzzle. Cragg has not made any meaningful

showing that the word "portion" as is ordinarily used in the English language requires an actual physical attachment. Nor has Cragg argued that its specification has specially defined the word "portion" in a manner different from its ordinary usage in the English language. Indeed, Cragg even cites to Merriam Webster's Collegiate Dictionary, 10th Ed. (1994) in its brief at final hearing for the meaning of "portion," which states: "part of something." Note that "part of something" can be conceptual and does not necessarily require a physical connection at all times. Moreover, we note that even Cragg's so called "portions" are not physically connected at all times; indisputably, they have to be preassembled prior to introduction into the patient.

Alternatively, our decision on preliminary motion held that even assuming that the "unitary" feature argued by Cragg is included in all of Cragg's claims corresponding to the count, Fogarty's claim 41 still would have rendered obvious Cragg's claimed invention such as Cragg's claim 59.

Cragg argues (Br. at 18):

> The Board states that insertion of the anchor section and the first tubular graft as a unitary whole is only one of two possibilities with regard to the insertion of the Fogarty structure. Paper No. 108, p.15. There is a third possibility ignored by the Board, namely, inserting the anchor section and both tubular grafts at the same time.

The argument is without merit. We stated (Paper No. 108, at 15) that there are "only two possibilities with regard to the insertion of the anchor section and the first tubular graft" (emphasis added). In that context, the second tubular graft is uninvolved, and how it is introduced is irrelevant.

We adopt and reiterate herein the following portion of our decision on preliminary motions concerning Cragg's preliminary motion 2 (Paper No. 108, pp. 14-16):

> Additionally, with respect to Fogarty's claims 41-69, Goicoechea is improperly reading into those claims a specific embodiment from Fogarty's disclosure rather than focusing on the language of the claims themselves. As we discussed in the context of Goicoechea's preliminary motion 1, Fogarty's independent claim 41 is broadly recited and imposes no particular manner for the insertion of the anchor section and the first tabular graft.
>
> Given Fogarty's claim 41, it is left to the discretion of one with ordinary skill in the art just how to introduce the anchor section and the first tubular graft. One with ordinary skill in the art possesses a certain basic level of skill. See, e.g., In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) ([Applicant's] argument presumes stupidity rather than skill). A conclusion of obviousness also may be made based on the common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 163 USPQ 545, 549 (CCPA 1969). It cannot be reasonably argued that one with ordinary skill in the art is so devoid of skill and common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined in situ, or inserted as a unitary whole.

> Those are the only two possibilities with regard to the insertion of the anchor section and the first tubular graft. In our view, selecting one of the two readily apparent choices would have been well within the basic level of skill and common sense possessed by one with ordinary skill in the art. Moreover, it is incumbent upon Goicoechea as the movant to establish why, given Fogarty's independent claim 41, one with ordinary skill in the art would not have known that the anchor section and the first tabular graft can be inserted as one or separately. Goicoechea set forth no persuasive reasons in that regard.

Cragg dismisses our citation to In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) and In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969), by arguing that "[b]oth Bozek and Sovish required a disclosure in the prior art references to render the claims obvious."). It appears that Cragg completely misses the point for which we cited to those cases, i.e., that one with ordinary skill in the art is presumed to possess some logic and skill that is independent of what is disclosed in an item of prior art. Here, the starting point is Fogarty's claim 41. In that sense, Fogarty's claim 41 is the disclosure with which one with ordinary skill in the art is presented, in determining whether claims such as Cragg's claim 59 would have been obvious over Fogarty's claim 41. We agree entirely with the following two paragraphs in Fogarty's opposition brief at pages 14-15:

> Second, while Cragg would argue that *Sovish* and *Bozek* are somehow anomalous, the principle for which

> they were actually cited in the Decision has been repeatedly followed by this Board; e.g., Ex parte Research and Manufacturing Co., 10 USPQ2d 1657, 1664 (Bd. Pat. App. & Intf. 1989)(skill is presumed on the part of the artisan rather than the converse); Ex parte George, 21 USPQ2d 1058, 1060 n.1 (Bd. Pat. App. & Int. 1991) (the ability of one having ordinary skill in the art should not be underestimated); Ex parte Nesbit, 25 USPQ2d 1817, 1823 (Bd. Pat. App. & Intf. 1992)(the law presumes skill on the part of the artisan rather than the converse); Ex parte GPAC Inc., 29 USPQ2d 1401, 1405 (Bd. Pat. App. & Intf. 1993)(the skill of the art must be presumed, not the contrary).
>
> The Board thus found that the worker is not so devoid of skill or common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined *in situ*, or inserted as a unitary whole. (Emphasis in original).

Cragg's citation to Al-Site Corp. v. VSI Intern., Inc., 174 F.3d 1308, 1323, 50 USPQ2d 1161 (Fed. Cir. 1999) is inapposite. The Al-Site case does not stand for the proposition that Fogarty's claim 41 must be combined with another prior art reference in order to render obvious a Cragg claim which corresponds to the count. In contrast, the case supports the position that the perspective from which a prior art reference is viewed is that of a person with ordinary skill in the art.

Cragg further argues that the Board has not explained how, if Fogarty's anchor section and first tubular graft are inserted as one piece, a skilled worker would successfully position that device. According to Cragg, because the first tubular graft of

Fogarty is within the fabric liner leg 28, one ends up with an anchor section-fabric liner-tubular graft assembly that is not rigid and is not supported. The argument is misdirected and in any event unpersuasive. Here, the starting point for the obviousness analysis is not some embodiment disclosed in Fogarty's specification, but Fogarty's claim 41 which does not require placing the first tubular graft in a fabric liner leg. Moreover, in any event Cragg has submitted no meaningful evidence in the form of declaration or affidavit testimony from anyone to establish that one with ordinary skill in the art would not have known how to introduce the anchor section together with the first tubular graft. As Fogarty has pointed out in its opposition brief, attorney argument cannot take the place of evidence lacking in the record. See, e.g., Knorr v. Pearson, 671 F.2d 1368, 1373, 213 USPQ 196, 200 (CCPA 1982); Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA), cert. denied, 434 U.S. 854, 195 USPQ 465 (1977); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972).

Cragg's preliminary motion 2 further seeks to have all of Fogarty's claims corresponding to the count, i.e., claims 27-69, designated as not corresponding to the count. We ruled in the decision on preliminary motions that per 37 CFR § 1.637(c)(4), the motion is without merit because it failed to demonstrate that

each of Fogarty's claims 27-69 does not define the same patentable invention as any of Cragg's claims and Martin claims whose correspondence to the count is not disputed by Cragg.

Cragg's arguments with regard to designating Fogarty's claims as not corresponding to the count is merely a reference to its arguments alleging no interference-in-fact between Cragg's claims and Fogarty's claims. Cragg evidently is of the view that if it has demonstrated no interference-in-fact between its claims and Martin's claims on the one hand and Fogarty's claims on the other hand, then the case has been made that Fogarty's claims corresponding to the count should be designated as not corresponding to the count. But Cragg has failed to demonstrate no interference-in-fact between its claims and Martin's claims on the one hand and Fogarty's claims on the other hand. Thus, no reason has been shown to designate Fogarty's claims 27-69 as not corresponding to the count. Note also that even if there was no interference-in-fact with respect to any Fogarty claim, Fogarty's application would become uninvolved and there would be no need to designate any of its claims as not corresponding to the count.

For the foregoing reasons, Cragg has shown no error in the denial of Cragg's preliminary motion 2.

Judgment

It is

ORDERED that judgment as to the subject matter of the count is herein entered against junior party ERIC C. MARTIN and also against junior party ANDREW H. CRAGG and MICHAEL D. DAKE;

FURTHER ORDERED that the junior party ERIC C. MARTIN is not entitled to his patent claims 2-17 which correspond to the count;

FURTHER ORDERED that junior party ANDREW H. CRAGG and MICHAEL D. DAKE are not entitled to their application claims 55, 59, 62-65, 88 and 90 which correspond to the count; and

FURTHER ORDERED that a copy of this paper shall be given a paper number and filed in the respective involved application/patent of the parties.[10]

---

[10] Failure to file a copy of any agreement regarding the termination of this proceeding may render the agreement and any resulting patent unenforceable. See section 35 U.S.C. § 135(c) and 37 CFR § 1.661.

MSK

Fred E. McKelvey, Senior
Administrative Patent Judge)

Richard E. Schafer
Administrative Patent Judge)

Jameson Lee
Administrative Patent Judge)

Sally C. Medley
Administrative Patent Judge)

BOARD OF PATENT
APPEALS
AND
INTERFERENCES

Interference No. 104,192
Cragg v. Martin v. Fogarty

By Federal Express

Attorney for party Cragg:

Paul F. Prestia
RATHER & PRESTIA
Suite 301
One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, Pennsylvania 19482-0980

Attorney for party Fogarty:

Bruce M. Collins
MATHEWS, COLLINS, SHEPHERD & GOULD, P.A.
100 Thanet Circle, Suite 306
Princeton, New Jersey 08540-3674

Attorney for party Martin:

Robert J. Koch
FULBRIGHT & JAWORSKI
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Merriam-Webster's Collegiate® Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

John \'jän\ *n* [fr. ... *John*] (1856) 1 : TOILET 2 : a prostitute's ...

John \'jän\ *n* [LL *Johannes*, fr. Gk *Iōannēs*, fr. Heb *Yōḥānān*] 1 : an ... Jewish prophet who according to Gospel accounts foretold Jesus's ... messianic ministry and baptized him — called also *John the Baptist* 2 ... an apostle who according to various Christian traditions wrote the ... fourth Gospel, the three Johannine Epistles, and the Book of Revela... ; the fourth Gospel in the New Testament — see BIBLE table 4 ... any of three short didactic letters addressed to early Christians and ... 3 : any of four books in the New Testament — see BIBLE table

John Barleycorn *n* (ca. 1620) : alcoholic liquor personified

John-boat \'jän-ˌbōt\ *n* [fr. the name *John*] (1905) : a narrow flat-bottomed square-ended boat usu. propelled by a pole or paddle and used on inland waterways

John Bull \-'bu̇l\ *n* [*John Bull*, character typifying the English nation in *The History of John Bull* (1712) by John Arbuthnot] (1778) 1 : the English nation personified : the English people 2 : a typical Englishman — **John Bull-ish** \-'bu̇-lish\ *adj* — **John Bull-ish-ness** *n* — **John Bull-ism** \-li-zəm\ *n*

John Doe \-'dō\ *n* (ca. 1659) 1 : a party to legal proceedings whose true name is unknown 2 : an average man

John Do-ry \-'dōr-ē, -'dȯr-\ *n, pl* **John Dories** [earlier *dory*, fr. ME *dorre*, lit., gilded one] (1754) : a common yellow to olive food fish (*Zeus faber*) of Europe and Africa with an oval compressed body, long dorsal spines, and a dark spot on each side; *also* : a closely related and possibly identical fish (*Z. capensis*) widely distributed in southern seas

John-es's disease \'yō-nəz-\ *n* [Heinrich A. *Johne* †1910 Ger. bacteriologist] (1907) : a chronic often fatal contagious enteritis of ruminants and esp. of cattle that is caused by a bacterium (*Mycobacterium paratuberculosis*) and is characterized by persistent diarrhea and gradual emaciation

John Han-cock \'jän-'han-ˌkäk\ *n* [*John Hancock*; fr. the prominence of his signature on the Declaration of Independence] (1903) : an autograph signature

John Hen-ry \-'hen-rē\ *n* [fr. the name *John Henry*, fr. confusion with *John Hancock*] (1914) : an autograph signature

John Mark *n* : MARK 1a

johnny \'jä-nē\ *n, pl* **johnnies** [fr. the name *Johnny*] (1673) 1 *often cap* : FELLOW, GUY 2 : a short-sleeved collarless gown that is open in the back and is worn by persons (as hospital patients) undergoing medical examination or treatment

johnny-cake \'jä-nē-ˌkāk\ *n* [prob. fr. the name *Johnny*] (1739) : a bread made with cornmeal

Johnny-come-late-ly \'jä-nē-(ˌ)kəm-'lāt-lē\ *n, pl* **Johnny-come-latelies** *or* **Johnnies-come-lately** (1839) 1 : a late or recent arrival : NEWCOMER 2 : UPSTART (established families tend to hold themselves above the *Johnny-come-latelies* —William Zeckendorf †1976)

johnny-jump-up \ˌjä-nē-'jəmp-ˌəp\ *n* (1842) 1 : a common and long-cultivated European viola (*Viola tricolor*) which has short-spurred flowers usu. blue or purple mixed with white and yellow and from which most of the garden pansies are derived; *broadly* : any of various small-flowered cultivated pansies 2 : any of various American violets

John-ny-on-the-spot \'jä-nē-ˌȯn-thə-'spät, -ˌän-\ *n* (1896) : a person who is on hand and ready to perform a service or respond to an emergency

Johnny Reb \-'reb\ *n* [fr. the name *Johnny* + *reb* rebel] (1865) : a Confederate soldier

John-son-ese \ˌjän(t)-sə-'nēz, -'nēs\ *n* [Samuel *Johnson*] (1843) : a literary style characterized by balanced phraseology and Latinate diction

johnson-grass \'jän(t)-sən-ˌgras\ *n, often cap* [William *Johnston* †1859 Am. agriculturist] (1884) : a tall perennial sorghum (*Sorghum halepense*) orig. of the Mediterranean region that is widely used for forage in warm areas and often becomes naturalized

joie de vi-vre \ˌzhwä-də-'vēvr\ *n* [F, lit., joy of living] (1889) : keen or buoyant enjoyment of life

1join \'jȯin\ *vb* [ME, fr. OF *joindre*, fr. L *jungere* — more at YOKE] *vt* (13c) 1 a : to put or bring together so as to form a unit (~ two blocks of wood with glue) b : to connect (as points) by a line c : ADJOIN 2 : to put or bring into close association or relationship (~*ed* in marriage) 3 : to engage in (battle) 4 a : to come into the company of (~*ed* us for lunch) b : to associate oneself with (~*ed* the church) ~ *vi* 1 a : to come together so as to be connected (nouns ~ to form compounds) b : ADJOIN (the two estates ~) 2 : to come into close association or relationship: as a : to form an alliance b : to become a member of a group c : to take part in a collective activity (~ in singing) — **join-able** \'jȯi-nə-bəl\ *adj*

syn JOIN, COMBINE, UNITE, CONNECT, LINK, ASSOCIATE, RELATE mean to bring or come together into some manner of union. JOIN implies a bringing into contact or conjunction of any degree of closeness (*joined* forces in an effort to win). COMBINE implies some merging or mingling with corresponding loss of identity of each unit (*combined* jazz and rock to create a new music). UNITE implies somewhat greater loss of separate identity (the colonies *united* to form a republic). CONNECT suggests a loose or external attachment with little or no loss of identity (a mutual defense treaty *connected* the two nations). LINK may imply strong connection or inseparability of elements still retaining identity (a name forever *linked* with liberty). ASSOCIATE stresses the mere fact of frequent occurrence or existence together in space or in logical relation (opera is popularly *associated* with high society). RELATE suggests the existence of a real or presumed logical connection (*related* what he observed to what he already knew).

2join *n* (1825) 1 : JOINT 2 : UNION 2d

join-der \'jȯin-dər\ *n* [F *joindre* to join, fr. OF] (1601) 1 : CONJUNCTION 1 2 a (1) : a joining of parties as plaintiffs or defendants in a suit (2) : a joining of causes of action or defense b : acceptance of an issue tendered

join-er \'jȯi-nər\ *n* (14c) : one that joins: as a : a person whose occupation is to construct articles by joining pieces of wood b : a gregarious or civic-minded person who joins many organizations

join-ery \'jȯi-nə-rē, 'jȯin-rē\ *n* (1678) 1 : the art or trade of a joiner 2 : work done by a joiner

join-ing \'jȯi-niŋ\ *n* (14c) 1 : the act or an instance of joining one thing to another : JUNCTURE 2 a : the place or manner of being joined together b : something that joins two things together

1joint \'jȯint\ *n* [ME *joint*, fr. OF, fr. *jointre*] (13c) 1 a (1) : the point of contact between elements of an animal skeleton with the parts that surround and support it (2) : NODE 5b b : a part or space included between two articulations, knots, or nodes c : a large piece of meat for roasting 2 a : a place where two things or parts are joined b : a space between the adjacent surfaces of two bodies joined and held together (as by cement or mortar) c : a fracture or crack in rock not accompanied by dislocation d : the fleshy part of a cover along either backbone edge of a book e : the junction of two or more members of a framed structure f : a union formed by two abutting rails in a track including the elements (as bars and bolts) necessary to hold the abutting rails together g : an area at which two ends, surfaces, or edges are attached. 3 a : a shabby or disreputable place of entertainment b : PLACE, ESTABLISHMENT c *slang* : PRISON 2 4 : a marijuana cigarette — **joint-ed** \'jȯin-təd\ *adj* — **joint-ed-ly** *adv* — **joint-ed-ness** *n* — **out of joint** 1 a *of a bone* : having the head slipped from its socket b : at variance 2 a : DISORDERED 2a b : being out of humor : DISSATISFIED

2joint *adj* [ME, fr. MF, fr. pp. *of joindre*, fr. OF] (14c) 1 : UNITED, COMBINED (the ~ influences of culture and climate) 2 : common to two or more: as a (1) : involving the united activity of two or more (a ~ effort) (2) : constituting an activity, operation, or organization in which elements of more than one armed service participate (~ maneuvers) (3) : constituting an action or expression of two or more governments (~ peace talks) b : shared by or affecting two or more (a ~ fine) 3 : united, joined, or sharing with another (as in a right or status) (~ heirs) 4 : being a function of or involving two or more variables and esp. random variables — **joint-ly** *adv*

3joint *vb* [*2joint*] *vt* (1530) 1 : to separate the joints of (as meat) 2 a : to unite by a joint : fit together b : to provide with a joint : ARTICULATE c : to prepare (as a board) for joining by planing the edge ~ *vi* 1 : to fit as if by joints (the stones ~ neatly) 2 : to form joints as a stage in growth — used esp. of small grains

Joint Chiefs of Staff (1946) : a military advisory group composed of the chiefs of staff of the army and air force, the chief of naval operations, and sometimes the commandant of the marine corps

joint-er \'jȯin-tər\ *n* (1678) : one that joints; *esp* : any of various tools used in making joints

joint grass *n* (1835) : a coarse creeping grass (*Paspalum distichum*) with jointed stems that is used for fodder and for erosion control

joint resolution *n* (1838) : a resolution passed by both houses of a legislative body that has the force of law when signed by or passed over the veto of the executive

joint-ress \'jȯin-trəs\ *n* (1602) : a woman having a legal jointure

joint-stock company *n* (1776) : a company or association consisting of individuals organized to conduct a business for gain and having a joint stock of capital represented by shares owned individually by the members and transferable without the consent of the group

join-ture \'jȯin-chər\ *n* (14c) 1 a : an act of joining : the state of being joined b : JOINT 2 a : an estate settled on a wife to be taken by her in lieu of dower b : a settlement on the wife of a freehold estate for her lifetime

joint-worm \'jȯint-ˌwərm\ *n* (1851) : the larva of any of several small chalcid wasps (genus *Harmolita*) that attacks the stems of grain and causes swellings like galls at or just above the first joint

joist \'jȯist\ *n* [ME *joiste*, fr. MF *giste*, fr. (assumed) VL *jacitum*, fr. L *jacēre* to lie — more at ADJACENT] (13c) : any of the small timbers or metal beams ranged parallel from wall to wall in a structure to support a floor or ceiling

jo-jo-ba \hō-'hō-bə\ *n* [MexSp] (1923) : a shrub or small tree (*Simmondsia chinensis* syn. *S. californica*) of the box family of southwestern No. America with edible seeds that yield a valuable liquid wax

1joke \'jōk\ *n* [L *jocus*; perh. akin to OHG *gehan* to say, Skt *yācati* he asks] (1670) 1 a : something said or done to provoke laughter; *esp* : a brief oral narrative with a climactic humorous twist b (1) : the humorous or ridiculous element in something (2) : an instance of jesting : KIDDING (can't take a ~) c : PRACTICAL JOKE d : LAUGHING-STOCK 2 : something not to be taken seriously : a trifling matter (consider his skiing a ~ —Harold Callender) — often used in negative construction (it is no ~ to be lost in the desert)

2joke *vb* **joked**; **jok-ing** (1670) : to make jokes : JEST ~ *vt* : to make the object of a joke : KID — **jok-ing-ly** \'jō-kiŋ-lē\ *adv*

jok-er \'jō-kər\ *n* (1729) 1 a : a person given to joking : WAG b : FELLOW, GUY; *esp* : an insignificant, obnoxious, or incompetent person (a shame to let a ~ like this win —Harold Robbins) 2 : a playing card added to a pack as a wild card or as the highest-ranking card 3 a (1) : an ambiguous or apparently immaterial clause inserted in a legislative bill to make it inoperative or uncertain in some respect (2) : an unsuspected, misleading, or misunderstood clause, phrase, or word in a document that nullifies or greatly alters it b : something (as an expedient or stratagem) held in reserve to gain an end or escape from a predicament c : an unsuspected or not readily apparent fact, factor, or condition that thwarts or nullifies a seeming advantage

joke-ster \'jōk-stər\ *n* (1877) : JOKER 1

jok-ey *also* **joky** \'jō-kē\ *adj* **jok-i-er**; **-est** (ca. 1825) 1 : given to joking 2 : HUMOROUS, COMICAL 3 : amusingly ridiculous : LAUGHABLE — **jok-i-ly** \-kə-lē\ *adv* — **jok-i-ness** \-kē-nəs\ *n*

jol-li-fi-ca-tion \ˌjä-li-fə-'kā-shən\ *n* (1809) : FESTIVITY, MERRYMAKING

jol-li-ty \'jä-lə-tē\ *n, pl* **-ties** (14c) 1 : the quality or state of being jolly : MERRIMENT 2 *Brit* : a festive gathering

1jol-ly \'jä-lē\ *adj* **jol-li-er**; **-est** [ME *joli*, fr. OF] (14c) 1 a (1) : full of high spirits : JOYOUS (2) : given to conviviality : JOVIAL b : expressing, suggesting, or inspiring gaiety : CHEERFUL 2 : extremely pleasant or agreeable : SPLENDID *syn* see MERRY

TAB 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BOSTON SCIENTIFIC TECHNOLOGY, INC.,	
Plaintiff,	**Case No.** 1:01CV02015
v.	Judge: Gladys Kessler
MEDTRONIC ANEURX, INC. and ERIC C. MARTIN,	
Defendants.	

~~[PROPOSED]~~ ORDER EXTENDING TIME TO RESPOND TO COMPLAINT

Defendant Medtronic Aneurx, Inc. has moved to extend to Monday, December 17, 2001 the time in which they may answer, move or otherwise respond to the Complaint of plaintiff, Boston Scientific Technology, Inc. Plaintiff does not oppose this motion.

Accordingly, upon motion of the defendant and for good cause shown, the motion is GRANTED.

Dated: November 15, 2001

Gladys Kessler
United States District Judge

TAB 4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff,

CASE NO. 1:01CV 2015 (GK)

v.

MEDTRONIC AVE, INC.
and ERIC C. MARTIN,

Defendants.

~~[PROPOSED]~~ ORDER ALLOWING FILING OF SECOND AMENDED COMPLAINT

Plaintiff Scimed Life Systems, Inc. ("Scimed") has moved to file a Second Amended Complaint pursuant to Rule 15(a), Fed.R.Civ.P. and Local Rule 7.1. Defendant Medtronic AVE, Inc. ("Medtronic AVE") and defendant Eric C. Martin ("Martin") have consented in writing to this motion.

Accordingly, upon motion of plaintiff, the motion is GRANTED.

Dated: December 14, 2001

Honorable Gladys Kessler
United States District Judge for the
District of Columbia

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the

(1) STIPULATED JOINT MOTION TO FILE SECOND AMENDED COMPLAINT,

(2) SECOND AMENDED COMPLAINT, and

(3) [PROPOSED] ORDER ALLOWING FILING OF SECOND AMENDED COMPLAINT

were served this _____ day of December, 2001 by Hand, on the attorneys for defendants as follows:

Charles R. Work, Esq.
Donna M. Tanguay, Esq.
Mark G. Davis, Esq.
John R. Fuisz, Esq.
McDermott, Will & Emery
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096

Counsel for Medtronic AVE, Inc.

and

Robert J. Koch, Esq.
Fulbright and Jaworski
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Counsel for Eric C. Martin

TAB 5

F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff and Counterclaim-Defendant,

v.

MEDTRONIC AVE, INC.,

Defendant and Counterclaimant,

and ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

CASE NO. 1:01CV 2015 (RJL)

[PROPOSED] ORDER GRANTING SCIMED'S MOTION TO FILE UNDER SEAL SCIMED'S OPPOSITION BRIEF AND THE DECLARATION OF GIDON D. STERN IN SUPPORT OF SCIMED'S OPPOSITION TO MEDTRONIC'S REQUEST FOR ENTRY OF DEFAULT JUDGMENT AS TO SCIMED

The matter having come before the Court on plaintiff Scimed Life Systems, Inc. ("Scimed") Motion To File Under Seal (1) SCIMED'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MEDTRONIC'S MOTION FOR ENTRY OF DEFAULT JUDGMENT AS TO SCIMED ("Scimed's Opposition Memorandum) and (2) the DECLARATION OF GIDON D. STERN in support of Scimed's Opposition Memorandum and attached exhibits to be filed under seal pursuant to Local Rule 5.1(j), and the Court having fully considered the arguments in support of and in opposition to that motion:

IT IS HEREBY ORDERED THAT:

The aforementioned motion is GRANTED.

Scimed's Memorandum of Points and Authorities in Opposition to Metronic's Motion for Entry of Default Judgment As to Scimed ("Scimed's Opposition Memorandum) and the

19

DECLARATION OF GIDON D. STERN in support of Scimed's Opposition Memorandum and attached exhibits shall be filed under seal, with the exception that the memorandum, declarations and exhibits thereof shall be available to defendant, Medtronic AVE, Inc. and defendant, Eric C. Martin.

SO ORDERED.

Dated: May 1st, 2002

Honorable Richard J. Leon

United States District Judge for the
District of Columbia

LIST OF PERSONS TO BE NOTIFIED
OF ENTRY OF ORDER

Marcia H. Sundeen, Esq.
PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
Tel: (202) 496-4400
Fax: (202) 496-4444

Gidon D. Stern, Esq.
Thomas E. Friebel, Esq.
Alexandra N. Haner, Esq.
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036
Tel: (212) 790-9090
Fax: (212) 869-9741

Paul F. Prestia, Esq.
Joshua L. Cohen, Esq.
RATNER & PRESTIA
Suite 301, One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, PA 19482-0908
Tel: (610) 407-0700
Fax: (610) 407-0701

Charles R. Work, Esq.
Donna M. Tanguay, Esq.
Mark G. Davis, Esq.
John R. Fuisz, Esq.
McDERMOTT, WILL & EMERY
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
Tel: (202) 756-8029
Fax: (202) 756-8087

Robert J. Koch, Esq.
FULLBRIGHT & JAWORSKI
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Tel: (202) 662-4765
Fax: (202) 662-4643

TAB 6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	**Case Number 01-2015 (RJL)**
	)	
	)	
MEDTRONIC AVE INC.,	)	
	)	
Defendant and Counterclaimant,	)	
	)	
and ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant	)	

MEMORANDUM OPINION AND ORDER
(August 30, 2003) (# 17, 22, 29, 34)

Three motions are now pending before the Court in the above captioned case. The first is the motion for default judgment by defendant and counterclaimant Medtronic AVE, Inc. ("Medtronic") against defendant and counterclaim-defendant Eric C. Martin and plaintiff and counterclaim-defendant Scimed Life Systems, Inc. ("Scimed"). Second is Scimed's motion to dismiss Medtronic's counterclaim for lack of subject matter jurisdiction. Finally, Medtronic has filed a Rule 11 motion for sanctions against Scimed, arguing that Scimed's case is a "sham," and that Scimed's papers contain material

(N)

#45

misrepresentations of fact.

For the reasons set forth below the Court hereby grants Medtronic's motion for entry of default judgment against Martin, but reserves ruling on the relief to which Medtronic is entitled. The Court denies Medtronic's motion for default judgment as to Scimed and denies Scimed's motion to dismiss Medtronic's counterclaim. Finally, the Court also denies Medtronic's Rule 11 motion for sanctions.

I. BACKGROUND

Plaintiff and counterclaim-defendant Scimed brought the instant action pursuant to 35 U.S.C. § 146 to contest the decision of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("USPTO") regarding certain patent applications for an apparatus for reinforcing a bifurcated lumen. Plaintiff Scimed and defendant and counterclaimant Medtronic each are assignees of record of two, different patent applications for a bifurcated lumen invention;[1] defendant and

[1] Andrew Cragg and Michael Dake filed an application with the USPTO regarding the bifurcated lumen apparartus on June 5, 1995. The application was assigned the serial number 08/461,402 (the "'402 application"). Cragg and Dake assigned all rights in the '402 application to Boston Scientific Technology, Inc., which merged into plaintiff Scimed. Scimed is now the present legal owner of the '402 application. Defendant and counterclaimant Medtronic was assigned its rights in a patent application for the invention by Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively referred to as party "Fogarty" in the underlying proceedings at the USPTO). That application was filed with the USPTO on June 5, 1995, and assigned the serial number 08/463,836 (the "'836 application"). Fogarty assigned its rights in the '836 application to Medtronic Aneurx, Inc., which merged into Medtronic AVE, Inc. Defendant Medtronic is now the

counterclaim-defendant Eric C. Martin was awarded a patent for the same apparatus. The USPTO declared an interference on April 23, 1998, between Scimed's patent application (the "Cragg" or "'402 application"), Medtronic's patent application (the "Fogarty" or "'836 application") and Martin's patent (the "Martin" or "'817 patent"). This interference proceeding was assigned Interference No. 104,192, and is referred to as the "'192 interference." Shortly thereafter, on September 20, 1998, Martin and Scimed entered into an option and license agreement under which Scimed had an exclusive option to purchase the rights to Martin's '817 patent. Neither Scimed nor Martin disclosed the existence of this agreement to Medtronic or the Board before the Board rendered its decision in the '192 interference.[2]

The Board yielded its decisions pertaining to the '192 interference on July 27, 2001. Scimed filed a complaint in this Court on September 25, 2001, challenging the Board's decisions that were adverse to its interests in the '402 application. Subsequently, Scimed filed an amended complaint on November 9, 2001, and a second amended complaint on December 21, 2001. Defendant Medtronic filed its answer to the second amended complaint and its counterclaim on January 2, 2002. In turn, Scimed filed its

---

legal owner of the '836 application.

[2] Scimed disclosed the existence of the agreement with Martin on March 21, 2002; Medtronic maintains that the disclosure was untimely and in violation of the pertinent regulations contained in 37 C.F.R. § 1.602. *See* Medtronic Mot. for Default Judgment at 3-4. Scimed contends that the disclosure was timely and proper. As this issue is irrelevant to the Court's resolution of the motions now before it, the Court will not consider the parties' arguments on this issue at this time.

answer to Medtronic's counterclaim on January 18, 2002, and then separately filed a motion to dismiss the counterclaim almost five months later, on May 17, 2002, arguing that this Court lacks subject matter jurisdiction to hear Medtronic's claims.

As defendant and counterclaim-defendant Martin never filed an answer to Medtronic's counterclaim, Medtronic filed a motion for default judgment against Martin on April 23, 2002.[3] In its motion for default judgment, Medtronic asked this Court not only to grant default judgment as to Martin, but also as to Scimed for Martin's failure to answer the counterclaim. According to Medtronic, because Scimed is the owner of an exclusive license to Martin's '817 patent, it has a duty under that license to litigate all claims stemming from the patent. Under Medtronic's theory, default as to Martin is default as to Scimed, even though Scimed filed a timely answer to the counterclaim.

Additionally, Medtronic brings a Rule 11 motion for sanctions against Scimed, coincidentally filed on the same day as Scimed's motion to dismiss Medtronic's counterclaim. Medtronic argues that Scimed has materially misrepresented its relationship with Martin as to whether Scimed or Martin owns all right, title, and interest in the '817 patent. Due to these alleged misrepresentations, Medtronic asks the Court to dismiss this case "as sanction for Scimed's conduct and Martin's collusion in that conduct." Medtronic Mot. for Sanctions at 10.

---

[3] The Clerk of Courts made an entry of default against Martin on the same day.

II. ANALYSIS

A. Scimed's Rule 12(b)(1) Motion to Dismiss Medtronic's Counterclaim for Lack of Subject Matter Jurisdiction is Denied

Scimed asks this Court to dismiss Medtronic's counterclaim against it and against Martin pursuant to Federal Rule of Civil Procedure 12(b)(1), claiming that the Court lacks subject matter jurisdiction under 35 U.S.C. § 146 to hear Medtronic's claim.[4] The Court disagrees, and denies Scimed's motion to dismiss.

In its counterclaim against Scimed and Martin, Medtronic asks this Court, in essence, to affirm the Board's decisions that were favorable to Medtronic, reverse those that were not, and to adjudge that Medtronic is entitled to a Letters Patent of the United States for the bifurcated lumen invention. *See* Medtronic Counterclaim at 10. At issue for purposes of Scimed's motion to dismiss are three preliminary motions filed by Fogarty — who assigned its rights in the patent application to Medtronic — with the Board. In Preliminary Motion No. 1, Fogarty argued that the claims contained in the Cragg/Scimed patent application were not patentable. Additionally, in Preliminary Motion No. 3, Fogarty challenged any benefit awarded to the Cragg/Scimed patent application due to an earlier filing date of a European patent application. Finally, Fogarty alleged in

---

[4] Section 146 provides, in relevant part, that "Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days . . . ."

Preliminary Motion No. 4 that certain claims in Martin's patent and in the Cragg/Scimed patent application were unpatentable.

The Board denied each of these motions on February 11, 2000. Six months later on August 14, 2000, the Board asked Fogarty "to file a paper identifying all [previous] motion decisions adverse to party Fogarty which Fogarty believes still must be considered at final hearing even if all issues raised by Party Cragg [Scimed] for final hearing are decided against party Cragg." Scimed Mot. to Dismiss at 2. In response, Fogarty submitted to the Board that Preliminary Motion Nos. 1, 3, 4, among others, "would become moot and need not be considered in the event judgment is entered against Cragg. (While the motions thus need not be reviewed, reference to Cragg's position and/or the Board's rulings with respect to certain of these may still be required.)." At the final hearing before the Board on the '192 interference, Preliminary Motions 1, 3 and 4 were neither discussed by Cragg or Fogarty nor briefed by the parties as part of the proceeding. When the Board rendered its decision on July 27, 2001 awarding priority of invention to the '836 or Fogarty/Medtronic application over the '402 or Cragg/Scimed application, the judgment did not address any of the issues raised in Fogarty's Preliminary Motions 1, 3 and 4. *See* Medtronic Mot. for Default Judgment, Exh. A (Board's Op. in the '192 interference).

Despite the fact that the issues were never briefed by the parties nor discussed by the Board during the final hearing proceedings on the '192 interference, Medtronic now

asks this Court to reverse the Board's rejection of Fogarty Preliminary Motions 1, 3 and 4. Both Medtronic and Scimed primarily cite the same cases as support for their arguments regarding this Court's subject matter jurisdiction to hear Medtronic's counterclaim: *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 9Fed. Cir. 1994) and *General Instrument Corp. v. Scientific-Atlanta*, 995 F.2d 209, 214 (Fed. Cir. 1993).

While the cases provide some guidance, they are not factually analogous to the situation presently before the Court. In *Conservolite*, the party bringing a Section 146 action in district court asked the court to consider an issue that the party did not raise either by preliminary motion or at the final hearing. The Federal Circuit in *Conservolite* held that a party's failure to raise the issue in a preliminary motion not only precluded it not from raising the matter at the final hearing, but also precluded district court review. *See Conservolite*, 21 F.3d at 1101. Here, the situation before the Court is different. Unlike the party that brought a Section 146 action in *Conservolite*, Medtronic raised in Preliminary Motions 1, 3, and 4 the same issues it now brings in its counterclaim, although those issues were not addressed at the final hearing.

The Court must therefore determine whether failure to introduce an issue during a final hearing on an interference — even if the issue was raised by preliminary motion — prevents a district court from considering the issue during a Section 146 action. While *Conservolite* states that "an action under § 146 is essentially a proceeding to review the action of the Board," *id.*, the Court cannot conclude that it stands for the proposition that

Scimed advances: that district courts lack subject matter jurisdiction over issues raised in preliminary motions but not addressed at a final hearing. *See* Scimed Reply at 4 (arguing that "[i]f an issue is not raised at final hearing or considered in the Board's final decision, it cannot be raised in a Section 146 action."). The Federal Circuit's opinion in *Conservolite* recognizes as much when it states that "[i]n order for an issue to have been raised adequately so that it qualifies for consideration in a Section 146 proceeding, the issue should have been raised as specified in the PTO's interference rules, for example, *through preliminary motions*, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or opposition to these motions." *Id.* at 1102 (emphasis added). Medtronic complied with that requirement by bringing Preliminary Motions 1, 3, and 4. *See* Scimed Reply at 5. Neither *Conservolite*, nor the pertinent statute and regulation, require more. *See* 35 U.S.C. § 146; 37 C.F.R. § 1.658.

Furthermore, the Court does not believe that allowing Medtronic to raise issues here that were not specifically briefed or raised during the final hearing to be inconsistent with the general principle that administrative remedies must be exhausted before seeking district court review. This is especially true because the Board itself limited the issues to be considered at the final hearing when it asked Medtronic to list only those issues Medtronic believed "still must be considered at final hearing *even if all issues raised by Party Cragg [Scimed] for final hearing are decided against party Cragg*." Scimed Mot. to Dismiss at 2. Medtronic's answer to that question was a qualified one: only if all issues

were decided against Cragg were Medtronic's preliminary motions moot. As the Board limited the issues to be considered, and because Fogarty/Medtronic raised the issues in preliminary motions which were denied by the Board, the Court concludes that permitting Medtronic to bring them here in its counterclaim is "not wasteful of administrative and judicial resources." *Conservolite*, 21 F.3d at 1102. Moreover, the Court does not find Medtronic waived its claims for the same reasons it finds that Medtronic sufficiently exhausted its administrative remedies.

For the reasons set forth above, the Court denies Scimed's motion to dismiss Medtronic's counterclaim.

B. Medtronic's Motion for Default Judgment Against Scimed is Denied

Medtronic has moved for default judgment against Scimed under the theory that Scimed was the true party-in-interest to Martin's patent, and had a duty to defend Martin in all litigation arising from that patent. Default against Martin, under the defendant's theory, is also default against the plaintiff, Scimed.

The standard in this court for granting a motion for default judgment is set forth in *Jackson v. Beech*, 636 F.2d 831 (D.C. Cir. 1980), as well as Rule 55 of the Federal Rules of Civil Procedure. In *Jackson*, the Circuit Court specifically explained that default judgment is disfavored when it stated that "modern federal procedure favors a trial on the merits over a default judgment," and that default judgment is normally reserved for a

"totally unresponsive party." *Id.* at 835. Scimed, in this case, has not been a totally unresponsive party. It has filed its opposition to the motion for default judgment and the motion for sanctions in a timely manner. It cannot be said that Scimed is being unresponsive or otherwise dilatory in defending its interests.

This Court has been unable to find support in the law for entering default judgment against a party because that party has a duty to defend a second party, who is truly in default for failing to appear or is totally responsive, under a licensing agreement. Those cases where a duty to defend has resulted in default judgment have been limited to cases between an insured and an insurer — where there has been privity in contract between those parties, and the insured, rather than a third party, sought to enforce the contract and the insurer's duty to defend. *See, e.g., Weiss v. St. Paul Fire and Marine Ins. Co.* 283 F.3d 790 (6th Cir. 2002); *Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co.*, 219 F.3d 895 (9th Cir. 2000). The Court does not find support for a third party - like Medtronic - seeking to enforce a contractual duty to defend between two other parties in order to obtain default judgment.

In any event, Medtronic has not satisfied the test set for granting default judgment set forth by this Circuit in *Combs v. Nick Garin Trucking*, 825 F.2d 437 (D.C. Cir 1987). The Court in *Combs* listed three factors to consider when setting aside default judgment, which is relevant to this Court's determination as to whether default judgment is appropriate in the first place: whether the default was willful, whether denying default

judgment would prejudice the moving party, and whether the alleged defense - here, the plaintiff's claim - is meritorious. As mentioned previously, the Court does not find willful default in this case. Scimed has been responsive to every pleading and motion. The court also does not find that denying default judgment would prejudice Medtronic at this early stage in the proceedings.

Given this Circuit's disfavor toward default judgment and strong preference for adjudication of claims on their merits, if Medtronic's position is as truly meritorious as it claims in its papers, a motion for summary judgment would be the proper procedure for addressing which party is the true party at interest in the Martin patent. A motion for default judgment should not be used as a motion in limine to prevent a party from presenting proofs or making claims.

For those reasons set forth above, Medtronic's motion for default judgment against Scimed is denied.

C. Medtronic's Motion for Default Judgment Against Defendant and Counterclaim Defendant Martin is Granted

Although the Court denies Medtronic's motion for default judgment against Scimed, the Court grants its motion for entry of default judgment as to Martin, but reserves ruling on what relief should be granted.

Applying the *Combs* test, discussed above, the Court finds that Medtronic has satisfied the first requirement by showing that Martin's default is willful. Martin has been

served with copies of the pleadings and motions filed in this case. He has not responded to Scimed's complaint, Medtronic's counterclaim, or Medtronic's motion for default judgment. However, Martin has retained counsel and filed a declaration included as Exhibit 5 to Scimed's opposition to Medtronic's motion for entry of default judgment. Given that he has retained counsel, has received copies of all pleadings and motions filed in this case, and has been a "totally unresponsive party" to this filings, *Jackson*, 636 F.2d at 836, the Court can only conclude that Martin's default is willful, rather than the result of negligence on his or his attorney's part.

As Martin has neither opposed the entry of default judgment against him nor suggested he may have a meritorious defense to Medtronic's counterclaim, the Court need not consider the remaining two prongs of the *Combs* test. Although Martin has willfully defaulted, the question of the relief to which Medtronic is entitled due to his default is a complicated one. In its motion for default judgment, Medtronic, in essence, asks this Court to reverse the Board's decisions that are adverse to Medtronic's interest in the '836 patent application, and affirm those that are favorable.[5] Entering a judgment against

---

[5] Specifically, Medtronic asks this Court to grant the following relief:

(1) Reversing the Patent Board's decision concerning Fogarty's Preliminary Motion No. 4;
(2) Reversing those portions of the Patent Board's decision of July 27, 2001 with regard to the '192 interference that are adverse to Fogarty; and
(3) Adjudging that Medtronic is entitled to a Letters Patent of the United States for the invention disclosed in the '836 Application

Martin for this relief, however, necessarily gives Medtronic the relief it seeks against Scimed as well — relief the Court denied to Medtronic when it rejected its motion for default judgment against Scimed. The Court cannot see how it is possible to enter default judgment against Martin without also simultaneously, and inadvertently, entering judgment against Scimed on the underlying issues of Medtronic's counterclaim.

While finding that Martin is in default, the Court will therefore reserve entering judgment against Martin until Medtronic's counterclaim is adjudicated on the merits.

D. Medtronic's Rule 11 Motion for Sanctions Against Scimed is Denied

Medtronic charges that Scimed has made misrepresentations to the Court that "go to the core of the dispute between the parties," Medtronic Mot. for Sanctions at 1, and requests that this Court sanction Scimed for this alleged misconduct by dismissing its complaint. The Court declines to do so.

The charges made in Medtronic's motion for sanctions and Scimed's opposition go, as Medtronic notes, to the heart of this case: which party is entitled to the rights for the bifurcated lumen patent. To resolve the motion for sanctions either in Scimed's or Medtronic's favor, the Court must necessarily resolve the merits of the underlying dispute without the benefit of discovery. To do so at this stage in the litigation would not be fair

---

Medtronic Mot. for Default Judgment at 5.

to either side. Therefore, without ruling one way or the other as to the factual allegations contained in Medtronic's motion and Scimed's opposition, the Court denies Medtronic's motion for sanctions.

III. CONCLUSION

For the reasons set forth above, the Court hereby:

GRANTS Medtronic's motion for entry of default judgment against Martin (#17), but reserves ruling on the relief to which Medtronic is entitled;

DENIES Medtronic's motion for default judgment as to Scimed (#17);

DENIES Scimed's motion to dismiss Medtronic's counterclaim (#22); and

DENIES Medtronic's motion for sanctions (#23).

In addition the Court also:

GRANTS Scimed's motion for Gideon Stern to appear *pro hac vice* for Scimed (#29); and

GRANTS Scimed's motion for leave to file the Patent Office's Decision to Pending Motions (#34).

SO ORDERED.

RICHARD J. LEON
UNITED STATES DISTRICT JUDGE

TAB 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff and Counterclaim-Defendant,

v.

MEDTRONIC AVE, INC.,

Defendant and Counterclaimant,

and

ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

Civil Action No. 1:01 CV 02015 (RJL)

STIPULATION AND ORDER

WHEREAS on July 27, 2001 the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office issued a Final Decision and Judgment ("July 27, 2001 Final Decision") in Interference No. 104,192 involving a single count and the following applications and patent of the parties:

Fogarty *et al.* United States Patent Application Serial No. 08/463,836 owned by Medtronic AVE, Inc., now known as Medtronic Vascular, Inc. ("Medtronic");

Cragg *et al.* United States Patent Application Serial No. 08/461,402 owned by Scimed Life Systems, Inc. ("Scimed"); and

Martin United States Patent No. 5,575,817 owned by Eric. C. Martin ("Martin").

WHEREAS the July 27, 2001 Final Decision awarded priority of invention to Fogarty *et al.* (Medtronic) for the subject matter of the single count;

WHEREAS on December 17, 2001 Scimed filed a Second Amended Complaint requesting review of certain rulings in the July 27, 2001 Final Decision, including the award of priority of invention to Fogarty *et al.* (Medtronic);

WHEREAS on January 2, 2002, Medtronic filed an Answer, Counterclaim and Cross-Claim requesting review of certain rulings in the July 27, 2001 Final Decision;

WHEREAS Martin did not respond to Scimed's Second Amended Complaint or to Medtronic's Answer and Cross-Claim; and

WHEREAS the Court ruled Martin in default for failure to respond to Medtronic's Cross-Claim.

NOW THEREFORE Medtronic and Scimed desire to limit and expedite the remaining issues in dispute between them and therefore agree as follows:

1. Scimed agrees that in this action it will not rely on Martin's alleged date of invention to prove a date of invention for the inventors of Scimed's Cragg *et al.* Application Serial No. 08/461,402. Medtronic and Scimed reserve all rights against Martin.

2. Medtronic agrees to withdraw, with prejudice, the Complaint in *Medtronic Vascular Inc. v. James E. Rogan and Nicholas P. Goldici*, Case No. 1:03 CV 02466, filed on November 24, 2003 in the United States District Court for the District of Columbia.

3. Medtronic and Scimed agree to limit the issues in this case to the following:

(a) Whether the Board erroneously affirmed its grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application No. 94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192;[1]

(b) If the answer to issue (a) is yes and the Court elects to determine the issue of priority, then whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192; and

(c) If the answer to issue (a) is yes and the Court elects not to determine the issue of priority, then the case may be remanded to the Board of Patent Appeals and Interferences for determination of whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192.

4. Medtronic and Scimed further agree that if the answer to issue (a) is no, then Fogarty *et al.* (Medtronic) is entitled to an award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be affirmed.

5. Medtronic and Scimed further agree that if the answer to (a) is yes and the Court determines that the answer to (b) is no, then Cragg *et al.* (Scimed) is entitled to an

[1] The applicable burdens of proof are not intended to be modified by this Agreement.

award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be reversed.

6. Medtronic and Scimed further agree that if the answer to (a) is yes and the Court determines that the answer to (b) is yes, then Fogarty *et al.* (Medtronic) is entitled to an award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be affirmed.

7. If either party is dissatisfied with the final judgment of the Court or the final decision of the Board of Patent Appeals and Interferences upon remand, the dissatisfied party may pursue appropriate review.

8. Medtronic and Scimed agree that amended pleadings will be filed in this case reflecting this agreement to limit the issues.

IT IS AGREED TO AND ORDERED THAT:

1. Pleadings filed in this case hereafter shall bear the following caption:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff and Counterclaim-Defendant, v. MEDTRONIC VASCULAR, INC., Defendant and Counterclaimant, and ERIC C. MARTIN, Defendant and Counterclaim-Defendant.	Civil Action No. 1:01 CV 02015 (RJL)

2. Medtronic is directed to withdraw, with prejudice, its Complaint in *Medtronic Vascular Inc. v. James E. Rogan and Nicholas P. Goldici*, Case No. 1:03 CV 02466, filed on November 24, 2003 in the United States District Court for the District of Columbia within 14 days of entry of this Order.

3. The issues as between Scimed and Medtronic in this action are limited to the following:

(a) Whether the Board erroneously affirmed its grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application

No. 94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192;

(b) If the answer to issue (a) is yes and the Court elects to determine the issue of priority, then whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192; and

(c) If the answer to issue (a) is yes and the Court elects not to determine the issue of priority, then the case may be remanded to the Board of Patent Appeals and Interferences for determination of whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192.

4. Scimed is directed to file a Third Amended Complaint consistent with the above statement within 14 days of entry of this Order. Medtronic is directed to file an Amended Answer and Counterclaim that is consistent with the above statements within 14 days of service of the Third Amended Complaint.

STIPULATED AND AGREED TO BY

Gidon D. Stern Thomas E. Friebel (D.C. Bar No. 290627) Cathy J. Chin Max Bachrach (D.C. Bar No. 477267) JONES DAY 222 East 41st Street New York, New York 10017 Attorneys for Scimed Life Systems, Inc.	Donna M. Tanguay (D.C. Bar No. 4496) Mark G. Davis (D.C. Bar No. 412228) John R. Fuisz (D.C. Bar No. 439698) McDERMOTT, WILL & EMERY 600 13th St., N.W. Washington, D.C. 20005-3096 Attorneys for Medtronic Vascular, Inc.

SO ORDERED

3/25/04

Honorable Richard J. Leon
UNITED STATES DISTRICT JUDGE

WDC99 853493-4.052734.0050

NYJD: 1490229.3

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the STIPULATION AND ORDER was served this 18th day of February, 2004, as follows:

Gidon D. Stern (Via Federal Express)
Thomas E. Friebel
Jones Day
222 East 41st Street
New York, NY 10017

Counsel for Plaintiff Scimed Life Systems, Inc.

Robert J. Koch (Via Hand Delivery)
Fulbright & Jaworski
801 Pennsylvania Ave., N.W.
Washington, DC 20004

Attorney for Defendant Eric C. Martin

WDC99 539970-1.052734.0050

TAB 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff,

v.

MEDTRONIC VASCULAR, INC.,

Defendant and Counterclaimant,

and ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

CASE NO. 1:01CV2015 (RJL)

PROTECTIVE ORDER

WHEREAS, Medtronic Vascular, Inc. ("Medtronic") and Scimed Life Systems, Inc. ("Scimed") each may seek discovery or documents, information or other materials which may contain or relate to, *inter alia*, valuable research, development, commercial, financial and technical proprietary data, or other information that another party or a nonparty regards as confidential, proprietary or trade secret information of another party or of a nonparty in the above-captioned action (the "Action");

IT IS HEREBY ORDERED that the following Protective Order be entered in this Action:

1. This Protective Order shall cover all information, documents, or tangible items disclosed and/or produced in connection with any discovery taken in the above-captioned action pursuant to the Federal Rules of Civil Procedure and Local Rules of Civil Practice and Procedure of the United States District Court for the District of Columbia or disclosed and/or produced in connection with any hearings or other proceedings in the above-captioned action. All

(2)

information, documents, or tangible items covered by this Protective Order shall be used only for the purposes of this litigation and shall not be used for any purpose outside of this litigation.

2. The following classification shall apply:

a. "Confidential Information" shall mean and include any document (whether in hard copy or electronic or computer readable form), thing, deposition testimony, interrogatory answers, responses to requests for admissions and/or production, or other information provided in discovery in this Action ("Discovery Material"), which contains non-public, confidential or proprietary information, whether personal or business-related, including but not limited to information that constitutes, reflects, or concerns trade secrets, know-how or proprietary data, business, financial or commercial information, the disclosure of which is likely to cause harm to the competitive position of the party making the confidential designations on Discovery Material ("the Designating Party").

b. All such Confidential designations shall be made in good faith by the Designating Party and made at the time of disclosure, production, or tender to the party receiving the same ("Receiving Party"), or at such other time as permitted by this Protective Order, provided that the inadvertent failure to so designate does not constitute a waiver of such claim, and a party may so designate Discovery Material after such Discovery Material has been produced, with the effect that such Discovery Material is thereafter subject to the protections of this Protective Order in accordance with such designation.

c. When the Designating Party produces files, records or materials for inspection, no marking need be made in advance of the inspection. All files, records, and materials subject to inspection shall be treated as "Confidential." Upon selection of files,

records, or materials for copying, the witness or producing party shall mark the copies with the appropriate classification prior to production to the inspecting party.

d. A Confidential Designation shall constitute a representation that such Discovery Material has been reviewed by an attorney for the Designating Party and that there is a valid basis for such designation.

3. The designation of Discovery Material as Confidential in the form of documents, responses to requests for admission and interrogatories, or other tangible materials (including, without limitation, CD-ROMs and tapes) other than depositions or other pretrial testimony shall be made by the Designating Party in the following manner:

a. Documents designated "Confidential" shall be so marked by conspicuously affixing the legend "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" on each page containing any Confidential Information (or in the case of computer medium on the medium and its label and/or cover) to which the designation applies. Such designated Discovery Material shall be identified by Bates number. To the extent practical, the Confidential legend shall be placed near the Bates number;

4. Confidential Information shall not include any Discovery Materials which:

a. Have been or become lawfully in the possession of the Receiving Party through communications other than production or disclosure in this Action, or in other litigation, for example, as a result of legitimate business dealings between the parties, unless those documents are covered by a separate non-disclosure or confidentiality agreement, in which case the Receiving Party may continue to use such documents in the course of its business subject to those agreements; or

b. Have been or become part of the public domain by publication or otherwise and not due to any unauthorized act or omission on the part of the Receiving Party or any of its authorized representatives or designees under this Protective Order. Nothing herein shall impose any restriction on the use or disclosure by a party or nonparty of its own documents or information.

5. Subject to paragraph 6 of this Protective Order, "Qualified Persons" having access to Discovery Material designated "Confidential Information" under this Protective Order, in this Action are:

a. McDermott, Will & Emery LLP, attorneys of record for Medtronic, their stenographic, clerical and paralegal employees whose duties and responsibilities require access to such materials;

b. Jones Day, attorneys of record for Scimed, their stenographic, clerical and paralegal employees whose duties and responsibilities require access to such materials;

c. For each party, a total of three (3) in-house counsel or patent agents (collectively "in-house counsel") whose names are listed below and who have responsibility for maintaining, defending or evaluating this litigation. The approved in-house counsel are as follows:

	Medtronic, Inc.	Scimed Life Systems, Inc.
Name Title	Sue R. Halverson Vice President, Assistant General Counsel, Litigation	Luke R. Dohmen Vice President and Chief Patent Counsel, Scimed Life Systems, Inc.
Name Title	Michael J. Jaro Chief Patent Counsel	Peter J. Gafner Director and Managing Counsel for Cardiology Litigation, Scimed Life Systems, Inc.

	Medtronic, Inc.	Scimed Life Systems, Inc.
Name Title		Steven A. McAuley Patent Counsel, Scimed Life Systems, Inc.

The parties may identify additional in-house counsel who meet[s] the above criteria for inclusion on this list following execution of this Protective Order by providing written notice of the names of the additional in-house counsel to the other parties pursuant to Paragraph 7. The parties to this Action may substitute in-house counsel who meet the above criteria for good cause shown;

d. Retained independent consultants or experts, for purposes of this Action only (as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials) who are not current employees of any party to this litigation, or any direct competitor of any party to this litigation;

e. The Court, Court personnel, and stenographic and video reporters engaged in proceedings incident to this Action;

f. Outside document copying services, document coding or computerization services, trial graphics consultants, jury and trial consultants, and other entities retained by counsel of record to aid in the preparation of or in the trial of this action. The class of persons identified in this subsection does not include any independent consultants or experts as set forth in subsection (d) above. Notwithstanding any other provision of this Protective Order, access to Confidential documents shall be permitted to the entities listed in this subsection (f), without need for the completion of Exhibit A or the execution of Exhibit B. The outside counsel providing Confidential documents to an entity listed in this subsection shall be responsible for that entity's compliance with the provisions of this Protective Order.

6. Qualified Persons defined in paragraph 5(d) shall be allowed access to Confidential Information only after complying with the following procedure:

a. A Receiving Party who desires to give access to Discovery Materials designated by another party or witness as Confidential Information to a person described in paragraph 5(d) shall first provide written notice to the Designating Party of the proposed person to receive such materials. The written notice shall include a written list, in a form similar to Exhibit A hereto, setting forth the name of the person, his or her occupation, and business address, a curriculum vitae and disclosure of any past or current relationship with any party in this Action. The Designating Party shall have seven (7) business days after receipt of the written notice to object in writing to the disclosure of Confidential Information to the proposed expert or consultant. If the parties are unable to resolve that objection, the objecting party shall, no later than five (5) business days after objection, move the Court for an order prohibiting the disclosure at issue. The objecting party shall have the burden of persuasion that disclosure should not be made. A failure by the Designating Party to timely serve an objection or file a motion shall be deemed to constitute approval of disclosure to the proposed person. If a written objection and a timely motion to prohibit disclosure has been made, no Confidential Information shall be made available to the proposed expert or consultant unless and until the Court rules that disclosure can be made. This objection procedure does not apply to the approved individuals already listed in paragraph 5(c);

b. Before receiving any Confidential Information, the person shall be furnished with a copy of this Protective Order and shall acknowledge, by executing the acknowledgment form attached hereto as Exhibit B, that he or she has read this Protective Order, understands it, and agrees to be bound by it, and also expressly consents to the jurisdiction of this

Court in connection with any proceeding or hearing relating to the enforcement of this Protective Order. In-house attorneys authorized to receive Confidential Information shall not be required to execute the acknowledgment form, but shall otherwise be bound by its terms;

c. Outside counsel for each Receiving Party shall retain a copy of each such written list (Exhibit A) and acknowledgment form (Exhibit B), and shall serve opposing counsel with a copy of these documents upon request and thereafter upon revision of such documents.

7. Confidential Information and the substance or content thereof, including any notes, memoranda or other similar documents relating thereto, shall be used by a Receiving Party and its authorized representative or designees under this Protective Order solely for the purpose of this Action and any appeals therefrom, and shall not be made available, or disclosed, or summarized to any persons, including the parties, other than as permitted by paragraphs 5-6 of this Protective Order. Confidential Information shall be maintained by the Receiving Party under the overall supervision of outside counsel.

8. Any person in possession of Confidential Information shall exercise care with regard to the storage, custody or use of such Confidential Information in order to ensure that the Confidential nature of the same is maintained.

9. If Confidential Information is disclosed to anyone other than in a manner authorized by this Protective Order, the party responsible for such disclosure must: (a) immediately bring all pertinent facts relating to such disclosure (including to whom the disclosure was made and the specific documents or information disclosed) to the attention of the Designating Party of the Confidential Information; (b) retrieve such information, or, where the information is not retrievable, certify that it has been lost or destroyed and that no copies are within the possession, custody or control of unauthorized recipients of the information,

documents, or materials; and (c) request that the person to whom the information was disclosed sign an acknowledgement in the form of Exhibit B; and (d) prevent further disclosure.

10. When Confidential Information is discussed, quoted or referred to in any deposition, the disclosing party shall ensure that only persons permitted by paragraph 5 of this Protective Order to have access to such Information are present. During any hearing or trial persons not authorized to have access to confidential information shall be asked to leave the courtroom when such Confidential Information is being published. The confidentiality of evidence not published in open court during any hearing or trial is not waived.

11. During the course of preparing for a deposition or testimony, a fact deponent/witness may be shown Confidential Information from another party's documents strictly limited to those documents which on their face reveal that they were authored or received in the normal course of business by the deponent/witness. Use of Confidential Information during a deposition shall be subject to compliance with this Order.

12. Any deposition transcript containing Confidential Information shall be marked on the cover as "Confidential Pursuant To Protective Order," and shall indicate as appropriate within the transcript what information has been so designated. Whenever possible, the stenographic reporter shall be requested prior to the deposition (where the attorneys have reason to believe the testimony will contain Confidential Information) or when the Confidential Information is disclosed (when not previously anticipated) to separate those portions of the transcript containing Confidential Information and separately bind it from the non-confidential portions. However, a party may designate any portion or all (if appropriate) of the transcript as containing Confidential Information by so advising, with reasonable precision as to the affected testimony, the deposition reporter, who shall accordingly indicate in the deposition transcript

what portion(s) of the testimony (or exhibits thereto) were so designated, or by so advising all other parties in writing, and with page and line designations, within ten (10) business days after receipt of the transcript. Until ten (10) business days have passed after the receipt of any transcript, that entire transcript shall be deemed to be Confidential. In the event of disagreement about the confidential status of a deposition transcript, it shall continue to be treated as Confidential until the Court rules otherwise.

13. Any Designating Party may redact from the documents and things it produces (1) sensitive matter not relevant to the subject matter of this litigation, and (2) matter that the Designating Party claims is subject to attorney-client privilege, work product immunity, a legal prohibition against disclosure, private patient medical data, or other privilege or immunity. The Designating Party shall mark each document or thing where matter has been redacted with a legend stating "REDACTED FOR RELEVANCE" or "REDACTED FOR PRIVILEGE" as appropriate, or a comparable notice. Where a document consists of more than one page, at least the first page and each page on which information has been redacted shall be so marked. The Designating Party shall preserve an unredacted version of each such document. This provision shall not affect any obligation to provide a log of information redacted or otherwise withheld on the basis of attorney-client privilege, work product immunity, a legal prohibition against disclosure, or other privilege or immunity.

14. Any pleading, paper or other document filed in this action which contains or discloses Confidential Information shall be filed under seal and shall be maintained under seal according to the terms of this Protective Order or as otherwise determined by the Court. When filing pleadings, motions, briefs, discovery materials, and other papers, which contain Confidential Information, the party so filing shall designate the following on the first page of

filed documents: "Filed Under Seal - Subject To Protective Order - Contains Confidential Material - May Only Be Opened by Order of the Court" and shall otherwise comply with the Court's order on the subject.

15. Entering into, agreeing to and/or producing or receiving Confidential Information or otherwise complying with the terms of this Protective Order shall not:

a. Operate as an admission by any party that any Discovery Material designated as Confidential Information contains or reflects trade secrets or any other type of confidential or proprietary information entitled to protection under applicable law;

b. Prejudice in any way the rights of any party to object to the production of documents it considers not subject to discovery, or operate as an admission by any party that the restrictions and procedures set forth herein constitute adequate protection for any particular information deemed by any party to be Confidential Information;

c. Prejudice in any way the rights of any party to object to the authenticity or admissibility into evidence of any document, testimony or the evidence subject to this Protective Order;

d. Prejudice in any way the rights of any party to seek a determination by the Court whether any Discovery Material or Confidential Information should be subject to the terms of this Protective Order;

e. Prejudice in any way the rights of any party to petition the Court for a further protective order, or modification or amendment of this order, relating to any purportedly Confidential Information;

f. Prejudice in any way the rights of any party to petition the Court for permission to disclose or use particular Confidential Information more broadly than would otherwise be permitted by the terms of this Protective Order; or

g. Prevent any Designating Party from agreeing to alter or waive the provisions or protections provided for herein with respect to any particular Discovery Material designated as Confidential Information by that party.

16. If a party disagrees with any designation of Confidential Information, such party shall first make its objection known to the producing party and request a change of designation. The parties shall first try to resolve such dispute in good faith on an informal basis. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court no sooner than five (5) days following the service of a written notice of disagreement. The burden of proving that information has been properly designated as Confidential is on the party making such designation. Until a determination by the Court, the information in issue shall be treated as originally designated by the producing party. Any failure to object to any material being designated as Confidential shall not be construed as an admission by any non-designating party that the material constitutes or contains a trade secret or other confidential information.

17. All provisions of this Protective Order restricting the use of information obtained during discovery shall continue to be binding on the parties and all persons who have received information under this Protective Order, after the conclusion of this action, including all appeals, until further Order of the Court, unless the parties agree otherwise in writing. Upon conclusion of this matter, outside experts and consultants shall return or destroy all Confidential Information in their possession, including notes or other documents prepared relating to such information. Any and all originals and copies of Discovery Materials designated Confidential (including all

originals or copies in the possession of any outside experts or consultants, and any notes or other documents prepared by such persons relating to any Confidential Materials) shall, at the request of the producing party, be returned to the party within sixty (60) days after a final judgment herein or settlement of this Action, or, at the option of the producing party, destroyed in that time frame, except that outside counsel for each party may maintain in its files one copy of each pleading filed with the Court, each deposition transcript together with the exhibits marked at the deposition, and documents constituting work product which were internally generated based upon or which include Confidential Information. In the event that outside counsel maintains such documents, it shall not disclose material containing any type of Confidential Information to another party absent subpoena or court order. In the event that documents are returned to or destroyed at the request of the producing party, the other party or its outside counsel shall certify in writing that all such documents have been returned or destroyed, as the case may be.

18. By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Protective Order who becomes subject to a motion to disclose another party's information designated Confidential Information pursuant to this Protective Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed. If any Receiving Party is subpoenaed in another action, served with a demand in another action to which it is a party, or served with any other legal process by one not a party to this action seeking information which was produced or designated as Confidential by someone other than the receiving party, the receiving party shall transmit a copy of such subpoena, demand, or legal process, by hand or facsimile transmission, within three

business days of receipt of such subpoena, demand, or legal process, to the producing party and prepare timely objections to production of the Confidential Information. Should the person seeking access to the Confidential Information take action against the receiving party or anyone else covered by this Protective Order to enforce such a subpoena, demand, or other legal process, the receiving party shall respond by setting forth the existence of this Protective Order. Nothing herein shall be construed as requiring the receiving party or anyone else covered by this Protective Order to challenge or appeal any order requiring production of information covered by this Protective Order, subject itself to any penalties for noncompliance with any legal process or order, or seek any relief from this Court.

19. The inadvertent production in discovery of any privileged or otherwise protected or exempted information, as well as the inadvertent production in discovery of information without an appropriate designation of confidentiality, shall not be deemed a waiver or impairment of any claim or privilege or protection including but not limited to the attorney-client privilege, the protection afforded to work-product materials or the subject matter thereof, or the confidential nature of any such information, provided that the producing party shall immediately notify the Receiving Party in writing when inadvertent production is discovered. Upon receiving written notice from the producing party that privileged information or work-product material has been inadvertently produced, all such information, and all copies thereof, shall be returned to the producing party, and the Receiving Party and counsel shall not use such information for any purpose. Any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information shall immediately be destroyed.

20. Any violation of the terms of this Protective Order shall be punishable by money damages, interim or final injunctive or other equitable relief, sanctions, contempt of court

citation, or such other or additional relief as deemed appropriate by the Court. The foregoing remedies shall be in addition to any other common law or statutory relief available for violation of the terms of this Protective Order.

21. Discovery Material produced by third parties may be designated by them as Confidential Information pursuant to the terms of this Protective Order and, when so designated, shall be treated by the parties in conformance with this Protective Order.

22. The Court retains jurisdiction subsequent to settlement or entry of judgment to enforce the terms of this Protective Order.

AGREED:

OF COUNSEL:

Donna M. Tanguay (D.C. Bar No. 414496)
John R. Fuisz (D.C. Bar No. 439698)
Stephen K. Shahida (D.C. Bar No. 454970)
McDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8000

Attorneys for Defendant and Counterclaimant
Medtronic Vascular, Inc.

Sep. 9, 2004

OF COUNSEL:

Gidon D. Stern
Thomas E. Friebel (D.C. Bar No. 290627)
Catharina J. Chin Eng
JONES DAY
222 East 41st Street
New York, NY 10017

Max Bachrach (D.C. Bar No. 477267)
JONES DAY
51 Louisiana Avenue N.W.
Washington, D.C. 20001-2113
(202) 496-4456

Attorneys for Plaintiff
Scimed Life Systems, Inc.

Sept 8, 2004

The parties, having entered into the above stipulation, and having shown good cause herein, it is SO ORDERED:

Leon, J.

9/12/04

EXHIBIT A

LIST OF QUALIFIED PERSONS, paragraphs 5(c) and 5(d)

NAME	BUSINESS ADDRESS	OCCUPATION/ TITLE	GOVERNING PARAGRAPH	DATE IDENTIFIED

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff, v. MEDTRONIC VASCULAR, INC., Defendant and Counterclaimant, and ERIC C. MARTIN, Defendant and Counterclaim-Defendant.	CASE NO. 1:01CV2015 (RJL)

I hereby certify (i) my understanding that Discovery Material and/or Confidential Information are being provided to me pursuant to the terms and restrictions of the Protective Order (the "Order") entered by the United States District Court for the District of Columbia (the "District Court") in this Action, and (ii) that I have read the Order. I understand the terms of the Order, I agree to be fully bound by the Order, and I hereby submit to the jurisdiction of the District Court for purposes of enforcement of the Order. I understand that violation of the Order may be punishable by contempt of court, or other sanction, penalty, injunction, or damages available at law or equity.

Dated: _____ Signature: _____

Name: _____

Address: _____

_____

_____

TAB 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff

v.

MEDTRONIC VASCULAR, INC., and ERIC C. MARTIN

Defendants

Case No. 1:01 CV 02015 RJL

JOINT STIPULATED REQUEST TO EXTEND DISCOVERY

Plaintiff Scimed Life Systems, Inc. and Defendant Medtronic Vascular, Inc. jointly and respectfully request this Court to extend the discovery deadline and all subsequent dates in this case by two months.

The parties have engaged in written discovery with all deliberate speed. In order to avoid any duplication of efforts, however, depositions have not taken place pending the completion of all document production. Given the number of witnesses located in and outside the United States and the fast approaching holiday season, the parties jointly propose the following extensions of the dates set forth in the Court's Scheduling Order:

Close of factual discovery	February 1, 2005
Deadline for filing discovery motions	February 15, 2005
Service of expert reports on those issues as to which a party has the burden of proof	March 14, 2005

(M)

Service of expert reports on those issues to which opposing party has the burden of proof	April 15, 2005
Completion of expert depositions	May 25, 2005
Deadline for filing summary judgment motions	June 22, 2005

(The parties are not precluded from filing summary judgment motions prior to this date.)

Opposition to summary judgment motions	21 days after filing of motion
Reply memorandum in support of summary judgment motions	14 days after filing of opposition
Hearing on summary judgment motions	To be scheduled by Court
The pretrial conference	On or after July 25, 2005

Respectfully submitted,

Friebel / SKS

Gidon D. Stern
Thomas E. Friebel (D.C. Bar No. 290627)
Catharina J. Chin Eng
JONES DAY
222 East 41st Street
New York, NY
Attorneys for Plaintiff
Scimed Life Systems, Inc.

Donna M. Tanguay (D.C. Bar No. 414496)
John R. Fuisz (D.C. Bar No. 439698)
Stephen K. Shahida (D.C. Bar No. 454970)
McDERMOTT, WILL & EMERY
600 13th St., N.W.
Washington, D.C. 20005-3096
Attorneys for Defendant
Medtronic Vascular, Inc.

It is so ORDERED

Dated November 2, 2004

Honorable Richard J. Leon
United States District Judge

WDC99 999766-1.052734.0050

TAB 10

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim-Defendant,	)	
	)	
v.	)	
	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
	)	**Civil Case No. 01-2015 (RJL)**
Defendant and Counterclaim-Plaintiff,	)	
	)	
	)	
and	)	
	)	
ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant.	)	

MEMORANDUM OPINION
(March 31, 2006) [# 76, 100, 102, 103]

Plaintiff, Scimed Life Systems, Inc. ("Scimed"), brought this action against defendants, Medtronic Vascular, Inc. ("Medtronic") and Eric C. Martin, under Title 35 of the United States Code Section 146, challenging the Final Decision and Judgment of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("USPTO") regarding Patent Interference No. 104,192 between certain patent applications for an apparatus for reinforcing a bifurcated lumen. Presently before the Court are Medtronic's Motion for Summary Judgment, Scimed's First and Second Motions for Summary Judgment, and Medtronic's Motion to Compel Production of Documents and

Things. After due consideration of the parties' submissions, the relevant law and the entire record herein, the Court finds that the Board did not erroneously affirm its Grant of the Fogarty *et al.* United States Patent Application Serial No. 08/463,836 (now owned by Medtronic) Motion 12 in its July 27, 2001 Final Decision and Judgment. Accordingly, this Court affirms the Board's Final Decision and Judgment and, therefore, GRANTS Medtronic's Motion for Summary Judgment, DENIES Scimed's First and Second Motions for Summary Judgment, and DENIES AS MOOT Medtronic's Motion to Compel Production of Documents and Things.

I. BACKGROUND

Plaintiff Scimed and defendant/counterclaimant Medtronic are each assignees of record of two different patent applications for a bifurcated lumen invention.[1] Andrew Cragg and Michael Dake (collectively referred to as party "Cragg" in the underlying proceedings at the USPTO) filed an application with the USPTO regarding the bifurcated lumen apparatus on June 5, 1995. The application was assigned the serial number 08/461,402 (the "'402 application"). Cragg and Dake assigned all rights in the '402 application to Boston Scientific Technology, Inc., which later merged into plaintiff Scimed. Scimed is now the present legal owner of the '402 application. Medtronic was assigned its rights in a patent application for the same invention by Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively referred to as party "Fogarty" in the underlying proceedings at the

[1] The "Background" section of this Memorandum Opinion has been partially adapted from this Court's earlier Memorandum Opinion in *Scimed Life Systems, Inc. v. Medtronic Ave Inc.*, 297 F. Supp. 2d 4 (D.D.C. 2003).

USPTO). That application was also filed with the USPTO on June 5, 1995, and assigned the serial number 08/463,836 (the "'836 application"). Party Fogarty assigned its rights in the '836 application to Medtronic Aneurx, Inc., which merged into Medtronic AVE, Inc. which later became the defendant/counterclaimant Medtronic. Medtronic is now the legal owner of the '836 application. Defendant/counterclaim-defendant Eric Martin owns patent No. 5,575,817 (the "Martin" or "'817 patent"), based on application 08/293,541, filed on August 19, 2004.

On April 23, 1998, the USPTO Board declared an interference between Scimed's patent application (the "Cragg" or "'402 application"), Medtronic's patent application (the "Fogarty" or "'836 application") and the Martin patent. This interference proceeding was assigned Interference No. 104,192, and is referred to as the "'192 interference."[2] On July 2, 1998, the Board set the following as the sole "count"[3]:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:
> an upper limb, configured to fit within the lumen upstream of the bifurcation;
> a first lower limb, configured to extend into the first leg of said bifurcation when said first section is positioned in the lumen, and

---

2 "The purpose of an interference proceeding is to resolve the question of priority of invention when more than one applicant seeks a patent on substantially the same invention." 3A-10 Donald S. Chisum, Chisum on Patents § 10.09[1][a] (2006). This action was brought in federal Court pursuant to 35 U.S.C. § 146, which allows a party dissatisfied with the decision of the Board in an interference to bring a civil action as long as the Board's decision is not being appealed to the United States Court of Appeals for the Federal Circuit "and such appeal is pending or has been decided." *See* 35 U.S.C. § 146.

3 "A count defines the interfering subject matter. In *In re Van Geuns* (1993), the Federal Circuit noted that (1) '[a]lthough claims of one or more of the parties may be identical to the count of an interference, the count is not a claim to an invention,' and (2) '[t]he count of an interference is merely the vehicle for contesting the priority of invention and determining what evidence is relevant to the issue of priority.'" 3A-10 Donald S. Chisum, Chisum on Patents § 10.09[3] (2006).

a second lower limb, shorter that said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,
and further comprising
a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

Cragg et al. v. Martin v. Fogarty et al., Patent Interference No. 104,192, Paper No. 187, Final Decision and Judgment at 5-6 (United States Patent and Trademark Office, Board of Patent Appeals and Inferences July 21, 2001)("Board's Final Judgment"). The purpose of the '192 Interference was for the Board to determine who among the three parties had priority of inventorship, and was, therefore, entitled to the invention defined by the count.

At the time of declaration of the interference, party Cragg was accorded by the USPTO the benefit of the filing dates of two European patent applications (i.e. February 9 and June 10, 1994), which had been filed by a French Company known as Mintec SARL. At the time of declaration of the interference, party Fogarty, on the other hand, was accorded by the USPTO the benefit of the earlier filing date of U.S. patent application 08/255,681: i.e. on June 8, 1994. Thus, at the start of the interference, party Cragg was designated the "senior party,"[4] on the basis of the accorded benefit date of February 9, 1994. On March 13, 2000, party Fogarty filed a preliminary motion attacking the benefit accorded party Cragg to

---

4 "In an interference proceeding, the first party to file is designated as the 'senior party' and all other parties as 'junior.' The junior party bears the burden of going forward with evidence as to actual reduction to practice prior to the senior party's filing date or conception prior to the senior party's filing date plus continuous and reasonable diligence during the critical period. If the senior party desires to show a date of conception or reduction to practice prior to his filing date, he bears the burden of going forward with evidence." 3A-10 Donald S. Chisum, Chisum on Patents § 10.03[1][c][ii] (2006).

the filing dates of the two European applications and sought to be made the senior party in the interference. On April 7, 2000, the Board granted party Fogarty's preliminary motion 12, declaring party Fogarty the senior party in the interference and party Cragg and party Martin as junior parties in the interference. *Cragg et al. v. Martin v. Fogarty et al.*, Patent Interference No. 104,192, Paper No. 130, Decision on Party Cragg's Motion to Correct the Preliminary Statement and on Party Fogarty's Preliminary Motion No. 12 at 7 (United States Patent and Trademark Office, Board of Patent Appeals and Inferences April 24, 2000)("Decision on Preliminary Motion No. 12"). In that same opinion, the Board denied party Cragg's motion to amend its preliminary statement to name Michael D. Dake and Andrew H. Cragg as co-inventors of the party Cragg invention. *Id.* at 7. Party Cragg requested reconsideration of that decision claiming that the Board had erred in its ruling and claimed that Mintec filed the European applications as assignees of both Dake and Cragg, the co-inventors of the subject matter of the patent application.

On April 24, 2000, the Board issued a Decision on Reconsideration denying the request for reconsideration on the basis that Dake's assignment of his rights in the patent application came after the filing of the European application and that 35 U.S.C. § 119 could not be interpreted to allow Mintec the benefit of priority with this subsequent assignment of rights. *Cragg et al. v. Martin v. Fogarty et al.*, Patent Interference No. 104,192, Paper No. 138, Decision on Reconsideration (United States Patent and Trademark Office, Board of Patent Appeals and Inferences April 24, 2000)("Board's Decision on Reconsideration"). In

its decision, the Board interpreted Title 35 of the United States Code Section 119 to require that "the previously filed foreign application must have been filed by the person or one who was, at the time of filing of the previously filed foreign application, already a legal representative or assign of that person." *Id.* at 3. The Board went on to state that their interpretation of Section 119 "is necessary to ensure a link between the presently involved application and the earlier filed foreign application with respect to the particular inventor. A contrary interpretation would cause entitlement to benefit to be negotiable as a commodity between unrelated entities." *Id.* In essence, the Board rejected party Cragg's position on the assignment of rights to the patent and stated:

> We are unpersuaded that an assignment of ownership rights changes on whose behalf an application was previously already filed. It would appear that only filings subsequent to the assignment of rights from Michael D. Dake can be deemed as being executed or performed on his behalf.

Id. at 5. Party Cragg requested a final hearing for review of the Board's decision claiming that the Board had erroneously interpreted Section 119 and that Dake and Cragg were co-inventors and that Mintec SARL was the assignee of both Dake and Cragg for the subject matter invention even though the assignments occurred after the European patent applications were filed. *See id* at 11-23. On July 27, 2001, the Board issued its Final Decision and Judgment. *See* Board's Final Judgment.

In its Final Judgment, the Board adopted its earlier interpretation of 35 U.S.C.§ 119. *Id.* at 9. The Board cited *Vogel v. Jones*, 486 F.2d 1068, 1072 (C.C.P.A. 1973), for the proposition that "a foreign application made by the assignee of a U.S. applicant, on behalf

of one other that the United States inventor, is irrelevant to the rights of priority of the U.S. inventor." *Id.* at 10. The Board stated that the "plain statutory language" of Section 119 does not put "an assignee in the same position as if it were a 'legal representative' or 'assign' of the inventor at a previous time when a foreign application for the same invention was filed by that assignee." *Id.* at 12. The Board found that Dake assigned his invention to Mintec, Inc. more than two years *after* the filing of the two European patent applications. *Id.* at 11-12. The Board went on to state, that even assuming that party Cragg's preliminary statement identified both Cragg and Dake as co-inventors of the subject matter of the count, that fact would not help party Cragg as "Cragg also did not assign his rights to Mintec, Inc. until after" the two European patent applications were filed. *Id.* at 20. The Board found that "MINTEC SARL was not an assign of either Michael D. Dake nor Andrew H. Cragg when it filed European applications EP944oo284.9 and EP94401306.9." *Id.* For those reasons, and others, the Board found that there was no error in the granting of party Fogarty's preliminary motion 12. *Id.* at 23.

On September 25, 2001, Scimed filed this appeal under Title 35 of the United States Code Section 146, seeking this Court's review of the Board's Final Decision and Judgment in the '192 Interference. The parties to this action entered into a stipulation and order limiting the issues in this case. The stipulated issue to be resolved is:

> Whether the Board erroneously affirmed its Grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application No.

94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192.

(*See* Stipulation and Order entered March 25, 2004, Dkt. 50.) On July 22, 2005, both parties moved for summary judgment on this remaining issue and provided the Court with exhibits supporting their positions.

II. STANDARD OF REVIEW

Summary Judgment is appropriate when the pleadings and the record demonstrate that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a Court must look to the substantive law on which each claims rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248. Additionally, to be a genuine issue of fact, it must be supported by sufficient admissible evidence such that a reasonable trier of fact could find for the nonmovant. *See Laningham v. United States Navy*, 813 F.2d 1236, 1242-43 (D.C. Cir. 1987).

The moving party bears the initial burden of "identifying those portions of the 'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrates the absence of a genuine issue of material fact." *See Celotex*, 477 U.S. at 323. In order to prevail on its motion for summary judgment,

the movant must show that the nonmovant "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322.

In opposing summary judgment, the "nonmoving party [must] go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and 'admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324. The Court must view the facts in the light most favorable to the nonmovant, giving the nonmovant the benefit of all justifiable inferences derived from the evidence in the record. *Anderson*, 477 U.S. at 255 (1986). The nonmovant, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252.

In order for Scimed to prevail on summary judgment, Scimed must put forth evidence and legal support that meets the standard of proof this Court is required to apply when reviewing decisions of the Board of Patent Appeals and Interferences of the USPTO. In determining whether or not the Board erroneously affirmed its Grant of party Fogarty's preliminary motion 12 and, therefore, erroneously awarded priority for the subject matter of the single count in the '192 Interference to Medtronic, this Court will apply the standard of proof set forth in *Morgan v. Daniels*, in that when a decision has been made by the Patent Office in an action contesting priority of invention, "the decision there made must be accepted as controlling upon that question of fact in any subsequent suit between the same parties, unless the contrary is established by testimony which in character and amount *carries*

thorough conviction." *Morgan*, 153 U.S. 120, 125 (1894) (emphasis added) (determining the standard of review for a Patent Office decision when no additional evidence was put forth to the Circuit Court). Our Circuit Court, in *United States v. Szuecs*, 240 F.2d 886 (D.C. Cir. 1957), upheld the *Morgan* standard of proof that must be applied by a District Court when reviewing a decision of the Patent Office pursuant to 35 U.S.C. § 146. "To reach a conclusion contrary to that of the Patent Office," the *Morgan* standard requires the evidence to carry "'thorough conviction.'" *Szuecs*, 240 F.2d at 887 (citing *Morgan*, 153 U.S. at 125) (reversing and remanding the case to the District Court to apply the correct standard of proof).

Another District Court Judge of this Court reaffirmed the application of *Morgan* in reviewing Patent Office cases under 35 U.S.C. § 146. *Anderson v. Anderson*, 403 F. Supp. 834, 844-45 (D.D.C. 1975) (affirming the decision of the Board of Patent Interferences after reviewing the full administrative record and hearing additional oral testimony), *aff'd*, 543 F.2d 1389 (D.C. Cir. Nov. 11, 1976). In *Anderson*, Judge John H. Pratt found that the "Patent Office is entitled to a presumption of correctness and regularity." *Id.* at 844 (citing *Vogel v. Jones*, 346 F. Supp. 1005 (D.D.C. 1972). Judge Pratt went on to reiterate that the District Court could not overturn the Board's decision unless the evidence put forth by the movant carried "thorough conviction," and "[t]he 'thorough conviction' standard imposes a heavy burden on plaintiffs in an action under 35 U.S.C. § 146," and that "[a] mere preponderance of the evidence is not enough to justify reversing the Patent Office." *Id.* at

845. For the following reasons, the Court finds that the plaintiff has failed to meet its heavy burden, and concludes that the Board did not err in its interpretation of Section 119.

III. ANALYSIS

A. *Interpretation of 35 U.S.C. § 119*

In the Board's Final Judgment, it reaffirmed its earlier decision that the "plain statutory language" of Section 119 requires that the person who filed the foreign patent application must have been a legal representative or assign of the person who filed the patent application in the United States at the time that the foreign patent application was filed.[5] Board's Final Judgment 9-10. The pertinent part of Section 119 reads:

> (a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country.

35 U.S.C. § 119(a). The Board's interpretation of Section 119 is supported by *Vogel v. Jones*, 486 F.2d 1068 (C.C.P.A. 1973). *See* Board's Final Decision 10-11. In *Vogel*, the Court of Customs and Patent Appeal, the predecessor to the current Court of Appeals for the Federal Circuit, read Section 119 to mean "that an applicant for a United States patent can rely for priority on the 'first filed' application by an assignee on his behalf." 486 F.2d at

---

5 While counsel for Scimed is quick to point out its own grammatical analysis of Section 119 without citing to any grammar reference guide, the Court notes that it is quite capable of reading the statute, interpreting the language of the statute, researching the case law pertaining to the statute and applying that law to the present action.

1072. In order for the foreign patent application to be filed on behalf of the United States applicant, the person filing the foreign application must be an assignee or legal representative *at the time* that the foreign application was filed. *Id.* If the foreign applicant was allowed to become the legal representative or assign of the United States applicant *after* the foreign application was filed, it would be impossible for the foreign application to have been filed *on the behalf* of the United States applicant. If the Board or this Court held otherwise, the right of priority could be, as the Board noted, traded or sold as a commodity to the highest bidder. *See* Board's Decision on Reconsideration 3; Board's Final Decision 9. Therefore, this Court does not find that the Board erred in its interpretation of Section 119 and Scimed has neither cited any precedent or legislative history that would warrant interpreting the statute otherwise.[6]

---

[6] Scimed argues that the Board's construction of Section 119 is inconsistent with the Paris Convention for the Protection of Industrial Property, *opened for signature* Mar. 20, 1883, as amended at Stockholm, July 14, 1967, 21 U.S.T. 1630, 828 U.N.T.S. 305 ("Paris Convention"), and asks this Court to find that the Board's erroneously construed Section 119 as the Board's construction is inconsistent with and violates Article 4 of the Paris Convention. While Section 119, and its predecessor R.S. 4887, were enacted in order to implement Article 4 of the Paris Convention, *Vogel*, 486 F.2d at 1072, the Board's construction of Section 119, which this Court finds correct, does not violate and is not inconsistent with the Paris Convention. The Paris Convention is not self-executing and, therefore, the U.S. was free to implement the Paris Convention in the manner and form that Congress deemed appropriate. *In re Dr. Matthais Rath*, 402 F.3d 1207, 1209-10 (Fed. Cir. 2005). Congress executed Article 4 of the Paris Convention first with R.S. 4887, and then with Section 119, and Section 119 requires that in order to claim a right of priority in a foreign application, the foreign application must have been filed by the U.S. applicant or a person or entity who was a legal representative or assign of the U.S. applicant at the time that the foreign application was filed. The concern expressed by Scimed that upholding the Board's construction of Section 119 would have in foreign countries is conjecture and "based on pure speculation." *See Kawai v. Metlestics*, 480 F.2d 880, 889 (C.C.P.A. 1973).

B. *Review of Board's Decision*

Having found that the Board did not err in its reading and interpretation of Section 119, the question remains whether the Board erred in granting Medtronic's preliminary motion 12 seeking to deny Scimed the benefit of the filing date of its European patent applications. It did not. While a review by this Court of a Board's Final Decision is a "hybrid of an appeal and a trial de novo" because the Court considers evidence before the Board "as well as evidence that was not before the Board," *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (quoting *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997)), it nonetheless must treat the Board's decision as controlling "unless the contrary is established by testimony which in character and amount carries thorough conviction." *Morgan*, 153 U.S. at 125.

Scimed argues that the '284 European application was either filed on Dake's behalf "pursuant to the constructive trust imposed upon that application" when Mintec SARL filed the application, or a theory of an equitable assignment to party Cragg. (Scimed's Mem. of P&A in Opp'n to Medtronic's Mot. For Summ. J. 29, 35-36 ("Scimed's Opp'n"); Mem. of P&A in Supp. of Scimed's Second Mot. For Summ J. That Scimed is Entitled to the Priority of Its EP '284 Application Even Under the Board's Construction of 35 U.S.C. § 119(a)) 31-33 ("Scimed's Second Mot. For Summ. J.".) As this Court earlier recognized, "[t]he Federal Circuit in *Conservolite* [*Inc., v. Widmayer*] held that a party's failure to raise the issue in a preliminary motion not only precluded it not from raising the matter at the final hearing, but

also precluded district Court review." *Scimed Life Systems, Inc. v. Medtronic AVE, Inc.*, 297 F. Supp. 2d 4, 8 (D.D.C. 2003) (citing *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994)). The Federal Circuit has stated that "[i]n order for an issue to have been raised adequately so that it qualifies for consideration in a § 146 proceeding, the issue should have been raised as specified in the PTO's interference rules, for example, through preliminary motions, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or oppositions to these motions." *Conservolite*, 21 F.3d at 1102. Therefore, Scimed is precluded from arguing that the Board erred in denying priority to Scimed either under the newfound constructive trust or equitable assignment theories advanced before this Court.

Thus, applying the *Morgan* standard of proof to this review and not having conducted a *de novo* review as in *Winner*, the Court finds that Scimed has not presented sufficient evidence that Mintec SARL was either the legal representative or assign of Dake or Cragg *at* the time that the relevant European patent applications were filed. Accordingly, party Cragg and Scimed cannot claim the benefit of priority of the European patent applications. Therefore, this Court finds that the Board did not err in its granting of party Fogarty's (Medtonic's) motion No. 12 which denied Cragg *et al.* (Scimed) the benefit of the earlier filing date of European application No. 94400284.9 and affirms the Board's award of priority to Fogarty *et al.* (Medtronic) in its July 27, 2001 Final Decision and Judgment.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS defendant and counterclaim-plaintiff Medtronic's Motion for Summary Judgment [#100]; DENIES Plaintiff and counterclaim-defendant Scimed's First Motion for Summary Judgment [#102]; DENIES Plaintiff and counterclaim-defendant Scimed's Second Motion for Summary Judgment [#103]; and DENIES AS MOOT defendant and counterclaim-plaintiff Medtronic's Motion to Compel Production of Documents and Things [#76]. An order consistent with this decision accompanies this Memorandum Opinion.

RICHARD J. LEON
United States District Judge

TAB 11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim-Defendant,	)	
	)	
v.	)	
	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
	)	**Civil Case No. 01-2015 (RJL)**
Defendant and Counterclaim-Plaintiff,	)	
	)	
	)	
and	)	
	)	
ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant.	)	

FINAL JUDGMENT

For the reasons set forth in the Memorandum Opinion entered this date, it is, this 31st day of March 2006, hereby

ORDERED that defendant and counterclaim defendant Medtronic Vascular, Inc's ("Medtronic") Motion to Compel Motion to Compel Production of Documents and Things [#76] is **DENIED AS MOOT**; and it is further

ORDERED that Medtronic's Motion for Summary Judgment [#100] is **GRANTED**; and it is further

ORDERED that Scimed Life Systems, Inc.'s ("Scimed") First Motion for Summary Judgment [#102] is **DENIED**; and it is further

ORDERED that Scimed Life Systems, Inc.'s ("Scimed") Second Motion for Summary Judgment [#103] is **DENIED**; and it is further

ORDERED that judgment is entered in favor of defendant and counterclaim defendant Medtronic, that the Board of Patent Appeals and Interferences Final Decision and Judgment issued on July 27, 2001, is affirmed, and that the case is dismissed with prejudice.

SO ORDERED.

RICHARD J. LEON
United States District Judge

TAB 12

United States Court of Appeals for the Federal Circuit

2006-1434

BOSTON SCIENTIFIC SCIMED, INC.
(formerly known as Scimed Life Systems, Inc.),

Plaintiff-Appellant,

v.

MEDTRONIC VASCULAR, Inc.
(also known as Medtronic AVE, Inc.),

Defendant-Appellee,

and

ERIC C. MARTIN,

Defendant.

Gregory A. Castanias, Jones Day, of Washington, DC, argued for the plaintiff-appellant. With him on the brief were Gidon D. Stern, Thomas E. Friebel, Catharina J. Chin Eng, and Brent P. Ray, of New York, New York.

Brian E. Ferguson, McDermott Will & Emery LLP, of Washington, DC, argued for the defendant-appellee. On the brief were Paul Devinsky, John R. Fuisz, Stephen K. Shahida, and Natalia V. Blinkova. Of counsel were Joel M. Freed and Amanda E. Koenig.

Appealed from: United States District Court for the District of Columbia

Judge Richard J. Leon

United States Court of Appeals for the Federal Circuit

2006-1434

BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiff-Appellant,

v.

MEDTRONIC VASCULAR, Inc. (also known as Medtronic AVE, Inc.),

Defendant-Appellee,

and

ERIC C. MARTIN,

Defendant.

DECIDED: August 8, 2007

Before MAYER, BRYSON and PROST, Circuit Judges.

MAYER, Circuit Judge.

Boston Scientific Scimed, Inc. ("Scimed")* appeals the district court's grant of summary judgment affirming the Board of Patent Appeals and Interferences' final decision, which denied Scimed the priority benefit of an earlier-filed European patent application for the subject matter at issue in Patent Interference Number 104,192 ("the

---

* Plaintiff-appellant Boston Scientific Scimed, Inc., was formerly known as Scimed Life Systems, Inc., and will be referred to throughout this opinion as "Scimed."

'192 interference"). Scimed Life Sys., Inc. v. Medtronic Vascular, Inc., 486 F. Supp. 2d 60 (D.D.C. 2006). We affirm.

Background

This appeal stems from an interference proceeding before the United States Patent and Trademark Office Board of Patent Appeals and Interferences. Scimed and Medtronic Vascular, Inc. ("Medtronic") are each assignees of different United States patent applications covering the same invention. Andrew Cragg and Michael Dake (collectively "Cragg") filed patent application 08/461,402 ("the '402 application") for the invention in question on June 5, 1995. Cragg then assigned all rights in the '402 application to Boston Scientific Technology, Inc., which later merged into Scimed, the plaintiff-appellant and current legal owner of the '402 application. Also on June 5, 1995, Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively "Fogarty") filed patent application 08/463,836 ("the '836 application") for the same invention. Fogarty assigned their rights in the '836 application to a company that eventually became Medtronic, the defendant-appellee and current legal owner of the '836 application. Eric Martin, a third-party to the instant appeal, owns U.S. Patent No. 5,575,817 (the "Martin patent" or "'817 patent"), which resulted from an application filed on August 19, 1994.

On April 23, 1998, the board declared an interference between Scimed's '402 application, Medtronic's '836 application, and Martin's '817 patent. The purpose of the interference was to determine which party had priority of inventorship, thereby entitling it to the invention as set forth in the sole count of the interference:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:

an upper limb, configured to fit within the lumen upstream of the bifurcation;

a first lower limb, configured to extend into the first leg of said bifurcation when said first section is positioned in the lumen, and

a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation, and further comprising

a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

Cragg v. Martin v. Fogarty, Patent Interference No. 104,192, Paper No. 187, 2001 WL 1339890 at *2-3 (B.P.A.I. July 21, 2001) ("Final Interference Decision").

The board initially gave Cragg the benefit of the filing dates of two European patent applications filed by MinTec SARL ("MinTec"), a French company. The earlier of these dates was February 9, 1994. At the time these European applications were filed, no legal relationship existed between MinTec and Cragg, nor was MinTec acting on behalf of Cragg. Fogerty was granted the benefit of the filing date of U.S. patent application 08/255,681, which was June 8, 1994. Martin was accorded benefit of the application that led to the '817 patent, which was filed on August 19, 1994. Accordingly, the PTO initially designated Cragg as the senior party in the interference.

Fogarty responded by filing a motion attacking the priority benefit granted to Cragg. The board granted the motion, declaring Fogarty the senior party in the interference. After Cragg protested this decision, the board issued a final decision denying his request to be declared the senior party. The board ruled that Cragg was not entitled to priority benefit under 35 U.S.C. § 119 because neither Cragg nor Dake had assigned their rights to MinTec until after it had filed the European applications. Final Interference Decision, 2001 WL 1339890, at *5.

Scimed, the assignee of Cragg's U.S. patent application, then brought an action in the United States District Court for the District of Columbia challenging the board's final decision in the '192 interference. The district court affirmed the board's final decision, Scimed, 486 F. Supp. 2d at 61, and Scimed filed this appeal. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

Discussion

We review a district court's grant of summary judgment de novo. Monsanto Co. v. Scruggs, 459 F.3d 1328, 1344 (Fed. Cir. 2006). We also apply a de novo standard when reviewing questions of law, including a trial court's interpretation of statutory language. Pitsker v. Office of Pers. Mgmt., 234 F.3d 1378, 1381 (Fed. Cir. 2000).

At issue here is whether 35 U.S.C. § 119(a)** permits an applicant for a United States patent to benefit from the priority of a foreign application previously filed by an entity that was not acting on behalf of the U.S. applicant at the time of filing. We hold that it does not.

A similar issue was addressed by the Court of Customs and Patent Appeals in Vogel v. Jones, 486 F.2d 1068 (CCPA 1973), which, to the extent relevant here, is binding upon us, South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982)

** 35 U.S.C. § 119(a) reads in relevant part:

> An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed . . . .

(en banc). According to Vogel, "§ 119 gives rise to a right of priority that is personal to the United States applicant." 486 F.2d at 1072. Due to the personal nature of this right, an applicant for a U.S. patent may only benefit from the priority of a foreign application if it was filed by the U.S. applicant or "on his behalf." Id.

Scimed argues that Vogel does not require the foreign applicant to have been acting on behalf of the U.S. applicant at the time the foreign application was filed. It points to the following passage in support:

> This practice [of allowing a U.S. applicant to claim priority from a foreign application filed by someone else] arose because it was recognized that in many foreign countries, unlike in the United States, the actual applicant for a patent can be other than the inventor, e.g., an assignee. In light of this, we regard the language in § 119 referring to legal representatives and assigns to merely represent a codification of the actual practice under [the predecessor statute to § 119]. Since under United States law an application for patent must be made by the inventor, that practice was based on the requirement that the foreign application, regardless of the identity of the applicant, must have been filed for an invention actually made by the inventive entity seeking to rely upon it for priority purposes. We think § 119 must be construed to the same end.

Id. (footnote omitted). Scimed attempts to construe this language as permitting a U.S. applicant to benefit from a foreign application's earlier filing date whenever "the invention described in the foreign application [is the same] one actually made by the U.S. applicant," "'regardless of the identity of the applicant' of the foreign application." According to its interpretation, "the Vogel court did not hold that the foreign application must have been filed by a person who was an assignee or legal representative of the U.S. inventor at the time the foreign application was filed, or that the foreign application must have been filed on his behalf in order for there to be priority benefit." We disagree.

Vogel clearly held that the above-quoted passage "means that an applicant for a United States patent can rely for priority on the 'first filed' application by an assignee on his behalf." Id. (emphasis added). Moreover, "the existence of an application made by [the inventor's] assignee in a foreign country on behalf of one other than the United States inventor is irrelevant to his right of priority based on applications made on his behalf." Id. In other words, while the foreign application must obviously be for the same invention and may be filed by someone other than the inventor, section 119(a) also requires that a nexus exist between the inventor and the foreign applicant at the time the foreign application was filed. Indeed, as a matter of pure logic, an entity could not have filed a foreign application "on behalf of" an inventor without the inventor's knowledge or consent; that the foreign application may have been filed in accordance with the laws of the country in which it was filed has no bearing here. Therefore, to the extent that there may have been any uncertainty or ambiguity in Vogel, we now explicitly hold that a foreign application may only form the basis for priority under section 119(a) if that application was filed by either the U.S. applicant himself, or by someone acting on his behalf at the time the foreign application was filed.

Scimed also contends that the district court erred by precluding it from presenting evidence relating to theories of constructive trust and equitable assignment. A party may present new evidence to the trial court when appealing a board decision in an interference proceeding. Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994). A party may not, however, advance new legal theories at the trial court level, even if the overarching legal issue was presented below. See id. ("[A]n action under [35 U.S.C.] § 146 is essentially a proceeding to review the action of the Board. . . . [T]he

parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources."). Failure to advance legal theories before the board constitutes a failure to "make a complete presentation of the issues," and permitting a party to raise those theories for the first time before the trial court would be both inefficient and "wasteful of administrative and judicial resources." The parties stipulated that the only issue to be resolved by the district court was whether the board correctly ruled on Fogarty's motion attacking the priority benefit initially granted to Cragg, Scimed, 486 F. Supp. 2d at 64, and Scimed did not raise either of these theories before the board, see Final Interference Decision, 2001 WL 1339890, at *3-10. The district court therefore did not err by precluding Scimed from presenting evidence to support these new legal theories.

Conclusion

Accordingly, the judgment of the United States District Court for the District of Columbia is affirmed.

AFFIRMED

Electronic Acknowledgement Receipt

EFS ID:	4738770
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Joshua L. Cohen/denise morgan
Filer Authorized By:	Joshua L. Cohen
Attorney Docket Number:	BSI-010US4
Receipt Date:	05-FEB-2009
Filing Date:	15-OCT-2001
Time Stamp:	12:16:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Brief Filed	appealbrief.PDF	937022 c26226ce5f46e4e4c69d74cb684a4fddc5522fc5	no	24
Warnings:					
Information:					
2	Affidavit/Dec/Exhibit after Notice of Appeal	tab1.PDF	124457 a113de51b09064db72915e86df88295e19e9c7f8	no	5
Warnings:					
Information:					
3	Affidavit/Dec/Exhibit after Notice of Appeal	tab2.PDF	3216757 8b9376fc6c934eb591c66e598c91bf76291690f0	no	74
Warnings:					
Information:					
4	Affidavit/Dec/Exhibit after Notice of Appeal	tab3.PDF	31923 277f4e4d185023b0e602bdf81aa17a6856a940e0	no	2
Warnings:					
Information:					
5	Affidavit/Dec/Exhibit after Notice of Appeal	tab4.PDF	52910 8e3339b464254520356f16fc8c627a313ec86605	no	3
Warnings:					
Information:					
6	Affidavit/Dec/Exhibit after Notice of Appeal	tab5.PDF	88225 f18ec9db1d20fff9ce03d4ddfaea5bda40f49a75	no	4
Warnings:					
Information:					
7	Affidavit/Dec/Exhibit after Notice of Appeal	tab6.PDF	569373 3a73652cce7e77f5baff6404254717dd8556d8e7	no	16
Warnings:					
Information:					
8	Affidavit/Dec/Exhibit after Notice of Appeal	tab7.PDF	298711 e0f68236c535d84628924e0a81a5168b14bdfb31	no	9
Warnings:					
Information:					
9	Affidavit/Dec/Exhibit after Notice of Appeal	tab8.PDF	790011 0c9d9339af52211c87d56ba19e098473b52e2c12	no	18

Warnings:					
Information:					
10	Affidavit/Dec/Exhibit after Notice of Appeal	tab9.PDF	76806 3ac090287e850ee95fe03f5a0c4d1a476ce9918b	no	3
Warnings:					
Information:					
11	Affidavit/Dec/Exhibit after Notice of Appeal	tab10.PDF	781301 c8538bfc29b875920da8710a374b53ff77b356c8	no	16
Warnings:					
Information:					
12	Affidavit/Dec/Exhibit after Notice of Appeal	tab11.PDF	56734 9f839e4542d78c817817770e16fc3b5f17782f59	no	3
Warnings:					
Information:					
13	Affidavit/Dec/Exhibit after Notice of Appeal	tab12.PDF	333981 142d01806ead899d5f49bab6df1f95f49b51e03d	no	9
Warnings:					
Information:					
		Total Files Size (in bytes):	7358211		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 05/11/2009

EXAMINER	

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

ART UNIT	PAPER NUMBER

DATE MAILED: 05/11/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 09/977,826	Applicant(s) GOICOECHEA ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3774	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on _____ is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☒ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☐ Other (including any explanation in support of the above items):

The Related Proceedings Appendix is incomplete..

/William H. Matthews/
Primary Examiner
Art Unit: 3774

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 05/21/2009

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
05/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3774	

All participants (applicant, applicant's representative, PTO personnel):

(1) *William H. Matthews (Howie)*. (3)_____.

(2) *Stanley Weinberg*. (4)_____.

Date of Interview: *18 May 2009*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussed the requirements of the notice of defective Appeal Brief. Examiner requested Applicant to list the copies under the Related Proceedings Appendix heading*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/William H. Matthews/ Primary Examiner, Art Unit 3774	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoechea et al.
Filed:	October 15, 2001
Title:	ENDOLUMINAL STENT
TC/A.U.:	3774
Examiner:	William Matthews
Confirmation No.:	4645
Docket No.:	BSI-010US4
Notice of Appeal Filed:	June 12, 2008
Docket No.:	BSI-010US4

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated March 24, 2008 of claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken, within two months from the date of the Notice of Appeal, or within an extension of that time period.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, are provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Boston Scientific Scimed, Inc. by virtue of Articles of Merger of Boston Scientific Scimed, Inc. wth and ito Scimed Life Systems, Inc. dated December 22, 2004.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal, except as follows:

Interference No. 104,083. A copy of the Judgment of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 1. This Interference involved related Application Serial No. 08/461,402 of Andrew H. Cragg et al., filed June 5, 1995, titled BIFURCATED ENDOLUMINAL PROSTHESIS.

Interference No. 104,192. A copy of the Final Decision and Judgment of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 2. This Interference also involved related Application Serial No. 08/461,402.

Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL). This was an appeal from the Board's decision in Interference No. 104,192. The following interlocutory orders, and/or decisions, memorandum opinion, and final judgment were entered in that appeal, with copies included in the Related Proceedings Appendix (Section X) at the indicated Tabs:

DATE	ORDER OR OPINION	TAB
11/15/01	Order	3
12/21/01	Order	4
5/2/02	Order	5
8/30/03	Memorandum Opinion and Order	6
3/25/04	Stipulation and Order	7
9/12/04	Protective Order	8
12/14/04	Joint Stipulated Request To Extend Discovery	9
3/31/06	Memorandum Opinion	10
3/31/06	Final Judgment	11

Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), United States Court of Appeals for the Federal Circuit, No. 2006-1434. This was an appeal from the decision of the U.S. District Court for the District of Columbia. A copy of the decision of the Federal Circuit is provided in the Related Proceedings Appendix (Section X) at Tab 12.

III. STATUS OF CLAIMS

Claims 20, 22-41, 43-49 and 54-62 are pending. Claims 26, 34-38, 40, and 58-62 have been withdrawn from consideration. Claims 1-19, 21, 42, 50-53 have been canceled. Claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 stand rejected and are being appealed. A copy of the rejected claims is provided in the Claims Appendix (Section VIII).

To assist the Board in correlating dependent claims with their corresponding independent claims, appellants provide the following chart of the pending claims that have not been withdrawn:

20	Dependent on claim 54
22	Dependent on claim 20
23	Dependent on claim 20
24	Dependent on claim 20
25	Dependent on claim 20
27	Dependent on claim 20
28	Dependent on claim 27
29	Dependent on claim 28
30	Dependent on claim 29
31	Dependent on claim 54
32	Dependent on claim 54
33	Dependent on claim 32
39	Dependent on claim 54
41	Dependent on claim 31
43	Dependent on claim 54
44	Dependent on claim 43
45	Dependent on claim 44
46	Dependent on claim 44
47	Dependent on claim 43
48	Dependent on claim 47
49	Dependent on claim 47
54	Independent
55	Dependent on claim 20

56	Independent
57	Dependent on claim 56

IV. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 54

The invention recited in claim 54 is a stent including a plurality of hoops aligned along a common axis. Each of the hoops is non-helical and oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the stent. The stent also includes means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

For example, and for purposes of illustration only, one exemplary embodiment of the invention is shown as stent 10 in Fig. 1A (page 19, lines 5-7; page 22, lines 17-18). Part of a stent such as stent 10 is also shown in Figs. 2A (page 19, lines 11-13; page 23, lines 11-12), 3 (page 19, lines 17-19; page 25, line 27-page 26, line 1), and 4A (page 19, lines 20-22; page 22, lines 17-18). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). Each hoop is non-helical and is oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent (page 9, lines 15-19, 13-19; page 10, lines 16-17).

Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices such as apices 22 (Fig. 2A, page 23, lines 11-20) that point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

The stent also has means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop (page 10, lines 16-23 and Figs. 1A, 1B, 2A, 4A-4F). This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following

paragraphs set forth exemplary structures described in the specification as corresponding to the claimed function.

The securing means may comprise a loop element of a suture material, for example, to tie the abutting juxtaposed apices together. The loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol (page 10, lines 20-28). FIGS. 4B-4F are partial exploded views of embodiments of a stent illustrating exemplary means for securing juxtaposed apices of the stent (page 20, lines 1-4).

Referring to Fig. 4A, for example, abutting juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 which may be, for example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has an abutting juxtaposed apex of a neighboring hoop 20 is tied to the abutting juxtaposed apex 22 in this embodiment. In other embodiments of the invention, only some of the juxtaposed apices 22 may be secured in this way (page 25, lines 4-11).

In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. 4B. The securing means may also comprise a bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in FIG. 4C. Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in FIGS. 4D, 4E, and 4F respectively (page 25, lines 12-21).

The foregoing, exemplary structures correspond to the function recited in claim 54 of securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop. Equivalent structures for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop are also within the literal scope of claim 54 under 35 U.S.C. § 112, sixth paragraph.

B. Claim 56

The invention recited in claim 56 is a stent including a tubular member that has a plurality of hoops aligned adjacent one another along the

longitudinal axis of the tubular member. Each of the hoops has a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices that axially point in a direction along the longitudinal axis of the stent. At least some of the vertices axially abut and are individually connected to oppositely pointed veritices of elongate elements of an adjacent hoop. The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, a stent such as stent 10 includes a tubular member (page 8, lines 8-10). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). The exemplary hoops are aligned adjacent one another along the longitudinal axis of the tubular member (Fig. 1A; page 9, lines 19-27; page 23, lines 24-27).

Each of the hoops includes a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices such as vertices 22 (Fig. 2A, page 23, lines 11-20) that axially point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

At least some of the vertices axially abut (Figs. 2A, 4A) and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop (Figs. 2A, 4A). For example, a loop element of a suture material connects oppositely pointed vertices of adjacent hoops (page 10, lines 18-23). Exemplary suture material is shown as element 99a in Fig. 4B (page 25, lines 13-15). Other materials for connecting oppositely pointed vertices of adjacent hoops are shown in Figs 4A and 4C to 4F (page 25, lines 4-21).

The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member (page 9, lines 15-19; page 10, lines 2-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following provides a concise statement of each ground of rejection presented for review:

Whether claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, as set forth in the Final Office Action.

VII. ARGUMENT

Paragraph 4 of the Final Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. It generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-7 of the Final Office Action provide more specific reasons for the rejections. Paragraph 2 of the Final Office Action explains why the Examiner disagreed with Applicants' arguments regarding claims 56 and 57 in their December 26, 2007 Request for Reconsideration.

EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169. *Accord*, MPEP §

Accord, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION OF CLAIM 54 AND ITS DEPENDENT CLAIMS 20, 22-25, 27-33, 39, 41, 43-49, 55

Contrary To The Final Office Action's Contention, The Disclosure Does Support "Means For Securing An Apex Of One Hoop To An Abutting Juxtaposed Apex Of A Neighboring Hoop"

Paragraph 5 of the Final Office Action has rejected these claims because independent claim 54 recites vertices that abut which, in the Examiner's view, is not disclosed in the specification. Instead, the Examiner contends that the specification only discloses juxtaposed vertices, which, he contends, may or may not imply contact.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) implicitly and inherently supports these claim limitations. The Examiner, on the other hand, has not established a *prima facie* case, with reasons, explaining why a person skilled in

the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

> Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. . . . (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The Examiner has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that claim 54 finds clear support in stent embodiments such as those selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show embodiments having "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." The Examiner has not explained why a person skilled in the art would not recognize that the figures show this feature.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the Examiner has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports

claim 54. Paragraph 5 of the Final Office Action states: "[t]he specification only discloses juxtaposed vertices." This statement fails to provide evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

Paragraph 5 of the Final Office Action also contends that "the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply)." The Examiner's contentions disregard not only page 10, lines 16-23 but also other significant aspects of Applicants' disclosure and fail to present required evidence demonstrating that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention.

Applicants' specification also states:

> [J]uxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 (see Figure 4(a)), which are, in this example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22. (page 25, lines 4-9)
>
> In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in Fig. 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Fig. 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Fig. 4(d), 4(e), and 4(f) respectively. (page 25, lines 12-21).

These passages explain the relationship of juxtaposed apices that can be tied together or secured together as shown in Figures 4A through 4F, each of which also shows an embodiment having abutting apices. Taken together, the disclosure's statement that juxtaposed apices can be tied together or secured together, along with Figures 4A through 4F, combined with the explanation that "each hoop is supported by its neighbors" would inexorably lead one skilled in the art to conclude

that the juxtaposed apices of at least some disclosed embodiments are abutting. The Examiner has not presented any evidence to the contrary.

For all of the above reasons, Applicants' specification discloses "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop."

Claim 54 also recites, in part,

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Paragraph 6 of the Final Office Action has rejected claim 54 and its dependent claims "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the Examiner's view, "[t]he specification only disclose [sic] embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical 'offset' feature."

Applicants' specification expressly describes two alternative categories of embodiments of hoops -- helical and substantially perpendicular. The specification states:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is <u>not helical</u> because the specification describes an <u>alternative</u> to a <u>helical</u> embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is <u>non-helical</u>.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this

invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

> Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

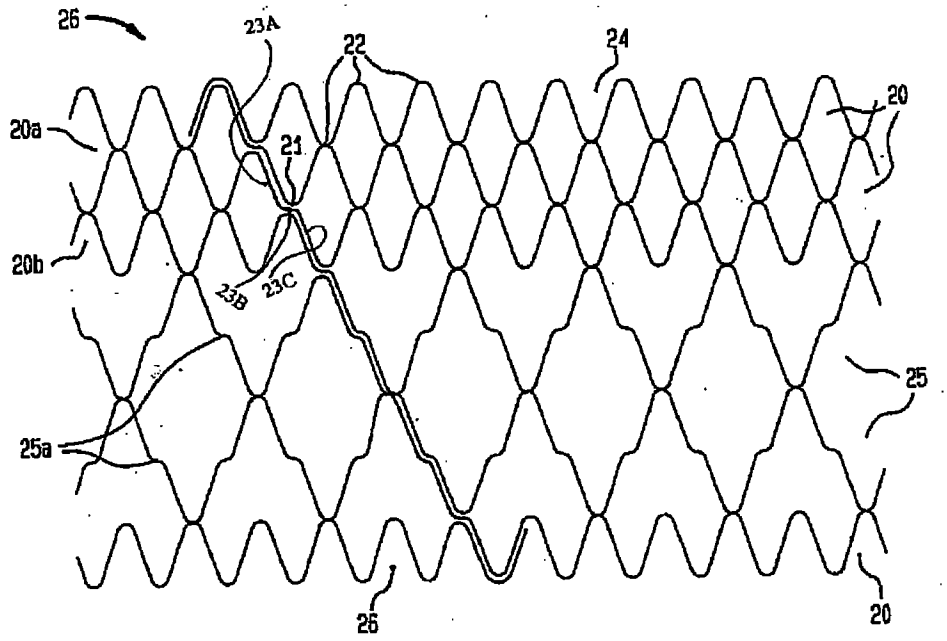
One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

In paragraph 2, at the top of page 3[1], the Final Office Action indicates that it has interpreted "non-helical" to require that the claimed embodiment "lack[s] **any** helical features." Based upon this interpretation of "non-helical," the Examiner contends that Fig. 4A shows "a helical aspect (i.e. the longitudinal displacements described at page 23 lines 24-27)."

But page 23, lines 24-27 describes Figs. 2A and 2B, not Fig. 4A, and describes how hoops 20a and 20b in those figures are formed. Figs. 2A and 2B are reproduced below, with reference numbers 23A, 23B and 23C added to Fig. 2A for the Board's ease of reference.

[1] The opening sentence of paragraph 2 of the Final Office Action states that it only pertains to claims 56 and 57. Since claims 56-57 do not contain a "non-helical" recitation, the Examiner's contentions regarding "non-helical" must pertain to claim 54.

FIG. 2A



The referenced portion of the specification states:

> When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b.

Hoops 20a and 20b are shown in both figures.

Part of hoop 20a is formed by wire portion 23A. In order to form the adjoining hoop 20b, the point of winding of wire portion 23A is displaced longitudinally at wire portion 23B, and becomes wire portion 23C. Apparently, the Examiner contends that wire portion 23B precludes Applicants from reciting "hoops being non-helical." The Examiner is wrong.

The recitation at issue is: "**hoops** being non-helical." Figs. 1A, 1B, 2A, 3, 4A all show embodiments of non-helical **hoops**. Regardless of how the hoops are formed, and regardless of how one hoop flows into another hoop, the **hoops themselves** are non-helical. The disclosure therefore supports "**hoops** being non-helical."

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

THE REJECTION OF CLAIM 56 AND ITS DEPENDENT CLAIM 57

Contrary To The Final Office Action's Contention, The Disclosure Does Support "At Least Some Of Said Vertices Axially Abut"

Claim 56 recites, in part,

> at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop.

In addition to the contentions stated in paragraph 4 of the Final Office Action, the Examiner's reasoning is further explained in paragraph 2 of the Final Office Action, which contends that

> the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the question of how tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.

As was the case regarding claim 54, even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. In addition, the Examiner has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

As Applicants argued above regarding the rejection of claim 54, the specification describes, and the figures illustrate, embodiments in which "each hoop is supported by its neighbors" (page 10, line 20), "vertices . . . are individually connected to oppositely pointed vertices" using various connecting elements (page 10, lines 23-29; page 25, lines 4-9, 12-21), and apices are tied together. See also, Figs. 1A, 1B, 2A, and 4A-4F.

Taken together, the specification and the figures demonstrate that "at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop."

The Final Office Action has disregarded the above-described teachings in the specification because, in its view, the teachings "are not equivalent to a connection created by adhesive or welding." This statement makes the unsupported assumption that any two things (including juxtaposed apices) can abut only if they are connected by adhesive or welding or only if they are connected by something that is equivalent to adhesive or welding. The Board must reject these contentions because the Examiner has not supported them with any evidence and because they are clearly wrong. For example, a pencil resting on a desk top abuts the desk top even though the pencil is not connected to the desk top at all or by adhesive, welding, or anything equivalent to adhesive or welding. Applicants' disclosure demonstrates embodiments in which apices abut, even though the disclosure does not expressly refer to adhesive or welding.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Claim 56 also recites, in part:

> vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Final Office Action has rejected claims 56 and 57 because, in the view of the Examiner, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the Examiner, the specification only supports a recitation that for the perpendicular embodiment apices of "one or more" hoops lie in such a plane. The Final Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A). Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). "Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel." (page 23, lines 20-23)

Fig. 22 illustrates another embodiment of a stent using configurations such as the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

Page 3 of the Final Office Action has mischaracterized Applicants' arguments. Applicants have not suggested that "it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments." As explained above, Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). As stated above, therefore, since both stent embodiments may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops. Contrary to the belief of the Examiner, therefore, one skilled

in the art would understand that the specification does interrelate at least Figs. 1-4 with at least Figs. 22 and 23. The Final Office Action fails to demonstrate that one skilled in the art would not have such an understanding.

For the above reasons, Applicants' disclosure fully supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member."

CONCLUSION

In view of the foregoing remarks, Applicants submit that the grounds for rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 are improper. Applicants respectfully request that the Board reverse the Examiner's rejection of all pending rejected claims.

Respectfully submitted,

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicant

Dated: May 28, 2009

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

VIII. CLAIMS APPENDIX

1-19 (Canceled)

20. (Previously Presented) A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

21. (Canceled)

22. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

26. (Withdrawn) A stent as recited in claim 22 wherein said axially aligned segments are connected to one another by a tubular fabric element.

27. (Previously Presented) A stent as recited in claim 20 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment.

28. (Previously Presented) A stent as recited in claim 27 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment.

29. (Previously Presented) A stent as recited in claim 28 wherein at least one of said first and second additional stent segments is of frustoconical shape

and is further combined with a third an additional stent segment, one end of which includes a mating frustoconical shape.

30. (Previously Presented) A stent as recited in claim 29, wherein said mating frustoconical stent segments are adapted to be separately placed in a bifurcated artery and then, by expansion of one of said frustoconical stent segments, secured to one another.

31. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. (Previously Presented) An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

34. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

35. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a staple.

36. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is wire twisted into loop.

37. (Withdrawn) An endoluminal stent as claimed in claim 36 wherein said wire is nitinol.

38. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is bead of thermoplastic material.

39. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

40. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said stent is at least partially covered in fabric.

41. (Previously Presented) An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

42. (Canceled)

43. (Previously Presented) An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is gold.

50-53. (Cancelled)

54. (Previously Presented) A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

55. (Previously Presented) A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. (Previously Presented) A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. (Previously Presented) A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

58. (Withdrawn) A method of reinforcing a body vessel using a tubular sheath disposed between an entry location in a body and an implantation location, said method comprising the steps of:

a. providing a stent as recited in claim 56;

b. compressing the stent into its compressed configuration;

c. inserting the compressed stent into the tubular sheath;

d. delivering the compressed stent through the tubular sheath to the implantation location; and

e. withdrawing the sheath while holding the stent at the implantation location within the vessel and expanding the stent within the implantation location as the sheath is withdrawn by permitting the self-expandable stent, as the constraint of the sheath is removed to return to said expanded configuration;

whereby the stent is securely disposed in the implanted state against said body vessel.

59. (Withdrawn) A method according to claim 58, wherein said stent is comprised of a shape memory material.

60. (Withdrawn) A method according to claim 59, wherein said shape memory material is nitinol and step (b) is performed at low temperature.

61. (Withdrawn) A method according to claim 58, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

62. (Withdrawn) A prosthesis for placement in a body lumen comprising a tubular graft supported and adapted to be retained in said lumen by a stent as recited in claim 56.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

Tab 1 Judgment of the Board of Patent Appeals and Interferences in Interference No. 104,083.

Tab 2 Final Decision and Judgment of the Board of Patent Appeals and Interferences in Interference No. 104,192.

Tab 3 11/15/01 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 4 12/21/01 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 5 5/2/02 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 6 8/30/03 Memorandum Opinion and Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 7 3/25/04 Stipulation and Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 8 9/12/04 Protective Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 9 12/14/04 Joint Stipulated Request To Extend Discovery, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 10 3/31/06 Memorandum Opinion, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 11 3/31/06 Final Judgment, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 12 8/8/07 Decision, Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), U.S. Court of Appeals for the Federal Circuit, No. 2006-1434.

TAB 1

BSI-944

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 33

Filed by: Trial Section Merits Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ERIC C. MARTIN,

Junior Party
(Patent No. 5,575,817)[1],

v.

ANDREW H. CRAGG, and MICHAEL D. DAKE

Senior Party
(Application 08/461,402)[2]

Patent Interference No. 104,083

Before McKelvey, Senior Administrative Patent Judge, Schafer, Lee and Torczon, Administrative patent Judges.

PER CURIAM

JUDGMENT

Junior party Martin has failed to serve its case-in-chief testimony on priority by the time such service was due, i.e.,

[1] Filed August 19, 1994.

[2] Assigned to Boston Scientific Technology, Inc. Accorded the benefit of European applications EP9440284.9, filed February 9, 1994, and EP94401306.9, filed June 10, 1994. Also accorded the benefit of U.S. applications 08/317,763, filed October 4, 1994, and 08/312,881, filed September 27, 1994.

March 1, 1999. Based on party Martin's failure to take testimony, party Cragg has filed a miscellaneous motion for judgment or a show cause order under 37 CFR § 1.652.

In a telephone conference conducted at 2:45 PM, March 8, 1999, between administrative patent judge Jameson Lee and counsel to the respective parties, Mr. Peter Davis, counsel to party Martin, indicated that the failure to serve its case-in-chief evidence was not inadvertent and that the junior party would have no objection to the Board's entering adverse judgment against party Martin on the basis that its case-in-chief evidence was not served. Accordingly, entry of judgment against party Martin is now appropriate.

It is **ORDERED** that judgment as to the subject matter of count 1 is entered against junior party Martin and awarded in favor of senior party Cragg.

It is **ORDERED** that Eric C. Martin is not entitled to a patent containing claim 1 of his involved patent, which corresponds to count 1.

It is **ORDERED** that on this record, Andrew H. Cragg and Michael D. Dake are entitled to a patent containing their application claim 89 which corresponds to the count.

It is **ORDERED** that upon return of party Cragg's involved application to the primary examiner, party Cragg shall inform the

examiner of the administrative patent judge's decision (Paper No. 20) granting party Cragg's motion to correct inventorship (Paper No. 16), and request that the correction, inclusive of the accompanying petition and amendment, be processed and entered in the official file of party Cragg's involved application.

It is **FURTHER ORDERED** that in light of this entry of judgment, party Cragg's motion for judgment or an order to show cause why judgment should not be entered against party Martin is dismissed as moot.

Fred E. Mckelvey, Senior)
Administrative Patent Judge)
)
)
Richard E. Schafer)
Administrative Patent Judge)
) BOARD OF PATENT
) APPEALS
) AND
Jameson Lee) INTERFERENCES
Administrative Patent Judge)
)
)
Richard Torczon)
Administrative Patent Judge)

Paul F. Prestia
Ratner & Prestia
Suite 301
One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, Pennsylvania 19482-0980

Robert J. Koch
Fulbright & Jaworski
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

TAB 2

The opinion in support of the decision being entered today is not binding precedent of the Board.

Filed by: Trial Section Merits Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

Paper No. 187

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

ANDREW H. CRAGG and MICHAEL D. DAKE,

Junior Party,
(Application 08/461,402),[1]

v.

ERIC C. MARTIN,

Junior Party,
(Application 5,575,817),[2]

v.

THOMAS J. FOGARTY, JAY A. LENKER, TIMOTHY J. RYAN and KIRSTEN FREISLINGER,

Senior Party,
(Application 08/463,836).[3]

Patent Interference No. 104,192

[1] Filed 06/05/95. Accorded the benefit of application 08/317,763, filed October 4, 1994, now Patent No. 5,609,627, and application 08/312,881, filed September 27, 1994. The real party in interest is Boston Scientific Technology, Inc.

[2] Based on application 08/293,541, filed August 19, 1994.

[3] Filed June 5, 1995. Accorded the benefit of application 08/255,681, filed June 8, 1994. The real party in interest is Medtronic Aneurx, Inc.

Interference No. 104,192
Cragg v. Martin v. Fogarty

Before McKELVEY, Senior Administrative Patent Judge, and SCHAFER, LEE and MEDLEY, Administrative Patent Judges.

LEE, Administrative Patent Judge.

FINAL DECISION AND JUDGMENT

Introduction

When this interference was declared on April 23, 1998, current junior party Cragg was then senior party Goicoechea. Because of the granting of a motion to correct inventorship in related Interference No. 104,083 for application 08/461,402, the same application that is involved in this interference, co-inventors George Goicoechea, John Hudson, and Claude Mialhe were deleted and the only remaining inventors in that application are Andrew H. Cragg and Michael D. Dake. Thus, party Goicoechea became party Cragg. Any reference to party Goicoechea should be understood as a reference to party Cragg.

A decision on the parties' preliminary motions was rendered on February 11, 2000 (Paper No. 108), after which party Fogarty filed a miscellaneous motion (Paper No. 112) for leave to file, out of time, a preliminary motion 12 to attack the benefit accorded party Cragg of European Applications EP94400284.9 and EP94401306.9. The motion for leave as well as the preliminary motion 12 (Paper No. 113) were granted by a panel consisting of administrative patent judges Schafer and Lee (Paper No. 130).

The decision on Fogarty's preliminary motion 12 was adhered to on reconsideration (Paper No. 138) by a panel consisting of Senior Administrative Patent Judge McKelvey, and Administrative Patent Judges Schafer and Lee. This interference was re-declared in Paper No. 131 to change the junior/senior status of parties Cragg and Fogarty, with Cragg now being junior party.

Junior party Martin did not file a preliminary statement. It has indicated to the administrative patent judge to which this case was assigned that it did not want to participate in this interference except to "ride along" for the possibility that (1) the only interference-in-fact is determined to be between parties Cragg and Martin (a Cragg contention), and (2) that party Cragg will be deprived of its accorded benefit date (a Fogarty contention) and cannot demonstrate a sufficiently early date to prevail over Martin.

Because junior party Cragg filed no case-in-chief during the priority phase of this proceeding, it was placed under an order to show cause why judgment should not be entered against Cragg. Party Cragg requested final hearing for review of the Board's decision on Cragg's preliminary motions 1 and 2 and on Fogarty's preliminary motion 12. According to party Cragg it should not have been made a junior party and thus need not have had to put on a priority case in the first instance. Party Fogarty

requested review of the Board's decision on its preliminary motions 8 and 10. Oral argument was made on February 28, 2001, before administrative patent judges Schafer, Lee and Medley.

Findings of Fact

The below-listed findings as well as those contained in the discussion portion of this opinion are supported by a preponderance of the evidence:

1. This interference was declared on April 23, 1998, between three parties, Martin, Fogarty, and Goicoechea (now Cragg).

2. The involved patent of Martin is Patent No. 5,575,817, based on application 08/293,541, filed August 19, 1994.

3. The involved application of Cragg is application 08/461,402, filed June 5, 1995.

4. The involved application of Fogarty is application 08/463,836, filed June 5, 1995.

5. At the time of declaration of this interference, the named inventors of Cragg's involved application 08/461,402 were George Goicoechea, John Hudson, Claude Mialhe, Andrew H. Cragg, and Michael D. Dake.

6. Cragg's application 08/461,402, was also involved in a related interference, Interference No. 104,083, between parties Cragg and Martin but not Fogarty, wherein a motion to correct

inventorship was granted, deleting George Goicoechea, John Hudson, and Claude Mialhe as co-inventors, and leaving only Andrew H. Cragg and Michael D. Dake.

7. This interference was re-declared on June 2, 1999 (Paper No. 106) to reflect that only Andrew H. Cragg and Michael D. Dake are named inventors in Cragg's involved application.

8. Independent claim 1 of Martin's involved patent reads identically as the count in related Interference No. 104,083, and judgment was entered against party Martin in that interference on March 10, 1999.

9. Claim 2 of Martin's involved patent depends from claim 1, and if re-written in independent form it would read the same as the count in this interference.

10. The count of this interference reads as follows (Paper No. 16):

> An apparatus for reinforcing a bifurcated lumen comprising:
>
> a first section, configured to be positioned within the lumen, comprising:
>
> an upper limb, configured to fit within the lumen upstream of the bifurcation;
>
> a first lower limb, configured to extend into a first leg of said bifurcation when said first section is positioned in the lumen, and

> a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,
>
> and further comprising
>
> a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

11. Cragg's preliminary statement identifies only Michael D. Dake as the inventor of the subject matter of the count.

12. After the rendering of the Board's decision on preliminary motions (Paper No. 108) and subsequent service of the preliminary statement of party Cragg, Cragg filed a miscellaneous motion to amend or correct its preliminary statement to identify Andrew H. Cragg and Michael D. Dake as co-inventors of the subject matter of the count. (Paper No. 117).

13. Cragg's motion to amend was denied. (Paper No. 130). A written opinion explaining the basis of that denial followed. (Paper No. 140). Cragg requested reconsideration. The original decision was adhered to on reconsideration. (Paper No. 146).

14. Cragg has not sought review of the Board's denial of Cragg's motion to amend or correct its preliminary statement to name both Andrew H. Cragg and Michael D. Dake as inventors.

15. Upon declaration of this interference, Cragg was accorded benefit of U.S. application 08/317,763, filed October 4, 1994, European application EP94400284.9, filed February 9, 1994, and European application EP94401306.9, filed June 10, 1994. The European applications did not identify any inventor and were filed by the entity MINTEC SARL.

16. Based on representations from individuals associated with party Cragg, party Fogarty regarded as true, until the service of party Cragg's preliminary statement, that European applications EP94400284.9 and EP94401306.9 were filed by MINTEC SARL on behalf of inventors Goicoechea, Hudson, Mialhe, and Cragg. (Fogarty Preliminary Motion 12, Fact No. 5 - not disputed by Cragg).

17. Michael D. Dake made an assignment of rights, including his interests in the invention covered by Cragg's involved application relating to a bifurcated stent-graft, to MinTec, Inc., for a one time payment of eight hundred thousand U.S. dollars (U.S. $800,000) and other considerations, on May 6, 1996, with a stated effective date of April 30, 1996. (Cragg Exhibit 1025, CE-1025). The date of assignment was nearly two years and three months from the date of filing of EP94400284.9 on February 9, 1994, and nearly two years from the date of filing of EP94401306.9 on June 10, 1994.

18. Parties Cragg and Fogarty evidently treat, without dispute, that MinTec, Inc. and MINTEC SARL are related entities such that an assignment of interest to the former means the latter is an "assign."

19. Andrew H. Cragg made an assignment of rights, including his interests in the invention covered by Cragg's involved application relating to a bifurcated endoluminal prosthesis, to MINTEC, INC. on August 22, 1994. (Cragg Exhibit 1021, CE-1021). The date of assignment was six months after the date of filing of EP94400284.9 on February 9, 1994, and two months after the date of filing of EP94401306.9 on June 10, 1994.

Discussion

A. Fogarty's Preliminary Motion 12

In the "Relief Requested" portion of Fogarty's preliminary motion 12, it is stated:

> Fogarty moves under 37 CFR § 1.633(g) to deny the senior party the benefit of EP94400284.9 and EP94401306.9 on the grounds that neither application was filed by (i) the individual now identified as the inventor or (ii) on his behalf by his legal representatives or assigns.

The statutory basis of Fogarty's preliminary motion 12 is 35 U.S.C. § 119, which states, in pertinent part:

> (a) An application for patent for an invention filed in this country by **any person who has, or whose legal representatives or assigns have,** previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; . . . . (Emphasis added.)

As the motion panel's decision on reconsideration (Paper No. 138) states on page 3, a statement with which we agree and adopt herein:

> We interpret the above-quoted "any person who has, or whose legal representatives or assigns have" language as meaning that the previously filed foreign application must have been filed by the person or one who was, at the time of filing of the previously filed foreign application, already a legal representative or assign of that person. This view is necessary to ensure a link between the presently involved application and the earlier filed foreign application with respect to the particular inventor. A contrary interpretation would cause entitlement to benefit to be negotiable as a commodity between unrelated entities. Note that if party Martin or party Fogarty now assigned its involved patent or application to MINTEC, that does not and should not mean party Martin or party Fogarty's involved case should suddenly be entitled to the benefit of the earlier filing dates of party Cragg's European applications, on the basis that the European applications were previously filed by MINTEC who is now the assignee of party Martin or party Fogarty's involved patent or application.

Our view is consistent with the opinion of the Court of Customs and Patent Appeals in Vogel v. Jones, 486 F.2d 1068, 1072, 179 USPQ 425, 428 (CCPA 1973), wherein the court determined that a foreign application made by the assignee of a U.S. applicant, on behalf of one other than the United States inventor, is irrelevant to the rights of priority of the U.S. inventor. The Vogel case concerns 35 U.S.C. § 119, not 35 U.S.C. § 116 or § 120. Contrary to a suggestion by party Cragg in its reply brief at final hearing, Vogel has not been made outdated by statutory amendments to 35 U.S.C. § 116 and § 120 in 1984. The inventive entity may not always be identical between a U.S. application as a whole and an ancestral corresponding application in a foreign application. E.g., Reitz v. Inoue, 39 USPQ2d 1838, 1840 (Bd. Pat. App. & Int. 1996) ("the proposition that the inventive entity must be the same in both the foreign and the corresponding U.S. application in order to obtain benefit can no longer be accepted, if it ever was, as a hard and fast rule in view of the liberalization of the requirements for filing a U.S. application as joint inventors wrought by the 1984 amendment of 35 U.S.C. § 116."). But with regard to any particular invention at issue or involved in an interference, 35 U.S.C. § 119 still includes the language concerning filing in a foreign country by

assigns or legal representatives of the one who files for that invention in the United States.

We have reviewed Schmitt v. Babcock, 377 F.2d 994, 153 USPQ 719 (CCPA 1967), a case mentioned by Cragg during oral argument at final hearing as somehow being in support of its position, but it does not help Cragg's position. The Schmitt case, from a pre-1984 era, relates to an inconsistency or disagreement in inventorship between the U.S. application and the foreign application and a resolution of that disagreement prior to accordance of benefit. Here, inconsistency or disagreement in inventorship is not the issue. Nothing in Schmitt purports to not recognize the filing by assigns requirement of 35 U.S.C. § 119. Even if it does, that would be contrary to the Vogel case which is later in time and thus takes precedent over Schmitt.

It is not in dispute that the assignment from Michael D. Dake to Mintec, Inc. occurred subsequent to the filing of the two European applications. In its request for reconsideration (Paper No. 137) of the granting of Fogarty's preliminary motion 12, on pages 4-5, Cragg stated:

> Mintec, the applicant in the EP applications in question, was the assignee of both Dr. Cragg and Dr. Dake, albeit the assignment by Dr. Cragg came several months after those applications had been filed and the assignment by Dr. Dake came more than a year after they had been filed.

Note Cragg's exhibit CE-1025, an assignment document from Mr. Michael D. Dake to MinTec, Inc., which was executed on May 6, 1996, more than two years after the filing of EP94400284.9, and nearly two years after the filing of EP94401306.9.

Cragg's brief at final hearing does not appear to argue that under 35 U.S.C. § 119, a subsequent assignment puts an assignee in the same position as if it were a "legal representative" or "assign" of the inventor at a previous time when a foreign application for the same invention was filed by that assignee. In any event, that argument, if made, would be rejected because it ignores plain statutory language to the contrary. Cragg has not set forth evidence of legislative history which clearly indicates that the statute does not mean what it plainly says.

Two new arguments have been raised for the first time by party Cragg in its reply brief at final hearing, which should have been raised, if at all, in its opposition to Fogarty's preliminary motion 12. The first new argument is this: That the two European applications were filed by MINTEC SARL for an invention "actually made" by Michael D. Dake and Andrew H. Cragg, regardless of assignment, and that this should satisfy the filing by assign or legal representative requirement of 35 U.S.C. § 119. The second new argument is raised by the last sentence on page 10 of Cragg's reply brief, which reads: "There is no requirement

either in Section 119 or in case law that the assignment must have been perfected before the EP applications were filed in order to rely on those applications for priority purposes." The statement implies that somehow there was at least an obligation of assignment which only was not perfected or formalized until after the filing of the European applications, and that this should satisfy 35 U.S.C. § 119.

The two new arguments were not in Cragg's opposition to Fogarty's preliminary motion 12, and still not in Cragg's request for reconsideration of the motion panel's decision on Fogarty's preliminary motion 12. They further still do not appear to be contained in Cragg's principal brief at final hearing.[4] These arguments do not involve mere statutory construction, but are also fact determinative. If the new arguments were timely raised in Cragg's opposition to Fogarty's preliminary motion 12,

---

[4] In its principal brief at final hearing on page 24, Cragg states: "Michael Dake had assigned his invention to Mintec and his collaboration with Andrew Cragg on the claimed invention prior to the filing of the EP applications is acknowledged. CE1025-1." This cannot be reasonably construed as an argument that the European applications filed by MINTEC SARL were for an invention actually made by Michael D. Dake and that that would satisfy the filing by assigns requirement of 35 U.S.C. § 119. In any event, raising such an argument for the first time in the principal brief at final hearing would nonetheless be untimely. Exhibit CE1025 also does not speak of any "collaboration" in the sense of there being a common goal, but mere discussion, consultation, and communication between Michael D. Dake and one or more of Messr. Goicoechea, Cragg, and Hudson on a topic and "whatever contributions Dr. Dake may have made" (Emphasis added).

pertinent facts could have been presented by both parties and Fogarty would have had an opportunity to explore and possibly discredit Cragg's assertions. We decline to entertain new arguments which were not presented in Cragg's opposition to Fogarty's preliminary motion 12.

Accordingly, we address only those arguments of Cragg which were raised in its opposition to Fogarty's preliminary motion 12.

Cragg argues that Fogarty's preliminary motion 12 was based on the representation in Cragg's preliminary statement that Michael D. Dake was the inventor for the subject matter of the count, and yet applicable precedent indicates that preliminary statements can only be used as an effective admission of the earliest or limiting date of invention provable by the party. Cragg's argument overlooks the 1984 changes to 35 U.S.C. § 116 and a corresponding change to 37 CFR § 1.622 regarding the content of preliminary statements. Cragg's argument is rejected.

There are many precedents, including the one cited by Cragg, Dewey v. Lawton, 347 F.2d 629, 631, 146 USPQ 187, 188 (CCPA 1965), which set forth the law that the date alleged in a party's preliminary statement only constitutes a limiting date. Thus, although a party may prove a date of invention that is earlier or later than the alleged date, it cannot be entitled to a date that is prior to the alleged date. Those cases all focus on

the assertion of a date of invention and are not concerned with any identification of inventorship in the preliminary statement. Identification of inventorship did not become a requirement for preliminary statements until an amendment was made to 37 CFR § 1.622 in 1984 when Title 35, United States Code, was amended to provide that not every named inventor has to have made a contribution to every claim in a patent application. In pertinent part, 35 U.S.C. § 116 now states:

> § 116 Inventors
>
> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Thus, when an application is filed which names multiple inventors, it is not known which inventor(s) contributed to the subject matter of which claims, or to the count in an interference, even though that information may be relevant to the requirements for accordance of benefit in an interference. Rule 1.622, as amended in 1984, partially addresses that problem by requiring in a preliminary statement identification of the inventors of the subject matter of the count. It reads, in pertinent part:

> (a) A party's preliminary statement must identify the inventor who made the invention defined by each count and must state on behalf of the inventor the facts required by paragraph (a) of §§ 1.623, 1.624, and 1.625 as may be appropriate. . . .

Thus, the established precedent focusing on the effect of assertions of invention dates and not concerned with identification of inventorship are not apposite.

Cragg argues:

> Rule 629, entitled "Effect of preliminary statement," is the only rule that addresses the consequences for allegations made in a preliminary statement, such consequences being limited to dates and issues of proving priority. Importantly, Rule 629 was amended at the same time Rule 622 was amended (in 1984) to require identification of inventors in a preliminary statement, but the amendment did not create an admission as to inventorship. Rule 629(a) states:
>
> > A party shall be held to <u>any date alleged</u> in the preliminary statement. Doubts as to definiteness or sufficiency of <u>any allegation</u> in a preliminary statement . . . will be resolved against the party filing the statement by restricting the party to its <u>effective date</u> or the <u>latest date</u> of a period alleged in the preliminary statement. (Emphasis in original).

But again, this rule focuses on the effect of assertions as to a date of invention. It is concerned with ambiguities or indefiniteness in the assertion of a date of invention, and is not concerned with anything about the naming of inventors. The rule gives notice of something not so plain and obvious, i.e., that if a range of dates is asserted, then the party making the

assertion is limited to the latest of such dates. For instance, if a party asserts that its invention was made in a period from January through March of a certain year, then the earliest date of invention the party is entitled would be March 31st.

There need not be a rule to state that which is plainly so, e.g., that what a party represents to an administrative tribunal or an opposing party can be used against the party if the representation is relevant to an adjudication of the party's own rights or the rights between the parties. Party Cragg is not charged with a crime and is not being interrogated in a criminal investigation such that it must be "mirandized" -- warned that anything it says can and will be used against it in a court of law -- before it makes a usable statement. What is important is that party Cragg be given an opportunity to explain or correct any misstatement it might have made and which has been relied upon by either the tribunal or the opposing party. There was ample such opportunity in this case.

Concurrently with the filing of its opposition to Fogarty's preliminary motion 12, Cragg filed a motion under 37 CFR § 1.628 to amend or correct its preliminary statement, to name not just Michael D. Dake as the only inventor of the subject matter of the count, but Andrew H. Cragg and Michael D. Dake as co-inventors. That was a full opportunity for party Cragg to present all the

evidence it wanted to present on the issue, to demonstrate that it had made an error in only naming Michael D. Dake as the inventor of the subject matter of the count. That motion was denied on April 7, 2000, in Paper No. 130. Party Cragg requested reconsideration of that decision. The original decision was adhered to in a reconsideration decision on June 27, 2000, in Paper No. 146. Party Cragg has not sought review of that decision at final hearing.

Party Cragg further argues that the outcome here is unfair because as the original senior party it need not have filed a preliminary statement, and if it did not file a preliminary statement, then none of this would have ensued. The argument is rejected. If Cragg had not filed a preliminary statement, it would not have revealed information which ultimately led to its being deprived of benefit to the earlier filing dates of foreign applications. But this result is not unfair if, as it is here, all pertinent information were known, Cragg would not be entitled, under the law, to those earlier filing dates. Cragg had ample opportunity to show that the information it had first given was a mistake but failed to make a successful showing.

When 35 U.S.C. § 116 was amended in 1984 to permit co-inventors to be jointly listed as inventors without all of them having contributed to each and every claim in an application, a

corresponding change was made in 35 U.S.C. § 120 (relating to benefit to the earlier filing date of previously filed United States applications) to require not identity but merely an overlap of inventor(s) between the application seeking benefit and the earlier filed application. The change to 35 U.S.C. § 120 was necessary because additional or non-overlapping inventors may be present due to the inclusion of claims drawn to different subject matter. No such change was necessary, however, with respect to the requirement of 35 U.S.C. § 119 that the person who has filed for a patent on an invention (here the invention of the count) must have previously regularly filed for a patent on the same invention in a foreign country, whether it is through legal representatives or assigns. Indeed, no change was made. The contexts and requirements of 35 U.S.C. § 119 and 35 U.S.C. § 120 are different. That Michael D. Dake being a sole inventor for the subject matter of the count is not a problem under 35 U.S.C. § 120 with respect to earlier filed United States applications does not mean Cragg can expect that it should also not be a problem insofar as benefit to foreign applications are concerned. Satisfaction of requirements under 35 U.S.C. § 120 entitles a party only to the earlier filing date of a previously filed United States application, not a foreign application.

Alternatively, even assuming that Cragg's identification of Michael D. Dake as the only inventor for the subject matter of the count is a mistake and that Cragg has been allowed to amend its preliminary statement to identify both Andrew H. Cragg and Michael D. Dake as co-inventors of the subject matter of the count, that still does not help party Cragg in any meaningful way. Like Michael D. Dake, Andrew H. Cragg also did not assign his rights to MinTec, Inc. until after European application EP94400284.9 was filed on February 9, 1994, and European application EP94401306.9 was filed on June 10, 1994.

Cragg's Exhibit CE1021 is an assignment from Andrew Cragg, Claude Mialhe, George Goicoechea, and John Hudson to MINTEC, INC. It was executed by Andrew H. Cragg on August 22, 1994. Accordingly, MINTEC SARL was not an assign of either Michael D. Dake nor Andrew H. Cragg when it filed European applications EP94400284.9 and EP94401306.9. In that connection, we vacate the Board's previous finding in paragraph no. 7 of Paper No. 130 which stated: "The European applications EP94400284.9 and EP94401306.9 were filed by the assignee MINTEC SARL on behalf of inventors Andrew H. Cragg, George Goicoechea, John Hudson, and Claude Mialhe." That finding was made when the question of when Andrew H. Cragg assigned his rights was not an issue and also prior to party Cragg's representation to the Board in its request

for reconsideration of the Board's granting of Fogarty's preliminary motion 12 that Andrew H. Cragg did not assign his rights to Mintec until several months after the European applications were filed. It lacks adequate basis in the record.[5]

Cragg still further argues that because it has been accorded benefit to the September 27, 1994 filing date of application 08/312,881 (granting of Cragg's preliminary motion 7) and because that application claims foreign priority to EP94400284.9 and EP94401306.9, which claim was granted by an examiner and not challenged in this interference, it still should have benefit of the filing dates of EP94400284.9 and EP94401306.9. The argument is without merit.

As the Board's decision on reconsideration (Paper No, 138) has stated on page 6:

> Benefit to the two European applications cannot be obtained indirectly through the intermediate application 08/312,881, where the required overlap in inventor/filer is missing between the involved application and the European applications. This is not the same issue as satisfying the "filing within one year requirement of § 119" through an intermediary United States parent application.

---

[5] Our authority and discretion to vacate the previous finding does not depend on whether Fogarty has asked the Board to reconsider the finding or when the request by Fogarty was made. We dismiss Cragg's argument that Fogarty was late in asking the Board to reconsider the previous finding.

Cragg has offered no reason why the above-quoted analysis is erroneous. Here, we add the following observations.

Having benefit to the 9/27/94 filing date of application 08/312,881 means Cragg's involved application is deemed to have been filed not on the actual filing date of June 5, 1995, but on September 27, 1994. That brings Cragg's involved application much closer in time, by approximately 8 months, to any foreign application with respect to which it desires to be accorded benefit. With that shortening of the time gap, it is easier to satisfy the "within twelve months" time requirement of 35 U.S.C. § 119. It does not mean Cragg's involved application stands in the shoes or otherwise takes the place of the earlier filed domestic application. Benefit is still considered from the perspective of the claims or counts at issue in Cragg's involved application. Whether application 08/312,881 is entitled to benefit with respect to any claim contained therein is irrelevant, not at issue, and has not been determined in this proceeding. We are concerned with the claims of Cragg's involved application and the count in this interference. Fogarty is also correct in stating (Opp. Brief at 8):

> Cragg's further argument on page 24 that 35 USC § 119 priority "has not been challenged" for Serial No. 08/312,881 also is irrelevant. In the context of an interference, rights under 35 USC § 119 and § 120 arise with respect to an embodiment within the count in a

> benefit application. Hunt v. Treppschuh, 523 F.2d 1386, 187 USPQ 426 (CCPA 1975). It is thus inaccurate to speak of priority between applications without reference to claims and/or a count. (Emphasis in original.)

For the foregoing reasons, Cragg has shown no error in the motion panel's granting of Fogarty's preliminary motion 12.

B. Fogarty's Preliminary Motions 8 and 10

In a decision mailed February 11, 2000 (Paper No. 108), the motions panel denied Fogarty's preliminary motion 8 under 37 CFR § 1.633(e)(1) which sought to declare another interference between proposed new claim 62 of an uninvolved application 08/684,508 of Fogarty and claim 89 of Cragg's involved application 08/461,402, and claim 1 of Martin's involved Patent No. 5,575,817. The decision gave two grounds for denying the preliminary motion:

> (1) that the proposed new interference is barred by 35 U.S.C. § 135(b) because no claim which is the same or substantially the same as Martin's supposedly interfering patent claim 1 had been made by Fogarty within the critical one year period of 35 U.S.C. § 135(b); and
>
> (2) that Fogarty failed to demonstrate that there is interference-in-fact between the allegedly interfering claims.

Fogarty argues, first, that we misapplied the requirements of 35 U.S.C. § 135(b) and that if correctly applied, the requirements of 35 U.S.C. § 135(b) are met. Fogarty further

argues that there is no requirement in 37 CFR § 1.637 or otherwise, in connection with a preliminary motion to declare an additional interference, that the moving party has to demonstrate the existence of an interference-in-fact between the allegedly interfering claims.

1. Interference-In-Fact

According to Fogarty, it can find nothing in the interference rules which requires that in order for a preliminary motion to declare an additional interference to be granted, the preliminary motion must establish or demonstrate that an interference-in-fact exists between the claims sought to be involved in the additional interference. While there may be no express requirement, the decision on preliminary motions (Paper No. 108) on page 53, lines 18-22, states that the requirement is an implicit one:

> Secondly, it is implicit that to demonstrate entitlement to the declaration of an additional interference as is requested in Fogarty's motion, Fogarty must demonstrate that there is interference-in-fact between Goicoechea's [Cragg after deleting Goicoechea as a co-inventor] application claim 89 and claim 62 of Fogarty's uninvolved application 08/684,508. (Emphasis added.)

Party Fogarty's brief at final hearing does not explain why it is not an implicit requirement that a motion to have an

interference declared must demonstrate that the claims said to interfere with each other actually interfere with each other, i.e., that there is interference-in-fact between the allegedly interfering claims. Moreover, the very first sentence of 37 CFR § 1.637(a) is this: "A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion." (Emphasis added).

We decline to simply take a moving party's word that one of its claims interferes with one or more claims of other parties. We reiterate our holding in the decision on preliminary motions that it is an implicit requirement for a preliminary motion to have another interference declared that the motion must demonstrate that there is interference-in-fact between the allegedly interfering claims. Fogarty's brief at final hearing does not address the point of "implicit" requirement and thus has not shown that the motion panel was erroneous.

Fogarty also asserts that in any event the Board's two-way interference-in-fact analysis follows the Trial Section's precedential decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999), but that was not the criteria in October 1998 when preliminary motions were filed in this proceeding. We suppose that what Fogarty is arguing is that had it known of the two-way analysis requirement at the time it filed its preliminary

motion 8, it could have tried to demonstrate satisfaction of the two-way requirement. That is true, but as was explained in our initial decision, Fogarty has failed to explain why there is interference-in-fact, in either direction, e.g., neither from Martin's claim 1 or Cragg's claim 89 to Fogarty's claim 62, nor from Fogarty's claim 62 to Martin's claim 1 or Cragg's claim 89.[6] Note also that the declaration of an interference is a discretionary matter. See Ewing v. Fowler Car Co., 244 U.S. 1, 10-11 (1917) (explicitly rejecting the assertion of an applicant's right to declaration of an interference). It is not an abuse of discretion to not declare an interference where the moving party has not demonstrated that there is a conflict or interference-in-fact between opposing claims, regardless of whether the interference rules expressly require a demonstration of conflicting subject matter or interference-in-fact.

---

[6] The motion panel's decision observed that Fogarty's position that Cragg's claim 89 and Martin's claim 1 are unpatentable over prior art while Fogarty's claim 62 is patentable over that same prior art is contrary to the position that Fogarty's claim 62 defines the same patentable invention as Cragg's claim 89 and Martin's claim 1. Fogarty's brief at final hearing points out that the motion panel rejected Fogarty's prior art argument and that Cragg has not sought review of that issue. But at best the circumstance pointed out by Cragg only eliminates an apparent inconsistency. It does not demonstrate affirmatively that the claims define the same patentable invention.

2. 35 U.S.C. § 135(b) Bar

There is no dispute that Fogarty's amendment in its uninvolved application 08/684,508, proposing to add claim 62 to provoke an interference with claim 89 of Cragg's application 08/461,402 and claim 1 of Martin's Patent No. 5,575,817, is filed more than one year after the date of issuance of Martin's Patent No. 5,575,817. The question at issue is whether Fogarty had another claim, drawn to the same or substantially the same invention as Martin's claim 1, that was pending within one year subsequent to the date of issuance of the Martin patent. If so, claim 62 is not barred. If not, then claim 62 is barred.

In pertinent part, 35 U.S.C. § 135(b) states:

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Even though the new interference proposed by Fogarty involves claim 1 of Martin's patent, Fogarty attempted to demonstrate that it had a claim drawn to substantially the same subject matter as Martin's claim 1 by showing that it was claiming, within the critical one year period, the same invention as Martin's claim 2. Martin's claim 2 depends from claim 1 and in independent form represents the count of this interference.

In the motion panel's initial decision (Paper No. 108, pages 52-53), it was stated:

> There is no indication anywhere by any party that Fogarty's uninvolved application 08/684,508 had a claim drawn to substantially the same subject matter as Martin's claim 2. While Fogarty's involved application [08/463,836] in this interference include claims which correspond to the count which is Martin's claim 2, that does not mean Fogarty's uninvolved application 08/684,508 has at any time included a claim drawn to substantially the same subject matter as Martin's claim 2.

In its brief for final hearing, Fogarty argues that so long as it was claiming the required subject matter in some earlier application within one year of the issuance of the Martin patent, it passes muster under 35 U.S.C. § 135(b). Fogarty cites two decisions of the Court of Customs and Patent Appeals, In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981) and Corbett v. Chisholm, 568 F.2d 759, 196 USPQ 337 (CCPA 1977), two decisions of the Board of Patent Interferences, Tezuka v. Wilson, 224 USPQ 1030, 1036 (Bd. Pat. Int. 1984), Olin v. Duerr, 175 USPQ 707 (Bd. Pat. Int. 1972), and one decision of the Board of Patent Appeals and Interferences, Bowen v. Bihlmaier, 231 USPQ 662 (Bd. Pat. App. & Int. 1986), in support of its view. Fogarty points out that its uninvolved application 08/684,508 is a file wrapper continuation of application 08/255,681, to which it has been

accorded benefit in this interference and with respect to which Fogarty's involved application is a divisional application.

Cragg's opposition brief does not take up and address the issue as noted above. We find Fogarty's presentation persuasive at least in the circumstances of this case. Consequently, we no longer rely on the above-quoted portion of the motion panel's decision to deny Fogarty's preliminary motion 8.

Another issue, however, nonetheless undermines and precludes the granting of Fogarty's preliminary motion 8. As was explained in the motion panel's decision on page 53:

> [W]e disagree with Fogarty's contention that if a claim the same as Martin's claim 2 is made in an application, then a claim the same as Martin's claim 1 is also necessarily made, simply because Martin's claim 2 depends from Martin's claim 1 and thus includes all features of Martin's claim 1. The case cited by Fogarty, In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981), does not hold that so long as every feature of a claim is present in another claim then substantially the same subject matter is being claimed. In Schutte, no other difference between two claims is at issue, except for the one which the Court regarded as different in language but same in substance.

Fogarty's view leads to the erroneous result that a claim directed to patentably distinct and separately patentable subject matter as that of another claim can be regarded, at the same time, as claiming the same or substantially the same invention as that other claim. Party Cragg should note that Martin's claim 2 can be separately patentable and patentably distinct from

Martin's claim 1 even though it depends from claim 1 and undoubtedly includes every limitation of claim 1.

Because it is important that we fully address Fogarty's arguments, we reproduce portions of Fogarty's brief below (Br. at 7-8):

> Fogarty responded to Cragg's assertion of noncompliance with 35 USC § 135(b) by noting that the determination under the statute is:
>
> > [W]hether the claim which was pending had *all the material limitations* of the patent claim. *In re Schutte*, 244 F.2d 323, 113 USPQ 537 (CCPA 1981). If the pending claims had all the material limitations there is compliance with the statute even if different language is employed. [Fogarty Reply, p. 5, original italics]
>
> This principle of law has been applied for at least half a century, as is apparent from the authorities cited in the last two paragraphs on page 5 of Fogarty's Reply, i.e., *Ex parte Bowen*, 80 USPQ 106 (Bd. App. 1947), *Stalego v. Heymes*, *supra*, *Olin v. Duerr*, *supra*, and *In re Schutte*, *supra*.
>
> The decision adopted Cragg's argument but with one possible exception did not address (nor acknowledge) the precedents cited by Fogarty.
>
> The test in each of *Bowen*, *Stalego*, *Olin* and *Schutte* for determining compliance with 35 USC § 135(b) is straight forward: is a limitation of the patent claim material and if so, is it claimed by the applicant, expressly or inherently? [Footnote omitted] Application of this test to different fact patterns is seen in a comparison of the results in, for example, (i) *Corbett v. Chisholm*, *supra*, where there was no compliance because a limitation was material but was neither disclosed nor inherent, (ii) *Bowen v.*

Bihlmaier, supra where compliance was found because the material limitation was substantially claimed albeit in different language, (iii) *Connin v. Andrews*, 223 USPQ 243 (Bd. Pat. Int'f. 1984) where the limitation, while material and undisclosed, was inherent, and (iv) *Pizzurro v. Pfund*, 1 USPQ2d 1056 (Bd. Pat. Int'f. 1984) where a limitation was material and claimed.

In our view, none of the authorities Fogarty cites sets forth the principle that so long as every material limitation of a patent claim is included in an applicant's claim, then the applicant has claimed substantially the same invention as the patent claim regardless of whether the applicant's claim includes additional features which may render the applicant's claim patentably distinct or separately patentable from the patent claim.

Except for In re Tanke, 213 F.2d 551, 102 USPQ 83 (CCPA 1954), Stalego v. Heymes, 263 F.2d 334, 120 USPQ 473 (CCPA 1959), Wetmore v. Miller, 477 F.2d 960, 177 USPQ 699 (CCPA 1973), and Corbett v. Chisholm, 568 F.2d 759, 196 USPQ 337 (CCPA 1977), none of the other cases cited by Fogarty[7] for determining whether substantially the same invention was being claimed by an

---

[7] Not Rieser v. Williams, 255 F.2d 419, 118 USPQ 96 (CCPA 1958); not In re Schutte, 244 F.2d 323, 113 USPQ 537 (CCPA 1981); not Ex parte Bowen, 80 USPQ 106 (Bd. App. 1947); not Olin v. Duerr, 175 USPQ 707 (Bd. Pat. Int. 1972); not Connin v. Andrews, 223 USPQ 243 (Bd. Pat. Int. 1984); not Pizzurro v. Pfund, 1 USPQ2d 1056 (Bd. Pat. Int. 1984); not Bowen v. Bihlmaier, 231 USPQ 662 (Bd. Pat. App. & Int. 1986).

applicant discussed as an issue whether the applicant's claim contained additional features which made the application claim not substantially the same as the patent claim. Fogarty too strictly applied the principle that if every material feature of the patent claim is present in the application claim then substantially the same invention is being claimed by the applicant. The mistake lies in not recognizing that the applicant's claim may include material features that render the applicant's claim patentably distinct and separately patentable from the patent claim.

In Stalego v. Heymes, 263 F.2d 334, 335, 120 USPQ 473, 475 (CCPA 1959), the Court of Customs and Patent Appeals stated:

> Those decisions [citing to precedents] hold, in effect, that claims are not for substantially the same subject matter if one of them contains one or more material limitations which are not found in the other. Accordingly, the ultimate question to be decided in such cases is generally whether specific differences between claims are material; and that is a question which must be decided largely on the basis of the particular circumstances of each case.

In Stalego, the Court reviewed the additional features of the reissue applicant's claim and stated that it did not regard any of those limitations as important. In analyzing the additional features claimed by the reissue applicant, the Court in Stalego, 263 F.2d at 338, 120 USPQ at 477, referred to one feature as not having criticality and another as adding nothing of consequence.

The key is that the limitations of the applicant's claim at issue must be examined and are relevant too for materiality, not just the features of the patent claim. In Wetmore v. Miller, 477 F.2d 960, 177 USPQ 699, 701 (CCPA 1973), the Court of Customs and Patent Appeals cited to Rieser v. Williams, 255 F.2d 419, 118 USPQ 96 (1958) and Stalego v. Heymes, 263 F.2d 334, 120 USPQ 473 (1959), as setting forth the criterion that has been adopted by the CCPA for determining the applicability of section 135(b).

We do not regard Wetmore v. Miller as making any change to the criterion set forth in Stalego v. Heymes. Evidently, neither does Fogarty. In Wetmore, in light of the additional "fusible" limitation contained in the applicant's claim, the Court stated that the Board made too much emphasis on the fact that the patent claim applies to multiple embodiments and gave insufficient weight to embodiments in the patent using a heat fusible member. Note that the patent claim utilized means-plus-function features under 35 U.S.C. § 112, sixth paragraph. Clearly, the Court considered the technical significance of features in the applicant's claim in a comparison with the claim of the patentee.

In Corbett v. Chisholm, supra, and as Fogarty itself has noted, (Reply at 6, lines 19-25), in response to a restriction requirement the applicant elected to prosecute apparatus claims instead of method claims as the patentee had claimed and the

patentee's method could be practiced with apparatus materially different from that which the applicant elected. On that basis, the Court held that the applicant's claim and the patentee's claim defined patentably distinct inventions. Thus, the applicant was not claiming substantially the same invention as the patentee. What this suggests is that the features claimed by the applicant, over and above that which is claimed by the patentee, are important and cannot be ignored.[8]

As for In re Tanke, 213 F.2d 551, 102 USPQ 83 (CCPA 1954), it does not hold, as Fogarty argues on page 8 of its reply, that "a mere distinction in breadth or scope" does not define a separate invention. The language of In re Tanke must be read in context. What it actually conveys is that where the subject matter of the differently claimed inventions has already been determined as being directed to substantially the same invention, the specific variations are a mere distinction in breadth or scope within the same or substantially the same subject matter and thus do not define separate inventions or inventions which are not substantially the same. Note that In re Tanke states, 213 F.2d at 555, 102 USPQ at 85:

---

[8] Note also that other claims of the applicant did not include one or more material features of the patentee's claim.

> Furthermore, it should be noted that the terms "draft structure" defined by appellants' original claims 6 and 14, and the terms such as "drawbar-receiving member" and "bail-receiving member" in the appealed claims seem to be merely different expressions for essentially the same apparatus both structurally and functionally.
>
> The final conclusion of the board in this case holding that the recitation of the draft structure in the appealed claims "to be different in scope from that recited in claim 14" does not appear to legally establish that such claims are not for substantially the same subject matter.
>
> In dealing with competing claims, one group of which was drawn to a spring which assisted in both lifting and lowering certain plow beams therein defined, and another group which merely defined the function of the spring as assisting in the lifting of said beams, the Supreme Court held that **both groups of claims were for the same combination;** . . . and that such [one group of] claims should they consist of nothing more than a mere distinction in breadth or scope when compared to the [other group of] patented claims, do not define a separate invention or subject matter which is not substantially the same. Miller v. Eagle Manufacturing Co., 151 U.S. 186 [citations omitted]. (Empahsis added.)

Fogarty's claim 27, the same as original claim 27 in Fogarty's parent application 08/255,681 filed on June 8, 1994, was made within the one-year of November 19, 1996, the date of issuance of Martin's Patent No. 5,575,817. Even assuming that claim 27 includes every feature of Martin's dependent claim 2, and therefor it must include every feature of Martin's independent claim 1, that does not mean Fogarty had claimed substantially the same invention as Martin's claim 1. Martin's

independent claim 1 formed the basis of the count in related Interference No. 104,083. Martin's dependent claim 2 forms the basis of the count in this interference (See Paper No. 16). Martin's claim 2 adds a feature which is not present in Martin's claim 1. Fogarty had notice that the examiner regarded Martin's claim 2 as patentably distinct from Martin's claim 1. On page 3 of the examiner's Rule 1.609(b) submission, it is stated:

> **Distinction between Counts 1 and 2.**
>
> The important feature of count 1 [the count in Interference 104,083] is that the bifurcated prosthesis has two limbs but only one limb extends across the bifurcation and into the lumen of the vessel. Count 2 [the count in this interference] requires an additional stent to be added to the short limb, thus making a two piece graft that extends into both branches of the vessel. The count 2 is patentably distinct from count 1 for this reason.

Moreover, on page 9 of Fogarty's preliminary motion 8, Fogarty expressly recognized that the USPTO has regarded the counts of Interference No. 104,083 and this interference, represented by Martin's claims 1 and 2, as being directed to separately patentable inventions. Fogarty did not challenge that position. Instead, Fogarty stated that "[t]he same would apply to the Count of the present interference and proposed Count F-2 [for the additional interference]."

In summary, according to Fogarty, because its claim 27 was pending within the critical one-year period of 35 U.S.C. § 135(b)

and because claim 27 includes every feature of Martin's dependent claim 2, and therefore Martin's independent claim 1, Fogarty was claiming substantially the same invention as Martin's claim 1 within the critical one-year period of 35 U.S.C. § 135(b). We reject Fogarty's argument, because it regards as irrelevant whether the additional feature added by Martin's dependent claim 2 renders Martin's claim 2 patentably distinct and separaetly patentable from Martin's claim 1. If it is, as it apparently is so based on the examiner's Rule 1.609(b) submission, a position Fogarty has not disputed and in fact urged as similarly true with the count in this interference as compared to the proposed count (see Fogarty's preliminary motion 8, Section 7 on page 9), then Fogarty cannot be deemed as claiming substantially the same invention as Martin's claim 1 by way of having a claim the same as Martin's claim 2.[9] Fogarty has failed to demonstrate that it had been claiming substantially the same invention as Martin's claim 1 within the one-year period of 35 U.S.C. § 135(b).

3. Cragg's Assertion that claim 62 of Fogarty's uninvolved application is unpatentable under 35 U.S.C. § 112, first and second paragraphs

---

[9] This is in contrast with the applicant's claiming the same patentable invention as the patentee but merely adds features which are of no criticality or significance. See Stalego v. Heymes, 263 F.2d at 338, 120 USPQ at 477.

In opposing Fogarty's preliminary motion 8, Cragg never asserted that any claim of Fogarty was unpatentable for indefiniteness under 35 U.S.C. § 112, second paragraph. The brief for final hearing is not an occasion to be raising such issues for the first time. Accordingly, we decline to entertain Cragg's argument that claim 62 of Fogarty's uninvolved application is unpatentable under 35 U.S.C. § 112, second paragraph.

The motion panel's decision on preliminary motions (Paper No. 108) stated that it was manifestly apparent based on the entirety of the pleadings that claim 62 and not claim 63 of Fogarty's uninvolved application was the claim at issue in connection with Fogarty's motion to have an additional interference declared. It further found that parties Cragg and Martin would not be prejudiced by a recognition that Fogarty's motion concerned claim 62 of Fogarty's uninvolved application. While opposing Fogarty's motion, Cragg asserted that Fogarty's claims 62 and 63 are unpatentable under 35 U.S.C. § 112, first paragraph, but meaningfully discussed only the features of Fogarty's claim 63. Because nothing meaningful was presented with regard to Fogarty's claim 62, the decision on preliminary motions did not discuss Cragg's mere conclusion that Fogarty's claim 62 is unpatentable under 35 U.S.C. § 112, first paragraph.

In its opposition brief at final hearing, Cragg asserts that claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph, and makes a detailed analysis, for the first time, as to why the assertion has merit. This substantive analysis directed to Fogarty's claim 62 was not previously provided in Cragg's opposition to Fogarty's preliminary motion 8. Accordingly, such analysis will not be entertained for the first time at final hearing.

We will not compare Fogarty's claims 62 and 63 and attempt to figure out which features are common therebetween such that when Cragg discussed a certain feature of claim 63 when opposing Fogarty's preliminary motion 8 it was the same as if it were discussing a corresponding feature in Fogarty's claim 62. It was incumbent upon Cragg when opposing Fogarty's motion to clearly set forth why Fogarty's claim 62 is unpatentable under 35 U.S.C. § 112, first paragraph. It is not the role of the Board to act as an advocate for either party by making arguments, presentations, or comparisons which should have been made by the parties themselves.

Because no meaningful argument was presented by Cragg in its opposition to Fogarty's preliminary motion 8 as to why claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph, we reject Cragg's

argument at final hearing that claim 62 of Fogarty's uninvolved application 08/684,508 is unpatentable under 35 U.S.C. § 112, first paragraph.

Alternatively, even if we do consider the substantive arguments made for the first time by Cragg in its opposition brief at final hearing concerning claim 62 of Fogarty's uninvolved application 08/684,508, the arguments are without merit and do not make out a prima facie case that claim 62 of Fogarty's application 08/684,508 is without written description support in the specification.

According to Cragg, the features (1) a first leg joined to said anchor section, and (2) means for joining a second leg to said anchor section, of claim 62 of Fogarty's uninvolved application 08/684,508 are without support in the specification of application 08/684,508. Cragg contends that "Fogarty's first leg is never joined to an anchor section." Cragg explains that Fogarty's first leg is positioned within a fiber fabric liner at a location spaced below the anchor section. According to Cragg, Fogarty's second leg is also not joined to the anchor section, evidently for the same reason, and thus there can be no description for a "means for joining a second leg to said anchor section." Cragg's arguments assume that there must be direct contact between the first leg and the anchor section and between

the second leg and the anchor section. We see no reason, however, to construe claim 62 of Fogarty's uninvolved application 08/684,508 so narrowly as to require direct or immediate contact between the first and second legs and the anchor section.

Cragg does not contend that Fogarty's application 08/684,508 sets forth a special definition for the word "join" that is different from the ordinary meaning of the term. We understand the word "join" as sufficiently broad to encompass an indirect connection through an intermediate member. See, for example, Merriam-Webster's Collegiate Dictionary, Tenth Edition, Copyright © 1999, which defines "join" as follows:

> 1 a: to put or bring together so as to form a unit . . . . b: to connect (as points) by a line c: ADJOIN 2: to put or bring into close association or relationship . . . 3: to engage in (battle) 4 a: to come into the company of . . . b: to associate oneself with . . .

If the first and second legs in Fogarty's application 08/684,508 are connected to the anchor section by way of a fiber fabric liner, as Cragg apparently indicates, that does not mean the first and the second legs are not joined to the anchor section. Cragg argues that the tubular liner means cannot also be the means for joining because if it is then that would render meaningless the tubular liner means element of claim 62. The argument is without merit, because the recitation of a tubular liner means in claim 62 further specifies that the liner

structure defines a continuous flow path from the anchor section to the first leg and an opening disposed toward the second branch lumen. We note further that nothing precludes the same disclosed physical element from being the corresponding structure of two or more means-plus-function elements in a claim, provided that the structure performs the recited functions of those means-plus-function clauses.

4. Fogarty's argument that notwithstanding any 35 U.S.C. § 135(b) bar relative to patentee Martin, Fogarty is not precluded from having an interference with Cragg is without merit

Fogarty points out that in related Interference No. 104,083 involving only Martin and Cragg, specifically Cragg claim 89 and Martin claim 1, judgment has been entered against patentee Martin and thus claim 1 of Martin is as good as cancelled. According to Fogarty, the time bar under 35 U.S.C. § 135(b) is for protecting patentees from perpetually under threat of an interference proceeding initiated by applicants. Thus, Fogarty argues that because judgment has been entered against Martin's patent claim 1 in Interference No. 104,083, protection for Martin under 35 U.S.C. § 135(b) insofar as Martin's claim 1 is concerned is moot and unnecessary. Fogarty's view is that in this circumstance, application of the bar under 35 U.S.C. § 135(b) only protects another applicant, i.e., party Cragg, whose claim 89 would be shielded from a priority determination relative to Fogarty.

While 35 U.S.C. § 135(b) was primarily enacted to protect patentees, the language of the statute is not such that only a patentee may benefit from the bar. The statutory section is written in terms of a bar on the presentation of a claim, not as a bar on having an interference with a patentee. If an applicant is time-barred by 35 U.S.C. § 135(b) from presenting a certain claim, then it follows that the barred claim cannot serve as the basis of an interference with respect to another applicant whose claim for the same patentable invention is not subject to the bar. Thus, if applicable, the bar under 35 U.S.C. § 135(b) yields an incidental benefit to potentially opposing applicants. The statutory section does not restrict or limit who may benefit from application of the bar, as it only precludes the presentation of a claim. Note that 35 U.S.C. § 135(b) has been upheld as an applicable ground of rejection in ex parte prosecution before the USPTO. In re McGrew, 120 F.3d 1236, 43 USPQ2d 1632 (Fed. Cir. 1997).

Fogarty would have us read into 35 U.S.C. § 135(b) language that is not there, to turn it into a bar against having certain types of interferences instead of simply a bar on the presentation of certain claims as it so plainly reads. We decline to so distort or add to the statutory language. In our

view, if Fogarty cannot present a claim, then it cannot have an interference based on that claim with another party, whether that other party is an applicant or a patentee.

Fogarty's claim 62 was presumed by the parties as being for substantially the same invention as Martin's patent claim 1. Because it was presented outside of the one year period from the date of issuance of the Martin patent, and because Fogarty can demonstrate no other claim which was pending prior to the one year period and which was directed to substantially the same invention as Martin's claim 1, Fogarty's claim 62 is barred.

The fact that Martin's patent claim 1 has been determined unpatentable to Martin because of an adverse judgment in Interference No. 104,083 does not help Fogarty. The language of 35 U.S.C. § 135(b) refers to a claim for the same or substantially the same subject matter as "a claim of an issued patent" and does not purport to add the qualifications that such a claim must remain valid, non-canceled, patentable, non-disclaimed, and/or enforceable. We decline to read into 35 U.S.C. § 135(b) these conditions in the absence of a showing by Fogarty of a clear legislative intent to that effect. The operative word is "issued," similar to the word "born." Just as a baby cannot be un-born, an issued claim cannot become non-issued whatever its status becomes subsequent to issuance.

The public's interest is not harmed by applying 35 U.S.C. § 135(b) the way it is written and enacted by Congress. Fogarty is also under a mistaken belief that it is prejudiced by its not being successful with preliminary motion 8 to get into an interference with Cragg who has a dominating claim. Fogarty's predicament arises from its not having established, in connection with a proposed new interference involving Cragg's claim 89, interference-in-fact with respect to a Fogarty claim that is not time barred under 35 U.S.C. § 135(b). Alternatively, if Fogarty believes that Cragg's dominating claim 89 and any Fogarty claim involved in this interference define the same patentable subject matter, Fogarty could have moved to broaden out the count in this interference to the scope of Cragg's claim 89 and to have Cragg's claim 89 designated as corresponding to the revised new count. Fogarty did not take such action in this case. On these circumstances, that Cragg has a dominating claim not involved in this interference or a new interference with Fogarty does not mean Fogarty has been subjected to prejudice. A dominating claim is not necessarily a claim drawn to the same patentable invention as a dominated claim. In either case, however, with regard to Cragg's allegedly dominating claim 89 Fogarty has shown no prejudice by the denial of its preliminary motion 8.

5. Fogarty's preliminary motion 10

Fogarty's preliminary motion 10 sought to be accorded benefit of the earlier filing date of application 08/255,681, with respect to the count proposed in connection with Fogarty's preliminary motion 8. Consequently, preliminary motion 10 is contingent upon the granting of preliminary motion 8. Because Fogarty's preliminary motion 8 was properly denied, Fogarty's preliminary motion 10 was correctly dismissed as moot.

6. Cragg's Motion to Suppress

Cragg has filed a motion to suppress five exhibits FE-3001, FE-3002, FE-3004, FE-3005, and CE-1019. These are exhibits identified by party Fogarty, prior to submission of its brief at final hearing, as those which Fogarty intended to rely upon at final hearing in connection with its seeking review of the motion panel's decision of Fogarty's preliminary motion 8. According to Cragg, Fogarty may not rely on these exhibits at final hearing because Fogarty did not rely on these exhibits when filing its preliminary motion 8.

Cragg has not pointed out, and it is not immediately apparent, where in Fogarty's briefs at final hearing are references made to exhibits FE-3001, FE-3002, FE-3004, FE-3005, and CE-1019, or how the substance of these exhibits have been relied upon by Fogarty in meaningful furtherance of any argument.

Thus, with regard to these exhibits, Cragg has failed to make out a prima facie case of why the motion to suppress should be granted. Alternatively, even without suppressing these exhibits, Fogarty's arguments concerning its preliminary motions 8 and 10 have not been shown to have merit. Accordingly, Cragg's motion to suppress is denied and alternatively dismissed as moot.

C. Cragg's Preliminary Motion 1

In Cragg's preliminary motion 1, it is alleged that Fogarty's claims 41-69, not all of Fogarty's claims corresponding to the count, are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description in the specification. Fogarty's claims 42-69 depend either directly or indirectly from claim 41. Cragg's preliminary motion 1 (Paper No. 39, pp. 6-7) specifically identified the following feature of Fogarty's method claim 41 as that which is without written description:

> [I]ntroducing into a patient's vasculature an anchor section and first tubular graft of the vascular graft so that the anchor section is disposed within the primary artery and the first tubular graft is disposed within the first branch artery to form a first continuous flow path from the primary artery to the first branch artery.

According to Cragg's preliminary motion 1, the above-quoted feature of Fogarty's method claim 41 requires the anchor section and the first tubular graft to be introduced in a single step, not sequentially as is disclosed in Fogarty's specification. We

reproduce the following paragraph from page 10 of Cragg's preliminary motion 1, which clearly reveals Cragg's position:

> The Fogarty Application fails to suggest introducing an anchor section and first tubular graft in a single step. Instead, the Fogarty Application teaches (1) first introducing the bifurcated base structure so that the anchor section is positioned within a primary vessel; (2) *after the bifurcated base structure is anchored,* the first tubular graft is introduced into the first connector leg and anchored between the leg and the first branch artery; and (3) the second tubular graft is *then* inserted into the second connector section and anchored between the described second connector and the second branch artery. See Fogarty Application at Page 6, lines 1-9. (Emphasis in original).

The decision on preliminary motions rejected Cragg's argument, stating (Paper No. 108, p. 10):

> We reject Goicoechea's [Cragg's] argument because we do not read or interpret the above-quoted language of claim 41 as requiring that the anchor section and the first tubular graft be introduced "in a single step" or simulataneously. The words "in a single step" do not appear in claim 41, nor do the words "simulataneously," "concurrently," "unison," or any other term which means the same. The language is simply broadly recited and imposes no particular order for the insertion of the anchor section and the first tubular graft.

In its principal brief at final hearing, Cragg does not continue to argue that Fogarty's claim 41 requires that the anchor section and the first tubular graft be introduced in a single step or simultaneously. Rather, a new argument is made through the back door that the claim is so broad that the full

scope of what is claimed is not described in the specification. Specifically, on page 20 of its brief, in a section entitled "CRAGG MOTION 1 SHOULD BE GRANTED," Cragg states:

> If the Board adheres to its broad construction of claim 41 [that no specific sequence of introduction is required], then the Fogarty specification lacks written description for claim 41 because as discussed it only describes the sequential introduction of the anchor section and the first tubular graft but not the introduction of the anchor section and first tubular graft as a unitary structure. There is nothing in the Fogarty application to convey to those skilled in the art that Fogarty was in possession of that aspect of the invention of claim 41, if claim 41 is broadly construed as proposed.

We have again reviewed Cragg's preliminary motion 1 (Paper No. 39). Nothing therein can reasonably be considered as an alternative or contingent argument that if the Board is not persuaded by Cragg's primary argument that Fogarty's claim 41 requires the introduction of the anchor section and the first tubular graft in a single step then the claim is nonetheless not described in the specification because of undue breadth. In the case of Cragg's preliminary motion 1, the one argument actually made is the only argument made. Consequently, the issue now raised by Cragg at final hearing was neither developed and briefed by the parties during the preliminary motions stage of this interference, nor considered by the motions panel when preliminary motions were decided.

In short, Cragg wants the board to now hold Fogarty's claims 41-69 as being without written description in the specification for a reason other than that articulated and set forth by Cragg in its preliminary motion 1. We decline to consider this new argument at the final hearing stage of the proceeding. Final hearing under the interference rules is not a place to begin preliminary motions afresh. Rather, we are here to review the decision by a three-member motions panel on preliminary motions made by the parties, on the evidence and arguments which formed the basis of the decision on preliminary motions.

A new reason for granting a motion should not be considered at final hearing if it was not included in the original motion and not supported by a showing of good cause why the argument was not earlier presented. Fredkin v. Irasek, 397 F.2d 342, 346, 158 USPQ 280, 284 (CCPA 1968); Koch v. Lieber, 141 F.2d 518, 520, 61 USPQ 127, 129 (CCPA 1944); Bayles v. Elbe, 16 USPQ2d 1389, 1391 (Bd. Pat. & Int. 1990) ("It has been a longstanding practice that a party whose motion was denied cannot present at final hearing grounds not included in the original motion."). It is inappropriate for a party to present arguments in its brief which were not a part of the motion or opposition. Lawson v. Enloe, 26 USPQ2d 1594 (Bd. Pat. App. & Int. 1992).

All reasons for granting a party's desired relief should be advanced in the party's motion. A piecemeal presentation in which a party may start over with new arguments after an adverse decision has been rendered would make an orderly proceeding next to impossible to conduct. Cragg's brief offered no excuse for raising the issue of undue breadth issue so late, more than two years after the filing of Cragg's preliminary motion 1 on October 16, 1998, and ten months after the decision on preliminary motions has been rendered.

Cragg cannot credibly assert that it had no idea that Fogarty's claim 41 can possibly be construed so as to not require the introduction of the anchor section and the first tubular graft in a single step or simultaneously. As the moving party, Cragg was attempting to persuade the Board to adopt a narrow interpretation of Fogarty's claim 41, i.e., that the claim required the introduction of the anchor section and the first tubular graft in a single step or simultaneously. The mere filing of Cragg's motion reflects an awareness that the claim may not be so construed. Cragg was very much on notice that the Board may not adopt the narrow interpretation urged by Cragg. Cragg may not credibly claim to have been blind-sided by the Board's not adopting its position.

An interference is an inter partes proceeding. The Board may not suitably act as an advocate for either party, either to fill in gaps left open in either party's presentation, or to offer an alternate rationale and to try to fit the facts to that rationale, all on its own, particularly when the considerations are complex and the parties may well differ in their views. In presenting a preliminary motion for judgment, a party may not simply plead a statutory section, e.g., 35 U.S.C. § 112, first paragraph, and then rely on the Board to propose different ways in which the opponent's claims may possibly be attacked as being without written description in the specification. With regard to Cragg's preliminary motion 1, our decision on preliminary motions addressed the arguments made by Cragg. The new argument now presented by Cragg is not entitled to consideration.

For the foregoing reasons, the motions panel properly denied Cragg's preliminary motion 1.

D. Cragg's Preliminary Motion 2

We adopt in its entirety the discussion in our decision on preliminary motions (Paper No. 108), which is reproduced below, and then add a few more comments to address Cragg's brief at final hearing:

By this motion, Goicoechea [Cragg] alleges that there is no interference-in-fact between its involved application 08/461,402 and Fogarty's involved application 08/463,836. As is stated in 37 CFR § 1.601(j):

> An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

In that regard, 37 CFR § 1.601(n) states:

> Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". (Emphasis in original.)

Resolution of an interference-in-fact issue involves a two-way patentability analysis. For there to be an interference-in-fact, the parties must each have at least one claim which collectively satisfy the following: The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must

anticipate or render obvious the claimed invention of Party A.

For a showing of no-interference-in-fact, the burden is on Goicoechea as the movant, see, e.g., 37 CFR § 1.637(a), to demonstrate that all of Goicoechea's claims 55, 59, 62-65, 88 and 90 which correspond to the count do not define the same patentable invention as any one of Fogarty's claims 27-69, or that all of Fogarty's claims 21-69 do not define the same patentable invention as any one of Goicoechea's claims 55, 59, 62-65, 88 and 90. Goicoechea has attempted to show that all of its claims 55, 59, 62-65, 88 and 90 define an invention process which is neither anticipated nor obvious over any one of Fogarty's claims 27-69.

Goicoechea argues that all of its claims include a "long-leg, short-leg" concept which is absent from and not suggested by any one of Fogarty's claims corresponding to the count. Also, apparently referring to the count, the motion on page 10 explains the subject matter "supposedly" in conflict as follows:

> The invention that is the subject of this Interference relates to a two-section apparatus comprising (1) a first section configured to be positioned within a

> bifurcated lumen and (2) a second section configured to be positioned separately in a branch of the bifurcated lumen and to extend into the bifurcated lumen. A first lower limb of the first section is configured so that it extends into a first leg of the bifurcation when the first section is positioned in the lumen. A second lower limb of the first section, which is shorter than the first lower limb, is configured so that it does not extend into a second leg of the bifurcation. Accordingly, the first section defines a "long-leg, short-leg" concept. Joining two components (the first and second sections) completes the apparatus. (Emphasis in original).

Of all Goicoechea claims which correspond to the count, claims 55, 59 and 90 are independent claims. Claim 90 is identical to the count. Claim 55 embodies the "long-leg, short-leg" idea by including step (a) -- disposing said proximal portion of said bifurcated prosthesis in said blood vessel such that said first distal portion of said bifurcated prosthesis extends into said first branched vessel [long-leg], and step (c) -- attaching said second prosthesis to said extension portion of said bifurcated prosthesis such that said second prosthesis extends into said second branched vessel [short-leg]. But claim 59 is broad and does not do the same. In that regard, claim 59 is reproduced below:

> 59. A bifurcated prosthesis for use with an angeological bifurcation of a blood vessel into two branched vessels comprising a bifurcated proximal portion adapted to be disposed within said blood vessel, a distal portion adapted to extend across the bifurcation into one of the branched vessels, and a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel.

Goicoechea has not shown that claim 59 requires that whenever the proximal portion is placed within the blood vessel, the first distal portion is already attached to the proximal portion and extending from the blood vessel into a branched vessel and the second distal segment is not yet joined to the proximal portion. Indeed, claim 59 is broad enough to cover the case of two short-legs, i.e., the proximal portion is introduced into the blood vessel first, and then the first distal portion and the second distal segment are introduced in sequence, each extending into a respective branched blood vessel.

For the foregoing reasons, the patentable distinction argued by Goicoechea does not exist with respect to at least Goicoechea's independent claim 59. That alone is sufficient ground to reject Goicoechea's motion for no interference-in-fact. Additionally, with

respect to Fogarty's claims 41-69, Goicoechea is improperly reading into those claims a specific embodiment from Fogarty's disclosure rather than focusing on the language of the claims themselves. As we discussed in the context of Goicoechea's preliminary motion 1, Fogarty's independent claim 41 is broadly recited and imposes no particular manner for the insertion of the anchor section and the first tabular graft.

Given Fogarty's claim 41, it is left to the discretion of one with ordinary skill in the art just how to introduce the anchor section and the first tubular graft. One with ordinary skill in the art possesses a certain basic level of skill. See, e.g., In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) ([Applicant's] argument presumes stupidity rather than skill). A conclusion of obviousness also may be made based on the common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 163 USPQ 545, 549 (CCPA 1969). It cannot be reasonably argued that one with ordinary skill in the art is so devoid of skill and

common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined in situ, or inserted as a unitary whole. Those are the only two possibilities with regard to the insertion of the anchor section and the first tubular graft. In our view, selecting one of the two readily apparent choices would have been well within the basic level of skill and common sense possessed by one with ordinary skill in the art. Moreover, it is incumbent upon Goicoechea as the movant to establish why, given Fogarty's independent claim 41, one with ordinary skill in the art would not have known that the anchor section and the first tabular graft can be inserted as one or separately. Goicoechea set forth no persuasive reasons in that regard.

For the foregoing reasons, Goicoechea has failed to demonstrate that all of its claims 55, 59, 62-65, 88 and 90 do not define the same patentable invention as any one of Fogarty's claims 27-69. Goicoechea's preliminary motion 2 insofar as it seeks a judgment based on no interference-in-fact is denied.

As for Goicoechea's assertion that Fogarty's claims 27-69, all of Fogarty's claims which have been designated as corresponding to the count in the declaration of this interference, do not correspond to the count, Goicoechea has to satisfy the requirements set forth in 37 CFR § 1.637(c)(4). Goicoechea has to show that each of Fogarty's claims 27-69 does not define the same patentable invention as any of Goicoechea's claims and Martin's claims whose correspondence to the count Goicoechea does not dispute.

As is already discussed above in connection with Goicoechea's assertion of no interference-in-fact, Goicoechea has not established patentable distinction between Fogarty's claims 41-69 and at least Goicoechea's claim 55 and claim 90, and also between Fogarty's claims 27-69 and at least Goicoechea's claim 59. Goicoechea's preliminary motion 2 to designate Fogarty's claims 27-69 as not corresponding to the count is denied.

Nothing presented by Cragg in its brief at final hearing demonstrates that our above-quoted analysis was in error. Fogarty is correct that Cragg continues to attempt an

inappropriate reading of extraneous limitations from the specification into the claims. Although the specification is useful in interpreting claim language, as the Court of Appeals for the Federal Circuit has nonetheless stated, "the name of the game is the claim." In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). See also Giles Sutherland Rich, Extent of Protection and Interpretation of Claims--American Perspectives, 21 Int' Rev. Indus. Prop. & Copyright L, 497, 499 (1990)("The U.S. is strictly an examination country and the main purpose of the examination, to which every application is subjected, is to try to make sure that what each claim defines is patentable. To coin a phrase, the name of the game is the claims."). Reading into the claims an extraneous limitation from the specification is simply improper. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988). In E.I. de Pont, 849 F.2d at 1433, 7 USPQ2d at 1131, the Federal Circuit stated:

> It is entirely proper to use the specification to interpret what the Patentee meant by a word or phrase in the claim. See, e.g., Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir. 1985). But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By "extraneous," we mean a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.

In interpreting its own claims, Cragg in its brief at final hearing begins with a section discussing its disclosure, entitled "Cragg Discloses A *Unitary* Bifurcated Long Leg/Short Leg Prosthesis" (Emphasis in original). That section ends with this one sentence paragraph:

> The specification supports that Cragg's claims require a unitary bifurcated long leg/short leg structure, where "unitary" requires a securing means connecting the portions of the structure.

By the time Cragg made the above-quoted conclusion, it has not yet recited, reproduced, or even referred to any actual language in its claims. That Cragg's specification has a description for a certain embodiment does not necessarily mean that all of Cragg's claims must include the elements of that embodiment. If the claims do not require a unitary structure in the sense that there is a securing means which connects all the parts together, these are extraneous limitations which should not be read into the claims from the specification. Moreover, even Cragg's own specification contains no reference to the term "unitary" on which Cragg now places so much emphasis. Neither does Cragg's own specification contain any reference to words which are generally synonymous with the word "unitary," such as "integral"

or "one-piece." Thus, what Cragg is arguing in this part is many steps removed from the actual language of the claims.

The bifurcated prosthesis according to Cragg's claim 59 requires (1) a proximal portion, (2) a distal portion, and (3) a separate distal segment. Unlike Cragg's claim 55, Cragg's claim 59 does not require disposing the proximal portion in the blood vessel such that the distal portion extends into a first branched vessel. That means claim 59 is sufficiently broad to have the proximal portion put in place without regard to whether the distal portion is also placed in working position.

Cragg argues that because the word "portion" means part of a whole, the proximal portion and the distal portion must be part of a unitary structure in which the proximal portion and the distal portion is unitary or connected together by some securing means before being introduced into the blood vessel. We are not persuaded by Cragg's argument.

While the word "portion" may indeed mean part of a whole or part of something, Cragg has not submitted any evidence that the so called parts of a whole must be physically attached to each other at all times. In that regard, note that a jig-saw puzzle has many parts or portions but the many pieces don't have to be connected to each other before properly being referred to as portions of the same puzzle. Cragg has not made any meaningful

showing that the word "portion" as is ordinarily used in the English language requires an actual physical attachment. Nor has Cragg argued that its specification has specially defined the word "portion" in a manner different from its ordinary usage in the English language. Indeed, Cragg even cites to Merriam Webster's Collegiate Dictionary, 10th Ed. (1994) in its brief at final hearing for the meaning of "portion," which states: "part of something." Note that "part of something" can be conceptual and does not necessarily require a physical connection at all times. Moreover, we note that even Cragg's so called "portions" are not physically connected at all times; indisputably, they have to be preassembled prior to introduction into the patient.

Alternatively, our decision on preliminary motion held that even assuming that the "unitary" feature argued by Cragg is included in all of Cragg's claims corresponding to the count, Fogarty's claim 41 still would have rendered obvious Cragg's claimed invention such as Cragg's claim 59.

Cragg argues (Br. at 18):

> The Board states that insertion of the anchor section and the first tubular graft as a unitary whole is only one of two possibilities with regard to the insertion of the Fogarty structure. Paper No. 108, p.15. There is a third possibility ignored by the Board, namely, inserting the anchor section and both tubular grafts at the same time.

The argument is without merit. We stated (Paper No. 108, at 15) that there are "only two possibilities with regard to the insertion of the anchor section and the first tubular graft" (emphasis added). In that context, the second tubular graft is uninvolved, and how it is introduced is irrelevant.

We adopt and reiterate herein the following portion of our decision on preliminary motions concerning Cragg's preliminary motion 2 (Paper No. 108, pp. 14-16):

> Additionally, with respect to Fogarty's claims 41-69, Goicoechea is improperly reading into those claims a specific embodiment from Fogarty's disclosure rather than focusing on the language of the claims themselves. As we discussed in the context of Goicoechea's preliminary motion 1, Fogarty's independent claim 41 is broadly recited and imposes no particular manner for the insertion of the anchor section and the first tabular graft.
>
> Given Fogarty's claim 41, it is left to the discretion of one with ordinary skill in the art just how to introduce the anchor section and the first tubular graft. One with ordinary skill in the art possesses a certain basic level of skill. See, e.g., In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) ([Applicant's] argument presumes stupidity rather than skill). A conclusion of obviousness also may be made based on the common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 163 USPQ 545, 549 (CCPA 1969). It cannot be reasonably argued that one with ordinary skill in the art is so devoid of skill and common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined in situ, or inserted as a unitary whole.

> Those are the only two possibilities with regard to the insertion of the anchor section and the first tubular graft. In our view, selecting one of the two readily apparent choices would have been well within the basic level of skill and common sense possessed by one with ordinary skill in the art. Moreover, it is incumbent upon Goicoechea as the movant to establish why, given Fogarty's independent claim 41, one with ordinary skill in the art would not have known that the anchor section and the first tabular graft can be inserted as one or separately. Goicoechea set forth no persuasive reasons in that regard.

Cragg dismisses our citation to In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985) and In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969), by arguing that "[b]oth Bozek and Sovish required a disclosure in the prior art references to render the claims obvious."). It appears that Cragg completely misses the point for which we cited to those cases, i.e., that one with ordinary skill in the art is presumed to possess some logic and skill that is independent of what is disclosed in an item of prior art. Here, the starting point is Fogarty's claim 41. In that sense, Fogarty's claim 41 is the disclosure with which one with ordinary skill in the art is presented, in determining whether claims such as Cragg's claim 59 would have been obvious over Fogarty's claim 41. We agree entirely with the following two paragraphs in Fogarty's opposition brief at pages 14-15:

> Second, while Cragg would argue that *Sovish* and *Bozek* are somehow anomalous, the principle for which

> they were actually cited in the Decision has been repeatedly followed by this Board; e.g., Ex parte Research and Manufacturing Co., 10 USPQ2d 1657, 1664 (Bd. Pat. App. & Intf. 1989)(skill is presumed on the part of the artisan rather than the converse); Ex parte George, 21 USPQ2d 1058, 1060 n.1 (Bd. Pat. App. & Int. 1991) (the ability of one having ordinary skill in the art should not be underestimated); Ex parte Nesbit, 25 USPQ2d 1817, 1823 (Bd. Pat. App. & Intf. 1992)(the law presumes skill on the part of the artisan rather than the converse); Ex parte GPAC Inc., 29 USPQ2d 1401, 1405 (Bd. Pat. App. & Intf. 1993)(the skill of the art must be presumed, not the contrary).
>
> The Board thus found that the worker is not so devoid of skill or common sense that he or she would not have readily recognized that the anchor section and the first tubular graft may either be separately inserted and then joined *in situ*, or inserted as a unitary whole. (Emphasis in original).

Cragg's citation to Al-Site Corp. v. VSI Intern., Inc., 174 F.3d 1308, 1323, 50 USPQ2d 1161 (Fed. Cir. 1999) is inapposite. The Al-Site case does not stand for the proposition that Fogarty's claim 41 must be combined with another prior art reference in order to render obvious a Cragg claim which corresponds to the count. In contrast, the case supports the position that the perspective from which a prior art reference is viewed is that of a person with ordinary skill in the art.

Cragg further argues that the Board has not explained how, if Fogarty's anchor section and first tubular graft are inserted as one piece, a skilled worker would successfully position that device. According to Cragg, because the first tubular graft of

Fogarty is within the fabric liner leg 28, one ends up with an anchor section-fabric liner-tubular graft assembly that is not rigid and is not supported. The argument is misdirected and in any event unpersuasive. Here, the starting point for the obviousness analysis is not some embodiment disclosed in Fogarty's specification, but Fogarty's claim 41 which does not require placing the first tubular graft in a fabric liner leg. Moreover, in any event Cragg has submitted no meaningful evidence in the form of declaration or affidavit testimony from anyone to establish that one with ordinary skill in the art would not have known how to introduce the anchor section together with the first tubular graft. As Fogarty has pointed out in its opposition brief, attorney argument cannot take the place of evidence lacking in the record. See, e.g., Knorr v. Pearson, 671 F.2d 1368, 1373, 213 USPQ 196, 200 (CCPA 1982); Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA), cert. denied, 434 U.S. 854, 195 USPQ 465 (1977); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972).

Cragg's preliminary motion 2 further seeks to have all of Fogarty's claims corresponding to the count, i.e., claims 27-69, designated as not corresponding to the count. We ruled in the decision on preliminary motions that per 37 CFR § 1.637(c)(4), the motion is without merit because it failed to demonstrate that

each of Fogarty's claims 27-69 does not define the same patentable invention as any of Cragg's claims and Martin claims whose correspondence to the count is not disputed by Cragg.

Cragg's arguments with regard to designating Fogarty's claims as not corresponding to the count is merely a reference to its arguments alleging no interference-in-fact between Cragg's claims and Fogarty's claims. Cragg evidently is of the view that if it has demonstrated no interference-in-fact between its claims and Martin's claims on the one hand and Fogarty's claims on the other hand, then the case has been made that Fogarty's claims corresponding to the count should be designated as not corresponding to the count. But Cragg has failed to demonstrate no interference-in-fact between its claims and Martin's claims on the one hand and Fogarty's claims on the other hand. Thus, no reason has been shown to designate Fogarty's claims 27-69 as not corresponding to the count. Note also that even if there was no interference-in-fact with respect to any Fogarty claim, Fogarty's application would become uninvolved and there would be no need to designate any of its claims as not corresponding to the count.

For the foregoing reasons, Cragg has shown no error in the denial of Cragg's preliminary motion 2.

Judgment

It is

ORDERED that judgment as to the subject matter of the count is herein entered against junior party ERIC C. MARTIN and also against junior party ANDREW H. CRAGG and MICHAEL D. DAKE;

FURTHER ORDERED that the junior party ERIC C. MARTIN is not entitled to his patent claims 2-17 which correspond to the count;

FURTHER ORDERED that junior party ANDREW H. CRAGG and MICHAEL D. DAKE are not entitled to their application claims 55, 59, 62-65, 88 and 90 which correspond to the count; and

FURTHER ORDERED that a copy of this paper shall be given a paper number and filed in the respective involved application/patent of the parties.[10]

---

[10] Failure to file a copy of any agreement regarding the termination of this proceeding may render the agreement and any resulting patent unenforceable. See section 35 U.S.C. § 135(c) and 37 CFR § 1.661.

MSK

Fred E. McKelvey, Senior
Administrative Patent Judge

Richard E. Schafer
Administrative Patent Judge

Jameson Lee
Administrative Patent Judge

Sally C. Medley
Administrative Patent Judge

BOARD OF PATENT
APPEALS
AND
INTERFERENCES

Interference No. 104,192
Cragg v. Martin v. Fogarty

By Federal Express

Attorney for party Cragg:

Paul F. Prestia
RATHER & PRESTIA
Suite 301
One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, Pennsylvania 19482-0980

Attorney for party Fogarty:

Bruce M. Collins
MATHEWS, COLLINS, SHEPHERD & GOULD, P.A.
100 Thanet Circle, Suite 306
Princeton, New Jersey 08540-3674

Attorney for party Martin:

Robert J. Koch
FULBRIGHT & JAWORSKI
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Merriam-Webster's Collegiate® Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

John \'jän\ *n* [fr. ... *John*] (1856) 1 : TOILET 2 : a prostitute's ...

John \'jän\ *n* [LL *Johannes*, fr. Gk *Iōannēs*, fr. Heb *Yōḥānān*] 1 : an ... Jewish prophet who according to Gospel accounts foretold Jesus's ... messianic ministry and baptized him — called also *John the Baptist* 2 ... an apostle who according to various Christian traditions wrote the ... fourth Gospel, the three Johannine Epistles, and the Book of Revela... ; the fourth Gospel in the New Testament — see BIBLE table 4 ... any of three short didactic letters addressed to early Christians and ... 3 : any of four books in the New Testament — see BIBLE table

John Barleycorn *n* (ca. 1620) : alcoholic liquor personified

John-boat \'jän-ˌbōt\ *n* [fr. the name *John*] (1905) : a narrow flat-bottomed square-ended boat usu. propelled by a pole or paddle and used on inland waterways

John Bull \-'bu̇l\ *n* [*John Bull*, character typifying the English nation in *The History of John Bull* (1712) by John Arbuthnot] (1778) 1 : the English nation personified : the English people 2 : a typical Englishman — **John Bull-ish** \-'bu̇-lish\ *adj* — **John Bull-ish-ness** *n* — **John Bull-ism** \-li-zəm\ *n*

John Doe \-'dō\ *n* (ca. 1659) 1 : a party to legal proceedings whose true name is unknown 2 : an average man

John Do-ry \-'dōr-ē, -'dȯr-\ *n, pl* **John Dories** [earlier *dory*, fr. ME *dorre*, lit., gilded one] (1754) : a common yellow to olive food fish (*Zeus faber*) of Europe and Africa with an oval compressed body, long dorsal spines, and a dark spot on each side; *also* : a closely related and possibly identical fish (*Z. capensis*) widely distributed in southern seas

John-es's disease \'yō-nəz-\ *n* [Heinrich A. *Johne* †1910 Ger. bacteriologist] (1907) : a chronic often fatal contagious enteritis of ruminants and esp. of cattle that is caused by a bacterium (*Mycobacterium paratuberculosis*) and is characterized by persistent diarrhea and gradual emaciation

John Han-cock \'jän-'han-ˌkäk\ *n* [*John Hancock*; fr. the prominence of his signature on the Declaration of Independence] (1903) : an autograph signature

John Hen-ry \-'hen-rē\ *n* [fr. the name *John Henry*, fr. confusion with *John Hancock*] (1914) : an autograph signature

John Mark *n* : MARK 1a

johnny \'jä-nē\ *n, pl* **johnnies** [fr. the name *Johnny*] (1673) 1 *often cap* : FELLOW, GUY 2 : a short-sleeved collarless gown that is open in the back and is worn by persons (as hospital patients) undergoing medical examination or treatment

johnny-cake \'jä-nē-ˌkāk\ *n* [prob. fr. the name *Johnny*] (1739) : a bread made with cornmeal

Johnny-come-late-ly \'jä-nē-(ˌ)kəm-'lāt-lē\ *n, pl* **Johnny-come-latelies** *or* **Johnnies-come-lately** (1839) 1 : a late or recent arrival : NEWCOMER 2 : UPSTART (established families tend to hold themselves above the *Johnny-come-latelies* —William Zeckendorf †1976)

johnny-jump-up \ˌjä-nē-'jəmp-ˌəp\ *n* (1842) 1 : a common and long-cultivated European viola (*Viola tricolor*) which has short-spurred flowers usu. blue or purple mixed with white and yellow and from which most of the garden pansies are derived; *broadly* : any of various small-flowered cultivated pansies 2 : any of various American violets

John-ny-on-the-spot \'jä-nē-ˌȯn-thə-'spät, -ˌän-\ *n* (1896) : a person who is on hand and ready to perform a service or respond to an emergency

Johnny Reb \-'reb\ *n* [fr. the name *Johnny* + *reb* rebel] (1865) : a Confederate soldier

John-son-ese \ˌjän(t)-sə-'nēz, -'nēs\ *n* [Samuel *Johnson*] (1843) : a literary style characterized by balanced phraseology and Latinate diction

johnson-grass \'jän(t)-sən-ˌgras\ *n, often cap* [William *Johnston* †1859 Am. agriculturist] (1884) : a tall perennial sorghum (*Sorghum halepense*) orig. of the Mediterranean region that is widely used for forage in warm areas and often becomes naturalized

joie de vi-vre \ˌzhwä-də-'vēvr\ *n* [F, lit., joy of living] (1889) : keen or buoyant enjoyment of life

1join \'jȯin\ *vb* [ME, fr. OF *joindre*, fr. L *jungere* — more at YOKE] *vt* (13c) 1 a : to put or bring together so as to form a unit (~ two blocks of wood with glue) b : to connect (as points) by a line c : ADJOIN 2 : to put or bring into close association or relationship (~*ed* in marriage) 3 : to engage in (battle) 4 a : to come into the company of (~*ed* us for lunch) b : to associate oneself with (~*ed* the church) ~ *vi* 1 a : to come together so as to be connected (nouns ~ to form compounds) b : ADJOIN (the two estates ~) 2 : to come into close association or relationship: as a : to form an alliance b : to become a member of a group c : to take part in a collective activity (~ in singing) — **join-able** \'jȯi-nə-bəl\ *adj*

syn JOIN, COMBINE, UNITE, CONNECT, LINK, ASSOCIATE, RELATE mean to bring or come together into some manner of union. JOIN implies a bringing into contact or conjunction of any degree of closeness (*joined* forces in an effort to win). COMBINE implies some merging or mingling with corresponding loss of identity of each unit (*combined* jazz and rock to create a new music). UNITE implies somewhat greater loss of separate identity (the colonies *united* to form a republic). CONNECT suggests a loose or external attachment with little or no loss of identity (a mutual defense treaty *connected* the two nations). LINK may imply strong connection or inseparability of elements still retaining identity (a name forever *linked* with liberty). ASSOCIATE stresses the mere fact of frequent occurrence or existence together in space or in logical relation (opera is popularly *associated* with high society). RELATE suggests the existence of a real or presumed logical connection (*related* what he observed to what he already knew).

2join *n* (1825) 1 : JOINT 2 : UNION 2d

join-der \'jȯin-dər\ *n* [F *joindre* to join, fr. OF] (1601) 1 : CONJUNCTION 1 2 a (1) : a joining of parties as plaintiffs or defendants in a suit (2) : a joining of causes of action or defense b : acceptance of an issue tendered

join-er \'jȯi-nər\ *n* (14c) : one that joins: as a : a person whose occupation is to construct articles by joining pieces of wood b : a gregarious or civic-minded person who joins many organizations

join-ery \'jȯi-nə-rē, 'jȯin-rē\ *n* (1678) 1 : the art or trade of a joiner 2 : work done by a joiner

join-ing \'jȯi-niŋ\ *n* (14c) 1 : the act or an instance of joining one thing to another : JUNCTURE 2 a : the place or manner of being joined together b : something that joins two things together

1joint \'jȯint\ *n* [ME *joint*, fr. OF, fr. *jointre*] (13c) 1 a (1) : the point of contact between elements of an animal skeleton with the parts that surround and support it (2) : NODE 5b b : a part or space included between two articulations, knots, or nodes c : a large piece of meat for roasting 2 a : a place where two things or parts are joined b : a space between the adjacent surfaces of two bodies joined and held together (as by cement or mortar) c : a fracture or crack in rock not accompanied by dislocation d : the fleshy part of a cover along either backbone edge of a book e : the junction of two or more members of a framed structure f : a union formed by two abutting rails in a track including the elements (as bars and bolts) necessary to hold the abutting rails together g : an area at which two ends, surfaces, or edges are attached. 3 a : a shabby or disreputable place of entertainment b : PLACE, ESTABLISHMENT c *slang* : PRISON 2 4 : a marijuana cigarette — **joint-ed** \'jȯin-təd\ *adj* — **joint-ed-ly** *adv* — **joint-ed-ness** *n* — **out of joint** 1 a *of a bone* : having the head slipped from its socket b : at variance 2 a : DISORDERED 2a b : being out of humor : DISSATISFIED

2joint *adj* [ME, fr. MF, fr. pp. *of joindre*, fr. OF] (14c) 1 : UNITED, COMBINED (the ~ influences of culture and climate) 2 : common to two or more: as a (1) : involving the united activity of two or more (a ~ effort) (2) : constituting an activity, operation, or organization in which elements of more than one armed service participate (~ maneuvers) (3) : constituting an action or expression of two or more governments (~ peace talks) b : shared by or affecting two or more (a ~ fine) 3 : united, joined, or sharing with another (as in a right or status) (~ heirs) 4 : being a function of or involving two or more variables and esp. random variables — **joint-ly** *adv*

3joint *vb* [*2joint*] *vt* (1530) 1 : to separate the joints of (as meat) 2 a : to unite by a joint : fit together b : to provide with a joint : ARTICULATE c : to prepare (as a board) for joining by planing the edge ~ *vi* 1 : to fit as if by joints (the stones ~ neatly) 2 : to form joints as a stage in growth — used esp. of small grains

Joint Chiefs of Staff (1946) : a military advisory group composed of the chiefs of staff of the army and air force, the chief of naval operations, and sometimes the commandant of the marine corps

joint-er \'jȯin-tər\ *n* (1678) : one that joints; *esp* : any of various tools used in making joints

joint grass *n* (1835) : a coarse creeping grass (*Paspalum distichum*) with jointed stems that is used for fodder and for erosion control

joint resolution *n* (1838) : a resolution passed by both houses of a legislative body that has the force of law when signed by or passed over the veto of the executive

joint-ress \'jȯin-trəs\ *n* (1602) : a woman having a legal jointure

joint-stock company *n* (1776) : a company or association consisting of individuals organized to conduct a business for gain and having a joint stock of capital represented by shares owned individually by the members and transferable without the consent of the group

join-ture \'jȯin-chər\ *n* (14c) 1 a : an act of joining : the state of being joined b : JOINT 2 a : an estate settled on a wife to be taken by her in lieu of dower b : a settlement on the wife of a freehold estate for her lifetime

joint-worm \'jȯint-ˌwərm\ *n* (1851) : the larva of any of several small chalcid wasps (genus *Harmolita*) that attacks the stems of grain and causes swellings like galls at or just above the first joint

joist \'jȯist\ *n* [ME *joiste*, fr. MF *giste*, fr. (assumed) VL *jacitum*, fr. L *jacēre* to lie — more at ADJACENT] (13c) : any of the small timbers or metal beams ranged parallel from wall to wall in a structure to support a floor or ceiling

jo-jo-ba \hō-'hō-bə\ *n* [MexSp] (1923) : a shrub or small tree (*Simmondsia chinensis* syn. *S. californica*) of the box family of southwestern No. America with edible seeds that yield a valuable liquid wax

1joke \'jōk\ *n* [L *jocus*; perh. akin to OHG *gehan* to say, Skt *yācati* he asks] (1670) 1 a : something said or done to provoke laughter; *esp* : a brief oral narrative with a climactic humorous twist b (1) : the humorous or ridiculous element in something (2) : an instance of jesting : KIDDING (can't take a ~) c : PRACTICAL JOKE d : LAUGHING-STOCK 2 : something not to be taken seriously : a trifling matter (consider his skiing a ~ —Harold Callender) — often used in negative construction (it is no ~ to be lost in the desert)

2joke *vb* **joked**; **jok-ing** (1670) : to make jokes : JEST ~ *vt* : to make the object of a joke : KID — **jok-ing-ly** \'jō-kiŋ-lē\ *adv*

jok-er \'jō-kər\ *n* (1729) 1 a : a person given to joking : WAG b : FELLOW, GUY; *esp* : an insignificant, obnoxious, or incompetent person (a shame to let a ~ like this win —Harold Robbins) 2 : a playing card added to a pack as a wild card or as the highest-ranking card 3 a (1) : an ambiguous or apparently immaterial clause inserted in a legislative bill to make it inoperative or uncertain in some respect (2) : an unsuspected, misleading, or misunderstood clause, phrase, or word in a document that nullifies or greatly alters it b : something (as an expedient or stratagem) held in reserve to gain an end or escape from a predicament c : an unsuspected or not readily apparent fact, factor, or condition that thwarts or nullifies a seeming advantage

joke-ster \'jōk-stər\ *n* (1877) : JOKER 1

jok-ey *also* **joky** \'jō-kē\ *adj* **jok-i-er**; **-est** (ca. 1825) 1 : given to joking 2 : HUMOROUS, COMICAL 3 : amusingly ridiculous : LAUGHABLE — **jok-i-ly** \-kə-lē\ *adv* — **jok-i-ness** \-kē-nəs\ *n*

jol-li-fi-ca-tion \ˌjä-li-fə-'kā-shən\ *n* (1809) : FESTIVITY, MERRYMAKING

jol-li-ty \'jä-lə-tē\ *n, pl* **-ties** (14c) 1 : the quality or state of being jolly : MERRIMENT 2 *Brit* : a festive gathering

1jol-ly \'jä-lē\ *adj* **jol-li-er**; **-est** [ME *joli*, fr. OF] (14c) 1 a (1) : full of high spirits : JOYOUS (2) : given to conviviality : JOVIAL b : expressing, suggesting, or inspiring gaiety : CHEERFUL 2 : extremely pleasant or agreeable : SPLENDID *syn* see MERRY

TAB 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BOSTON SCIENTIFIC TECHNOLOGY, INC.,	
Plaintiff,	**Case No.** 1:01CV02015
v.	Judge: Gladys Kessler
MEDTRONIC ANEURX, INC. and ERIC C. MARTIN,	
Defendants.	

~~[PROPOSED]~~ ORDER EXTENDING TIME TO RESPOND TO COMPLAINT

Defendant Medtronic Aneurx, Inc. has moved to extend to Monday, December 17, 2001 the time in which they may answer, move or otherwise respond to the Complaint of plaintiff, Boston Scientific Technology, Inc. Plaintiff does not oppose this motion.

Accordingly, upon motion of the defendant and for good cause shown, the motion is GRANTED.

Dated: November 15, 2001

Gladys Kessler
United States District Judge

TAB 4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff,

CASE NO. 1:01CV 2015 (GK)

v.

MEDTRONIC AVE, INC.
and ERIC C. MARTIN,

Defendants.

~~[PROPOSED]~~ ORDER ALLOWING FILING OF SECOND AMENDED COMPLAINT

Plaintiff Scimed Life Systems, Inc. ("Scimed") has moved to file a Second Amended Complaint pursuant to Rule 15(a), Fed.R.Civ.P. and Local Rule 7.1. Defendant Medtronic AVE, Inc. ("Medtronic AVE") and defendant Eric C. Martin ("Martin") have consented in writing to this motion.

Accordingly, upon motion of plaintiff, the motion is GRANTED.

Dated: December 14, 2001

Honorable Gladys Kessler
United States District Judge for the
District of Columbia

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the

(1) STIPULATED JOINT MOTION TO FILE SECOND AMENDED COMPLAINT,

(2) SECOND AMENDED COMPLAINT, and

(3) [PROPOSED] ORDER ALLOWING FILING OF SECOND AMENDED COMPLAINT

were served this _____ day of December, 2001 by Hand, on the attorneys for defendants as follows:

Charles R. Work, Esq.
Donna M. Tanguay, Esq.
Mark G. Davis, Esq.
John R. Fuisz, Esq.
McDermott, Will & Emery
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096

Counsel for Medtronic AVE, Inc.

and

Robert J. Koch, Esq.
Fulbright and Jaworski
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Counsel for Eric C. Martin

TAB 5

F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff and Counterclaim-Defendant,

v.

MEDTRONIC AVE, INC.,

Defendant and Counterclaimant,

and ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

CASE NO. 1:01CV 2015 (RJL)

[PROPOSED] ORDER GRANTING SCIMED'S MOTION TO FILE UNDER SEAL SCIMED'S OPPOSITION BRIEF AND THE DECLARATION OF GIDON D. STERN IN SUPPORT OF SCIMED'S OPPOSITION TO MEDTRONIC'S REQUEST FOR ENTRY OF DEFAULT JUDGMENT AS TO SCIMED

The matter having come before the Court on plaintiff Scimed Life Systems, Inc. ("Scimed") Motion To File Under Seal (1) SCIMED'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MEDTRONIC'S MOTION FOR ENTRY OF DEFAULT JUDGMENT AS TO SCIMED ("Scimed's Opposition Memorandum) and (2) the DECLARATION OF GIDON D. STERN in support of Scimed's Opposition Memorandum and attached exhibits to be filed under seal pursuant to Local Rule 5.1(j), and the Court having fully considered the arguments in support of and in opposition to that motion:

IT IS HEREBY ORDERED THAT:

The aforementioned motion is GRANTED.

Scimed's Memorandum of Points and Authorities in Opposition to Metronic's Motion for Entry of Default Judgment As to Scimed ("Scimed's Opposition Memorandum) and the

19

DECLARATION OF GIDON D. STERN in support of Scimed's Opposition Memorandum and attached exhibits shall be filed under seal, with the exception that the memorandum, declarations and exhibits thereof shall be available to defendant, Medtronic AVE, Inc. and defendant, Eric C. Martin.

SO ORDERED.

Dated: May 1st, 2002

Honorable Richard J. Leon

United States District Judge for the
District of Columbia

LIST OF PERSONS TO BE NOTIFIED
OF ENTRY OF ORDER

Marcia H. Sundeen, Esq.
PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
Tel: (202) 496-4400
Fax: (202) 496-4444

Gidon D. Stern, Esq.
Thomas E. Friebel, Esq.
Alexandra N. Haner, Esq.
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036
Tel: (212) 790-9090
Fax: (212) 869-9741

Paul F. Prestia, Esq.
Joshua L. Cohen, Esq.
RATNER & PRESTIA
Suite 301, One Westlakes (Berwyn)
P.O. Box 980
Valley Forge, PA 19482-0908
Tel: (610) 407-0700
Fax: (610) 407-0701

Charles R. Work, Esq.
Donna M. Tanguay, Esq.
Mark G. Davis, Esq.
John R. Fuisz, Esq.
McDERMOTT, WILL & EMERY
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
Tel: (202) 756-8029
Fax: (202) 756-8087

Robert J. Koch, Esq.
FULLBRIGHT & JAWORSKI
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Tel: (202) 662-4765
Fax: (202) 662-4643

TAB 6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	**Case Number 01-2015 (RJL)**
	)	
	)	
MEDTRONIC AVE INC.,	)	
	)	
Defendant and Counterclaimant,	)	
	)	
and ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant	)	

MEMORANDUM OPINION AND ORDER
(August 30, 2003) (# 17, 22, 29, 34)

Three motions are now pending before the Court in the above captioned case. The first is the motion for default judgment by defendant and counterclaimant Medtronic AVE, Inc. ("Medtronic") against defendant and counterclaim-defendant Eric C. Martin and plaintiff and counterclaim-defendant Scimed Life Systems, Inc. ("Scimed"). Second is Scimed's motion to dismiss Medtronic's counterclaim for lack of subject matter jurisdiction. Finally, Medtronic has filed a Rule 11 motion for sanctions against Scimed, arguing that Scimed's case is a "sham," and that Scimed's papers contain material

(2)

#45

misrepresentations of fact.

For the reasons set forth below the Court hereby grants Medtronic's motion for entry of default judgment against Martin, but reserves ruling on the relief to which Medtronic is entitled. The Court denies Medtronic's motion for default judgment as to Scimed and denies Scimed's motion to dismiss Medtronic's counterclaim. Finally, the Court also denies Medtronic's Rule 11 motion for sanctions.

I. BACKGROUND

Plaintiff and counterclaim-defendant Scimed brought the instant action pursuant to 35 U.S.C. § 146 to contest the decision of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("USPTO") regarding certain patent applications for an apparatus for reinforcing a bifurcated lumen. Plaintiff Scimed and defendant and counterclaimant Medtronic each are assignees of record of two, different patent applications for a bifurcated lumen invention;[1] defendant and

[1] Andrew Cragg and Michael Dake filed an application with the USPTO regarding the bifurcated lumen apparartus on June 5, 1995. The application was assigned the serial number 08/461,402 (the "'402 application"). Cragg and Dake assigned all rights in the '402 application to Boston Scientific Technology, Inc., which merged into plaintiff Scimed. Scimed is now the present legal owner of the '402 application. Defendant and counterclaimant Medtronic was assigned its rights in a patent application for the invention by Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively referred to as party "Fogarty" in the underlying proceedings at the USPTO). That application was filed with the USPTO on June 5, 1995, and assigned the serial number 08/463,836 (the "'836 application"). Fogarty assigned its rights in the '836 application to Medtronic Aneurx, Inc., which merged into Medtronic AVE, Inc. Defendant Medtronic is now the

counterclaim-defendant Eric C. Martin was awarded a patent for the same apparatus. The USPTO declared an interference on April 23, 1998, between Scimed's patent application (the "Cragg" or "'402 application"), Medtronic's patent application (the "Fogarty" or "'836 application") and Martin's patent (the "Martin" or "'817 patent"). This interference proceeding was assigned Interference No. 104,192, and is referred to as the "'192 interference." Shortly thereafter, on September 20, 1998, Martin and Scimed entered into an option and license agreement under which Scimed had an exclusive option to purchase the rights to Martin's '817 patent. Neither Scimed nor Martin disclosed the existence of this agreement to Medtronic or the Board before the Board rendered its decision in the '192 interference.[2]

The Board yielded its decisions pertaining to the '192 interference on July 27, 2001. Scimed filed a complaint in this Court on September 25, 2001, challenging the Board's decisions that were adverse to its interests in the '402 application. Subsequently, Scimed filed an amended complaint on November 9, 2001, and a second amended complaint on December 21, 2001. Defendant Medtronic filed its answer to the second amended complaint and its counterclaim on January 2, 2002. In turn, Scimed filed its

---

legal owner of the '836 application.

[2] Scimed disclosed the existence of the agreement with Martin on March 21, 2002; Medtronic maintains that the disclosure was untimely and in violation of the pertinent regulations contained in 37 C.F.R. § 1.602. *See* Medtronic Mot. for Default Judgment at 3-4. Scimed contends that the disclosure was timely and proper. As this issue is irrelevant to the Court's resolution of the motions now before it, the Court will not consider the parties' arguments on this issue at this time.

answer to Medtronic's counterclaim on January 18, 2002, and then separately filed a motion to dismiss the counterclaim almost five months later, on May 17, 2002, arguing that this Court lacks subject matter jurisdiction to hear Medtronic's claims.

As defendant and counterclaim-defendant Martin never filed an answer to Medtronic's counterclaim, Medtronic filed a motion for default judgment against Martin on April 23, 2002.[3] In its motion for default judgment, Medtronic asked this Court not only to grant default judgment as to Martin, but also as to Scimed for Martin's failure to answer the counterclaim. According to Medtronic, because Scimed is the owner of an exclusive license to Martin's '817 patent, it has a duty under that license to litigate all claims stemming from the patent. Under Medtronic's theory, default as to Martin is default as to Scimed, even though Scimed filed a timely answer to the counterclaim.

Additionally, Medtronic brings a Rule 11 motion for sanctions against Scimed, coincidentally filed on the same day as Scimed's motion to dismiss Medtronic's counterclaim. Medtronic argues that Scimed has materially misrepresented its relationship with Martin as to whether Scimed or Martin owns all right, title, and interest in the '817 patent. Due to these alleged misrepresentations, Medtronic asks the Court to dismiss this case "as sanction for Scimed's conduct and Martin's collusion in that conduct." Medtronic Mot. for Sanctions at 10.

---

[3] The Clerk of Courts made an entry of default against Martin on the same day.

II. ANALYSIS

A. Scimed's Rule 12(b)(1) Motion to Dismiss Medtronic's Counterclaim for Lack of Subject Matter Jurisdiction is Denied

Scimed asks this Court to dismiss Medtronic's counterclaim against it and against Martin pursuant to Federal Rule of Civil Procedure 12(b)(1), claiming that the Court lacks subject matter jurisdiction under 35 U.S.C. § 146 to hear Medtronic's claim.[4] The Court disagrees, and denies Scimed's motion to dismiss.

In its counterclaim against Scimed and Martin, Medtronic asks this Court, in essence, to affirm the Board's decisions that were favorable to Medtronic, reverse those that were not, and to adjudge that Medtronic is entitled to a Letters Patent of the United States for the bifurcated lumen invention. *See* Medtronic Counterclaim at 10. At issue for purposes of Scimed's motion to dismiss are three preliminary motions filed by Fogarty — who assigned its rights in the patent application to Medtronic — with the Board. In Preliminary Motion No. 1, Fogarty argued that the claims contained in the Cragg/Scimed patent application were not patentable. Additionally, in Preliminary Motion No. 3, Fogarty challenged any benefit awarded to the Cragg/Scimed patent application due to an earlier filing date of a European patent application. Finally, Fogarty alleged in

---

[4] Section 146 provides, in relevant part, that "Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days . . . ."

Preliminary Motion No. 4 that certain claims in Martin's patent and in the Cragg/Scimed patent application were unpatentable.

The Board denied each of these motions on February 11, 2000. Six months later on August 14, 2000, the Board asked Fogarty "to file a paper identifying all [previous] motion decisions adverse to party Fogarty which Fogarty believes still must be considered at final hearing even if all issues raised by Party Cragg [Scimed] for final hearing are decided against party Cragg." Scimed Mot. to Dismiss at 2. In response, Fogarty submitted to the Board that Preliminary Motion Nos. 1, 3, 4, among others, "would become moot and need not be considered in the event judgment is entered against Cragg. (While the motions thus need not be reviewed, reference to Cragg's position and/or the Board's rulings with respect to certain of these may still be required.)." At the final hearing before the Board on the '192 interference, Preliminary Motions 1, 3 and 4 were neither discussed by Cragg or Fogarty nor briefed by the parties as part of the proceeding. When the Board rendered its decision on July 27, 2001 awarding priority of invention to the '836 or Fogarty/Medtronic application over the '402 or Cragg/Scimed application, the judgment did not address any of the issues raised in Fogarty's Preliminary Motions 1, 3 and 4. *See* Medtronic Mot. for Default Judgment, Exh. A (Board's Op. in the '192 interference).

Despite the fact that the issues were never briefed by the parties nor discussed by the Board during the final hearing proceedings on the '192 interference, Medtronic now

asks this Court to reverse the Board's rejection of Fogarty Preliminary Motions 1, 3 and 4. Both Medtronic and Scimed primarily cite the same cases as support for their arguments regarding this Court's subject matter jurisdiction to hear Medtronic's counterclaim: *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 9Fed. Cir. 1994) and *General Instrument Corp. v. Scientific-Atlanta*, 995 F.2d 209, 214 (Fed. Cir. 1993).

While the cases provide some guidance, they are not factually analogous to the situation presently before the Court. In *Conservolite*, the party bringing a Section 146 action in district court asked the court to consider an issue that the party did not raise either by preliminary motion or at the final hearing. The Federal Circuit in *Conservolite* held that a party's failure to raise the issue in a preliminary motion not only precluded it not from raising the matter at the final hearing, but also precluded district court review. *See Conservolite*, 21 F.3d at 1101. Here, the situation before the Court is different. Unlike the party that brought a Section 146 action in *Conservolite*, Medtronic raised in Preliminary Motions 1, 3, and 4 the same issues it now brings in its counterclaim, although those issues were not addressed at the final hearing.

The Court must therefore determine whether failure to introduce an issue during a final hearing on an interference — even if the issue was raised by preliminary motion — prevents a district court from considering the issue during a Section 146 action. While *Conservolite* states that "an action under § 146 is essentially a proceeding to review the action of the Board," *id.*, the Court cannot conclude that it stands for the proposition that

Scimed advances: that district courts lack subject matter jurisdiction over issues raised in preliminary motions but not addressed at a final hearing. *See* Scimed Reply at 4 (arguing that "[i]f an issue is not raised at final hearing or considered in the Board's final decision, it cannot be raised in a Section 146 action."). The Federal Circuit's opinion in *Conservolite* recognizes as much when it states that "[i]n order for an issue to have been raised adequately so that it qualifies for consideration in a Section 146 proceeding, the issue should have been raised as specified in the PTO's interference rules, for example, *through preliminary motions*, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or opposition to these motions." *Id.* at 1102 (emphasis added). Medtronic complied with that requirement by bringing Preliminary Motions 1, 3, and 4. *See* Scimed Reply at 5. Neither *Conservolite*, nor the pertinent statute and regulation, require more. *See* 35 U.S.C. § 146; 37 C.F.R. § 1.658.

Furthermore, the Court does not believe that allowing Medtronic to raise issues here that were not specifically briefed or raised during the final hearing to be inconsistent with the general principle that administrative remedies must be exhausted before seeking district court review. This is especially true because the Board itself limited the issues to be considered at the final hearing when it asked Medtronic to list only those issues Medtronic believed "still must be considered at final hearing *even if all issues raised by Party Cragg [Scimed] for final hearing are decided against party Cragg*." Scimed Mot. to Dismiss at 2. Medtronic's answer to that question was a qualified one: only if all issues

were decided against Cragg were Medtronic's preliminary motions moot. As the Board limited the issues to be considered, and because Fogarty/Medtronic raised the issues in preliminary motions which were denied by the Board, the Court concludes that permitting Medtronic to bring them here in its counterclaim is "not wasteful of administrative and judicial resources." *Conservolite*, 21 F.3d at 1102. Moreover, the Court does not find Medtronic waived its claims for the same reasons it finds that Medtronic sufficiently exhausted its administrative remedies.

For the reasons set forth above, the Court denies Scimed's motion to dismiss Medtronic's counterclaim.

B. Medtronic's Motion for Default Judgment Against Scimed is Denied

Medtronic has moved for default judgment against Scimed under the theory that Scimed was the true party-in-interest to Martin's patent, and had a duty to defend Martin in all litigation arising from that patent. Default against Martin, under the defendant's theory, is also default against the plaintiff, Scimed.

The standard in this court for granting a motion for default judgment is set forth in *Jackson v. Beech*, 636 F.2d 831 (D.C. Cir. 1980), as well as Rule 55 of the Federal Rules of Civil Procedure. In *Jackson*, the Circuit Court specifically explained that default judgment is disfavored when it stated that "modern federal procedure favors a trial on the merits over a default judgment," and that default judgment is normally reserved for a

"totally unresponsive party." *Id.* at 835. Scimed, in this case, has not been a totally unresponsive party. It has filed its opposition to the motion for default judgment and the motion for sanctions in a timely manner. It cannot be said that Scimed is being unresponsive or otherwise dilatory in defending its interests.

This Court has been unable to find support in the law for entering default judgment against a party because that party has a duty to defend a second party, who is truly in default for failing to appear or is totally responsive, under a licensing agreement. Those cases where a duty to defend has resulted in default judgment have been limited to cases between an insured and an insurer — where there has been privity in contract between those parties, and the insured, rather than a third party, sought to enforce the contract and the insurer's duty to defend. *See, e.g., Weiss v. St. Paul Fire and Marine Ins. Co.* 283 F.3d 790 (6th Cir. 2002); *Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co.*, 219 F.3d 895 (9th Cir. 2000). The Court does not find support for a third party - like Medtronic - seeking to enforce a contractual duty to defend between two other parties in order to obtain default judgment.

In any event, Medtronic has not satisfied the test set for granting default judgment set forth by this Circuit in *Combs v. Nick Garin Trucking*, 825 F.2d 437 (D.C. Cir 1987). The Court in *Combs* listed three factors to consider when setting aside default judgment, which is relevant to this Court's determination as to whether default judgment is appropriate in the first place: whether the default was willful, whether denying default

judgment would prejudice the moving party, and whether the alleged defense - here, the plaintiff's claim - is meritorious. As mentioned previously, the Court does not find willful default in this case. Scimed has been responsive to every pleading and motion. The court also does not find that denying default judgment would prejudice Medtronic at this early stage in the proceedings.

Given this Circuit's disfavor toward default judgment and strong preference for adjudication of claims on their merits, if Medtronic's position is as truly meritorious as it claims in its papers, a motion for summary judgment would be the proper procedure for addressing which party is the true party at interest in the Martin patent. A motion for default judgment should not be used as a motion in limine to prevent a party from presenting proofs or making claims.

For those reasons set forth above, Medtronic's motion for default judgment against Scimed is denied.

C. Medtronic's Motion for Default Judgment Against Defendant and Counterclaim Defendant Martin is Granted

Although the Court denies Medtronic's motion for default judgment against Scimed, the Court grants its motion for entry of default judgment as to Martin, but reserves ruling on what relief should be granted.

Applying the *Combs* test, discussed above, the Court finds that Medtronic has satisfied the first requirement by showing that Martin's default is willful. Martin has been

served with copies of the pleadings and motions filed in this case. He has not responded to Scimed's complaint, Medtronic's counterclaim, or Medtronic's motion for default judgment. However, Martin has retained counsel and filed a declaration included as Exhibit 5 to Scimed's opposition to Medtronic's motion for entry of default judgment. Given that he has retained counsel, has received copies of all pleadings and motions filed in this case, and has been a "totally unresponsive party" to this filings, *Jackson*, 636 F.2d at 836, the Court can only conclude that Martin's default is willful, rather than the result of negligence on his or his attorney's part.

As Martin has neither opposed the entry of default judgment against him nor suggested he may have a meritorious defense to Medtronic's counterclaim, the Court need not consider the remaining two prongs of the *Combs* test. Although Martin has willfully defaulted, the question of the relief to which Medtronic is entitled due to his default is a complicated one. In its motion for default judgment, Medtronic, in essence, asks this Court to reverse the Board's decisions that are adverse to Medtronic's interest in the '836 patent application, and affirm those that are favorable.[5] Entering a judgment against

---

[5] Specifically, Medtronic asks this Court to grant the following relief:

(1) Reversing the Patent Board's decision concerning Fogarty's Preliminary Motion No. 4;
(2) Reversing those portions of the Patent Board's decision of July 27, 2001 with regard to the '192 interference that are adverse to Fogarty; and
(3) Adjudging that Medtronic is entitled to a Letters Patent of the United States for the invention disclosed in the '836 Application

Martin for this relief, however, necessarily gives Medtronic the relief it seeks against Scimed as well — relief the Court denied to Medtronic when it rejected its motion for default judgment against Scimed. The Court cannot see how it is possible to enter default judgment against Martin without also simultaneously, and inadvertently, entering judgment against Scimed on the underlying issues of Medtronic's counterclaim.

While finding that Martin is in default, the Court will therefore reserve entering judgment against Martin until Medtronic's counterclaim is adjudicated on the merits.

D. Medtronic's Rule 11 Motion for Sanctions Against Scimed is Denied

Medtronic charges that Scimed has made misrepresentations to the Court that "go to the core of the dispute between the parties," Medtronic Mot. for Sanctions at 1, and requests that this Court sanction Scimed for this alleged misconduct by dismissing its complaint. The Court declines to do so.

The charges made in Medtronic's motion for sanctions and Scimed's opposition go, as Medtronic notes, to the heart of this case: which party is entitled to the rights for the bifurcated lumen patent. To resolve the motion for sanctions either in Scimed's or Medtronic's favor, the Court must necessarily resolve the merits of the underlying dispute without the benefit of discovery. To do so at this stage in the litigation would not be fair

---

Medtronic Mot. for Default Judgment at 5.

to either side. Therefore, without ruling one way or the other as to the factual allegations contained in Medtronic's motion and Scimed's opposition, the Court denies Medtronic's motion for sanctions.

III. CONCLUSION

For the reasons set forth above, the Court hereby:

GRANTS Medtronic's motion for entry of default judgment against Martin (#17), but reserves ruling on the relief to which Medtronic is entitled;

DENIES Medtronic's motion for default judgment as to Scimed (#17);

DENIES Scimed's motion to dismiss Medtronic's counterclaim (#22); and

DENIES Medtronic's motion for sanctions (#23).

In addition the Court also:

GRANTS Scimed's motion for Gideon Stern to appear *pro hac vice* for Scimed (#29); and

GRANTS Scimed's motion for leave to file the Patent Office's Decision to Pending Motions (#34).

SO ORDERED.

RICHARD J. LEON
UNITED STATES DISTRICT JUDGE

TAB 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff and Counterclaim-Defendant,

v.

MEDTRONIC AVE, INC.,

Defendant and Counterclaimant,

and

ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

Civil Action No. 1:01 CV 02015 (RJL)

STIPULATION AND ORDER

WHEREAS on July 27, 2001 the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office issued a Final Decision and Judgment ("July 27, 2001 Final Decision") in Interference No. 104,192 involving a single count and the following applications and patent of the parties:

Fogarty *et al.* United States Patent Application Serial No. 08/463,836 owned by Medtronic AVE, Inc., now known as Medtronic Vascular, Inc. ("Medtronic");

Cragg *et al.* United States Patent Application Serial No. 08/461,402 owned by Scimed Life Systems, Inc. ("Scimed"); and

Martin United States Patent No. 5,575,817 owned by Eric. C. Martin ("Martin").

WHEREAS the July 27, 2001 Final Decision awarded priority of invention to Fogarty *et al.* (Medtronic) for the subject matter of the single count;

WHEREAS on December 17, 2001 Scimed filed a Second Amended Complaint requesting review of certain rulings in the July 27, 2001 Final Decision, including the award of priority of invention to Fogarty *et al.* (Medtronic);

WHEREAS on January 2, 2002, Medtronic filed an Answer, Counterclaim and Cross-Claim requesting review of certain rulings in the July 27, 2001 Final Decision;

WHEREAS Martin did not respond to Scimed's Second Amended Complaint or to Medtronic's Answer and Cross-Claim; and

WHEREAS the Court ruled Martin in default for failure to respond to Medtronic's Cross-Claim.

NOW THEREFORE Medtronic and Scimed desire to limit and expedite the remaining issues in dispute between them and therefore agree as follows:

1. Scimed agrees that in this action it will not rely on Martin's alleged date of invention to prove a date of invention for the inventors of Scimed's Cragg *et al.* Application Serial No. 08/461,402. Medtronic and Scimed reserve all rights against Martin.

2. Medtronic agrees to withdraw, with prejudice, the Complaint in *Medtronic Vascular Inc. v. James E. Rogan and Nicholas P. Goldici*, Case No. 1:03 CV 02466, filed on November 24, 2003 in the United States District Court for the District of Columbia.

3. Medtronic and Scimed agree to limit the issues in this case to the following:

(a) Whether the Board erroneously affirmed its grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application No. 94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192;[1]

(b) If the answer to issue (a) is yes and the Court elects to determine the issue of priority, then whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192; and

(c) If the answer to issue (a) is yes and the Court elects not to determine the issue of priority, then the case may be remanded to the Board of Patent Appeals and Interferences for determination of whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192.

4. Medtronic and Scimed further agree that if the answer to issue (a) is no, then Fogarty *et al.* (Medtronic) is entitled to an award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be affirmed.

5. Medtronic and Scimed further agree that if the answer to (a) is yes and the Court determines that the answer to (b) is no, then Cragg *et al.* (Scimed) is entitled to an

[1] The applicable burdens of proof are not intended to be modified by this Agreement.

award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be reversed.

6. Medtronic and Scimed further agree that if the answer to (a) is yes and the Court determines that the answer to (b) is yes, then Fogarty *et al.* (Medtronic) is entitled to an award of priority for the subject matter of the single count in Interference No. 104,192, and the Board's award of priority to Fogarty *et al.* (Medtronic) in the July 27, 2001 Final Decision should be affirmed.

7. If either party is dissatisfied with the final judgment of the Court or the final decision of the Board of Patent Appeals and Interferences upon remand, the dissatisfied party may pursue appropriate review.

8. Medtronic and Scimed agree that amended pleadings will be filed in this case reflecting this agreement to limit the issues.

IT IS AGREED TO AND ORDERED THAT:

1. Pleadings filed in this case hereafter shall bear the following caption:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff and Counterclaim-Defendant, v. MEDTRONIC VASCULAR, INC., Defendant and Counterclaimant, and ERIC C. MARTIN, Defendant and Counterclaim-Defendant.	Civil Action No. 1:01 CV 02015 (RJL)

2. Medtronic is directed to withdraw, with prejudice, its Complaint in *Medtronic Vascular Inc. v. James E. Rogan and Nicholas P. Goldici*, Case No. 1:03 CV 02466, filed on November 24, 2003 in the United States District Court for the District of Columbia within 14 days of entry of this Order.

3. The issues as between Scimed and Medtronic in this action are limited to the following:

(a) Whether the Board erroneously affirmed its grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application

No. 94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192;

(b) If the answer to issue (a) is yes and the Court elects to determine the issue of priority, then whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192; and

(c) If the answer to issue (a) is yes and the Court elects not to determine the issue of priority, then the case may be remanded to the Board of Patent Appeals and Interferences for determination of whether Fogarty *et al.* (Medtronic) has established a date of invention prior to February 9, 1994 for the subject matter of the single count in Interference No. 104,192.

4. Scimed is directed to file a Third Amended Complaint consistent with the above statement within 14 days of entry of this Order. Medtronic is directed to file an Amended Answer and Counterclaim that is consistent with the above statements within 14 days of service of the Third Amended Complaint.

STIPULATED AND AGREED TO BY

Gidon D. Stern Thomas E. Friebel (D.C. Bar No. 290627) Cathy J. Chin Max Bachrach (D.C. Bar No. 477267) JONES DAY 222 East 41st Street New York, New York 10017 Attorneys for Scimed Life Systems, Inc.	Donna M. Tanguay (D.C. Bar No. 4496) Mark G. Davis (D.C. Bar No. 412228) John R. Fuisz (D.C. Bar No. 439698) McDERMOTT, WILL & EMERY 600 13th St., N.W. Washington, D.C. 20005-3096 Attorneys for Medtronic Vascular, Inc.

SO ORDERED

3/25/04

Honorable Richard J. Leon
UNITED STATES DISTRICT JUDGE

WDC99 853493-4.052734.0050

NYJD: 1490229.3

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the STIPULATION AND ORDER was served this 18th day of February, 2004, as follows:

Gidon D. Stern (Via Federal Express)
Thomas E. Friebel
Jones Day
222 East 41st Street
New York, NY 10017

Counsel for Plaintiff Scimed Life Systems, Inc.

Robert J. Koch (Via Hand Delivery)
Fulbright & Jaworski
801 Pennsylvania Ave., N.W.
Washington, DC 20004

Attorney for Defendant Eric C. Martin

WDC99 539970-1.052734.0050

TAB 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff,

v.

MEDTRONIC VASCULAR, INC.,

Defendant and Counterclaimant,

and ERIC C. MARTIN,

Defendant and Counterclaim-Defendant.

CASE NO. 1:01CV2015 (RJL)

PROTECTIVE ORDER

WHEREAS, Medtronic Vascular, Inc. ("Medtronic") and Scimed Life Systems, Inc. ("Scimed") each may seek discovery or documents, information or other materials which may contain or relate to, *inter alia*, valuable research, development, commercial, financial and technical proprietary data, or other information that another party or a nonparty regards as confidential, proprietary or trade secret information of another party or of a nonparty in the above-captioned action (the "Action");

IT IS HEREBY ORDERED that the following Protective Order be entered in this Action:

1. This Protective Order shall cover all information, documents, or tangible items disclosed and/or produced in connection with any discovery taken in the above-captioned action pursuant to the Federal Rules of Civil Procedure and Local Rules of Civil Practice and Procedure of the United States District Court for the District of Columbia or disclosed and/or produced in connection with any hearings or other proceedings in the above-captioned action. All

(2)

information, documents, or tangible items covered by this Protective Order shall be used only for the purposes of this litigation and shall not be used for any purpose outside of this litigation.

2. The following classification shall apply:

a. "Confidential Information" shall mean and include any document (whether in hard copy or electronic or computer readable form), thing, deposition testimony, interrogatory answers, responses to requests for admissions and/or production, or other information provided in discovery in this Action ("Discovery Material"), which contains non-public, confidential or proprietary information, whether personal or business-related, including but not limited to information that constitutes, reflects, or concerns trade secrets, know-how or proprietary data, business, financial or commercial information, the disclosure of which is likely to cause harm to the competitive position of the party making the confidential designations on Discovery Material ("the Designating Party").

b. All such Confidential designations shall be made in good faith by the Designating Party and made at the time of disclosure, production, or tender to the party receiving the same ("Receiving Party"), or at such other time as permitted by this Protective Order, provided that the inadvertent failure to so designate does not constitute a waiver of such claim, and a party may so designate Discovery Material after such Discovery Material has been produced, with the effect that such Discovery Material is thereafter subject to the protections of this Protective Order in accordance with such designation.

c. When the Designating Party produces files, records or materials for inspection, no marking need be made in advance of the inspection. All files, records, and materials subject to inspection shall be treated as "Confidential." Upon selection of files,

records, or materials for copying, the witness or producing party shall mark the copies with the appropriate classification prior to production to the inspecting party.

d. A Confidential Designation shall constitute a representation that such Discovery Material has been reviewed by an attorney for the Designating Party and that there is a valid basis for such designation.

3. The designation of Discovery Material as Confidential in the form of documents, responses to requests for admission and interrogatories, or other tangible materials (including, without limitation, CD-ROMs and tapes) other than depositions or other pretrial testimony shall be made by the Designating Party in the following manner:

a. Documents designated "Confidential" shall be so marked by conspicuously affixing the legend "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" on each page containing any Confidential Information (or in the case of computer medium on the medium and its label and/or cover) to which the designation applies. Such designated Discovery Material shall be identified by Bates number. To the extent practical, the Confidential legend shall be placed near the Bates number;

4. Confidential Information shall not include any Discovery Materials which:

a. Have been or become lawfully in the possession of the Receiving Party through communications other than production or disclosure in this Action, or in other litigation, for example, as a result of legitimate business dealings between the parties, unless those documents are covered by a separate non-disclosure or confidentiality agreement, in which case the Receiving Party may continue to use such documents in the course of its business subject to those agreements; or

b. Have been or become part of the public domain by publication or otherwise and not due to any unauthorized act or omission on the part of the Receiving Party or any of its authorized representatives or designees under this Protective Order. Nothing herein shall impose any restriction on the use or disclosure by a party or nonparty of its own documents or information.

5. Subject to paragraph 6 of this Protective Order, "Qualified Persons" having access to Discovery Material designated "Confidential Information" under this Protective Order, in this Action are:

a. McDermott, Will & Emery LLP, attorneys of record for Medtronic, their stenographic, clerical and paralegal employees whose duties and responsibilities require access to such materials;

b. Jones Day, attorneys of record for Scimed, their stenographic, clerical and paralegal employees whose duties and responsibilities require access to such materials;

c. For each party, a total of three (3) in-house counsel or patent agents (collectively "in-house counsel") whose names are listed below and who have responsibility for maintaining, defending or evaluating this litigation. The approved in-house counsel are as follows:

	Medtronic, Inc.	Scimed Life Systems, Inc.
Name Title	Sue R. Halverson Vice President, Assistant General Counsel, Litigation	Luke R. Dohmen Vice President and Chief Patent Counsel, Scimed Life Systems, Inc.
Name Title	Michael J. Jaro Chief Patent Counsel	Peter J. Gafner Director and Managing Counsel for Cardiology Litigation, Scimed Life Systems, Inc.

	Medtronic Inc.	Scimed Life Systems, Inc.
Name Title		Steven A. McAuley Patent Counsel, Scimed Life Systems, Inc.

The parties may identify additional in-house counsel who meet[s] the above criteria for inclusion on this list following execution of this Protective Order by providing written notice of the names of the additional in-house counsel to the other parties pursuant to Paragraph 7. The parties to this Action may substitute in-house counsel who meet the above criteria for good cause shown;

d. Retained independent consultants or experts, for purposes of this Action only (as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials) who are not current employees of any party to this litigation, or any direct competitor of any party to this litigation;

e. The Court, Court personnel, and stenographic and video reporters engaged in proceedings incident to this Action;

f. Outside document copying services, document coding or computerization services, trial graphics consultants, jury and trial consultants, and other entities retained by counsel of record to aid in the preparation of or in the trial of this action. The class of persons identified in this subsection does not include any independent consultants or experts as set forth in subsection (d) above. Notwithstanding any other provision of this Protective Order, access to Confidential documents shall be permitted to the entities listed in this subsection (f), without need for the completion of Exhibit A or the execution of Exhibit B. The outside counsel providing Confidential documents to an entity listed in this subsection shall be responsible for that entity's compliance with the provisions of this Protective Order.

6. Qualified Persons defined in paragraph 5(d) shall be allowed access to Confidential Information only after complying with the following procedure:

a. A Receiving Party who desires to give access to Discovery Materials designated by another party or witness as Confidential Information to a person described in paragraph 5(d) shall first provide written notice to the Designating Party of the proposed person to receive such materials. The written notice shall include a written list, in a form similar to Exhibit A hereto, setting forth the name of the person, his or her occupation, and business address, a curriculum vitae and disclosure of any past or current relationship with any party in this Action. The Designating Party shall have seven (7) business days after receipt of the written notice to object in writing to the disclosure of Confidential Information to the proposed expert or consultant. If the parties are unable to resolve that objection, the objecting party shall, no later than five (5) business days after objection, move the Court for an order prohibiting the disclosure at issue. The objecting party shall have the burden of persuasion that disclosure should not be made. A failure by the Designating Party to timely serve an objection or file a motion shall be deemed to constitute approval of disclosure to the proposed person. If a written objection and a timely motion to prohibit disclosure has been made, no Confidential Information shall be made available to the proposed expert or consultant unless and until the Court rules that disclosure can be made. This objection procedure does not apply to the approved individuals already listed in paragraph 5(c);

b. Before receiving any Confidential Information, the person shall be furnished with a copy of this Protective Order and shall acknowledge, by executing the acknowledgment form attached hereto as Exhibit B, that he or she has read this Protective Order, understands it, and agrees to be bound by it, and also expressly consents to the jurisdiction of this

Court in connection with any proceeding or hearing relating to the enforcement of this Protective Order. In-house attorneys authorized to receive Confidential Information shall not be required to execute the acknowledgment form, but shall otherwise be bound by its terms;

c. Outside counsel for each Receiving Party shall retain a copy of each such written list (Exhibit A) and acknowledgment form (Exhibit B), and shall serve opposing counsel with a copy of these documents upon request and thereafter upon revision of such documents.

7. Confidential Information and the substance or content thereof, including any notes, memoranda or other similar documents relating thereto, shall be used by a Receiving Party and its authorized representative or designees under this Protective Order solely for the purpose of this Action and any appeals therefrom, and shall not be made available, or disclosed, or summarized to any persons, including the parties, other than as permitted by paragraphs 5-6 of this Protective Order. Confidential Information shall be maintained by the Receiving Party under the overall supervision of outside counsel.

8. Any person in possession of Confidential Information shall exercise care with regard to the storage, custody or use of such Confidential Information in order to ensure that the Confidential nature of the same is maintained.

9. If Confidential Information is disclosed to anyone other than in a manner authorized by this Protective Order, the party responsible for such disclosure must: (a) immediately bring all pertinent facts relating to such disclosure (including to whom the disclosure was made and the specific documents or information disclosed) to the attention of the Designating Party of the Confidential Information; (b) retrieve such information, or, where the information is not retrievable, certify that it has been lost or destroyed and that no copies are within the possession, custody or control of unauthorized recipients of the information,

documents, or materials; and (c) request that the person to whom the information was disclosed sign an acknowledgement in the form of Exhibit B; and (d) prevent further disclosure.

10. When Confidential Information is discussed, quoted or referred to in any deposition, the disclosing party shall ensure that only persons permitted by paragraph 5 of this Protective Order to have access to such Information are present. During any hearing or trial persons not authorized to have access to confidential information shall be asked to leave the courtroom when such Confidential Information is being published. The confidentiality of evidence not published in open court during any hearing or trial is not waived.

11. During the course of preparing for a deposition or testimony, a fact deponent/witness may be shown Confidential Information from another party's documents strictly limited to those documents which on their face reveal that they were authored or received in the normal course of business by the deponent/witness. Use of Confidential Information during a deposition shall be subject to compliance with this Order.

12. Any deposition transcript containing Confidential Information shall be marked on the cover as "Confidential Pursuant To Protective Order," and shall indicate as appropriate within the transcript what information has been so designated. Whenever possible, the stenographic reporter shall be requested prior to the deposition (where the attorneys have reason to believe the testimony will contain Confidential Information) or when the Confidential Information is disclosed (when not previously anticipated) to separate those portions of the transcript containing Confidential Information and separately bind it from the non-confidential portions. However, a party may designate any portion or all (if appropriate) of the transcript as containing Confidential Information by so advising, with reasonable precision as to the affected testimony, the deposition reporter, who shall accordingly indicate in the deposition transcript

what portion(s) of the testimony (or exhibits thereto) were so designated, or by so advising all other parties in writing, and with page and line designations, within ten (10) business days after receipt of the transcript. Until ten (10) business days have passed after the receipt of any transcript, that entire transcript shall be deemed to be Confidential. In the event of disagreement about the confidential status of a deposition transcript, it shall continue to be treated as Confidential until the Court rules otherwise.

13. Any Designating Party may redact from the documents and things it produces (1) sensitive matter not relevant to the subject matter of this litigation, and (2) matter that the Designating Party claims is subject to attorney-client privilege, work product immunity, a legal prohibition against disclosure, private patient medical data, or other privilege or immunity. The Designating Party shall mark each document or thing where matter has been redacted with a legend stating "REDACTED FOR RELEVANCE" or "REDACTED FOR PRIVILEGE" as appropriate, or a comparable notice. Where a document consists of more than one page, at least the first page and each page on which information has been redacted shall be so marked. The Designating Party shall preserve an unredacted version of each such document. This provision shall not affect any obligation to provide a log of information redacted or otherwise withheld on the basis of attorney-client privilege, work product immunity, a legal prohibition against disclosure, or other privilege or immunity.

14. Any pleading, paper or other document filed in this action which contains or discloses Confidential Information shall be filed under seal and shall be maintained under seal according to the terms of this Protective Order or as otherwise determined by the Court. When filing pleadings, motions, briefs, discovery materials, and other papers, which contain Confidential Information, the party so filing shall designate the following on the first page of

filed documents: "Filed Under Seal - Subject To Protective Order - Contains Confidential Material - May Only Be Opened by Order of the Court" and shall otherwise comply with the Court's order on the subject.

15. Entering into, agreeing to and/or producing or receiving Confidential Information or otherwise complying with the terms of this Protective Order shall not:

a. Operate as an admission by any party that any Discovery Material designated as Confidential Information contains or reflects trade secrets or any other type of confidential or proprietary information entitled to protection under applicable law;

b. Prejudice in any way the rights of any party to object to the production of documents it considers not subject to discovery, or operate as an admission by any party that the restrictions and procedures set forth herein constitute adequate protection for any particular information deemed by any party to be Confidential Information;

c. Prejudice in any way the rights of any party to object to the authenticity or admissibility into evidence of any document, testimony or the evidence subject to this Protective Order;

d. Prejudice in any way the rights of any party to seek a determination by the Court whether any Discovery Material or Confidential Information should be subject to the terms of this Protective Order;

e. Prejudice in any way the rights of any party to petition the Court for a further protective order, or modification or amendment of this order, relating to any purportedly Confidential Information;

f. Prejudice in any way the rights of any party to petition the Court for permission to disclose or use particular Confidential Information more broadly than would otherwise be permitted by the terms of this Protective Order; or

g. Prevent any Designating Party from agreeing to alter or waive the provisions or protections provided for herein with respect to any particular Discovery Material designated as Confidential Information by that party.

16. If a party disagrees with any designation of Confidential Information, such party shall first make its objection known to the producing party and request a change of designation. The parties shall first try to resolve such dispute in good faith on an informal basis. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court no sooner than five (5) days following the service of a written notice of disagreement. The burden of proving that information has been properly designated as Confidential is on the party making such designation. Until a determination by the Court, the information in issue shall be treated as originally designated by the producing party. Any failure to object to any material being designated as Confidential shall not be construed as an admission by any non-designating party that the material constitutes or contains a trade secret or other confidential information.

17. All provisions of this Protective Order restricting the use of information obtained during discovery shall continue to be binding on the parties and all persons who have received information under this Protective Order, after the conclusion of this action, including all appeals, until further Order of the Court, unless the parties agree otherwise in writing. Upon conclusion of this matter, outside experts and consultants shall return or destroy all Confidential Information in their possession, including notes or other documents prepared relating to such information. Any and all originals and copies of Discovery Materials designated Confidential (including all

originals or copies in the possession of any outside experts or consultants, and any notes or other documents prepared by such persons relating to any Confidential Materials) shall, at the request of the producing party, be returned to the party within sixty (60) days after a final judgment herein or settlement of this Action, or, at the option of the producing party, destroyed in that time frame, except that outside counsel for each party may maintain in its files one copy of each pleading filed with the Court, each deposition transcript together with the exhibits marked at the deposition, and documents constituting work product which were internally generated based upon or which include Confidential Information. In the event that outside counsel maintains such documents, it shall not disclose material containing any type of Confidential Information to another party absent subpoena or court order. In the event that documents are returned to or destroyed at the request of the producing party, the other party or its outside counsel shall certify in writing that all such documents have been returned or destroyed, as the case may be.

18. By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Protective Order who becomes subject to a motion to disclose another party's information designated Confidential Information pursuant to this Protective Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed. If any Receiving Party is subpoenaed in another action, served with a demand in another action to which it is a party, or served with any other legal process by one not a party to this action seeking information which was produced or designated as Confidential by someone other than the receiving party, the receiving party shall transmit a copy of such subpoena, demand, or legal process, by hand or facsimile transmission, within three

business days of receipt of such subpoena, demand, or legal process, to the producing party and prepare timely objections to production of the Confidential Information. Should the person seeking access to the Confidential Information take action against the receiving party or anyone else covered by this Protective Order to enforce such a subpoena, demand, or other legal process, the receiving party shall respond by setting forth the existence of this Protective Order. Nothing herein shall be construed as requiring the receiving party or anyone else covered by this Protective Order to challenge or appeal any order requiring production of information covered by this Protective Order, subject itself to any penalties for noncompliance with any legal process or order, or seek any relief from this Court.

19. The inadvertent production in discovery of any privileged or otherwise protected or exempted information, as well as the inadvertent production in discovery of information without an appropriate designation of confidentiality, shall not be deemed a waiver or impairment of any claim or privilege or protection including but not limited to the attorney-client privilege, the protection afforded to work-product materials or the subject matter thereof, or the confidential nature of any such information, provided that the producing party shall immediately notify the Receiving Party in writing when inadvertent production is discovered. Upon receiving written notice from the producing party that privileged information or work-product material has been inadvertently produced, all such information, and all copies thereof, shall be returned to the producing party, and the Receiving Party and counsel shall not use such information for any purpose. Any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information shall immediately be destroyed.

20. Any violation of the terms of this Protective Order shall be punishable by money damages, interim or final injunctive or other equitable relief, sanctions, contempt of court

citation, or such other or additional relief as deemed appropriate by the Court. The foregoing remedies shall be in addition to any other common law or statutory relief available for violation of the terms of this Protective Order.

21. Discovery Material produced by third parties may be designated by them as Confidential Information pursuant to the terms of this Protective Order and, when so designated, shall be treated by the parties in conformance with this Protective Order.

22. The Court retains jurisdiction subsequent to settlement or entry of judgment to enforce the terms of this Protective Order.

AGREED:

OF COUNSEL:

Donna M. Tanguay (D.C. Bar No. 414496)
John R. Fuisz (D.C. Bar No. 439698)
Stephen K. Shahida (D.C. Bar No. 454970)
McDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8000

Attorneys for Defendant and Counterclaimant
Medtronic Vascular, Inc.

Sep. 9, 2004

OF COUNSEL:

Gidon D. Stern
Thomas E. Friebel (D.C. Bar No. 290627)
Catharina J. Chin Eng
JONES DAY
222 East 41st Street
New York, NY 10017

Max Bachrach (D.C. Bar No. 477267)
JONES DAY
51 Louisiana Avenue N.W.
Washington, D.C. 20001-2113
(202) 496-4456

Attorneys for Plaintiff
Scimed Life Systems, Inc.

Sept 8, 2004

The parties, having entered into the above stipulation, and having shown good cause herein, it is SO ORDERED:

Leon, J.

9/12/04

EXHIBIT A

LIST OF QUALIFIED PERSONS, paragraphs 5(c) and 5(d)

NAME	BUSINESS ADDRESS	OCCUPATION/ TITLE	GOVERNING PARAGRAPH	DATE IDENTIFIED

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC., Plaintiff, v. MEDTRONIC VASCULAR, INC., Defendant and Counterclaimant, and ERIC C. MARTIN, Defendant and Counterclaim-Defendant.	CASE NO. 1:01CV2015 (RJL)

I hereby certify (i) my understanding that Discovery Material and/or Confidential Information are being provided to me pursuant to the terms and restrictions of the Protective Order (the "Order") entered by the United States District Court for the District of Columbia (the "District Court") in this Action, and (ii) that I have read the Order. I understand the terms of the Order, I agree to be fully bound by the Order, and I hereby submit to the jurisdiction of the District Court for purposes of enforcement of the Order. I understand that violation of the Order may be punishable by contempt of court, or other sanction, penalty, injunction, or damages available at law or equity.

Dated: _____ Signature: _____

Name: _____

Address: _____

_____

_____

TAB 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,

Plaintiff

v.

MEDTRONIC VASCULAR, INC., and ERIC C. MARTIN

Defendants

Case No. 1:01 CV 02015 RJL

JOINT STIPULATED REQUEST TO EXTEND DISCOVERY

Plaintiff Scimed Life Systems, Inc. and Defendant Medtronic Vascular, Inc. jointly and respectfully request this Court to extend the discovery deadline and all subsequent dates in this case by two months.

The parties have engaged in written discovery with all deliberate speed. In order to avoid any duplication of efforts, however, depositions have not taken place pending the completion of all document production. Given the number of witnesses located in and outside the United States and the fast approaching holiday season, the parties jointly propose the following extensions of the dates set forth in the Court's Scheduling Order:

Close of factual discovery	February 1, 2005
Deadline for filing discovery motions	February 15, 2005
Service of expert reports on those issues as to which a party has the burden of proof	March 14, 2005

(M)

Service of expert reports on those issues to which opposing party has the burden of proof	April 15, 2005
Completion of expert depositions	May 25, 2005
Deadline for filing summary judgment motions	June 22, 2005

(The parties are not precluded from filing summary judgment motions prior to this date.)

Opposition to summary judgment motions	21 days after filing of motion
Reply memorandum in support of summary judgment motions	14 days after filing of opposition
Hearing on summary judgment motions	To be scheduled by Court
The pretrial conference	On or after July 25, 2005

Respectfully submitted,

Friebel / SKS

Gidon D. Stern
Thomas E. Friebel (D.C. Bar No. 290627)
Catharina J. Chin Eng
JONES DAY
222 East 41st Street
New York, NY
Attorneys for Plaintiff
Scimed Life Systems, Inc.

Donna M. Tanguay (D.C. Bar No. 414496)
John R. Fuisz (D.C. Bar No. 439698)
Stephen K. Shahida (D.C. Bar No. 454970)
McDERMOTT, WILL & EMERY
600 13th St., N.W.
Washington, D.C. 20005-3096
Attorneys for Defendant
Medtronic Vascular, Inc.

It is so ORDERED

Dated November 2, 2004

Honorable Richard J. Leon
United States District Judge

WDC99 999766-1.052734.0050

TAB 10

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim-Defendant,	)	
	)	
v.	)	
	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
	)	**Civil Case No. 01-2015 (RJL)**
Defendant and Counterclaim-Plaintiff,	)	
	)	
	)	
and	)	
	)	
ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant.	)	

MEMORANDUM OPINION
(March 31, 2006) [# 76, 100, 102, 103]

Plaintiff, Scimed Life Systems, Inc. ("Scimed"), brought this action against defendants, Medtronic Vascular, Inc. ("Medtronic") and Eric C. Martin, under Title 35 of the United States Code Section 146, challenging the Final Decision and Judgment of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("USPTO") regarding Patent Interference No. 104,192 between certain patent applications for an apparatus for reinforcing a bifurcated lumen. Presently before the Court are Medtronic's Motion for Summary Judgment, Scimed's First and Second Motions for Summary Judgment, and Medtronic's Motion to Compel Production of Documents and

Things. After due consideration of the parties' submissions, the relevant law and the entire record herein, the Court finds that the Board did not erroneously affirm its Grant of the Fogarty *et al.* United States Patent Application Serial No. 08/463,836 (now owned by Medtronic) Motion 12 in its July 27, 2001 Final Decision and Judgment. Accordingly, this Court affirms the Board's Final Decision and Judgment and, therefore, GRANTS Medtronic's Motion for Summary Judgment, DENIES Scimed's First and Second Motions for Summary Judgment, and DENIES AS MOOT Medtronic's Motion to Compel Production of Documents and Things.

I. BACKGROUND

Plaintiff Scimed and defendant/counterclaimant Medtronic are each assignees of record of two different patent applications for a bifurcated lumen invention.[1] Andrew Cragg and Michael Dake (collectively referred to as party "Cragg" in the underlying proceedings at the USPTO) filed an application with the USPTO regarding the bifurcated lumen apparatus on June 5, 1995. The application was assigned the serial number 08/461,402 (the "'402 application"). Cragg and Dake assigned all rights in the '402 application to Boston Scientific Technology, Inc., which later merged into plaintiff Scimed. Scimed is now the present legal owner of the '402 application. Medtronic was assigned its rights in a patent application for the same invention by Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively referred to as party "Fogarty" in the underlying proceedings at the

[1] The "Background" section of this Memorandum Opinion has been partially adapted from this Court's earlier Memorandum Opinion in *Scimed Life Systems, Inc. v. Medtronic Ave Inc.*, 297 F. Supp. 2d 4 (D.D.C. 2003).

USPTO). That application was also filed with the USPTO on June 5, 1995, and assigned the serial number 08/463,836 (the "'836 application"). Party Fogarty assigned its rights in the '836 application to Medtronic Aneurx, Inc., which merged into Medtronic AVE, Inc. which later became the defendant/counterclaimant Medtronic. Medtronic is now the legal owner of the '836 application. Defendant/counterclaim-defendant Eric Martin owns patent No. 5,575,817 (the "Martin" or "'817 patent"), based on application 08/293,541, filed on August 19, 2004.

On April 23, 1998, the USPTO Board declared an interference between Scimed's patent application (the "Cragg" or "'402 application"), Medtronic's patent application (the "Fogarty" or "'836 application") and the Martin patent. This interference proceeding was assigned Interference No. 104,192, and is referred to as the "'192 interference."[2] On July 2, 1998, the Board set the following as the sole "count"[3]:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:
> an upper limb, configured to fit within the lumen upstream of the bifurcation;
> a first lower limb, configured to extend into the first leg of said bifurcation when said first section is positioned in the lumen, and

---

2 "The purpose of an interference proceeding is to resolve the question of priority of invention when more than one applicant seeks a patent on substantially the same invention." 3A-10 Donald S. Chisum, Chisum on Patents § 10.09[1][a] (2006). This action was brought in federal Court pursuant to 35 U.S.C. § 146, which allows a party dissatisfied with the decision of the Board in an interference to bring a civil action as long as the Board's decision is not being appealed to the United States Court of Appeals for the Federal Circuit "and such appeal is pending or has been decided." *See* 35 U.S.C. § 146.

3 "A count defines the interfering subject matter. In *In re Van Geuns* (1993), the Federal Circuit noted that (1) '[a]lthough claims of one or more of the parties may be identical to the count of an interference, the count is not a claim to an invention,' and (2) '[t]he count of an interference is merely the vehicle for contesting the priority of invention and determining what evidence is relevant to the issue of priority.'" 3A-10 Donald S. Chisum, Chisum on Patents § 10.09[3] (2006).

a second lower limb, shorter that said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,
and further comprising
a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

Cragg et al. v. Martin v. Fogarty et al., Patent Interference No. 104,192, Paper No. 187, Final Decision and Judgment at 5-6 (United States Patent and Trademark Office, Board of Patent Appeals and Inferences July 21, 2001)("Board's Final Judgment"). The purpose of the '192 Interference was for the Board to determine who among the three parties had priority of inventorship, and was, therefore, entitled to the invention defined by the count.

At the time of declaration of the interference, party Cragg was accorded by the USPTO the benefit of the filing dates of two European patent applications (i.e. February 9 and June 10, 1994), which had been filed by a French Company known as Mintec SARL. At the time of declaration of the interference, party Fogarty, on the other hand, was accorded by the USPTO the benefit of the earlier filing date of U.S. patent application 08/255,681: i.e. on June 8, 1994. Thus, at the start of the interference, party Cragg was designated the "senior party,"[4] on the basis of the accorded benefit date of February 9, 1994. On March 13, 2000, party Fogarty filed a preliminary motion attacking the benefit accorded party Cragg to

---

4 "In an interference proceeding, the first party to file is designated as the 'senior party' and all other parties as 'junior.' The junior party bears the burden of going forward with evidence as to actual reduction to practice prior to the senior party's filing date or conception prior to the senior party's filing date plus continuous and reasonable diligence during the critical period. If the senior party desires to show a date of conception or reduction to practice prior to his filing date, he bears the burden of going forward with evidence." 3A-10 Donald S. Chisum, Chisum on Patents § 10.03[1][c][ii] (2006).

the filing dates of the two European applications and sought to be made the senior party in the interference. On April 7, 2000, the Board granted party Fogarty's preliminary motion 12, declaring party Fogarty the senior party in the interference and party Cragg and party Martin as junior parties in the interference. *Cragg et al. v. Martin v. Fogarty et al.*, Patent Interference No. 104,192, Paper No. 130, Decision on Party Cragg's Motion to Correct the Preliminary Statement and on Party Fogarty's Preliminary Motion No. 12 at 7 (United States Patent and Trademark Office, Board of Patent Appeals and Inferences April 24, 2000)("Decision on Preliminary Motion No. 12"). In that same opinion, the Board denied party Cragg's motion to amend its preliminary statement to name Michael D. Dake and Andrew H. Cragg as co-inventors of the party Cragg invention. *Id.* at 7. Party Cragg requested reconsideration of that decision claiming that the Board had erred in its ruling and claimed that Mintec filed the European applications as assignees of both Dake and Cragg, the co-inventors of the subject matter of the patent application.

On April 24, 2000, the Board issued a Decision on Reconsideration denying the request for reconsideration on the basis that Dake's assignment of his rights in the patent application came after the filing of the European application and that 35 U.S.C. § 119 could not be interpreted to allow Mintec the benefit of priority with this subsequent assignment of rights. *Cragg et al. v. Martin v. Fogarty et al.*, Patent Interference No. 104,192, Paper No. 138, Decision on Reconsideration (United States Patent and Trademark Office, Board of Patent Appeals and Inferences April 24, 2000)("Board's Decision on Reconsideration"). In

its decision, the Board interpreted Title 35 of the United States Code Section 119 to require that "the previously filed foreign application must have been filed by the person or one who was, at the time of filing of the previously filed foreign application, already a legal representative or assign of that person." *Id.* at 3. The Board went on to state that their interpretation of Section 119 "is necessary to ensure a link between the presently involved application and the earlier filed foreign application with respect to the particular inventor. A contrary interpretation would cause entitlement to benefit to be negotiable as a commodity between unrelated entities." *Id.* In essence, the Board rejected party Cragg's position on the assignment of rights to the patent and stated:

> We are unpersuaded that an assignment of ownership rights changes on whose behalf an application was previously already filed. It would appear that only filings subsequent to the assignment of rights from Michael D. Dake can be deemed as being executed or performed on his behalf.

Id. at 5. Party Cragg requested a final hearing for review of the Board's decision claiming that the Board had erroneously interpreted Section 119 and that Dake and Cragg were co-inventors and that Mintec SARL was the assignee of both Dake and Cragg for the subject matter invention even though the assignments occurred after the European patent applications were filed. *See id* at 11-23. On July 27, 2001, the Board issued its Final Decision and Judgment. *See* Board's Final Judgment.

In its Final Judgment, the Board adopted its earlier interpretation of 35 U.S.C.§ 119. *Id.* at 9. The Board cited *Vogel v. Jones*, 486 F.2d 1068, 1072 (C.C.P.A. 1973), for the proposition that "a foreign application made by the assignee of a U.S. applicant, on behalf

of one other that the United States inventor, is irrelevant to the rights of priority of the U.S. inventor." *Id.* at 10. The Board stated that the "plain statutory language" of Section 119 does not put "an assignee in the same position as if it were a 'legal representative' or 'assign' of the inventor at a previous time when a foreign application for the same invention was filed by that assignee." *Id.* at 12. The Board found that Dake assigned his invention to Mintec, Inc. more than two years *after* the filing of the two European patent applications. *Id.* at 11-12. The Board went on to state, that even assuming that party Cragg's preliminary statement identified both Cragg and Dake as co-inventors of the subject matter of the count, that fact would not help party Cragg as "Cragg also did not assign his rights to Mintec, Inc. until after" the two European patent applications were filed. *Id.* at 20. The Board found that "MINTEC SARL was not an assign of either Michael D. Dake nor Andrew H. Cragg when it filed European applications EP944oo284.9 and EP94401306.9." *Id.* For those reasons, and others, the Board found that there was no error in the granting of party Fogarty's preliminary motion 12. *Id.* at 23.

On September 25, 2001, Scimed filed this appeal under Title 35 of the United States Code Section 146, seeking this Court's review of the Board's Final Decision and Judgment in the '192 Interference. The parties to this action entered into a stipulation and order limiting the issues in this case. The stipulated issue to be resolved is:

> Whether the Board erroneously affirmed its Grant of Fogarty *et al.* (Medtronic) Motion 12 in its July 27, 2001 Final Decision denying Cragg *et al.* (Scimed) benefit of the February 9, 1994 filing date of its European application No.

94400284.9 as a date of invention for the subject matter of the single count in Interference No. 104,192.

(*See* Stipulation and Order entered March 25, 2004, Dkt. 50.) On July 22, 2005, both parties moved for summary judgment on this remaining issue and provided the Court with exhibits supporting their positions.

II. STANDARD OF REVIEW

Summary Judgment is appropriate when the pleadings and the record demonstrate that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a Court must look to the substantive law on which each claims rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248. Additionally, to be a genuine issue of fact, it must be supported by sufficient admissible evidence such that a reasonable trier of fact could find for the nonmovant. *See Laningham v. United States Navy*, 813 F.2d 1236, 1242-43 (D.C. Cir. 1987).

The moving party bears the initial burden of "identifying those portions of the 'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrates the absence of a genuine issue of material fact." *See Celotex*, 477 U.S. at 323. In order to prevail on its motion for summary judgment,

the movant must show that the nonmovant "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322.

In opposing summary judgment, the "nonmoving party [must] go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and 'admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324. The Court must view the facts in the light most favorable to the nonmovant, giving the nonmovant the benefit of all justifiable inferences derived from the evidence in the record. *Anderson*, 477 U.S. at 255 (1986). The nonmovant, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252.

In order for Scimed to prevail on summary judgment, Scimed must put forth evidence and legal support that meets the standard of proof this Court is required to apply when reviewing decisions of the Board of Patent Appeals and Interferences of the USPTO. In determining whether or not the Board erroneously affirmed its Grant of party Fogarty's preliminary motion 12 and, therefore, erroneously awarded priority for the subject matter of the single count in the '192 Interference to Medtronic, this Court will apply the standard of proof set forth in *Morgan v. Daniels*, in that when a decision has been made by the Patent Office in an action contesting priority of invention, "the decision there made must be accepted as controlling upon that question of fact in any subsequent suit between the same parties, unless the contrary is established by testimony which in character and amount *carries*

thorough conviction." *Morgan*, 153 U.S. 120, 125 (1894) (emphasis added) (determining the standard of review for a Patent Office decision when no additional evidence was put forth to the Circuit Court). Our Circuit Court, in *United States v. Szuecs*, 240 F.2d 886 (D.C. Cir. 1957), upheld the *Morgan* standard of proof that must be applied by a District Court when reviewing a decision of the Patent Office pursuant to 35 U.S.C. § 146. "To reach a conclusion contrary to that of the Patent Office," the *Morgan* standard requires the evidence to carry "'thorough conviction.'" *Szuecs*, 240 F.2d at 887 (citing *Morgan*, 153 U.S. at 125) (reversing and remanding the case to the District Court to apply the correct standard of proof).

Another District Court Judge of this Court reaffirmed the application of *Morgan* in reviewing Patent Office cases under 35 U.S.C. § 146. *Anderson v. Anderson*, 403 F. Supp. 834, 844-45 (D.D.C. 1975) (affirming the decision of the Board of Patent Interferences after reviewing the full administrative record and hearing additional oral testimony), *aff'd*, 543 F.2d 1389 (D.C. Cir. Nov. 11, 1976). In *Anderson*, Judge John H. Pratt found that the "Patent Office is entitled to a presumption of correctness and regularity." *Id.* at 844 (citing *Vogel v. Jones*, 346 F. Supp. 1005 (D.D.C. 1972). Judge Pratt went on to reiterate that the District Court could not overturn the Board's decision unless the evidence put forth by the movant carried "thorough conviction," and "[t]he 'thorough conviction' standard imposes a heavy burden on plaintiffs in an action under 35 U.S.C. § 146," and that "[a] mere preponderance of the evidence is not enough to justify reversing the Patent Office." *Id.* at

845. For the following reasons, the Court finds that the plaintiff has failed to meet its heavy burden, and concludes that the Board did not err in its interpretation of Section 119.

III. ANALYSIS

A. *Interpretation of 35 U.S.C. § 119*

In the Board's Final Judgment, it reaffirmed its earlier decision that the "plain statutory language" of Section 119 requires that the person who filed the foreign patent application must have been a legal representative or assign of the person who filed the patent application in the United States at the time that the foreign patent application was filed.[5] Board's Final Judgment 9-10. The pertinent part of Section 119 reads:

> (a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country.

35 U.S.C. § 119(a). The Board's interpretation of Section 119 is supported by *Vogel v. Jones*, 486 F.2d 1068 (C.C.P.A. 1973). *See* Board's Final Decision 10-11. In *Vogel*, the Court of Customs and Patent Appeal, the predecessor to the current Court of Appeals for the Federal Circuit, read Section 119 to mean "that an applicant for a United States patent can rely for priority on the 'first filed' application by an assignee on his behalf." 486 F.2d at

---

[5] While counsel for Scimed is quick to point out its own grammatical analysis of Section 119 without citing to any grammar reference guide, the Court notes that it is quite capable of reading the statute, interpreting the language of the statute, researching the case law pertaining to the statute and applying that law to the present action.

1072. In order for the foreign patent application to be filed on behalf of the United States applicant, the person filing the foreign application must be an assignee or legal representative *at the time* that the foreign application was filed. *Id.* If the foreign applicant was allowed to become the legal representative or assign of the United States applicant *after* the foreign application was filed, it would be impossible for the foreign application to have been filed *on the behalf* of the United States applicant. If the Board or this Court held otherwise, the right of priority could be, as the Board noted, traded or sold as a commodity to the highest bidder. *See* Board's Decision on Reconsideration 3; Board's Final Decision 9. Therefore, this Court does not find that the Board erred in its interpretation of Section 119 and Scimed has neither cited any precedent or legislative history that would warrant interpreting the statute otherwise.[6]

---

[6] Scimed argues that the Board's construction of Section 119 is inconsistent with the Paris Convention for the Protection of Industrial Property, *opened for signature* Mar. 20, 1883, as amended at Stockholm, July 14, 1967, 21 U.S.T. 1630, 828 U.N.T.S. 305 ("Paris Convention"), and asks this Court to find that the Board's erroneously construed Section 119 as the Board's construction is inconsistent with and violates Article 4 of the Paris Convention. While Section 119, and its predecessor R.S. 4887, were enacted in order to implement Article 4 of the Paris Convention, *Vogel*, 486 F.2d at 1072, the Board's construction of Section 119, which this Court finds correct, does not violate and is not inconsistent with the Paris Convention. The Paris Convention is not self-executing and, therefore, the U.S. was free to implement the Paris Convention in the manner and form that Congress deemed appropriate. *In re Dr. Matthais Rath*, 402 F.3d 1207, 1209-10 (Fed. Cir. 2005). Congress executed Article 4 of the Paris Convention first with R.S. 4887, and then with Section 119, and Section 119 requires that in order to claim a right of priority in a foreign application, the foreign application must have been filed by the U.S. applicant or a person or entity who was a legal representative or assign of the U.S. applicant at the time that the foreign application was filed. The concern expressed by Scimed that upholding the Board's construction of Section 119 would have in foreign countries is conjecture and "based on pure speculation." *See Kawai v. Metlestics*, 480 F.2d 880, 889 (C.C.P.A. 1973).

B. *Review of Board's Decision*

Having found that the Board did not err in its reading and interpretation of Section 119, the question remains whether the Board erred in granting Medtronic's preliminary motion 12 seeking to deny Scimed the benefit of the filing date of its European patent applications. It did not. While a review by this Court of a Board's Final Decision is a "hybrid of an appeal and a trial de novo" because the Court considers evidence before the Board "as well as evidence that was not before the Board," *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (quoting *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997)), it nonetheless must treat the Board's decision as controlling "unless the contrary is established by testimony which in character and amount carries thorough conviction." *Morgan*, 153 U.S. at 125.

Scimed argues that the '284 European application was either filed on Dake's behalf "pursuant to the constructive trust imposed upon that application" when Mintec SARL filed the application, or a theory of an equitable assignment to party Cragg. (Scimed's Mem. of P&A in Opp'n to Medtronic's Mot. For Summ. J. 29, 35-36 ("Scimed's Opp'n"); Mem. of P&A in Supp. of Scimed's Second Mot. For Summ J. That Scimed is Entitled to the Priority of Its EP '284 Application Even Under the Board's Construction of 35 U.S.C. § 119(a)) 31-33 ("Scimed's Second Mot. For Summ. J.".) As this Court earlier recognized, "[t]he Federal Circuit in *Conservolite* [*Inc., v. Widmayer*] held that a party's failure to raise the issue in a preliminary motion not only precluded it not from raising the matter at the final hearing, but

also precluded district Court review." *Scimed Life Systems, Inc. v. Medtronic AVE, Inc.*, 297 F. Supp. 2d 4, 8 (D.D.C. 2003) (citing *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994)). The Federal Circuit has stated that "[i]n order for an issue to have been raised adequately so that it qualifies for consideration in a § 146 proceeding, the issue should have been raised as specified in the PTO's interference rules, for example, through preliminary motions, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or oppositions to these motions." *Conservolite*, 21 F.3d at 1102. Therefore, Scimed is precluded from arguing that the Board erred in denying priority to Scimed either under the newfound constructive trust or equitable assignment theories advanced before this Court.

Thus, applying the *Morgan* standard of proof to this review and not having conducted a *de novo* review as in *Winner*, the Court finds that Scimed has not presented sufficient evidence that Mintec SARL was either the legal representative or assign of Dake or Cragg *at* the time that the relevant European patent applications were filed. Accordingly, party Cragg and Scimed cannot claim the benefit of priority of the European patent applications. Therefore, this Court finds that the Board did not err in its granting of party Fogarty's (Medtonic's) motion No. 12 which denied Cragg *et al.* (Scimed) the benefit of the earlier filing date of European application No. 94400284.9 and affirms the Board's award of priority to Fogarty *et al.* (Medtronic) in its July 27, 2001 Final Decision and Judgment.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS defendant and counterclaim-plaintiff Medtronic's Motion for Summary Judgment [#100]; DENIES Plaintiff and counterclaim-defendant Scimed's First Motion for Summary Judgment [#102]; DENIES Plaintiff and counterclaim-defendant Scimed's Second Motion for Summary Judgment [#103]; and DENIES AS MOOT defendant and counterclaim-plaintiff Medtronic's Motion to Compel Production of Documents and Things [#76]. An order consistent with this decision accompanies this Memorandum Opinion.

RICHARD J. LEON
United States District Judge

TAB 11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Plaintiff and Counterclaim-Defendant,	)	
	)	
v.	)	
	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
	)	**Civil Case No. 01-2015 (RJL)**
Defendant and Counterclaim-Plaintiff,	)	
	)	
	)	
and	)	
	)	
ERIC C. MARTIN,	)	
	)	
Defendant and Counterclaim-Defendant.	)	

FINAL JUDGMENT

For the reasons set forth in the Memorandum Opinion entered this date, it is, this 31st day of March 2006, hereby

ORDERED that defendant and counterclaim defendant Medtronic Vascular, Inc's ("Medtronic") Motion to Compel Motion to Compel Production of Documents and Things [#76] is **DENIED AS MOOT**; and it is further

ORDERED that Medtronic's Motion for Summary Judgment [#100] is **GRANTED**; and it is further

ORDERED that Scimed Life Systems, Inc.'s ("Scimed") First Motion for Summary Judgment [#102] is **DENIED**; and it is further

ORDERED that Scimed Life Systems, Inc.'s ("Scimed") Second Motion for Summary Judgment [#103] is **DENIED**; and it is further

ORDERED that judgment is entered in favor of defendant and counterclaim defendant Medtronic, that the Board of Patent Appeals and Interferences Final Decision and Judgment issued on July 27, 2001, is affirmed, and that the case is dismissed with prejudice.

SO ORDERED.

RICHARD J. LEON
United States District Judge

TAB 12

United States Court of Appeals for the Federal Circuit

2006-1434

BOSTON SCIENTIFIC SCIMED, INC.
(formerly known as Scimed Life Systems, Inc.),

Plaintiff-Appellant,

v.

MEDTRONIC VASCULAR, Inc.
(also known as Medtronic AVE, Inc.),

Defendant-Appellee,

and

ERIC C. MARTIN,

Defendant.

Gregory A. Castanias, Jones Day, of Washington, DC, argued for the plaintiff-appellant. With him on the brief were Gidon D. Stern, Thomas E. Friebel, Catharina J. Chin Eng, and Brent P. Ray, of New York, New York.

Brian E. Ferguson, McDermott Will & Emery LLP, of Washington, DC, argued for the defendant-appellee. On the brief were Paul Devinsky, John R. Fuisz, Stephen K. Shahida, and Natalia V. Blinkova. Of counsel were Joel M. Freed and Amanda E. Koenig.

Appealed from: United States District Court for the District of Columbia

Judge Richard J. Leon

United States Court of Appeals for the Federal Circuit

2006-1434

BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiff-Appellant,

v.

MEDTRONIC VASCULAR, Inc. (also known as Medtronic AVE, Inc.),

Defendant-Appellee,

and

ERIC C. MARTIN,

Defendant.

DECIDED: August 8, 2007

Before MAYER, BRYSON and PROST, Circuit Judges.

MAYER, Circuit Judge.

Boston Scientific Scimed, Inc. ("Scimed")* appeals the district court's grant of summary judgment affirming the Board of Patent Appeals and Interferences' final decision, which denied Scimed the priority benefit of an earlier-filed European patent application for the subject matter at issue in Patent Interference Number 104,192 ("the

---

* Plaintiff-appellant Boston Scientific Scimed, Inc., was formerly known as Scimed Life Systems, Inc., and will be referred to throughout this opinion as "Scimed."

'192 interference"). Scimed Life Sys., Inc. v. Medtronic Vascular, Inc., 486 F. Supp. 2d 60 (D.D.C. 2006). We affirm.

Background

This appeal stems from an interference proceeding before the United States Patent and Trademark Office Board of Patent Appeals and Interferences. Scimed and Medtronic Vascular, Inc. ("Medtronic") are each assignees of different United States patent applications covering the same invention. Andrew Cragg and Michael Dake (collectively "Cragg") filed patent application 08/461,402 ("the '402 application") for the invention in question on June 5, 1995. Cragg then assigned all rights in the '402 application to Boston Scientific Technology, Inc., which later merged into Scimed, the plaintiff-appellant and current legal owner of the '402 application. Also on June 5, 1995, Thomas J. Fogarty, Timothy J. Ryan, and Kirsten Freislinger (collectively "Fogarty") filed patent application 08/463,836 ("the '836 application") for the same invention. Fogarty assigned their rights in the '836 application to a company that eventually became Medtronic, the defendant-appellee and current legal owner of the '836 application. Eric Martin, a third-party to the instant appeal, owns U.S. Patent No. 5,575,817 (the "Martin patent" or "'817 patent"), which resulted from an application filed on August 19, 1994.

On April 23, 1998, the board declared an interference between Scimed's '402 application, Medtronic's '836 application, and Martin's '817 patent. The purpose of the interference was to determine which party had priority of inventorship, thereby entitling it to the invention as set forth in the sole count of the interference:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:

an upper limb, configured to fit within the lumen upstream of the bifurcation;

a first lower limb, configured to extend into the first leg of said bifurcation when said first section is positioned in the lumen, and

a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation, and further comprising

a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

Cragg v. Martin v. Fogarty, Patent Interference No. 104,192, Paper No. 187, 2001 WL 1339890 at *2-3 (B.P.A.I. July 21, 2001) ("Final Interference Decision").

The board initially gave Cragg the benefit of the filing dates of two European patent applications filed by MinTec SARL ("MinTec"), a French company. The earlier of these dates was February 9, 1994. At the time these European applications were filed, no legal relationship existed between MinTec and Cragg, nor was MinTec acting on behalf of Cragg. Fogerty was granted the benefit of the filing date of U.S. patent application 08/255,681, which was June 8, 1994. Martin was accorded benefit of the application that led to the '817 patent, which was filed on August 19, 1994. Accordingly, the PTO initially designated Cragg as the senior party in the interference.

Fogarty responded by filing a motion attacking the priority benefit granted to Cragg. The board granted the motion, declaring Fogarty the senior party in the interference. After Cragg protested this decision, the board issued a final decision denying his request to be declared the senior party. The board ruled that Cragg was not entitled to priority benefit under 35 U.S.C. § 119 because neither Cragg nor Dake had assigned their rights to MinTec until after it had filed the European applications. Final Interference Decision, 2001 WL 1339890, at *5.

Scimed, the assignee of Cragg's U.S. patent application, then brought an action in the United States District Court for the District of Columbia challenging the board's final decision in the '192 interference. The district court affirmed the board's final decision, Scimed, 486 F. Supp. 2d at 61, and Scimed filed this appeal. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

Discussion

We review a district court's grant of summary judgment de novo. Monsanto Co. v. Scruggs, 459 F.3d 1328, 1344 (Fed. Cir. 2006). We also apply a de novo standard when reviewing questions of law, including a trial court's interpretation of statutory language. Pitsker v. Office of Pers. Mgmt., 234 F.3d 1378, 1381 (Fed. Cir. 2000).

At issue here is whether 35 U.S.C. § 119(a)** permits an applicant for a United States patent to benefit from the priority of a foreign application previously filed by an entity that was not acting on behalf of the U.S. applicant at the time of filing. We hold that it does not.

A similar issue was addressed by the Court of Customs and Patent Appeals in Vogel v. Jones, 486 F.2d 1068 (CCPA 1973), which, to the extent relevant here, is binding upon us, South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982)

** 35 U.S.C. § 119(a) reads in relevant part:

> An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed . . . .

(en banc). According to Vogel, "§ 119 gives rise to a right of priority that is personal to the United States applicant." 486 F.2d at 1072. Due to the personal nature of this right, an applicant for a U.S. patent may only benefit from the priority of a foreign application if it was filed by the U.S. applicant or "on his behalf." Id.

Scimed argues that Vogel does not require the foreign applicant to have been acting on behalf of the U.S. applicant at the time the foreign application was filed. It points to the following passage in support:

> This practice [of allowing a U.S. applicant to claim priority from a foreign application filed by someone else] arose because it was recognized that in many foreign countries, unlike in the United States, the actual applicant for a patent can be other than the inventor, e.g., an assignee. In light of this, we regard the language in § 119 referring to legal representatives and assigns to merely represent a codification of the actual practice under [the predecessor statute to § 119]. Since under United States law an application for patent must be made by the inventor, that practice was based on the requirement that the foreign application, regardless of the identity of the applicant, must have been filed for an invention actually made by the inventive entity seeking to rely upon it for priority purposes. We think § 119 must be construed to the same end.

Id. (footnote omitted). Scimed attempts to construe this language as permitting a U.S. applicant to benefit from a foreign application's earlier filing date whenever "the invention described in the foreign application [is the same] one actually made by the U.S. applicant," "'regardless of the identity of the applicant' of the foreign application." According to its interpretation, "the Vogel court did not hold that the foreign application must have been filed by a person who was an assignee or legal representative of the U.S. inventor at the time the foreign application was filed, or that the foreign application must have been filed on his behalf in order for there to be priority benefit." We disagree.

Vogel clearly held that the above-quoted passage "means that an applicant for a United States patent can rely for priority on the 'first filed' application by an assignee on his behalf." Id. (emphasis added). Moreover, "the existence of an application made by [the inventor's] assignee in a foreign country on behalf of one other than the United States inventor is irrelevant to his right of priority based on applications made on his behalf." Id. In other words, while the foreign application must obviously be for the same invention and may be filed by someone other than the inventor, section 119(a) also requires that a nexus exist between the inventor and the foreign applicant at the time the foreign application was filed. Indeed, as a matter of pure logic, an entity could not have filed a foreign application "on behalf of" an inventor without the inventor's knowledge or consent; that the foreign application may have been filed in accordance with the laws of the country in which it was filed has no bearing here. Therefore, to the extent that there may have been any uncertainty or ambiguity in Vogel, we now explicitly hold that a foreign application may only form the basis for priority under section 119(a) if that application was filed by either the U.S. applicant himself, or by someone acting on his behalf at the time the foreign application was filed.

Scimed also contends that the district court erred by precluding it from presenting evidence relating to theories of constructive trust and equitable assignment. A party may present new evidence to the trial court when appealing a board decision in an interference proceeding. Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994). A party may not, however, advance new legal theories at the trial court level, even if the overarching legal issue was presented below. See id. ("[A]n action under [35 U.S.C.] § 146 is essentially a proceeding to review the action of the Board. . . . [T]he

parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources."). Failure to advance legal theories before the board constitutes a failure to "make a complete presentation of the issues," and permitting a party to raise those theories for the first time before the trial court would be both inefficient and "wasteful of administrative and judicial resources." The parties stipulated that the only issue to be resolved by the district court was whether the board correctly ruled on Fogarty's motion attacking the priority benefit initially granted to Cragg, Scimed, 486 F. Supp. 2d at 64, and Scimed did not raise either of these theories before the board, see Final Interference Decision, 2001 WL 1339890, at *3-10. The district court therefore did not err by precluding Scimed from presenting evidence to support these new legal theories.

Conclusion

Accordingly, the judgment of the United States District Court for the District of Columbia is affirmed.

AFFIRMED

Electronic Acknowledgement Receipt

EFS ID:	5409867
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Joshua L. Cohen/denise morgan
Filer Authorized By:	Joshua L. Cohen
Attorney Docket Number:	BSI-010US4
Receipt Date:	28-MAY-2009
Filing Date:	15-OCT-2001
Time Stamp:	12:06:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Brief Filed	correctedappealbrief.PDF	984523 6da030903eff7f13eb04142ffe263c53348ff12e	no	25
Warnings:					
Information:					
2	NPL Documents	tab1.PDF	124457 a113de51b09064db72915e86df88295e19e9c7f8	no	5
Warnings:					
Information:					
3	NPL Documents	tab2.PDF	3216757 8b9376fc6c934eb591c66e598c91bf76291690f0	no	74
Warnings:					
Information:					
4	NPL Documents	tab3.PDF	31923 277f4e4d185023b0e602bdf81aa17a6856a940e0	no	2
Warnings:					
Information:					
5	NPL Documents	tab4.PDF	52910 8e3339b464254520356f16fc8c627a313ec86605	no	3
Warnings:					
Information:					
6	NPL Documents	tab5.PDF	88225 f18ec9db1d20fff9ce03d4ddfaea5bda40f49a75	no	4
Warnings:					
Information:					
7	NPL Documents	tab6.PDF	569373 3a73652cce7e77f5baff6404254717dd8556d8e7	no	16
Warnings:					
Information:					
8	NPL Documents	tab7.PDF	298711 e0f68236c535d84628924e0a81a5168b14bdfb31	no	9
Warnings:					
Information:					
9	NPL Documents	tab8.PDF	790011 0c9d9339af52211c87d56ba19e098473b52e2c12	no	18

Warnings:					
Information:					
10	NPL Documents	tab9.PDF	76806 3ac090287e850ee95fe03f5a0c4d1a476ce9918b	no	3
Warnings:					
Information:					
11	NPL Documents	tab10.PDF	781301 c8538bfc29b875920da8710a374b53ff77b356c8	no	16
Warnings:					
Information:					
12	NPL Documents	tab11.PDF	56734 9f839e4542d78c817817770e16fc3b5f17782f59	no	3
Warnings:					
Information:					
13	NPL Documents	tab12.PDF	333981 142d01806ead899d5f49bab6df1f95f49b51e03d	no	9
Warnings:					
Information:					
			Total Files Size (in bytes):	7405712	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoechea et al.
Filed:	October 15, 2001
Title:	ENDOLUMINAL STENT
TC/A.U.:	3774
Examiner:	William Matthews
Confirmation No.:	4645
Docket No.:	BSI-010US4

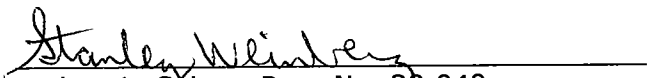
INTERVIEW SUMMARY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants thank the Examiner for the courtesies extended to their representative during a telephone interview on May 18, 2009 during which the May 11, 2009 Notification of Non-Compliant Appeal Brief was discussed. The Examiner stated a belief that the Related Proceedings Appendix required the word "None" to be typed on page 24 of Applicants' Appeal Brief. Applicants' representative explained that "None" would be inaccurate because there are 12 documents comprising the Related Proceedings Appendix. Consequently, the Examiner suggested that Applicants list the documents comprising the Related Proceedings Appendix on page 24.

Respectfully submitted,



Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicants

JLC/SW/dhm

Dated: May 28, 2009

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

Electronic Acknowledgement Receipt

EFS ID:	5414050
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Stanley Weinberg/denise morgan
Filer Authorized By:	Stanley Weinberg
Attorney Docket Number:	BSI-010US4
Receipt Date:	28-MAY-2009
Filing Date:	15-OCT-2001
Time Stamp:	16:02:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	interviewsummary.PDF	35096 4a6b73dc5d04dbb1497266d995047bc3de3a7aaf	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	35096		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 09/30/2009

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

EXAMINER	
MATTHEWS, WILLIAM H	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
09/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/977,826
Filing Date: October 15, 2001
Appellant(s): GOICOECHEA ET AL.

Joshua Cohen
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5-28-09 appealing from the Office action mailed 3-24-08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Interference No. 104,083

Interference No. 104,192

Scimed Life Systems, Inc. v. Medtroninc Vascular, Inc., et al., Civil Case No. 01-2015 (RJL), and including 9 Orders or Opinions attached as Tabs 3-11.

Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtroninc Vascular, Inc. (also known as Medtronic AVE), United States Court of Appeals for the Federal Circuit, No. 2006-1434.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Merriam Webster's Collegiate Dictionary, 10th Edition, 2001, pp. 14 and 636.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20,22-25,27-33,39,41,43-49,54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Independent claims 54 and 56 each recite vertices that abut which is not disclosed in the specification. The specification only discloses juxtaposed vertices. Juxtapose is defined by Merriam Webster's Collegiate Dictionary, 10th Ed. as: to place side by side and is synonymous with "adjacent". Adjacent is described as: may or may

not imply contact but always implies absence of anything of the same kind in between. Furthermore, the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply).

4. Independent claim 54 recites "non-helical" in combination with each hoop being substantially perpendicular and having connected apices. The specification only discloses embodiments wherein each hoop is substantially perpendicular and has connected apices in conjunction with a helical "offset" feature (see figure 2A, 3, 4A and the description at page 24 lines 5-19). The term non-helical implies a lack of helical features, whereas the "offset" feature is clearly helical.

5. Independent claim 56 recites "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" in combination with "axially abutting vertices of adjacent hoops", which is not disclosed in the specification. If "abutting vertices" were assumed to be supported by the original disclosure, the specification would only support "substantially perpendicular" for the combination (see page 23, lines 11-23). "Perpendicular" is described for the straight stents of figures 22-23, but the "perpendicular" embodiment of figures 22-23 is described for "one or more adjacent hoops" rather than each or all hoops as claimed (see page 44 lines 14-26, in particular line 23).

6. Claims 20,22-25,27-33,39,41,43-49,55, and 57 depend from, and include the limitations of claims 54 and 56 as described above.

(10) Response to Argument

Regarding claim 54 and the claimed phrase "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop", Appellant acknowledges at pages 8-11 of the Brief that the specification lacks explicit disclosure of abutting apices. Appellant relies upon the disclosure of "juxtaposed" in combination with the figures which may show contact between the apices. Appellant further points to the means for securing adjacent apices (suture, loop, rings), however none of the cited passages require contact between the apices. Examiner maintains that the means for securing apices only teach they connect apices, and do not require the apices to contact each other. Furthermore, although the figures may appear to show contacting/abutting apices, the specification fails to describe the apices as contacting. Thus, Examiner maintains the amendment to claim 54 filed on 08/08/2007 constitutes new matter.

Regarding claim 54 and the claimed phrase "non-helical", as introduced in the amendment on 08/08/2007, Appellant contends the disclosure at page 9 of the specification of a helical embodiment and an alternative embodiment inherently provides support for a "non-helical" embodiment. Examiner disagrees. The passage cited by Appellant may suggest a substantially non-helical embodiment, but non-helical implies an embodiment lacking helical features. As described in the rejection, each of the embodiments possesses a helical offset feature. Appellant argues at page 13 of the Brief that "regardless of how the hoops are formed, and regardless of how one hoop flows into another hoop, the hoops themselves are non-helical". This statement is not understood as the offsets are a part of the hoops and introduce a helical aspect the

hoops (see figure 2A). For these reasons, Examiner maintains the amendment to claim 54 filed on 08/08/2007 constitutes new matter.

Regarding claim 56 and the claimed phrase "at least some of said vertices axially abut", Appellant repeats that the specification and figures demonstrate the connected apices are abutting. Appellant further argues that Examiner's statement regarding welds or adhesives is improper because two objects may contact without being welded or adhesively joined. Examiner notes that the comment regarding welds/adhesive was merely to show that a connection by suture loops or rings is not equivalent to a connection by weld or adhesive which would inherently required contact. In contrast, the disclosed means for connecting vertices (suture, loops, rings) imply a space is present between the vertices unless the means are tied tightly, but the specification is silent as to how loose or tight the connections are. Therefore, Examiner maintains the specification fails to provide sufficient support for abutting vertices since the specification only describe juxtaposed vertices and a connection means which does not inherently require contacting vertices.

Regarding claim 56 and the claimed phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member", Appellant acknowledges the Examiner's points with respect to the two different embodiments (Figures 1A/2A and Figures 22/23), neither of which independently supports the combination of "each hoop" and "perpendicular" (see page 15 of the Brief, last paragraph). Figures 1A/2A are described to have vertices being "substantially perpendicular" (page 23, lines 20-23), while Figures 22/23 only describe

"one or more hoops" being perpendicular (page 44, lines 21-23). To overcome this deficiency, Appellant suggests the perpendicular hoops of Figures 22/23 could be incorporated into the stents of Figures 1A/2A since they are "formed in the same way". Alternatively, Appellant states figure 1A show vertices lying in a perpendicular plane.

These arguments are not persuasive because Figure 1A is described as having vertices lying in a substantially perpendicular plane and Figure 2A shows the detailed construction of Figure 1A, wherein Figure 2A do not show vertices lying in a perpendicular plane. Furthermore, the disclosure of "formed in the same way" appears to describe a manufacturing process rather than an explicit disclosure that features of the separate embodiments may be interchanged. Finally, and most importantly, the specification only describes "perpendicular hoops" in the context of "one or more hoops" rather than "each or all hoops". It is the Examiner's opinion that this is because the vertical offset shown in Figures 2A, 3, and 4A prevents a truly perpendicular hoop of vertices, and thus it would not be possible to provide a stent wherein "each hoop is perpendicular" as claimed in claim 56. Furthermore, it is conceivable that the description of figures 22-23 as having one or more perpendicular hoops only describes the vertices on the ends of the stent.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/William H. Matthews/

Primary Examiner AU 3774

Conferees:

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775

PTO/SB/82 (01-06)
Approved for use through 12/31/2008. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REVOCATION OF POWER OF ATTORNEY WITH NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3774
Examiner Name	William H. Matthews
Attorney Docket Number	94-P0273US19

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint the practitioners associated with the Customer Number: 54953

☒ Please change the correspondence address for the above-identified application to:

☒ The address associated with Customer Number: 54953

OR

☐ Firm *or* Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature	Victoria Poissant		
Name	Victoria Poissant		
Date	October 8, 2009	Telephone	(661) 949-4553

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*

☒ *Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.36. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/96 (01-08)
Approved for use through 04/30/2008 OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: George Goicoechea, et al.

Application No./Patent No.: 09/977,826 Filed/Issue Date: October 15, 2001

Entitled: Endoluminal Stent

Scimed Life Systems, Inc., a Corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or

2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is_____ %)

in the patent application/patent identified above by virtue of either:

A ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: George Goicoechea, et al. To: Mintec, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 007760, Frame 0520, or for which a copy thereof is attached.

2. From: Mintec, Inc. To: Boston Scientific Technology, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 008000, Frame 0405, or for which a copy thereof is attached.

3. From: Boston Scientific Technology, Inc. To: Scimed Life Systems, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 012520, Frame 0229, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Victoria Paissant — October 8, 2009
Signature — Date

Victoria Paissant — (612) 949-4553
Printed or Typed Name — Telephone Number

Sr. Patent Agent
Title

LIMITED AUTHORIZATION TO ACT ON BEHALF OF ASSIGNEE
REGARDING CERTAIN PATENT MATTERS
EFFECTIVE THROUGH: December 31, 2009

****

I, Lawrence J. Knopf, as Senior Vice President and Deputy General Counsel of Boston Scientific Corporation, the controlling corporation of:

A-Med Systems, Inc.; Advanced Stent Technologies, Inc.; AFx, Inc.; AMS Medinvent S.A.; BEI Medical Systems; BEI Medical Systems Operating Company (formerly known as Xylog Corporation); BEI Medical Systems International, Inc.; Boston Scientific BV; Boston Scientific Corporation Northwest Technology Center, Inc.; Boston Scientific Cupertino Corp.; Boston Scientific Ireland Limited; Boston Scientific Japan KK; Boston Scientific Limited; Boston Scientific Neuromodulation Corporation; Boston Scientific Scimed, Inc. (formerly known as Schneider (USA), Inc.); Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.); Cardiac Pacemakers, Inc.; Cardiac Pathways Corporation; Cardiothoracic Systems, Inc.; Cardiovascular Innovations Canada, Inc.; Catheter Innovations Corp.; Corvita Canada, Inc.; Corvita Corporation; Corvita Europe S.A.; CryoVascular Systems, Inc.; Embolic Protection, Inc.; Embro Vascular, LLC; Enable Medical Corporation; EndoTex Interventional Systems, Inc.; Endovascular Technologies, Inc. (EVT); Enteric Medical Technologies, Inc.; EP Technologies, Inc.; Fidus Medical Technology Corporation; Guidant Corporation; Guidant Holdings, Inc.; Guidant Intercontinental Corporation; Guidant Investment Corporation; Guidant Puerto Rico Sales Corporation; Guidant Sales Corporation; Heart Technologies; Inflow Dynamics Inc.; Intermedics, Inc.; Interventional Technologies, Inc.; Laboratoires Corvita S.A.R.L.; Meadox Medicals, Inc.; NAMIC Eireann Limited; NAMIC International, Inc.; Nilo Holding, S.A.; Origin Medsystems, Inc.; Precision Vascular Systems, Inc.; Prohold Medical Corporation; Prohold Technologies, Inc.; Provasis Therapeutics, Inc.; Quanum Corporation; Radio Therapeutics Corporation; Rubicon Medical Corporation; Rubicon Medical, Inc.; Schneider (Europe) GmbH; Schneider Belgium NV; Schneider Holland BV; Schneider Ireland BV; Schneider Puerto Rico (formerly known as NAMIC Caribe, Inc.); Schneider/NAMIC; Scimed Life Systems, Inc.; Smart Therapeutics, Inc.; Sub-Q, Inc.; Symbiosis Corporation; Target Therapeutics, Inc.; TriVascular, Inc.; and Vesica;

hereby authorize the following registered patent attorneys/agents (1) to act on behalf of any of the corporations identified above, including Boston Scientific Corporation, with regard to any matters before the United States Patent and Trademark Office, any foreign patent offices, and any international patent entities, (2) to execute power of attorney documents on behalf of any of the corporations identified above, including Boston Scientific Corporation, to appoint and/or establish any attorneys, agents, and/or law firms to act on behalf of any of the corporations identified above, including Boston Scientific Corporation, in any foreign or international patent applications filed with any foreign and/or international patent offices, and (3) to execute assignment and ownership documents on behalf of any of the corporations identified above, including Boston Scientific Corporation, with regard to any matters before the United States Patent and Trademark Office, any foreign patent offices, and any international patent offices:

Victoria Aguilera Poissant ..... Reg. No. 56,871	Albert K. Kau ..... Reg. No. 40,672
Alana Bergman ..... Reg. No. 47,420	Philip H. Lee ..... Reg. No. 50,645
James R. Chiapetta ..... Reg. No. 39,634	Kurt W. Lockwood ..... Reg. No. 40,704
Richard R. Clapp ..... Reg. No. 31,751	Jeffrey Z. Mann ..... Reg. No. 51,994
Jeffrey P. Cook ..... Reg. No. 48,649	Steven A. McAuley ..... Reg. No. 46,084
Luke R. Dohmen ..... Reg. No. 36,783	Todd P. Messal ..... Reg. No. 42,883
Peter J. Gafner ..... Reg. No. 36,517	Tyler L. Nasiedlak ..... Reg. No. 40,099
Lori J. Heinrichs ..... Reg. No. 43,667	William J. Shaw ..... Reg. No. 43,111

Lawrence J. Knopf, Senior Vice President and Deputy General Counsel

12/11/08
Date

COMMONWEALTH OF MASSACHUSETTS)
) ss
COUNTY OF MIDDLESEX)

On this 15th day of December, 2008 before me personally appeared Lawrence J. Knopf to me known and known to me to be the person described in and who executed the foregoing instrument, and he duly acknowledged to me that he executed the same for the uses and purposes set forth herein.

Nona E Hurd
Notary Public

Nona E Hurd
NOTARY PUBLIC
My commission expires Sept 18, 2009

[k:\LimitedAuthorizations 2009]

Electronic Acknowledgement Receipt

EFS ID:	6230665
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Correspondence Address:	Ratner & Prestia - One Westlakes, Berwyn, Suite 301 P.O. Box 980 Valley Forge PA 19482 US - -
Filer:	Joseph Charles Huebsch/Jillian Awe
Filer Authorized By:	Joseph Charles Huebsch
Attorney Docket Number:	BSI-010US4
Receipt Date:	08-OCT-2009
Filing Date:	15-OCT-2001
Time Stamp:	17:51:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	00092384.pdf	42523 6bd5133c2529778d8c59baa530087077f484acf8	no	1
Warnings:					
Information:					
2	Assignee showing of ownership per 37 CFR 3.73(b).	00092385.pdf	48287 8c8da66778e62a74dbffb1ab2644a652a6c24789	no	1
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	00092386.pdf	65017 6290e42b7f6143737353ee26545b15b063142704	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	155827		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/977,826	10/15/2001	George Goicoechea	94-P0273US19

CONFIRMATION NO. 4645

POA ACCEPTANCE LETTER

54953
BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

OC000000038291069

Date Mailed: 10/19/2009

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/08/2009.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/mnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/977,826	10/15/2001	George Goicoechea	BSI-010US4

CONFIRMATION NO. 4645

POWER OF ATTORNEY NOTICE

Ratner & Prestia
One Westlakes, Berwyn, Suite 301
P.O. Box 980
Valley Forge, PA 19482

OC00000038291047

Date Mailed: 10/19/2009

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/08/2009.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/mnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Docket No.: **94-P0273US19**
[209.1610039]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/977,826
Applicants:	:	George Goicoechea, et al.
Filed:	:	October 15, 2001
TC/A.U.	:	3774
Examiner:	:	ENDOLUMINAL STENT
Title:	:	

APPELLANTS' REPLY BRIEF TO EXAMINER'S ANSWER DATED SEPTEMBER 30, 2009 (37 CFR 41.41)

MS APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madame:

This Reply Brief, in compliance with 37 C.F.R. § 41.41, is in response to the Examiner's Answer dated September 30, 2009, and in furtherance of the Notice of Appeal filed under 37 C.F.R. § 41.31 on June 12, 2008.

The Examiner's Grounds for Rejection are substantially the same as those presented in the Final Office Action (FOA) dated March 24, 2008. Appellant has addressed these rejections in the Appeal Brief dated May 28, 2009.

In the Examiner's Answer dated September 30, 2009, the Examiner provides a response to the arguments presented in the Appeal Brief. Appellant respectfully traverses the assertions and conclusions provided in the Examiner's response. The following is the Appellant's Reply Brief in response to the Examiner's Answer dated September 30, 2009, which incorporates the Appeal Brief that was previously filed. Material provided in response to the Examiner's Answer has been included as addenda and has been marked accordingly.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37:

I. Real Party In Interest

II. Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

V. Summary of Claimed Subject Matter

VI. Grounds of Rejection to be Reviewed on Appeal

VII. Argument

VIII. Claims Appendix

IX. Evidence Appendix

X. Related Proceedings Appendix

Page 22 of this brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Boston Scientific Scimed, Inc. by virtue of Articles of Merger of Boston Scientific Scimed, Inc. with and to Scimed Life Systems, Inc. dated December 22, 2004.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal, except as follows:

Interference No. 104,083. A copy of the Judgment of the Board of Patent Appeals and Interferences in this Interference was provided in the Related Proceedings Appendix (Section X) at Tab 1 of the Appeal Brief filed May 28, 2009. This Interference involved related Application Serial No. 08/461,402 of Andrew H. Cragg et al., filed June 5, 1995, titled BIFURCATED ENDOLUMINAL PROSTHESIS.

Interference No. 104,192. A copy of the Final Decision and Judgment of the Board of Patent Appeals and Interferences in this Interference was provided in the Related Proceedings Appendix (Section X) at Tab 2 of the Appeal Brief filed May 28, 2009. This Interference also involved related Application Serial No. 08/461,402.

Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL). This was an appeal from the Board's decision in Interference No. 104,192. The following interlocutory orders, and/or decisions, memorandum opinion, and final judgment were entered in that appeal, with copies that were included in the Related Proceedings Appendix (Section X) at the indicated Tabs of the Appeal Brief filed May 28, 2009:

DATE	ORDER OR OPINION	TAB
11/15/01	Order	3
12/21/01	Order	4
5/2/02	Order	5
8/30/03	Memorandum Opinion and Order	6

3/25/04	Stipulation and Order	7
9/12/04	Protective Order	8
12/14/04	Joint Stipulated Request To Extend Discovery	9
3/31/06	Memorandum Opinion	10
3/31/06	Final Judgment	11

Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), United States Court of Appeals for the Federal Circuit, No. 2006-1434. This was an appeal from the decision of the U.S. District Court for the District of Columbia. A copy of the decision of the Federal Circuit is provided in the Related Proceedings Appendix (Section X) at Tab 12.

III. STATUS OF CLAIMS

Claims 20, 22-41, 43-49 and 54-62 are pending. Claims 26, 34-38, 40, and 58-62 have been withdrawn from consideration. Claims 1-19, 21, 42, 50-53 have been canceled. Claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 stand rejected and are being appealed. A copy of the rejected claims is provided in the Claims Appendix (Section VIII).

To assist the Board in correlating dependent claims with their corresponding independent claims, appellants provide the following chart of the pending claims that have not been withdrawn:

20	Dependent on claim 54
22	Dependent on claim 20
23	Dependent on claim 20
24	Dependent on claim 20
25	Dependent on claim 20
27	Dependent on claim 20
28	Dependent on claim 27
29	Dependent on claim 28
30	Dependent on claim 29
31	Dependent on claim 54
32	Dependent on claim 54
33	Dependent on claim 32
39	Dependent on claim 54

41	Dependent on claim 31
43	Dependent on claim 54
44	Dependent on claim 43
45	Dependent on claim 44
46	Dependent on claim 44
47	Dependent on claim 43
48	Dependent on claim 47
49	Dependent on claim 47
54	Independent
55	Dependent on claim 20
56	Independent
57	Dependent on claim 56

IV. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 54

The invention recited in claim 54 is a stent including a plurality of hoops aligned along a common axis. Each of the hoops is non-helical and oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the stent. The stent also includes means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

For example, and for purposes of illustration only, one exemplary embodiment of the invention is shown as stent 10 in Fig. 1A (page 19, lines 5-7; page 22, lines 17-18). Part of a stent such as stent 10 is also shown in Figs. 2A (page 19, lines 11-13; page 23, lines 11-12), 3 (page 19, lines 17-19; page 25, line 27-page 26, line 1), and 4A (page 19, lines 20-22; page 22, lines 17-18). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). Each hoop is non-helical and is oriented in a

plane that is substantially perpendicular to the longitudinal axis of the stent (page 9, lines 15-19, 13-19; page 10, lines 16-17).

Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices such as apices 22 (Fig. 2A, page 23, lines 11-20) that point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

The stent also has means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop (page 10, lines 16-23 and Figs. 1A, 1B, 2A, 4A-4F). This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following paragraphs set forth exemplary structures described in the specification as corresponding to the claimed function.

The securing means may comprise a loop element of a suture material, for example, to tie the abutting juxtaposed apices together. The loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol (page 10, lines 20-28). FIGS. 4B-4F are partial exploded views of embodiments of a stent illustrating exemplary means for securing juxtaposed apices of the stent (page 20, lines 1-4).

Referring to Fig. 4A, for example, abutting juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 which may be, for example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has an abutting juxtaposed apex of a neighboring hoop 20 is tied to the abutting juxtaposed apex 22 in this embodiment. In other embodiments of the invention, only some of the juxtaposed apices 22 may be secured in this way (page 25, lines 4-11).

In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. 4B. The securing means may also comprise a bead 99b

formed of a thermoplastic material around juxtaposed apices, as shown in FIG. 4C. Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in FIGS. 4D, 4E, and 4F respectively (page 25, lines 12-21).

The foregoing, exemplary structures correspond to the function recited in claim 54 of securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop. Equivalent structures for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop are also within the literal scope of claim 54 under 35 U.S.C. § 112, sixth paragraph.

B. Claim 56

The invention recited in claim 56 is a stent including a tubular member that has a plurality of hoops aligned adjacent one another along the longitudinal axis of the tubular member. Each of the hoops has a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices that axially point in a direction along the longitudinal axis of the stent. At least some of the vertices axially abut and are individually connected to oppositely pointed veritices of elongate elements of an adjacent hoop. The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, a stent such as stent 10 includes a tubular member (page 8, lines 8-10). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). The exemplary hoops are aligned adjacent one another along the longitudinal axis of the tubular member (Fig. 1A; page 9, lines 19-27; page 23, lines 24-27).

Each of the hoops includes a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices such as vertices 22 (Fig. 2A, page 23, lines 11-20) that axially point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

At least some of the vertices axially abut (Figs. 2A, 4A) and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop (Figs. 2A, 4A). For example, a loop element of a suture material connects oppositely pointed vertices of adjacent hoops (page 10, lines 18-23). Exemplary suture material is shown as element 99a in Fig. 4B (page 25, lines 13-15). Other materials for connecting oppositely pointed vertices of adjacent hoops are shown in Figs 4A and 4C to 4F (page 25, lines 4-21).

The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member (page 9, lines 15-19; page 10, lines 2-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following provides a concise statement of each ground of rejection presented for review:

Whether claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, as set forth in the Final Office Action.

VII. ARGUMENT

Paragraph 4 of the Final Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. It generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-7 of the Final Office Action provide more specific reasons for the rejections. Paragraph 2 of the Final Office Action explains why the Examiner disagreed with Applicants' arguments regarding claims 56 and 57 in their December 26, 2007 Request for Reconsideration.

EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169. *Accord*, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of

the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION OF CLAIM 54 AND ITS DEPENDENT CLAIMS 20, 22-25, 27-33, 39, 41, 43-49, and 55

Contrary To The Final Office Action's Contention, The Disclosure Does Support "Means For Securing An Apex Of One Hoop To An Abutting Juxtaposed Apex Of A Neighboring Hoop"

Paragraph 5 of the Final Office Action has rejected these claims because independent claim 54 recites vertices that abut which, in the Examiner's view, is not disclosed in the specification. Instead, the Examiner contends that the specification only discloses juxtaposed vertices, which, he contends, may or may not imply contact.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) implicitly and inherently supports these claim limitations. The Examiner, on the other hand, has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

> Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. . . . (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The Examiner has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that claim 54 finds clear support in stent embodiments such as those selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show embodiments having "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." The Examiner has not explained why a person skilled in the art would not recognize that the figures show this feature.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the Examiner has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports claim 54. Paragraph 5 of the Final Office Action states: "[t]he specification only discloses juxtaposed vertices." This statement fails to provide evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

Paragraph 5 of the Final Office Action also contends that "the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply)." The Examiner's contentions disregard not only page 10, lines 16-23 but also other significant aspects of Applicants' disclosure and

fail to present required evidence demonstrating that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention.

Applicants' specification also states:

> [J]uxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 (see Figure 4(a)), which are, in this example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22. (page 25, lines 4-9)
>
> In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in Fig. 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Fig. 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Fig. 4(d), 4(e), and 4(f) respectively. (page 25, lines 12-21).

These passages explain the relationship of juxtaposed apices that can be tied together or secured together as shown in Figures 4A through 4F, each of which also shows an embodiment having abutting apices. Taken together, the disclosure's statement that juxtaposed apices can be tied together or secured together, along with Figures 4A through 4F, combined with the explanation that "each hoop is supported by its neighbors" would inexorably lead one skilled in the art to conclude that the juxtaposed apices of at least some disclosed embodiments are abutting. The Examiner has not presented any evidence to the contrary.

For all of the above reasons, Applicants' specification discloses "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop."

Addendum: With regard to the "verticies that abut" language of claim 54, the Examiner's Answer dated September 30, 2009 continues the argument

previously set forth in the Final Office Action. Applicant maintains that the specification clearly provides support for the language used in claim 54.

For example, as stated above, the disclosure provides that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently, particularly in view of Figures 4A through 4F, each of which shows an embodiment having abutting apices.

Claim 54 also recites, in part,

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Paragraph 6 of the Final Office Action has rejected claim 54 and its dependent claims "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the Examiner's view, "[t]he specification only disclose [sic] embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical 'offset' feature."

Applicants' specification expressly describes two alternative categories of embodiments of hoops -- helical and substantially perpendicular. The specification states:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described

embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is not helical because the specification describes an alternative to a helical embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is non-helical.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

> Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

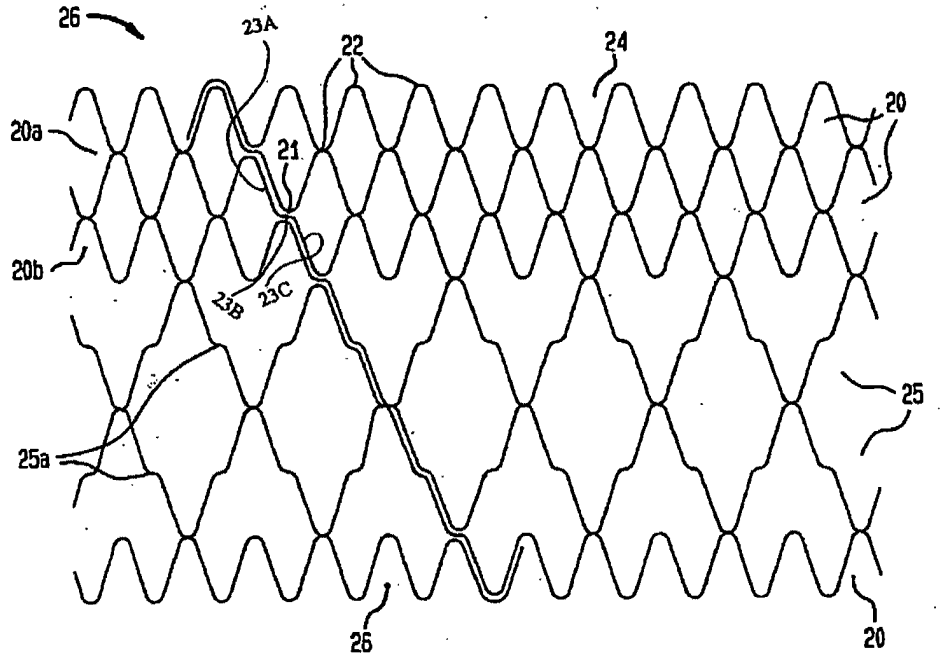
In paragraph 2, at the top of page 3[1], the Final Office Action indicates that it has interpreted "non-helical" to require that the claimed embodiment "lack[s] **any** helical features." Based upon this interpretation of "non-helical," the Examiner contends that Fig. 4A shows "a helical aspect (i.e. the longitudinal displacements described at page 23 lines 24-27)."

---

[1] The opening sentence of paragraph 2 of the Final Office Action states that it only pertains to claims 56 and 57. Since claims 56-57 do not contain a "non-helical" recitation, the Examiner's contentions regarding "non-helical" must pertain to claim 54.

But page 23, lines 24-27 describes Figs. 2A and 2B, not Fig. 4A, and describes how hoops 20a and 20b in those figures are formed. Figs. 2A and 2B are reproduced below, with reference numbers 23A, 23B and 23C added to Fig. 2A for the Board's ease of reference.

FIG. 2A



The referenced portion of the specification states:

> When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b.

Hoops 20a and 20b are shown in both figures.

Part of hoop 20a is formed by wire portion 23A. In order to form the adjoining hoop 20b, the point of winding of wire portion 23A is displaced longitudinally at wire portion 23B, and becomes wire portion 23C. Apparently, the Examiner contends that wire portion 23B precludes Applicants from reciting "hoops being non-helical." The Examiner is wrong.

The recitation at issue is: "**hoops** being non-helical." Figs. 1A, 1B, 2A, 3, 4A all show embodiments of non-helical **hoops**. Regardless of how the hoops are

formed, and regardless of how one hoop flows into another hoop, the **hoops themselves** are non-helical. The disclosure therefore supports "**hoops** being non-helical."

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Addendum: With regard to the "non-helical" language of claim 54, the Examiner's Answer dated September 30, 2009 states that the disclosure on page 9 of the specification that is cited above does not indicate an embodiment having non-helical features. Applicant strongly rebuts this assertion. The specification states "Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms **a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent**. (page 9, lines 13-19) emphasis added. A helix is defined as "something spiral in form" (Merriam-Webster Online Dictionary. 2009). What is described above is clearly not spiral in form and therefore is clearly non-helical.

THE REJECTION OF CLAIM 56 AND ITS DEPENDENT CLAIM 57

Contrary To The Final Office Action's Contention, The Disclosure Does Support "At Least Some Of Said Vertices Axially Abut"

Claim 56 recites, in part,

> at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop.

In addition to the contentions stated in paragraph 4 of the Final Office Action, the Examiner's reasoning is further explained in paragraph 2 of the Final Office Action, which contends that

> the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the

question of how tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.

As was the case regarding claim 54, even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. In addition, the Examiner has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

As Applicants argued above regarding the rejection of claim 54, the specification describes, and the figures illustrate, embodiments in which "each hoop is supported by its neighbors" (page 10, line 20), "vertices . . . are individually connected to oppositely pointed vertices" using various connecting elements (page 10, lines 23-29; page 25, lines 4-9, 12-21), and apices are tied together. See also, Figs. 1A, 1B, 2A, and 4A-4F.

Taken together, the specification and the figures demonstrate that "at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop."

The Final Office Action has disregarded the above-described teachings in the specification because, in its view, the teachings "are not equivalent to a connection created by adhesive or welding." This statement makes the unsupported assumption that any two things (including juxtaposed apices) can abut only if they are connected by adhesive or welding or only if they are connected by something that is equivalent to adhesive or welding. The Board must reject these contentions because the Examiner has not supported them with any evidence and because they are clearly wrong. For example, a pencil resting on a desk top abuts the desk top even though the pencil is not connected to the desk top at all or by adhesive, welding, or anything equivalent to adhesive or welding. Applicants' disclosure demonstrates embodiments in which apices abut, even though the disclosure does not expressly refer to adhesive or welding.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Addendum: With regard to the "at least some of said vertices axially abut" language of claim 56, the Examiner's Answer dated September 30, 2009 continues the argument previously set forth in the Final Office Action. Applicant maintains that the specification clearly provides support for the language used in claim 54.

For example, as stated above with respect to the addendum added to the discussion of claim 54 regarding the abutting language used therein, the disclosure provides that an apex of one hoop can be secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently, particularly in view of Figures 4A through 4F, each of which shows an embodiment having abutting apices.

Claim 56 also recites, in part:

> vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Final Office Action has rejected claims 56 and 57 because, in the view of the Examiner, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the Examiner, the specification only supports a recitation that for the perpendicular embodiment apices of "one or more" hoops lie in such a plane. The Final Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A).

Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). "Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel." (page 23, lines 20-23)

Fig. 22 illustrates another embodiment of a stent using configurations such as the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

Page 3 of the Final Office Action has mischaracterized Applicants' arguments. Applicants have not suggested that "it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments." As explained above, Fig. 22 illustrates, for example, a stent embodiment having a

proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). As stated above, therefore, since both stent embodiments may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops. Contrary to the belief of the Examiner, therefore, one skilled in the art would understand that the specification does interrelate at least Figs. 1-4 with at least Figs. 22 and 23. The Final Office Action fails to demonstrate that one skilled in the art would not have such an understanding.

For the above reasons, Applicants' disclosure fully supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member."

Addendum: With regard to the language "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" of claim 56, the Examiner's Answer dated September 30, 2009 states that the two embodiments illustrated in Figures 1A/2A and 22/23 do not support such language. Applicant strongly rebuts this assertion.

First, the Examiner admits at page 7 of the Examiner's Answer that the specification describes the relevant elements in Figures 1A/2A as "substantially perpendicular". Applicant asserts that one of ordinary skill in the art would understand what the claim language of claim 56 means even if it was only based upon this disclosure regarding Figures 1A/2A, however, the specification also provides other disclosures regarding perpendicular and perpendicular variety as discussed herein.

Further, the Examiner argues that the specification only discusses "'perpendicular hoops' in the context of 'one or more hoops' rather than 'each or all hoops'". Applicant asserts that the meaning of "one or more hoops" includes "each hoop" and "all hoop" type configurations contrary to Examiner's argument.

For example, as discussed previously above, the specification states "Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of **each hoop is substantially perpendicular** to the longitudinal axis of the stent."

(page 9, lines 13-19) emphasis added. As applied to the "one or more hoops" language, this clearly supports the language of claim 56 as it would be viewed by one of ordinary skill in the art. Further, as stated above, the terms "perpendicular" and of a "perpendicular variety" have been used elsewhere in the specification which clearly indicate to the reader that "perpendicular" is within the scope of potential claim language.

The Examiner also argues that Figures 2A, 3, and 4A prevent a truly perpendicular hoop of vertices, however, as stated above, the disclosure on Applicant's page 9 provides that the hoops are substantially perpendicular and that the language of the specification would indicate to the reader that "perpendicular" is within the scope of potential claim language.

Lastly, the Examiner argues that the disclosure describing Figures 22-23 as having one or more perpendicular hoops only describes the vertices on the ends of the stent. Such a discussion is irrelevant as the arguments provided above fully support use of the term "perpendicular".

CONCLUSION

In view of the foregoing remarks, Applicants submit that the grounds for rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 are improper. Applicants respectfully request that the Board reverse the Examiner's rejection of all pending rejected claims.

CONCLUSION

Appellants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner and/or members of the Board are invited to telephone Appellants' attorney Jeffery L. Cameron at (612) 236-0121 to facilitate this appeal.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS Appeal Brief-Patents** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 30th day of November, 2009.

Sarah L. Reinhard
Name

Signature

Respectfully Submitted,
Joseph M. Thielen, et al.

By their Representatives:
Brooks, Cameron & Huebsch, PLLC
1221 Nicollet Avenue, Suite 500
Minneapolis, MN 55403

Atty: Jeffery L. Cameron
Reg. No.: 43,527

11/30/09
Date:

VIII. CLAIMS APPENDIX

1-19 (Canceled)

20. (Previously Presented) A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

21. (Canceled)

22. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

26. (Withdrawn) A stent as recited in claim 22 wherein said axially aligned segments are connected to one another by a tubular fabric element.

27. (Previously Presented) A stent as recited in claim 20 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment.

28. (Previously Presented) A stent as recited in claim 27 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment.

29. (Previously Presented) A stent as recited in claim 28 wherein at least one of said first and second additional stent segments is of frustoconical shape and is further combined with a third an additional stent segment, one end of which includes a mating frustoconical shape.

30. (Previously Presented) A stent as recited in claim 29, wherein said mating frustoconical stent segments are adapted to be separately placed in a bifurcated artery and then, by expansion of one of said frustoconical stent segments, secured to one another.

31. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. (Previously Presented) An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

34. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

35. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a staple.

36. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is wire twisted into loop.

37. (Withdrawn) An endoluminal stent as claimed in claim 36 wherein said wire is nitinol.

38. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is bead of thermoplastic material.

39. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

40. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said stent is at least partially covered in fabric.

41. (Previously Presented) An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

42. (Canceled)

43. (Previously Presented) An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is gold.

50-53. (Cancelled)

54. (Previously Presented) A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

55. (Previously Presented) A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. (Previously Presented) A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. (Previously Presented) A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

58. (Withdrawn) A method of reinforcing a body vessel using a tubular sheath disposed between an entry location in a body and an implantation location, said method comprising the steps of:

a. providing a stent as recited in claim 56;

b. compressing the stent into its compressed configuration;

c. inserting the compressed stent into the tubular sheath;

d. delivering the compressed stent through the tubular sheath to the implantation location; and

e. withdrawing the sheath while holding the stent at the implantation location within the vessel and expanding the stent within the implantation location as the sheath is withdrawn by permitting the self-expandable stent, as the constraint of the sheath is removed to return to said expanded configuration;

whereby the stent is securely disposed in the implanted state against said body vessel.

59. (Withdrawn) A method according to claim 58, wherein said stent is comprised of a shape memory material.

60. (Withdrawn) A method according to claim 59, wherein said shape memory material is nitinol and step (b) is performed at low temperature.

61. (Withdrawn) A method according to claim 58, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

62. (Withdrawn) A prosthesis for placement in a body lumen comprising a tubular graft supported and adapted to be retained in said lumen by a stent as recited in claim 56.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

Tab 1 Judgment of the Board of Patent Appeals and Interferences in Interference No. 104,083.

Tab 2 Final Decision and Judgment of the Board of Patent Appeals and Interferences in Interference No. 104,192.

Tab 3 11/15/01 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 4 12/21/01 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 5 5/2/02 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 6 8/30/03 Memorandum Opinion and Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 7 3/25/04 Stipulation and Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 8 9/12/04 Protective Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 9 12/14/04 Joint Stipulated Request To Extend Discovery, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 10 3/31/06 Memorandum Opinion, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 11 3/31/06 Final Judgment, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 12 8/8/07 Decision, Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), U.S. Court of Appeals for the Federal Circuit, No. 2006-1434.

TFW AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	George Goicoechea, et al.	Confirmation No.	4645
Serial No.:	09/977,826	Examiner:	William H. Matthews
Filed:	October 15, 2001	Art Unit:	3774
		Docket:	**94-P0273US19** [209.1610039]

Title: ENDOLUMINAL STENT

MS APPEAL-BRIEF PATENTS
Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items and information (as indicated with an "X"):

X Return postcard(s) (1).

X Check in the amount of $540.00 to file Reply Brief

X Appellant's Reply Brief to Examiner's Answer dated September 30, 2009 (37 CFR 41.41) (31 pgs.).

PLEASE ASSOCIATE THIS APPLICATION WITH CUSTOMER NUMBER 54953

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS APPEAL-BREIF PATENTS** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 30th day of November, 2009.

Sarah L. Reinhard
Name

Signature

Respectfully Submitted,
George Goicoechea, et. al.

By: Brooks, Cameron & Huebsch, PLLC
1221 Nicollet Avenue, Suite 500
Minneapolis, MN 55403

Atty: Jeffery L. Cameron
Reg. No.: 43,527

11/30/09
Date:

Rev. 01/09

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

54953 7590 01/12/2010

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	**PAPER NUMBER**
3774	

MAIL DATE	DELIVERY MODE
01/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09977826	10/15/01	GOICOECHEA ET AL.	94-P0273US19

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

EXAMINER	
William H.. Matthews (Howie)	
ART UNIT	**PAPER**
3774	20100110

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The reply brief filed 12-9-09 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

/William H. Matthews/
Primary Examiner
Art Unit: 3774

PTO-90C (Rev.04-03)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

54953 7590 02/05/2010

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	**PAPER NUMBER**
3774	

MAIL DATE	DELIVERY MODE
02/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

United States Patent and Trademark Office

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BROOKS, CAMERON & HUEBSCH,
PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

Appeal No: 2010-003316
Application: 09/977,826
Appellant: George Goicoechea et al.

Board of Patent Appeals and Interferences
Docketing Notice

Application 09/977,826 was received from the Technology Center at the Board on January 19, 2010 and has been assigned Appeal No: 2010-003316.

A review of the file indicates that the following documents have been filed by appellant:

Appeal Brief filed on:	May 28, 2009
Reply Brief filed on:	December 09, 2009
Request for Hearing filed on:	NONE

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

BOARD OF PATENT APPEALS AND INTERFERENCES
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

The facsimile number of the Board is 571-273-0052. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 571-272-9797 and should be directed to a Program and Resource Administrator.

By order of the Board of Patent Appeals and Interferences.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

54953 7590 12/09/2011

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

EXAMINER	
MATTHEWS, WILLIAM H	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
12/09/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GEORGE GOICOECHEA,
JOHN HUDSON, CLAUDE MIALHE, ANDREW H. CRAGG, and
MICHAEL D. DAKE

Appeal 2010-003316
Application 09/977,826
Technology Center 3700

Before KEVIN F. TURNER, DANIEL S. SONG, and JOSIAH C. COCKS, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION ON APPEAL

A. STATEMENT OF THE CASE

This is a decision on appeal by an Appellant under 35 U.S.C. § 134(a) from a final rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57. We have jurisdiction under 35 U.S.C. § 6(b).

We *reverse*.

The Rejection on Appeal

The Examiner rejected claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

The Invention

The invention relates to a stent for implantation in a blood vessel. (Spec. 1-2.) Independent claim 54 is representative and reproduced below (App. Br. 20-21 Claims App'x.):

54. A stent comprising:

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and
>
> means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

B. ISSUES

1. Did the Examiner correctly determine that the specification lacks adequate written description support for the claim feature of a plurality of hoops that are "non-helical"?

2. Did the Examiner correctly determine that the specification lacks adequate written description support for the claim feature of hoops with apices that are "abutting" or "abut" an apex of a neighboring hoop?

3. Did the Examiner correctly determine that the specification lacks adequate written description support for the feature in claim 56 of "wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member"?

C. PRINCIPLES OF LAW

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000).

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that he or she was in possession of the claimed invention. *Id.*

One shows "possession" of the invention by describing the invention using such descriptive means as words, structures, or figures, that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997).

D. FINDINGS AND ANALYSIS

Claims 54 and 56 are independent claims. Each claim is directed to a stent and includes a plurality of "hoops" that are aligned along the longitudinal axis of the stent. The Examiner contends that each of claims 54 and 56 lack adequate written description for limitations directed to the particular configuration and arrangement of the hoops.

Claim 54

Claim 54 includes the feature: "each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent[.]" (App. Br. 21 Claims App'x.) According to the Examiner, the recitation that the hoops are "non-helical" has no support in the underlying specification. In particular, the Examiner contends (Ans. 4:5-9):

> The specification only discloses embodiments wherein each hoop is substantially perpendicular and has connected apices in conjunction with a helical "offset" feature (see figure 2A, 3, 4A and the description at page 24, lines 5-19). The term non-helical implies a lack of helical features, whereas the "offset" feature is clearly helical.

The Appellant challenges the Examiner contention, arguing that the specification provides ample written description for the non-helical aspect of the claims. The Appellant points in particular to Figures 1A, 1B, 2A, 3, and 4A and also page 9, lines 13-19 of the specification as showing and describing embodiments of its invention incorporating non-helical hoops. (App. Br 11-13; Reply Br. 13-16.) We agree with the Appellant.

At the outset, it is not clear what feature is identified by the Examiner in his reference to a "helical offset." The portion of the specification noted by the Examiner at page 24, lines 5-19, describes "offsets 25a" which are shown in Figure 2A as constituting a stepped or kinked portion formed in

segments of some of intermediate hoops 25 and are indicated as adding stability to the stent. The offsets, however, are not depicted or described as having any "helical" characteristics.

In any event, there is no dispute that the Appellant's specification does disclose some embodiments of its invention which incorporate helically arranged hoops. However, the specification also conveys, in no uncertain terms, that hoops may be formed in a configuration that is not helical. Specifically, the specification states (Spec. 9:13-19):

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent.

The novel configuration in which the hoops lie in a plane substantially perpendicular to the longitudinal axis of the stent is described as being advantageous, as compared for instance with a helical configuration, because it allows expansion of the stent without requiring that the stent twist as it changes in length. (Spec. 10:1-15.) Having reviewed the specification and drawings including the above-quoted portion, we do not share the Examiner's view that all described embodiments of the Appellant's require some "helical" characteristic, such as a "helical offset," thereby providing no written description for the claimed "non-helical" feature. A stent formed from a multitude of interconnected hoops which are each substantially perpendicular to the axis of the stent, as is clearly described in the specification, is one such embodiment that does not require hoops that are

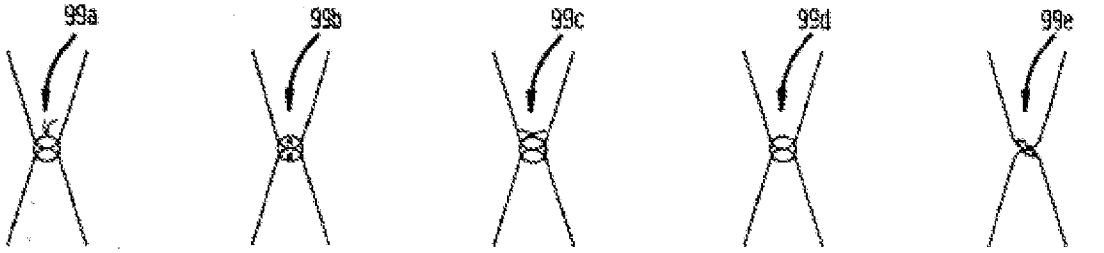
helical. We conclude that there is adequate support in the written description for the recitation in claim 54 of "hoops being non-helical."

Claim 54 also includes the limitation of "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." (App. Br. 21 Claims App'x.) The Examiner urges that apices of neighboring hoops which are "abutting," *i.e.*, contacting one another, is a feature not adequately described in the written description. The Appellant contends otherwise. We agree with the Appellant.

Although the term "abutting" does not appear in the specification, it is well settled that compliance with the written description requirement does not require that the exact same terms appearing in the claim must also appear in the description. *Purdue Pharma L.P.,* 230 F.3d at 1323. Rather, to satisfy the written description requirement, an applicant must simply convey with reasonable clarity to those skilled in the art that he or she was in possession of the claimed invention. *Id.* One shows "possession" of the invention by describing the invention using such descriptive means as words, structures, or figures that fully set forth the claimed invention. *Lockwood,* 107 F.3d at 1572.

Here, the specification characterizes the association of apices of neighboring hoops as "juxtaposed apices" which are tied together (Spec. 10:16-23) and illustrates examples, such as in Figures 4B-4F reproduced below, of apices of the hoops tied to one another via various mechanisms 99a-99e (*id.* at 25:12-21).

FIG. 4B FIG. 4C FIG. 4D FIG. 4E FIG. 4F



The figures above clearly show upper and lower apices which contact or abut one another when tied together. The description of juxtaposed hoop apices as being tied together and shown as contacting one another in their tied together state provides adequate written description support for the claim feature of "abutting juxtaposed" apices. We reject the Examiner's position to the contrary.

For the foregoing reasons, we do not sustain the Examiner's rejection of claim 54 under 35 U.S.C. § 112, first paragraph. Claims 20, 22-25, 27-33, 39, 41, 43-49, and 55 all ultimately depend from claim 54 and were rejected as thereby including the allegedly unsupported features of claim 54. We also do not sustain the Examiner's rejection of those dependent claims.

Claim 56

Independent claim 56 includes recitation of a stent formed as a tubular member and including a plurality of hoops with vertices that point in an axial direction along the longitudinal axis of the stent with some of the vertices positioned so as to "axially abut" one another. (App. Br. 21 Claims App'x.) As with claim 54, the Examiner alleges that there is lack of written description support in the specification for the "abut" feature. (Ans. 3:21-4:3.) For essentially the same reasons discussed above in connection with claim 54, we do not agree with the Examiner.

Claim 56 also includes the following feature: "wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." (App. Br. 21 Claims App'x.) Thus, claim 56 requires that the vertices of each hoop be pointed in the axial direction and be located in a plane that is "perpendicular" to the longitudinal axis of the stent. The Examiner takes the view that the term "perpendicular" is distinct from the term "substantially perpendicular" such that the embodiments in the specification describing hoops and hoop vertices that are in a plane "substantially perpendicular" to the stent's axis do not provide underlying support for claim 56. (Ans. 4:10-18; 6:16-7:17.) The Examiner postulates that the only embodiment set forth in the specification in which the term "perpendicular" is used to describe hoop configuration is found at page 44, lines 14-26 and its corresponding description does not express that "each" hoop is pointed in the axial direction and lies in the noted perpendicular plane. (*Id.*) The Examiner therefore contends that the requirement in claim 56 that the vertices of "each hoop" point in an axial direction and lies in a plane "perpendicular" to a longitudinal axis of the stent lacks adequate written description in the specification.

The Appellant challenges the Examiner's contention, arguing that its specification describes various embodiments of its invention as being of the "perpendicular variety" with hoops which are "substantially perpendicular" to the axis of the stent. (App. Br. 15-17; Reply Br. 18-21.) The Appellant submits that one of ordinary skill in the art would have recognized that its specification conveys multiple embodiments of the invention including hoops with apices which all lie in a plane that is perpendicular to the longitudinal axis of the stent. (*Id.*)

We do not agree with the Examiner that the disclosed embodiments described as incorporating hoops in a "substantially perpendicular" plane do not provide descriptive support for hoops that are specifically "perpendicular." The broader term "substantially perpendicular" does not exclude the narrower term "perpendicular," but rather, encompasses it. The specification also describes that stents of the invention include those of the "perpendicular variety" (Spec. 10:16-17) and explains that the stent may have hoops arranged such that "each hoop is substantially perpendicular to the longitudinal axis of the stent" (*id.* at 9:15-19.) Although, some embodiments of the invention formed of a single wire (such as that of Fig. 2A) are depicted or described as being formed with hoop apices that are not all absolutely or strictly perpendicular with the axis of the stent, *i.e.*, where the hoop transitions to an adjacent, successive hoop, other embodiments described are formed of continuous, sinuous shaped hoops with apices that extend axially in the same amount so as to lie in a common plane (*see* Figs. 1A, 1B, 4B-4F). In our view, the specification as a whole which describes numerous embodiments, including embodiments in which "each hoop" is substantially perpendicular to the longitudinal axis of the stent and sinuous shaped hoops with apices that extend axially in the same amount, adequately establishes that the inventors possessed an embodiment in which the associated vertices of each involved hoop lies in the required perpendicular plane.

For the foregoing reasons, we do not sustain the Examiner's rejection of claim 56 under 35 U.S.C. § 112, first paragraph. Claim 57 is dependent on claim 56 and was rejected for the same reasons as those advanced for claim 56. We also do not sustain the rejection of claim 57.

E. CONCLUSION

1. The Examiner did not correctly determine that the specification lacks adequate written description support for the claim feature of a plurality of hoops that are "non-helical."

2. The Examiner did not correctly determine that the specification lacks adequate written description support for the claim feature of hoops with apices that are "abutting" or "abut" an apex of a neighboring hoop.

3. The Examiner did not correctly determine that the specification lacks adequate written description support for the feature in claim 56 of "wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member."

F. ORDER

The rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement is **reversed**.

REVERSED

lb

Brooks, Cameron & Huebsch, PLLC
1221 Nicollet Avenue
Suite 500
Minneapolis, MN 55403

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

54953 7590 02/01/2012

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

EXAMINER
MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 02/01/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

TITLE OF INVENTION: ENDOLUMINAL STENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	05/01/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

54953 7590 02/01/2012

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

TITLE OF INVENTION: ENDOLUMINAL STENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	05/01/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTHEWS, WILLIAM H	3774	623-001110

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

54953 7590 02/01/2012

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	**PAPER NUMBER**
3774	

DATE MAILED: 02/01/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 904 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 904 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	HOWIE MATTHEWS	3774	

All participants (applicant, applicant's representative, PTO personnel):

(1) *HOWIE MATTHEWS*. (3)_____.

(2) *Kevin Waddick*. (4)_____.

Date of Interview: *18 January 2012*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *54 and 56*.

Identification of prior art discussed: *Andersen et al. USPN 5411552*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner found Andersen '552 and requested Examiner's Amendment to incorporate the limitations of claim 57 into independent claims 54 and 56 to overcome the disclosure in Andersen (Figure 1 and column 5, lines 9-28). Applicant agreed to the proposed amendments.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/William H. Matthews/ Primary Examiner, Art Unit 3774	

Notice of Allowability	Application No.	Applicant(s)	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	HOWIE MATTHEWS	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *interview summary on 1/18/12*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *20,22-33,35-41,43-49,54-56,58-62*.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☒ Certified copies of the priority documents have been received in Application No. *08/312,881* .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 6/26/06,7/3/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *1/18/12* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/William H. Matthews/
Primary Examiner, Art Unit 3774

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kevin Waddick on 1/18/12.

The application has been amended as follows:

In claim 54 at line 5 after "axis of the stent" insert ---, and wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop---.

At the end of claim 56 after "tubular member", insert ---, and wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop---.

Claims 34 and 57 are cancelled.

Claims 20,22-25,27-33,39,41,43-49,54-56 are allowable. The restriction requirement between method and stent and between species, as set forth in the Office actions mailed on 12/16/02 and 3/26/03, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 26,35-38,40, and 58-62 directed to non-

elected inventions are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

The information disclosure statements filed 7/3/03 and 6/26/06 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each lists citations lacking a date: IDS filed 7/3/03 (other documents #3 and #8) and IDS filed 6/26/06 (see sheet 6 of 6). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOWIE MATTHEWS whose telephone number is (571)272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774

Notice of References Cited	Application/Control No. 09/977,826	Applicant(s)/Patent Under Reexamination GOICOECHEA ET AL.	
	Examiner HOWIE MATTHEWS	Art Unit 3774	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,411,552	05-1995	Andersen et al.	623/2.18
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-3,304,557	02/21/1967	S. Polansky	
		US-3,657,744	04/25/1972	Ersek	
		US-3,805,301	04/23/1974	Liebig	
		US-4,130,904	12/26/1978	Whalen	
		US-4,202,349	05/13/1980	Jones	
		US-4,494,531	01/22/1985	Gianturco	
		US-4,530,113	07/23/1985	Matterson	
		US-4,545,082	10/08/1985	Hood	
		US-4,787,899	11/29/1988	Lazarus	
		US-4,795,463	01/03/1989	Gerow	
		US-5,163,958	11/17/1992	Pinchuk	
		US-5,192,310	03/09/1993	Herweck, et al.	
		US-5,306,294	04/26/1994	Winston et al.	
		US-5,330,500	07/19/1994	Song	
		US-5,342,387	08/30/1994	Summers	
		US,5,354,308	10/11/1994	Simon et al.	
		US-5,383,892	01/24/1995	Cardon	
		US-5,395,390	03/07/1995	Simon et al.	
		US-5,429,144	07/04/1995	Wilk	
		US-5,443,497	08/22/1995	Venbrux	
		US-5,522,880	06/04/1996	Barone et al.	
		US-5,540,712	07/30/1996	Kleshinski et al.	
		US-5,562,724	10/08/1996	Vorwerk et al.	
		US-5,562,727	10/08/1996	Turk et al.	
		US-5,571,170	11/05/1996	Palmaz et al.	
		US-5,609,605	03/11/1997	Marshall et al.	
		US-5,628,783	05/13/1997	Quiachon et al.	
		US-5,632,772	05/27/1997	Alcime	
		US-5,639,278	06/17/1997	Dereume et al.	
		US-5,662,675	09/02/1997	Polanskyj Stockert et al.	
		US-5,676,697	10/14/1997	MacDonald	
		US-5,683,448	11/04/1997	Cragg	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 2 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,697,970	12/16/1997	Schmitt	
		US-5,725,572	03/10/1998	Lam	
		US-5,741,332	04/21/1998	Schmitt	
		US-5,800,456	09/01/1998	Maeda et al.	
		US-5,824,042	10/20/1998	Lombardi	
		US-5,871,536	02/16/1999	Lazarus	
		US-5,876,432	03/02/1999	Lau et al.	
		US-6,090,137	07/18/2000	Schmitt	
		US-6,102,938	08/15/2000	Evans et al.	
		US-6,123,722	09/26/2000	Fogarty, et al.	
		US-6,129,756	10/10/2000	Kugler et al.	
		US-6,156,063	12/05/2000	Douglas	
		US-6,159,239	12/12/2000	Greenhalgh	
		US-6,162,246	12/19/2000	Barone	
		US-6,176,875	01/23/2001	Lenker, et al.	
		US-6,197,049	03/06/2001	Shaolian	
		US-6,200,339	03/13/2001	Leschinsky et al.	
		US-6,210,435	04/03/2001	Piplani et al.	
		US-6,221,099	04/24/2001	Andersen, et al.	
		US-6,221,102	04/24/2001	Baker et al.	
		US-6,235,050	05/22/2001	Quiachon, et al.	
		US-6,251,133	06/26/2001	Richter et al.	
		US-6,251,134	06/26/2001	Alt et al.	
		US-6,261,316	07/17/2001	Shaolian et al.	
		US-6,270,523	08/07/2001	Herweck, et al.	
		US-6,273,909	08/14/2001	Kugler et al.	
		US-6,280,467	08/28/2001	Leonhardt	
		US-6,283,991	09/04/2001	Cox, et al.	
		US-6,287,335	09/11/2001	Drasler et al.	
		US-6,312,462	11/06/2001	McDermott et al.	
		US-6,325,819	12/04/2001	Pavcnik et al.	
		US-6,325,826	12/04/2001	Vardi et al.	
		US-6,331,190	12/18/2001	Shokoohi et al.	
		US-6,334,869	01/01/2002	Leonhardt et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).
[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).
[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[6]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 3 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,344,056	02/05/2002	Dehdashtian	
		US-6,348,066	02/19/2002	Pinchuk et al.	
		US-6,361,557	03/26/2002	Gittings, et al.	
		US-6,395,019	05/28/2002	Chobotov	
		US-6,395,022	05/28/2002	Piplani et al.	
		US-6,398,803	06/04/2002	Layne, et al.	
		US-6,398,807	06/04/2002	Chouinard et al.	
		US-6,409,750	06/25/2002	Hyodoh et al.	
		US-6,409,756	06/25/2002	Murphy	
		US-6,416,542	07/09/2002	Marcade et al.	
		US-6,428,565	08/06/2002	Wisselink	
		US-6,440,166	08/27/2002	Kolluri	
		US-6,454,795	09/24/2002	Chuter	
		US-6,464,721	10/15/2002	Marcade et al.	
		US-6,485,524	11/26/2002	Strecker	
		US-6,517,572	02/11/2003	Kugler et al.	
		US-6,524,336	02/25/2003	Papazolgou, et al.	
		US-6,540,777	04/01/2003	Stenzel	
		US-6,547,820	04/15/2003	Staudenmeier	
		US-6,551,350	04/22/2003	Thornton et al.	
		US-6,565,596	05/20/2003	White et al.	
		US-6,576,007	06/10/2003	Dehdashtian et al.	
		US-6,576,009	06/10/2003	Ryan et al.	
		US-6,582,458	06/24/2003	White et al.	
		US-6,592,614	07/15/2003	Lenker, et al.	
		US-6,645,242	11/11/2003	Quinn	
		US-6,652,567	11/25/2003	Deaton	
		US-6,682,541	01/27/2004	Gifford, III, et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).
[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).
[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[6]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 4 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 0 464 755	01/08/1992	Nissho Corp.		
		GB 1205743	09/16/1970	Colin C. Didcott		☐
		GB 2269104	02/02/1994	Taha R. Lazim		
		FR 1602513	01/29/1971	National Research Development Corp.(GB)		
		JP 3133446 (w/English Abstract)	06-06-1991	Cook Inc.		
		JP 5305092	11/19/1993	Cook Inc.		
		JP H05-76554	03/30/1993	Endovascular Technologies, Inc.		
		JP 6023031	02/01/1994	Endovascular Technologies, Inc.		
		WO 83/03752	11-10-1983	Hans Wallstén		
		WO 92/06734	04/30/1992	Ho Young Song		
		WO 95/01761	01/19/1995	Dr. T. J. Fogarty		
		WO 97/09008	03/13/1997	Medtronic, Inc.		
		WO 98/27895	07/02/1998	Prograft Medical, Inc.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).
[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).
[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[6]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 5 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		CA 2,086,333	04/25/1991	Schneider (USA) Inc.		☐
		CA 2,158,373	10/27/1994	Pharmacyclics, Inc.		☐
		CA 2 144 305 C	02/02/1995	Cook Incorporated		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).
[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).
[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[6]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

PTO/SB/08a (08-03) (AW 10/2003)

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 6 of 6

Complete if Known	
Application Number	09/977,826
Filing Date	October 15, 2001
First Named Inventor	George Goicoechea
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket No.	BSI-010US4

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		~~Notice of Opposition by Scimed Life Sciences, Inc. to European Patent No. 0 676 937 B~~	☐
		~~Opposition by William Cook Apc to European Patent No. 0 676 937 B~~	☐
		Verlag, "Interventional Radiology," pp. 692-699 (1990)	☐
		Yoshioka et al., "Self-Expanding Endovascular Graft: An Experimental Study in Dogs," AJR 15: pp. 673-676 (1988)	☐
		~~U.S. App. 08/051,728~~	☐
		Official Action in Canadian Application No. 2,182,982, issued by the Canadian Intellectual Property Office on March 30, 2006	☐
			☐
			☐
			☐

Examiner Signature	/William Matthews/	Date Considered	01/25/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	19	(hoop and (apice or apex or vertex or vertice) and stent). clm.	USPAT; UPAD	OR	ON	2012/01/19 15:35
L2	71	((ring or band or hoop) and (apice or apex or vertex or vertice) and stent). clm.	USPAT; UPAD	OR	ON	2012/01/19 15:52

1/19/12 3:52:36 PM

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	HOWIE MATTHEWS	3774	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
interference text search EAST, see printout		1/18/2012	WHM

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
updated search	1/18/2012	WHM

FORM PTO-1449

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO
Information Disclosure Statement by Applicant (Use several sheets if necessary)	BSI-010US4	09/977,826
	APPLICANT G. Goicoechea, et al.	
	FILING DATE October 15, 2001	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
[illegible]		3,500,820	03/17/70	T. H. O. Almen			
		3,868,956	03/04/75	Alfidi et al.			
		3,878,565	04/22/75	Sauvage			
		3,890,977	06/24/75	Wilson			
		3,996,938	12/14/76	Clark, III			
		4,140,126	02/20/79	Choudhury			
		4,149,911	04/17/79	Clabburn			
		4,214,587	07/29/80	Sakura, Jr.			
		4,306,318	12/22/81	Mano et al.			
		4,425,908	01/17/84	Simon			
		4,503,569	03/12/85	Dotter			
		4,512,338	04/23/85	Balko et al.			
		4,553,545	11/19/85	Maass et al.			
		4,560,374	12/24/85	Hammerslag			
[illegible]		4,562,596	01/07/86	Kornberg			

FOREIGN PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES | NO	
[illegible]		0 145 166 B1	06/19/85	EPO				
		0 423 916 A1	04/24/91	EPO				
		0 480 667 A1	04/15/92	EPO				
		0 481 365 B1	06/22/94	EPO (Claims provided in English)				
		0 508 473 A2	10/14/92	EPO				
		0 536 164 B1	03/09/94	EPO				
		0 540 290 A2	05/05/93	EPO				
		0 556 850 A1	08/25/93	EPO				

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

		1)	Search Report
		2)	Dotter et al., "Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report", Technical Developments and Instrumentation, Radiology, Vol. 147, pp. 259-260 (April 1983)
[illegible]		3)	~~Schetky, "Shape-Memory Alloys", pp. 74-82~~

/W.M./
01/25/2012

I:\BSI\010US4\1449.doc

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO
Information Disclosure Statement by Applicant (Use several sheets if necessary)	BSI-010US4	09/977,826
	APPLICANT G. Goicoechea, et al.	
	FILING DATE October 15, 2001	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
		4,577,631	03/25/86	Kreamer			
		4,580,568	04/08/86	Gianturco			
		4,617,932	10/21/86	Kornberg			
		4,649,922	03/17/87	Wiktor			
		4,655,771	04/07/87	Wallsten			
		4,665,906	05/19/87	Jervis			
		4,665,918	05/19/87	Garza et al.			
		4,681,110	07/21/87	Wiktor			
		4,728,328	03/01/88	Hughes			
		4,729,766	03/08/88	Bergentz et al.			
		4,732,152	03/22/88	Wallsten et al.			
		4,733,665	03/29/88	Palmaz			
		4,739,762	04/26/88	Palmaz			
		4,762,128	08/09/88	Rosenbluth			
		4,768,507	09/06/88	Fischell et al.			
		4,772,264	09/20/88	Cragg			
		4,776,337	10/11/88	Palmaz			
		4,800,882	01/31/89	Gianturco			
		4,820,298	04/11/89	Leveen et al.			
		4,830,003	05/16/89	Wolff et al.			
		4,856,516	08/15/89	Hillstead			
		4,878,906	11/07/89	Lindemann et al.			
		4,886,062	12/12/89	Wiktor			
		4,886,065	12/12/89	Collins, Jr.			
		4,913,141	04/03/90	Hillstead			
		4,922,905	05/08/90	Strecker			
		4,969,458	11/13/90	Wiktor			
		4,969,890	11/13/90	Sugita et al.			
		4,994,032	02/19/91	Sugiyama et al.			
		4,994,071	02/19/91	MacGregor			
		5,019,085	05/28/91	Hillstead			
		5,019,090	05/28/91	Pinchuk			
		5,035,706	06/30/91	Gianturco			
		5,037,427	08/06/91	Harada et al.			
		5,041,126	08/20/91	Gianturco			
		5,047,050	09/10/91	Arpesani			
		5,057,092	10/15/91	Webster, Jr.			
		5,064,435	11/12/91	Porter			
		5,067,957	11/26/91	Jervis			
		5,078,726	01/07/92	Kreamer			
		5,078,736	01/07/92	Behl			
		5,085,635	02/04/92	Cragg			
		5,104,399	04/14/92	Lazarus			

I:\BSI\010US4\1449.doc

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO
Information Disclosure Statement by Applicant (Use several sheets if necessary)	BSI-010US4	09/977,826
	APPLICANT G. Goicoechea, et al.	
	FILING DATE October 15, 2001	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
WJ		5,104,404	04/14/92	Wolff			
		5,123,917	06/23/92	Lee			
		5,133,732	07/28/92	Wiktor			
		5,135,536	08/04/92	Hillstead			
		5,151,105	09/29/92	Kwan-Gett			
		5,161,547	11/10/92	Tower			
		5,183,085	02/02/93	Timmermans			
		5,192,297	03/09/93	Hull			
		5,201,901	04/13/93	Harada et al.			
		5,207,695	05/04/93	Trout			
		5,236,446	08/17/93	Dumon			
		5,275,622	01/04/94	Lazarus			
		5,282,824	02/01/94	Gianturco			
		5,290,305	03/01/94	Inone			
		5,292,331	03/08/94	Boneau			
		5,304,200	04/19/94	Spaulding			
		5,314,472	05/24/94	Fontaine			
		5,354,309	10/11/94	Schnepp-Pesch			
		5,360,443	11/01/94	Barone			
		5,366,504	11/1994	Anderson et al.			
		5,370,683	12/06/94	Fontaine			
		5,383,928	01/24/95	Scott et al.			
		5,387,235	02/07/95	Chuter			
		5,389,106	02/1995	Tower			
		5,395,349	03/07/95	Quiachon et al.			
		5,397,345	03/14/95	Lazarus			
		5,405,377	04/11/95	Cragg			
		5,415,664	05/16/95	Pinchuk			
		5,419,324	05/30/95	Dillow			
		5,443,496	08/22/95	Schwartz			
		5,443,498	08/22/95	Fontaine			
		5,456,713	10/10/95	Chuter			
		5,484,418	01/16/96	Quiachon et al.			
		5,507,767	04/16/96	Maeda			
WJ		5,507,771	04/16/96	Gianturco			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. BSI-010US4	SERIAL NO 09/977,826
Information Disclosure Statement by Applicant (Use several sheets if necessary)	APPLICANT G. Goicoechea, et al.	
	FILING DATE October 15, 2001	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
		5,364,354	11/15/94	Walker et al.			
		5,370,691	12/06/94	Samson			
		5,464,449	11/07/95	Ryan et al.			
		5,489,295	02/06/96	Piplani et al.			
		5,562,726	10/08/96	Chuter			
		5,562,728	10/08/96	Lazarus et al.			
		5,575,817	11/19/96	Martin			
		5,916,263	6/29/99	Goicoechea et al.			
		5,609,627	3/11/97	Goicoechea et al.			
		5,693,086	12/2/97	Goicoechea et al.			
		5,683,450	11/4/97	Goicoechea et al.			

FOREIGN PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES	NO
		0 551 179 A1	07/14/93	EPO				
		0 579 523 A1	01/19/94	EPO				
		0 621 015 A1	10/26/94	EPO				
		0 621 016 A1	10/26/94	EPO				
		0 622 088 A1	11/02/94	EPO				
		0 646 365 A1	04/05/95	EPO				
		0 656 197 A2	06/07/95	EPO				
		0 657 147 A2	06/14/95	EPO				
		0 662 307 A1	07/12/95	EPO				
		WO89/08433	09/21/89	PCT				
		WO91/07928	06/13/91	PCT				
		WO92/00043	01/09/92	PCT				
		WO93/13825	07/22/93	PCT				
		WO94/17754	08/18/94	PCT (Abstract provided in English)				
		WO95/01761	01/19/95	PCT				
		43 03 181	02/1993	DE				
		2 678 508 A1	01/08/93	France				
		3 918 736 A1	12/13/90	Germany				
		4 303 181 A1	08/11/94	Germany				
		1 491 202	11/09/77	United Kingdom				
		2 106 190 A	04/07/83	United Kingdom				
		0 423 619 A1	04/24/91	EPO				
		0 466 518 B1	01/15/92	EPO				

I:\BSI\010US4\1449.doc

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO
Information Disclosure Statement by Applicant (Use several sheets if necessary)	BSI-010US4	09/977,826
	APPLICANT G. Goicoechea, et al.	
	FILING DATE October 15, 2001	GROUP 3738

FOREIGN PATENT DOCUMENTS (CONTINUED)

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES | NO
JM		2,678,508	1/93	France			

OTHER DOCUMENTS
(Including Author, Title, Date, Pertinent Pages, Etc.)

		4)	K. Otsuka et al., "Shape-Memory Alloys - Pseudoelasticity", Metals Forum. Vol. 4, No. 3, pp. 142-152 (1981)
		5)	Cragg et al., "Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire", Radiology, Vol. 147, No. 1, pp. 261-263 (April 1983)
		6)	Cragg et al., "Percutaneous Arterial Grafting", Radiology, Vol. 150, No. 1, pp. 45-49 (1984)
		7)	Cragg. et al., "Stents Vascular Stents", Interventional Radiology, pp. 686-692 (1990)
✓		~~8)~~	~~T.W. Duerig et al., "An Engineer's Perspective of Pseudoelasticity", pp. 369-393~~
JM			

/W.M./

01/25/2012

I:\BSI\010US4\1449.doc

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO
Information Disclosure Statement by Applicant (Use several sheets if necessary)	BSI-010US4	09/977,826
	APPLICANT G. Goicoechea, et al.	
	FILING DATE October 15, 2001	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date

FOREIGN PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES	NO
WHW		DE 93 19 267.3 U	04/07/94	Germany				
		EP 734 235	06/22/95	Europe				
		PM 1537	04/06/95	Australia				
		WO 95/16406	06/22/95	PCT				
		WO 95/08966	04/06/95	PCT				
		EP 461 791 A1	12/18/91	Europe				
		EP 539 237 A1	04/28/93	Europe				

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

			Video cassette allegedly showing operation conducted by Geoffrey H. White on November 26, 1993
			Declaration of Geoffrey H. White executed February 18, 2000
			Declaration of Ian L. Gordon executed June 17, 2000
			Declaration of W. Davis dated February 28, 2000
			Declaration of Mark Dehdashtian dated June 16, 2000
			Communication of a Notice of Opposition dated January 26, 2001 for EP 783 873 (including Notice of Opposition)
WHW			Communication of a Notice of Opposition dated January 26, 2001 for EP 783 874 (including Notice of Opposition)

Examiner WHW	Date Considered 6/24/03

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

USPTO Form 1449 [R&P]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO
Information Disclosure Statement by Applicant (Use several sheets if necessary)	BSI-010US4	09/977,826
	APPLICANT: G. Goicoechea et al.	
	FILING DATE: October 15, 2001	GROUP: 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
WM		5,716,365	02/10/98	Goicoechea et al.			
		5,718,724	02/17/98	Goicoechea et al			
		5,776,180	07/07/98	Goicoechea et al			
		5,800,508	09/01/98	Goicoechea et al			
		5,938,696	08/17/99	Goicoechea et al			
		6,051,020	04/18/00	Goicoechea et al			
		6,117,167	09/12/00	Goicoechea et al			
		6,165,213	12/26/00	Goicoechea et al			
WM		6,302,906	10/16/01	Goicoechea et al.			

FOREIGN PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES	NO

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner	Will Hmt	Date Considered	6/24/03

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

USPTO Form 1449 [R&P]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /W.M./

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 4645

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/977,826	10/15/2001	623	3774	94-P0273US19

APPLICANTS

George Goicoechea, Grand Bahama, BAHAMAS;
John Hudson, Leicester, UNITED KINGDOM;
Claude Mialhe, Draguignan, FRANCE;
Andrew H. Cragg, Edina, MN;
Michael D. Dake, Stanford, CA;

**** CONTINUING DATA ***************************

This application is a CON of 09/313,593 05/18/1999 PAT 6,302,906
which is a CON of 08/662,484 06/13/1996 PAT 5,916,263
which is a CON of 08/317,763 10/04/1994 PAT 5,609,627
which is a CON of 08/312,881 09/27/1994

**** FOREIGN APPLICATIONS ***************************

EUROPEAN PATENT OFFICE (EPO) EP94400284.9 02/09/1994
EUROPEAN PATENT OFFICE (EPO) EP94401306.9 06/10/1994

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

11/05/2001

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☑ Yes ☐ No Verified and Acknowledged /WILLIAM H MATTHEWS/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		BAHAMAS	23	53	11

ADDRESS

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403
UNITED STATES

TITLE

ENDOLUMINAL STENT

FILING FEE RECEIVED		
2006	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Issue Classification	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/977,826	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	HOWIE MATTHEWS	3774	

ISSUE CLASSIFICATION

ORIGINAL			CROSS REFERENCE(S)						
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)						
623	1.16								
INTERNATIONAL CLASSIFICATION									
A 6 1 F	2/06								
	/								
	/								
	/								
	/								

(Assistant Examiner) (Date)	/William H. Matthews/ 1/19/12 (Primary Examiner) (Date)	Total Claims Allowed: 35	
(Legal Instruments Examiner) (Date)		O.G. Print Claim(s): 1	O.G. Print Fig.: 4A

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1	13	31	35	61		91		121		151		181
	2	15	32	31	62		92		122		152		182
	3	16	33		63		93		123		153		183
	4		34		64		94		124		154		184
	5	17	35		65		95		125		155		185
	6	18	36		66		96		126		156		186
	7	19	37		67		97		127		157		187
	8	20	38		68		98		128		158		188
	9	21	39		69		99		129		159		189
	10	22	40		70		100		130		160		190
	11	14	41		71		101		131		161		191
	12		42		72		102		132		162		192
	13	23	43		73		103		133		163		193
	14	24	44		74		104		134		164		194
	15	25	45		75		105		135		165		195
	16	26	46		76		106		136		166		196
	17	27	47		77		107		137		167		197
	18	28	48		78		108		138		168		198
	19	29	49		79		109		139		169		199
2	20		50		80		110		140		170		200
	21		51		81		111		141		171		201
3	22		52		82		112		142		172		202
5	23		53		83		113		143		173		203
6	24	1	54		84		114		144		174		204
7	25	12	55		85		115		145		175		205
4	26	30	56		86		116		146		176		206
8	27		57		87		117		147		177		207
9	28	32	58		88		118		148		178		208
10	29	33	59		89		119		149		179		209
11	30	34	60		90		120		150		180		210

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

54953 7590 02/01/2012
BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

electronically filed with

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being ~~deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to~~ the USPTO ~~(571) 273-2885~~, on the date indicated below.

Angela Miller	(Depositor's name)
A. Miller	(Signature)
May 1, 2012	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	94-P0273US19	4645

TITLE OF INVENTION: ENDOLUMINAL STENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	05/01/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTHEWS, WILLIAM H	3774	623-001110

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☒ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Brooks, Cameron + Huebsch, PLLC
2 1221 Nicollet Avenue, Suite 500
3 Minneapolis, MN 55403

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Scimed Life Systems, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Maple Grove, MN

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☒ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature K. G. Waddick Date May 1, 2012

Typed or printed name Kevin G. Waddick Registration No. 57,007

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB/47 (03-09)
Approved for use through 03/31/2012. OMB 0651-0016
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- OR -

Fax to:
571-273-6500

INSTRUCTIONS: The issue fee must have been paid for application(s) listed on this form. In addition, only an address represented by a Customer Number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. **When to check the first box below**: If you have a Customer Number to represent the fee address. **When to check the second box below**: If you have no Customer Number representing the desired fee address, in which case a completed Request for Customer Number (PTO/SB/125) must be attached to this form. For more information on Customer Numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☑ Customer Number: 000031111

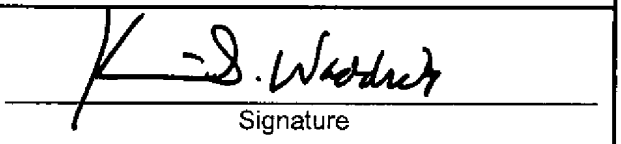
OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
	09/977,826

Completed by (check one):

☐ Applicant/Inventor



Signature

☑ Attorney or Agent of record 57,007 (Reg. No.)

Kevin G. Waddick
Typed or printed name

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

612-236-0126
Requester's telephone number

☐ Assignee recorded at Reel _____ Frame _____

May 1, 2012
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more that one signature is required, see below*.

☐ * Total of 2 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	09977826
Filing Date:	15-Oct-2001
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Filer:	Kevin Waddick/Angela Miller
Attorney Docket Number:	94-P0273US19

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1740	1740
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**2040**

Electronic Acknowledgement Receipt

EFS ID:	12678882
Application Number:	09977826
International Application Number:	
Confirmation Number:	4645
Title of Invention:	ENDOLUMINAL STENT
First Named Inventor/Applicant Name:	George Goicoechea
Customer Number:	54953
Filer:	Kevin Waddick/Angela Miller
Filer Authorized By:	Kevin Waddick
Attorney Docket Number:	94-P0273US19
Receipt Date:	01-MAY-2012
Filing Date:	15-OCT-2001
Time Stamp:	18:11:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Electronic Funds Transfer
Payment was successfully received in RAM	$2040
RAM confirmation Number	6397
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	00196303.PDF	71032 413b0740751cf9630d4c791fdc64a5a2e6cf0d16	no	1
Warnings:					
Information:					
2	Change of Address	00196304.PDF	91179 46a88de4fc8eca2507634d18ac58e1498717396f	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31892 5c68e19ab1cbe13d3b072296fe8ecdc1427384ba	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	194103		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	06/05/2012	8192482	94-P0273US19	4645

54953 7590 05/16/2012

BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1263 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

George Goicoechea, Grand Bahama, BAHAMAS;
John Hudson, Leicester, UNITED KINGDOM;
Claude Mialhe, Draguignan, FRANCE;
Andrew H. Cragg, Edina, MN;
Michael D. Dake, Stanford, CA;

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 **Director of the U.S. Patent and Trademark Office** **P.O. Box 1450** **Alexandria, VA 22313-1450**	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
12-cv-1791-GMS	12/28/2012	District of Delaware

PLAINTIFF	DEFENDANT
LifePort Sciences LLC	Endologix, Inc.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	5,489,295	2/6/1996	LifePort Sciences LLC
2	6,117,167	9/12/2000	LifePort Sciences LLC
3	US 6,302,906 B1	10/16/2001	LifePort Sciences LLC
4	5,993,481	11/30/1999	LifePort Sciences LLC
5	5,676,696	10/14/1997	LifePort Sciences LLC

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY				
8/12/2014	☑ Amendment	☐ Answer	☐ Cross Bill	☐ Other Pleading	
	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK		
1	US 8,192,482 B2	6/5/2012	LifePort Sciences LLC		
2					
3					
4					
5					

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**