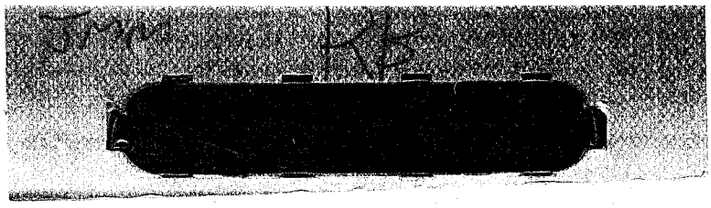

ISSUE CLASSIFICATION	Class	Subclass
	606	108

JC542 U.S. PTO
09/420249
10/19/99

PATENT NUMBER
6371962
6371962

U.S. UTILITY PATENT APPLICATION

O.I.P.E.	PATENT DATE
SCANNED AG. Q.A. KLO1	APR 16 2002

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	606 ~~604~~	108	3760	J. Yu

FILED WITH: ☐ DISK (CRF) ☐ FICHE
(Attached in pocket on right inside flap)

Con Yu

PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)						
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					
606	108	606	194					
INTERNATIONAL CLASSIFICATION								
A61F	11/00							
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	/							
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	/						☐ Continued on Issue Slip Inside File Jacket	

☒ TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.
	4	8	1,2	37	1

☐ a) The term of this patent subsequent to _____ (date) has been disclaimed.

_____ (Assistant Examiner) _____ (Date)

NOTICE OF ALLOWANCE MAILED

12/10/01

☒ b) The term of this patent shall not extend beyond the expiration date of U.S. Patent No. 6,207,543 and 6,123,712

JUSTINE R. YU
PRIMARY EXAMINER
(Primary Examiner) 11/28/01 (Date)

ISSUE FEE

Amount Due	Date Paid
#1280	2-26-02 AH

☐ c) The terminal ____ months of this patent have been disclaimed.

Everett Williams (Legal Instruments Examiner) 12-7-01 (Date)

ISSUE BATCH NUMBER

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The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 368. Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only.

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(Rev. 10/97)

ISSUE FEE IN FILE (LABEL AREA) Formal Drawings (4 sht(s)) set

PATENT APPLICATION

09420249

jc542 U.S. PTO
09/420249
10/19/99

INITIALS 10/29/99 12

CONTENTS

		Date received (Incl. C. of M.) or Date Mailed			Date received (Incl. C. of M.) or Date Mailed
1.	Application ___ papers.	10-19-99	42.		
2.	Pet Amdt A	11/12/99	43.		
3.	Remark	12-10-99	44.		
4.	IDS	03/20/00	45.		
5.	Rej (Imm)	8-15-00	46.		
6.	Returned filing receipt	3-7-00	47.		
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8.	Rej (3)	02/08/01	49.		
9.	EOF	6-11-01	50.		
10.	Amdt C	6-11-01	51.		
11.	REJECTION	08-20-01	52.		
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14.	Terminal Disclaimer	11-20-01	55.		
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Bib Data Sheet

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/420,249	10/19/1999 RULE _	604	3734	S6.2-8619

APPLICANTS

Louis g. ELLIS, ST. ANTHONY, MN ;
ANDREW j. DUSBABEK, DAYTON, MN ;
CHRISTOPHER r. LARSON, ST. PAUL, MN ;
TERRY v. BROWN, FRIDLEY, MN ;

** CONTINUING DATA **********

THIS APPLICATION IS A CON OF 08/702,150 08/23/1996 PAT 6,007,543

yes, JL

** FOREIGN APPLICATIONS **********

None, JL

IF REQUIRED, FOREIGN FILING LICENSE GRANTED **

** 11/09/1999

		STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
Foreign Priority claimed	☐ yes ☑ no	MN	4	~~34~~ 36	3
35 USC 119 (a-d) conditions met	☐ yes ☑ no ☐ Met after Allowance				
Verified and Acknowledged	Examiner's Signature Initials				

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TITLE

Ins. A1 ~~STENT DELIVERY SYSTEM~~ A1

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
1142	No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

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Foreign Priority claimed	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
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35 USC 119 (a-d) conditions met ☐ yes ☐ no ☐ Met after Allowance				
Verified and Acknowledged Examiner's Signature Initials				

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TITLE

STENT DELIVERY SYSTEM

FILING FEE RECEIVED		
1142	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

Express Mail Label No.: EL440581335US

NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-8619
	Total Pages in this Submission *(including checks and postcard)* 30

JC645 U.S. PTO 10/19/99

JC542 U.S. PTO 09/420249 10/19/99

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled: Stent Delivery System

and invented by: Louis G. Ellis; Andrew J. Dusbabek; Christopher R. Larson; Terry V. Brown

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*
☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 08/702,150, filed August 23, 1996

Enclosed (in addition to the 4 pages of this transmittal) are: **4 pages**

Application Elements

1. ☒ **Filing fee as calculated below:**
   a. ☒ **filing fee is NOT ENCLOSED - fee will be paid at the time of responding to the Notice of Missing Parts -- DO NOT CHARGE DEPOSIT ACCOUNT**
   b. ☐ **a check in the amount of $_____ to cover the filing fee is enclosed. ___ pages**
   c. ☐ **charge to Deposit Account as authorized at Item 2(a) on next page.**

FEE CALCULATION AND C L A I M S					
For	**No. Filed**	**No. Allowed**	**No. Extra**	**Rate**	**Fee**
Total Claims	34	- 20 =	14	x $18.00	$ 252.00
Indep. Claims	3	- 3 =	0	x $78.00	$ 0
				BASIC FEE	$760.00
				TOTAL FILING FEE	$1,012.00

continued on next page.....

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NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-8619
	Total Pages in this Submission *(including checks and postcard)* 30

2. **The Commissioner is hereby authorized to charge and credit Deposit Account No. 22-0350 as described below. A duplicate copy of this sheet is enclosed.**
   - a. ☐ **Charge the amount of $____ as filing fee.**
   - b. ☒ **Credit any overpayment.**
   - c. ☐ **Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.**
   - d. ☐ **Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).**

3. ☒ Specification having 11 pages and including the following: 11 pages
   - a. ☒ Application Cover Sheet - 1 page
   - b. ☒ Descriptive Title of the Invention -
   - c. ☐ Cross References to Related Applications *(if applicable)*
   - d. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   - e. ☐ Reference to Microfiche Appendix *(if applicable)*
   - f. ☒ Background of the Invention
   - g. ☒ Brief Summary of the Invention
   - h. ☒ Brief Description of the Drawings *(if applicable)*
   - i. ☒ Detailed Description
   - j. ☒ Claim(s) as Classified Below - 3 pages
   - k. ☒ Abstract of the Disclosure -1 page

4. ☒ Drawing(s) *(when necessary as prescribed by 35 U.S.C. 113)* 4 sheets 4 pages

5. ☒ Oath or Declaration - 3 pages
   - a. ☐ Newly executed *(original or copy)* ☐ Unexecuted
   - b. ☒ Copy from a prior application (37 C.F.R. 1.63(d)) *(for continuation/divisional application only)*

6. ☒ Separate Power of Attorney 1 page

   ☐ 37 C.F.R. 3.73(B) Statement *(when there is an assignee and power of attorney is from assignee)*. It is hereby certified that the undersigned has authority to make this certification and has reviewed all the documents in the chain of title of the patent application identified herein and, to the best of undersigned's knowledge and belief, title is in the assignee identified in the accompanying Power of Attorney.

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NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-8619
	Total Pages in this Submission *(including checks and postcard)* 30

☒ Power of Attorney filed in parent application.

7. ☐ Incorporation by Reference *(usable if Box 5b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 5b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

8. ☐ Computer Program in Microfiche *(Appendix)* ___ pages

9. ☐ Nucleotide and/or Amino Acid Sequence Submission ___ pages
(if applicable, all must be included)
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy *(identical to computer copy)*
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

10. ☒ Assignment Papers:
   a. ☐ Assignment Recordation Cover Sheet (Form PTO 1595)
   b. ☐ Assignment
   c. ☐ A check in the amount of $___ to cover the Recordal Fee
   d. ☒ Previously recorded on November 14, 1996, Reel 8281, Frame 0720

11. ☐ English Translation Document *(if applicable)* ___ pages

12. ☐ Information Disclosure Statement: ___ pages
   a. ☐ PTO Form 1449 b. ☐ Copies of IDS Citations

13. ☒ Preliminary Amendment 5 pages

14. ☒ Acknowledgement Postcard 1 page

15. ☒ Form of Mailing - Express Mail *(Specify Label No.)*: EL440581335US

16. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)* ___ pages

Express Mail Label No.: EL440581335US

NEW UTILITY PATENT APPLICATION TRANSMITTAL **(Large Entity)** *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-8619 Total Pages in this Submission *(including checks and postcard)* 30

17. ☒ Additional Enclosures *(please identify below)*: 1 page
- ☒ Constructive Petition for Extension of Time and Fee Authorization Pursuant to 37 C.F.R. §1.136(a)(3) - 1 page
- ☐ _____

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 19, 1999

By: _____
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DOCKET NO.S63.2-8619

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

INVENTORS: Louis G. Ellis; Andrew J. Dusbabek; Christopher R. Larson; Terry V. Brown

TITLE: STENT DELIVERY SYSTEM

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STENT DELIVERY SYSTEM

Background of the Invention

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through a vessel and advanced through therein until the distal end thereof is at a desired location in the vasculature. A guidewire and a dilatation catheter having a balloon on the distal end thereof are introduced through the guiding catheter with the guidewire sliding through the dilatation catheter. The guidewire is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guidewire until the dilatation balloon is properly positioned across the lesion. Once in position across the lesion, the flexible, expandable, preformed balloon is inflated to a predetermined size with a liquid or gas at relatively high pressures, such as greater than about four atmospheres, to radially compress the arthrosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile so that the dilatation catheter may be withdrawn from the patients vasculature and blood flow resumed through the dilated artery.

In angioplasty procedures of the kind described above, there may be restenosis of the artery, which either necessitates another angioplasty procedure, a surgical by-pass operation, or some method of repairing or strengthening the area. To prevent restenosis and strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, called a stent, inside the artery at the lesion. The stent is expanded to a larger diameter for placement in the vasculature, often by the balloon portion of the catheter. Stents delivered to a restricted coronary artery, expanded to a larger diameter as by a balloon catheter, and left in place in the artery at the site of a dilated lesion are shown in U.S. patent 4,740,207 to Kreamer; U.S. Patent 5,007,926 to Derbyshire; U.S. Patent 4,733,665 to Palmaz; U.S. Patent 5,026,377 to Burton et al.; U.S. Patent 5,158,548 to Lau et al.; U.S. Patent 5,242,399 to Lau et al.; U.S. 5,344,426 to Lau et al.; U.S. Patent 5,415,664 to Pinchuk; U.S. Patent 5,453,090 to Martinez et al.; U.S. Patent 4,950,227 to Savin; U.S. Patent 5,403,341 to Solar; U.S. Patent 5,108,416 to Ryan et al. and European Patent Application No. 707 837 A1 to Sheiban, all of which are

incorporated herein by reference. A stent particularly preferred for use with this invention is described in PCT Application No. 960 3092 A1, published 8 February 1996, the content of which is also incorporated herein by reference.

The present invention is particularly directed to improved arrangements for releasably attaching the stent to the catheter to facilitate delivery thereof.

Summary of the Invention

This invention concerns apparatus suitable for delivery of stents to body cavities. In general, stents are prosthetic devices which can be positioned within a body cavity, for example, a blood vessel of the body of a living human or in some other difficultly accessible place. The stent prosthesis is formed of a generally tubular body, the diameter of which can be decreased or increased. Stents are particularly useful for permanently widening a vessel which is either in a narrowed state, or internally supporting a vessel damaged by an aneurysm. Such stents are typically introduced into the body cavity by use of a catheter. The catheter is usually of the balloon catheter type in which the balloon is utilized to expand the stent, which is positioned over the balloon, to place it in a selected location in the body cavity. The present invention is particularly directed to improved arrangements for releasably attaching the stent to the catheter to facilitate delivery thereof. The stent is held in place on the catheter by means of an enlarged body carried by the catheter shaft within the balloon to which the stent and balloon are fitted, as by crimping.

Brief Description of the Figures

Figure 1 is an isometric view, a portion of which is enlarged and in longitudinal section, of a balloon catheter having a stent fixed to the catheter by being crimped thereto over the balloon;

Figure 2 is an even more enlarged view in longitudinal cross-section of the distal end portion of the catheter of Figure 1;

Figure 3 is an enlarged cross-sectional view of the distal end portion of the catheter of Figure 1 similar to that of enlarged view Figure 2 but showing the balloon in an expanded condition along with the expanded stent;

Figure 4 is a schematic showing of a preferred mounting body carried by the catheter shaft within the balloon, the body being spirally cut to improve flexibility;

Figure 5 is a schematic showing in cross-section of another embodiment of the invention with a stent not yet mounted;

Figure 6 is a schematic showing of another embodiment of the invention;

Figure 7 is a schematic showing of a means for conveniently crimping the stent on the embodiment shown in Figure 5, and

Figure 8 is a schematic showing of yet another embodiment of the invention.

Description of the Preferred Embodiments

Referring to Figures 1-3 a stent delivery system generally indicated at 10 includes a balloon catheter 12 having a balloon 14 on a distal end portion generally indicated at 16. Figure 1 shows a proximal portion of the catheter at 12a and a distal portion 12b in enlarged view. Figure 2 shows the distal end portion 16 in an even more enlarged view. The illustrative catheter 12 is of the type known as a rapid exchange or single operator catheter. However, other types of catheters may be used, such as over the wire and fixed wire types. The balloon 14 is fixed to the catheter 12 by standard means. The balloon is shown in its contracted state in Figures 1 and 2. A stent 18 is fixed about the balloon by crimping it thereto. The stent has a larger expanded diameter which is obtained when the balloon is expanded in the known manner. That is, the stent is released from the catheter upon expansion of the balloon as shown in Figure 3 to be placed in a vessel. When the balloon is then deflated, removal of the balloon and catheter may be accomplished while leaving the stent in place.

As is known in the art the balloon is either bonded at its ends by adhesive 20 and ~~22~~ 24, respectively to the outer member ~~24~~ 22 of the catheter and to the inner member 26 of the catheter in the manner as shown, or is made one-piece with the outer member as is known in the art. The catheter balloon may be inflated by fluid (gas or liquid) from an inflation port extending from a lumen 28 contained in the catheter shaft and opening into the balloon as shown, or by other known

arrangements, depending on the design of the catheter. The details and mechanics of balloon inflation and specific overall catheter construction will vary according to the particular design involved in any given instance, and are known in the art per se. All variations are acceptable for use with this invention.

Any balloon expandable stent may be used with this invention. Many are known in the art including plastic and metal stents. Some are more well known such as the stainless steel stent shown in U.S. Patent 4,735,665; the wire stent shown in U.S. Patent 4,950,227; another metal stent shown in European Patent Application EP0 707 837 A1 and that shown in U.S. Patent 5,445,646. All of these patents are incorporated herein by reference. Also, shape memory metal stents may be used. As already indicated the stent of PCT Application 960 3092 A1 is particularly preferred.

The stent is typically about 16mm long, while the balloon may be 20mm long. These dimensions, however, are merely representative for illustrative purposes only and are not meant to be limiting. The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as a pliers or the like to be mounted for delivery as shown in Figures 1 and 2. The crimping may be accomplished by either the manufacturer or the physician.

In accordance with this invention, a mounting body 30, best seen in Figures 2 and 3, is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent shaft to support and hold the stent and secure it during crimping and the delivery procedure. The mounting body may be located only in the body portion of the balloon or may extend into either or both of the cone portions of the balloon.

In the embodiment shown, mounting body 30 is cylindrical in form and takes the shape of a sleeve carried on inner lumen 26, providing an enlarged area or portion for receiving the balloon and stent when the latter is crimped. Marker bands 32 and 34 may also be included on inner 26 as shown. Any radiopaque material such as gold is useful for this purpose. A stop member 36 of generally conical shape or any other shape may also be included on the distal marker band 34 as shown to provide additional resistance to stent movement during delivery and to protect the leading edge of the stent during delivery. A proximal stop

member similar to member 36 (not shown) may be optionally included on marker band 32 if desired. Polyethylene or the like is suitable for the stop member(s). Although, the material of the mounting body may be hard, it is preferably of any deformable thermoplastic material, preferably an elastomer material and more preferably of a relatively resilient elastomer material, e.g., lower durometer silicone. A preferred deformable thermoplastic material is high density polyethylene (HDPE). A preferred lower durometer silicone is in the form of tubing. The deformation of resilient material of the mounting body when the stent/balloon is crimped to it causes a radial outward force on the stent/balloon increasing the friction therebetween despite a recoil of the stent.

During delivery, the balloon catheter is advanced through and positioned in a patient's vasculature so that the stent is adjacent to the portion of the vessel where treatment is to take place. The balloon is inflated to expand the stent to an enlarged diameter. When the stent has reached the desired diameter, the balloon is deflated so that the catheter may be removed leaving the stent in place.

Another embodiment of the invention is shown in Figure 4. In this embodiment the mounting body 30 is a spiral cut elastomer or other suitable material, such as a rigid or flexible plastic, to provide separation for flexibility in that portion of the catheter, allowing more easy movement or tracking around bends. The spiral cut may be only partly through the mounting body or may be all the way through as shown in Figure 4. Also, while stop members 36 are shown at both ends of mounting body 30 in this embodiment, one, or no stop members may be used.

Another similar version is shown in Figure 5 which includes a cylindrical mounting body 30 made up of a plurality of separate adjacent rings 30a. Rings 30a may be individual bodies carried on the sheath or bodies cut from a cylinder partially separating them or fully separating them.

The embodiment shown in Figure 6 includes another feature based on the geometry of the mounting body for further securing the stent upon crimping. This feature is referred to herein as interlocking. That is, the stent may be interlocked to the mount so that the stent cannot slide proximally or distally on the balloon unless it is deformed, such as by expansion. This can be seen by perusing the structure shown in Figure 6 which includes the inner 26 having a two-piece mounting body made up of spaced mounting bodies 30a and 30b. The spacing

between bodies 30a and 30b allows portions of the stent 18 and balloon 14 to be depressed or inserted between the bodies upon crimping of the stent thus forming an interlock against sliding longitudinally before the stent is released.

The interlock formation or crimping is readily accomplished by a two-piece die 40 as shown in Figure 7 or the like.

Figure 8 demonstrates that more than a two-piece mounting body arrangement may be used if desired. In this embodiment, the mounting body is comprised of three spaced bodies 30a, 30b and 30c on the inner 26. Preferably in the embodiments of Figures 6 and 8, the mounting bodies will be ring-like in shape or cylindrical in shape although other configurations will be readily apparent to those familiar with this art.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

Sub A3

1. A stent delivery system comprising:

a radially expandable stent of generally cylindrical configuration, and

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

2. The stent delivery system of claim 1 wherein the mounting body is of a material which resiliently deforms under radial pressure.

3. The stent delivery system of claim 2 wherein the material is elastomeric.

Sub A4

4. The stent delivery system of claim 2 wherein the material comprises HDPE.

5. The stent delivery system of claim 2 wherein the material comprises silicone.

Sub A5

6. The stent delivery system of claim 1 wherein the mounting body configuration includes at least one separation whereby the flexibility of the body and catheter is increased.

7. The stent delivery system of claim 6 wherein the separation is in the form of a spiral.

8. The stent delivery system of claim 1 wherein the stent is crimped to the mounting and retaining means for delivery.

Sub A6

9. The stent delivery system of claim 1 including a pair of stops, each of which is respectively positioned at opposite ends of the stent and carried by the shaft inside the inflatable means.

10. The stent delivery system of claim 9 wherein the stops are conical in shape.

Sub A7

11. The stent delivery system of claim 1 including marker bands positioned proximally and distally of the stent.

12. The stent delivery system of claim 1 wherein the inflatable means comprises a balloon.

Sub 18

13. The stent delivery system of claim 1 including a stop positioned at the distal end of the catheter and carried by the shaft inside the inflatable means.

Sub A9

14. A stent delivery system comprising:

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent to be delivered upon expansion of the inflatable means, the mounting and retaining means including at least one mounting body inside the inflatable means and carried and/or surrounding the shaft, and

a stent crimped to the inflatable means and the mounting body such that opposite end portions of the stent are deformed to a diameter less than that of the mounting body whereby the stent is interlocked with the mounting body until expansion of the stent and inflatable means to prevent accidental movement of the stent along the catheter during delivery.

15. The stent delivery system of claim 14 wherein the stent is generally tubular in shape and the mounting body is generally cylindrical in shape.

16. The stent delivery system of claim 14 wherein at least two spaced mounting bodies are included and the stent is additionally crimped to a lesser diameter and positioned between the mounting bodies.

B

17. The stent delivery system of claim 16 wherein the stent is generally tubular in shape and the mounting bodies are ring-~~like~~ Shaped.

Sub A10

18. The stent delivery system of claim 14 wherein at least three spaced mounting bodies are included and the stent is crimped to a lesser diameter between the bodies.

B

19. The stent delivery system of claim 18 wherein the stent is generally tubular in shape and the mounting bodies are ring-~~like~~ Shape.

Sub A11

20. A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft, a balloon associated with a distal portion of the shaft for receiving a stent, and means for inflating the balloon, the shaft including at least one, mounting body carried on the shaft inside the balloon whereby the diameter of

9

the shaft is increased inside the balloon to facilitate mounting of a stent to the catheter over the balloon.

21. The catheter of claim 20 wherein the mounting body is of a material which resiliently deforms under radial pressure.

22. The catheter of claim 21 wherein the material is elastomeric.

23. The catheter of claim 21 wherein the material is HDPE.

24. The catheter of claim 21 wherein the material is silicone.

25. The catheter of claim 20 wherein the mounting body is configured with at least one separation whereby trackability of the catheter is improved.

26. The catheter of claim 25 wherein the separation is in a spiral configuration.

27. The catheter of claim 20 including a pair of spaced stops.

28. The catheter of claim 27 wherein the stops are conical in shape.

29. The catheter of claim 20 including spaced marker bands.

30. The catheter of claim 20 wherein the mounting body is cylindrical in shape.

31. The catheter of claim 20 wherein at least two spaced mounting bodies are included.

32. The catheter of claim 31 wherein the mounting bodies are ring-shape ~~like~~.

33. The catheter of claim 20 wherein at least three spaced mounting bodies are included.

34. The catheter of claim 33 wherein the mounting bodies are ring-shape ~~like~~.

Abstract of the Disclosure

STENT DELIVERY SYSTEM

A stent delivery system to facilitate introduction and placement of a stent, including a catheter having an expandable distal portion constructed and arranged for expanding the outer diameter of the catheter from a contracted state to an expanded state: a stent positioned around the distal portion of the catheter having a contracted condition and being expandable to an expanded condition, and being sized in the contracted condition to closely surround the catheter in the contracted state, the expandable distal portion of the catheter including a balloon within which there is included on the catheter shaft at least one body of a diameter larger than the catheter shaft to which the stent and balloon are fitted, as by crimping, for holding the stent in place until it is released therefrom by expansion of the balloon.

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Fig. 1

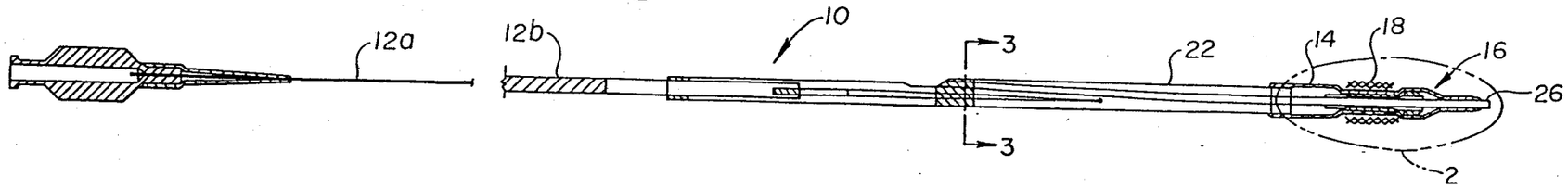


Fig. 2

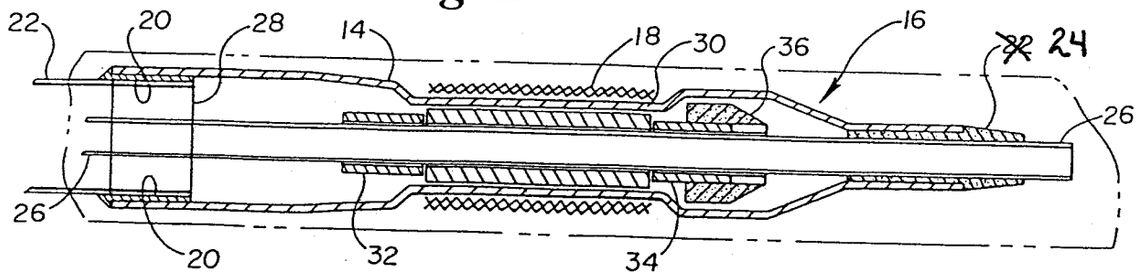


Fig. 3

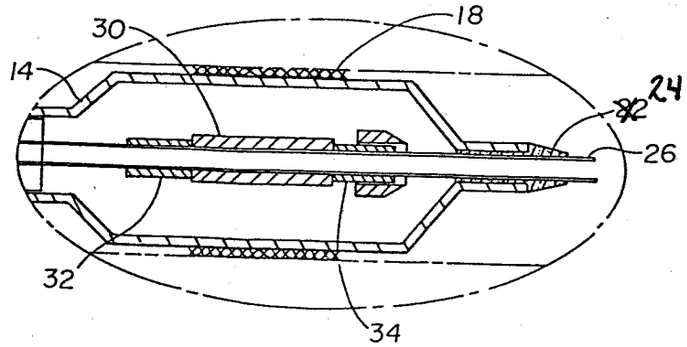


Fig. 4

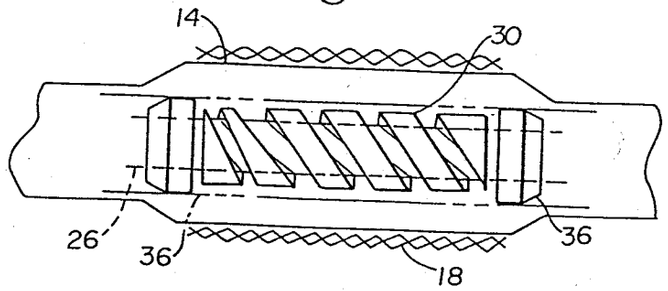
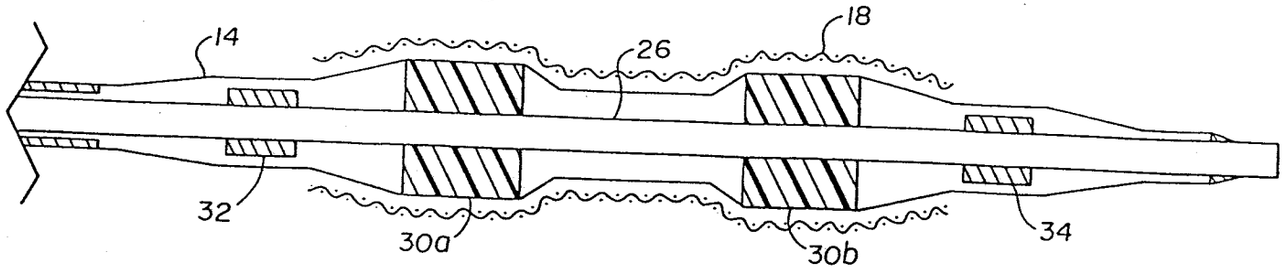


Fig. 6



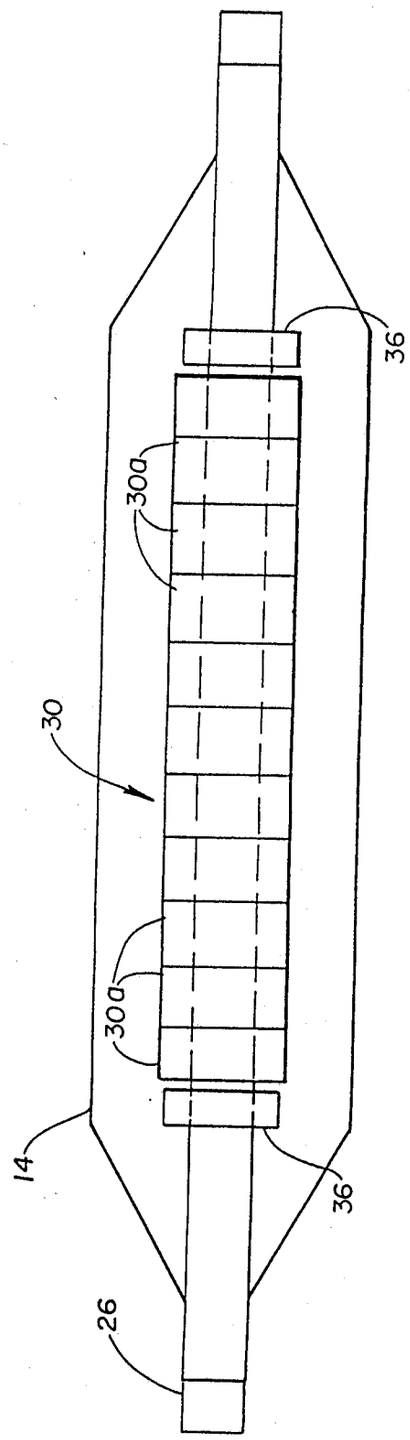


Fig. 5

Fig. 7

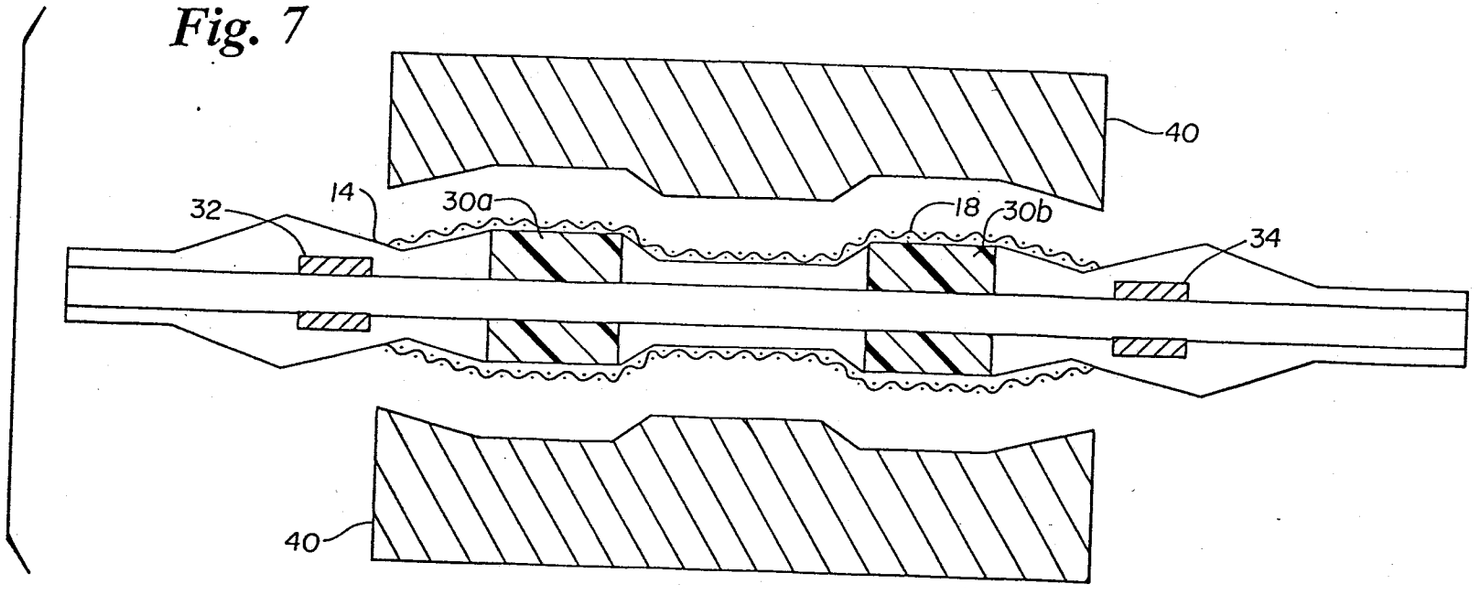
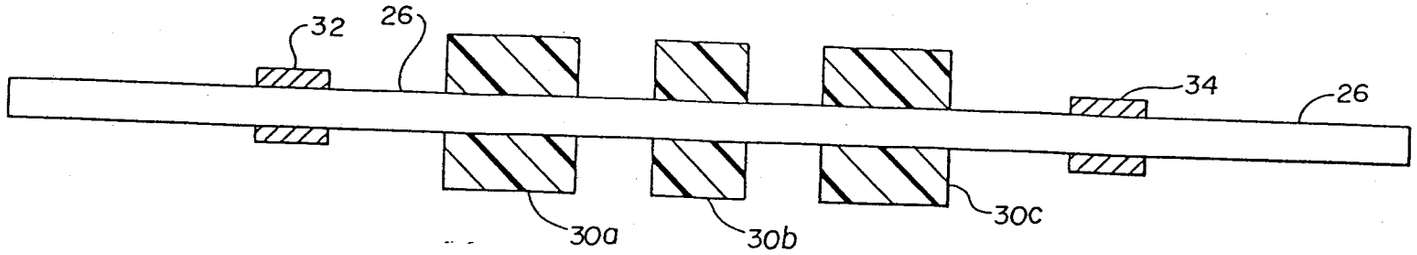


Fig. 8



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AS ORIGINALLY FILED

606/108

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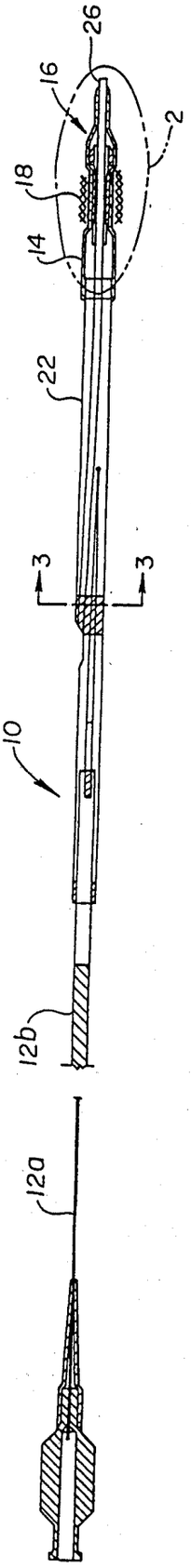


Fig. 1

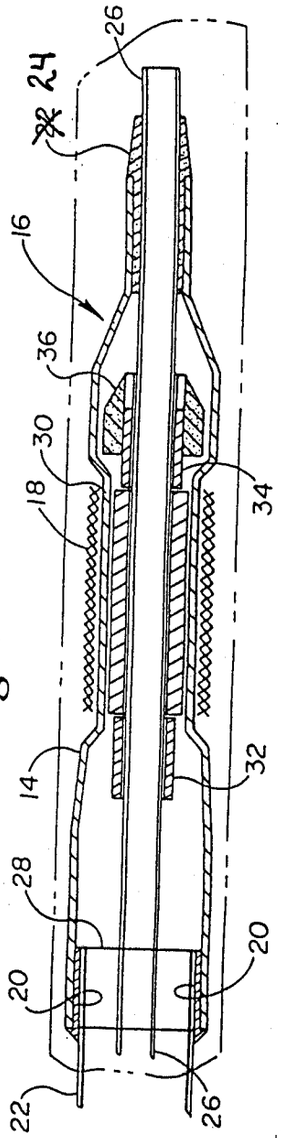


Fig. 2

Fig. 3

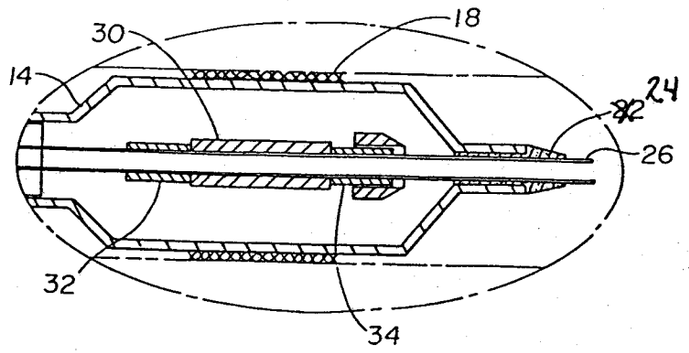


Fig. 4

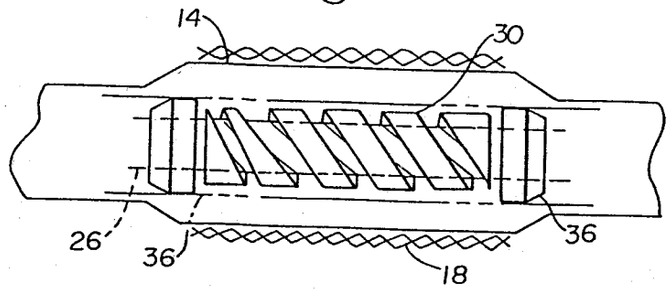
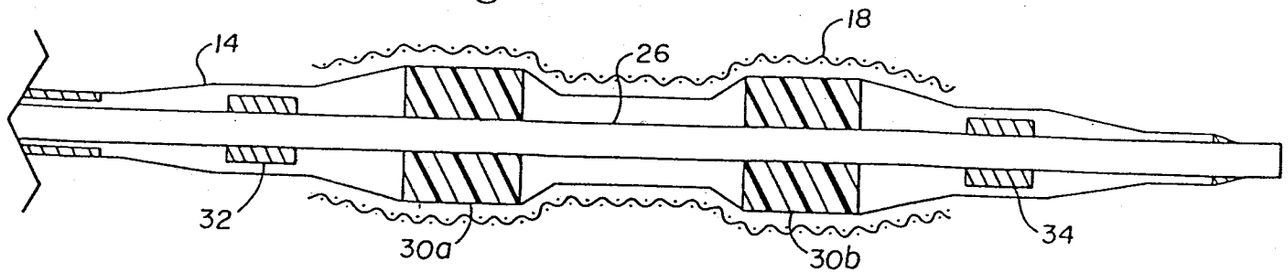


Fig. 6



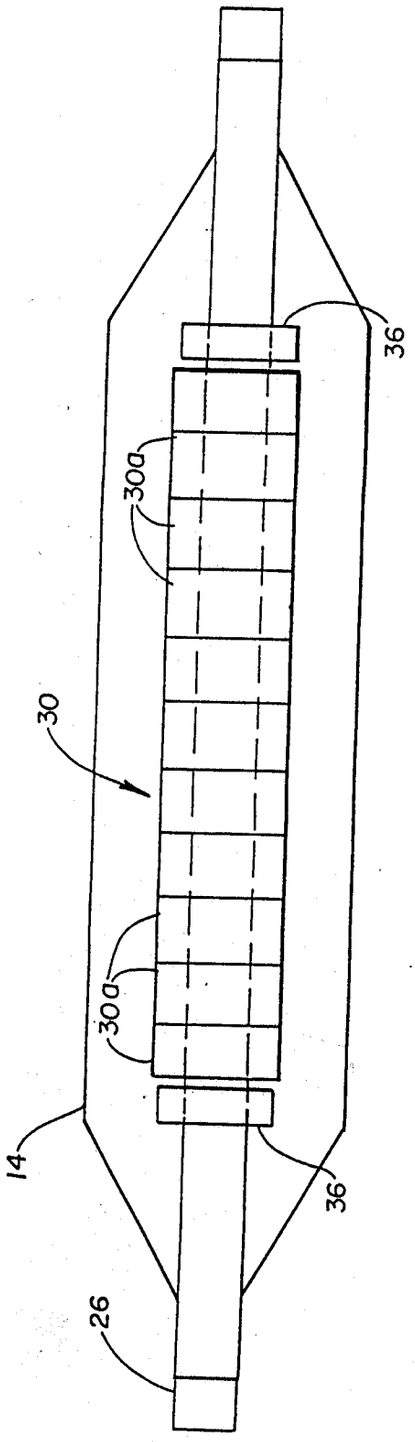


Fig. 5

PRINT OF DRAWING
AS ORIGINALLY FIL

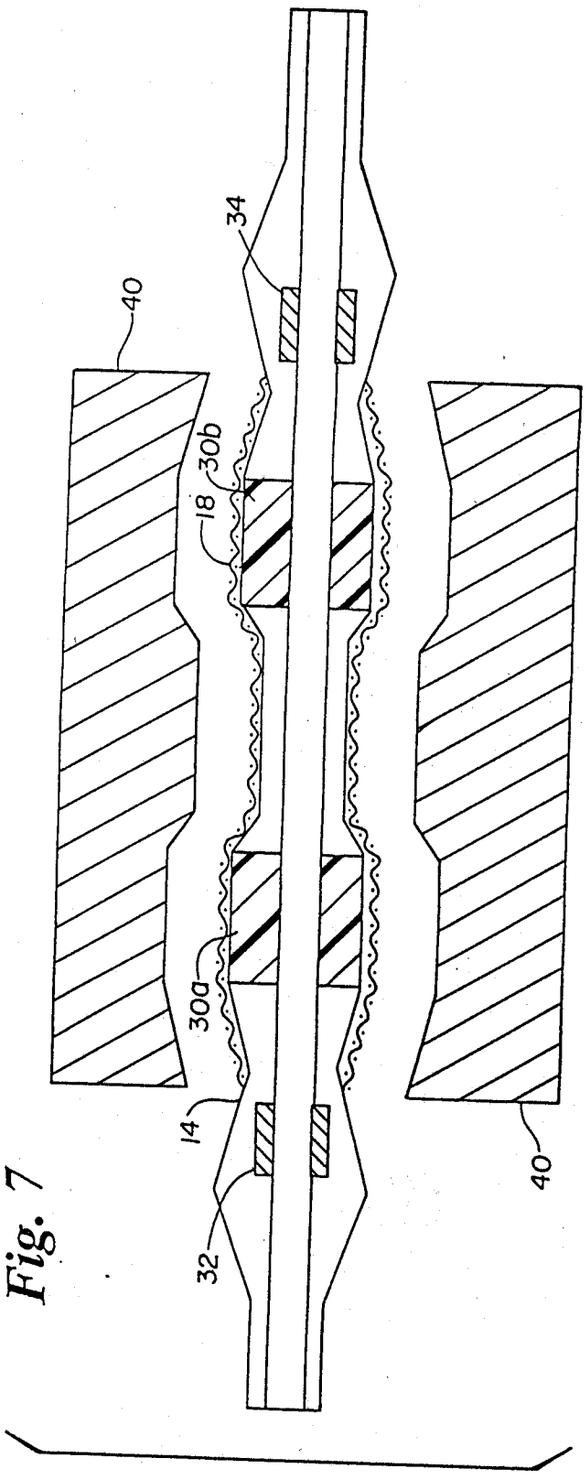


Fig. 7

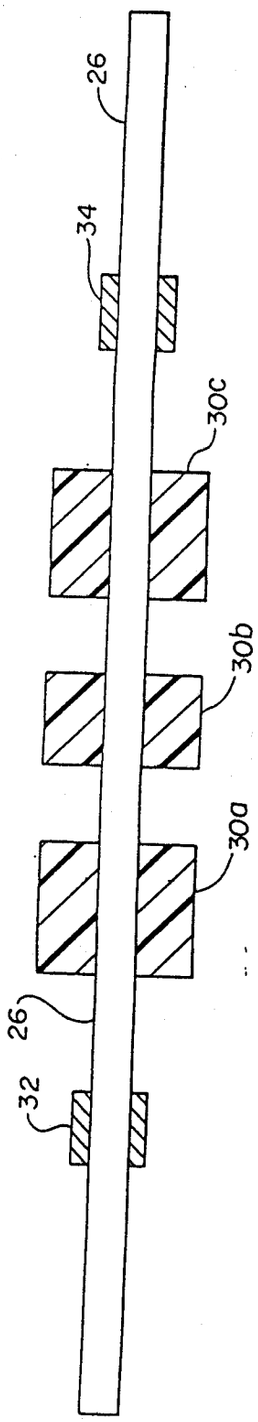


Fig. 8

UTILITY/DESIGN PATENT

Docket No. S63.2-6050

DECLARATION

As a below-named inventor, I(we) hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

- [X] original
- [ ] design
- [ ] supplemental
- [ ] national stage of PCT
- [ ] divisional
- [ ] continuation
- [ ] continuation-in-part (CIP)

INVENTORSHIP DECLARATION

My residence, post office address, and citizenship are as stated below next to my name;

I verily believe I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter which is claimed and for which a patent is sought on the invention entitled:

STENT DELIVERY SYSTEM

the specification of which

a) [ ] is being filed concurrently herewith

b) [X] was filed on 8/23/1996 and assigned Serial No. 08/702,150

c) [ ] was filed as PCT International Application No. _____ filed on _____ and amended under PCT Article 19 on _____.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56 including information occurring between the filing date of any prior application of which the present application is a continuation-in-part.

- [ ] In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119, of any foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the United States of America filed by me having the same subject matter having a filing date before that of the application on which priority is claimed.

a) ☐ no such applications have been filed.
b) ☒ such applications have been filed as follows:

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			☐YES ☐NO
			☐YES ☐NO
			☐YES ☐NO
			☐YES ☐NO

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATIONS(S) UNDER 35 U.S.C. §120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications(s) or PCT international applications(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior applications(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior applications(s) and the national or PCT international filing date of this application.

a) ☐ no such applications have been filed.
b) ☒ such applications have been filed as follows.

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1.	
2.	
PCT APPLICATIONS DESIGNATING THE U.S.	
PCT APPLICATION NO.	PCT FILING DATE
3.	

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Telephone calls and correspondence should be directed to: **Oliver F. Arrett,** VIDAS, ARRETT & STEINKRAUS, P.A., Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402-4014, Telephone: (612) 339-8801, Facsimile (612) 349-6858.

First Inventor

Full name: Louis G. Ellis

Inventor's signature: Louis G. Ellis

Date: 10-30-96

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St. Anthony, MN 55418

Residence:
(If different than above)

Second Inventor

Full name: Andrew J. Dusbabek

Inventor's signature: Andrew J. Dusbabek

Date: 10-30-96

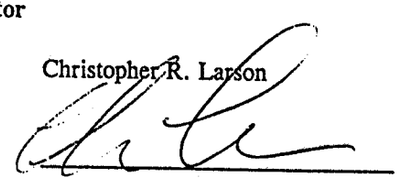
Citizenship: United States of America

Post office Address: 13750 Jonquil Lane North
Dayton, MN 55327

Residence:
(If different than above)

Third Inventor

Full name: Christopher R. Larson

Inventor's signature: 

Date: 11/4/96

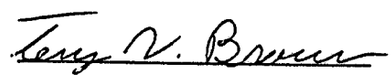
Citizenship: United States of America

Post office Address: 523 Desnoyer Avenue
St. Paul, MN 55104

Residence:
(If different than above)

Fourth Inventor

Full name: Terry V. Brown

Inventor's signature: 

Date: 30 Oct 96

Citizenship: United States of America

Post office Address: 6231 Trinity Drive Northeast
Fridley, MN 55432

Residence:
(If different than above)

Fifth Inventor

Full name:

Inventor's signature: _____

Date: _____

Citizenship:

Post office Address:

Residence:
(If different than above)

Sixth Inventor

Full name:

Inventor's signature: _____

Date: _____

Citizenship:

Post office Address:

Residence:
(If different than above)

Seventh Inventor

Full name:

Inventor's signature: _____

Date: _____

Citizenship:

Post office Address:

Residence:
(If different than above)

Eighth Inventor

Full name:

Inventor's signature: _____

Date: _____

Citizenship:

Post office Address:

Residence:
(If different than above)

UTILITY/DESIGN PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown
Title:	STENT DELIVERY SYSTEM
Filed:	☐ concurrently herewith ☒ on 8/23/96 (and assigned Serial No. 08/ 702,150

Docket No: **S63.2-6050**

Assistant Commissioner for Patents
Washington, DC 20231

POWER OF ATTORNEY FROM ASSIGNEE

As assignee of record of the entire interest of the above identified patent application, **SCIMED LIFE SYSTEMS, INC.** hereby appoints the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Oliver F. Arrett	Reg. No. 22,117
Scott Q. Vidas	Reg. No. 30,812
Walter J. Steinkraus	Reg. No. 29,592
Richard A. Arrett	Reg. No. 33,153
Robert O. Vidas	Reg. No. 20,164
Leoniede M. Brennan	Reg. No. 35,832
Jane H. Arrett	Reg. No. 33,355
William E. Anderson II	Reg. No. 37,766

all of **Vidas, Arrett & Steinkraus, P.A.**, Suite 1540, 920 Second Avenue South, Minneapolis, Minnesota 55402-4014, U.S.A., Telephone (612) 339-8801, and hereby authorizes them to act and rely on instructions from, and to communicate directly with, the firm or person which sent this case to Vidas, Arrett & Steinkraus, P.A., unless or until it instructs Vidas, Arrett & Steinkraus P.A., in writing to the contrary.

Dated this 21st day of October, 19 96.

(Company Name) SCIMED LIFE SYSTEMS, INC.

(Signature) By _____

(typed name) John A. Rissman

(title) Its: Vice President and Chief Intellectual Property Counsel

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Louis G. Ellis et al.
Application No.:	*(Not yet assigned)*
Filed:	*(Concurrently herewith)*
For:	STENT DELIVERY SYSTEM
Examiner:	*(Not yet assigned)*
Group Art Unit:	*(Not yet assigned)*

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-8619

CONSTRUCTIVE PETITION FOR EXTENSION OF TIME AND FEE AUTHORIZATION PURSUANT TO 37 C.F.R. §1.136(a)(3)

Applicant hereby requests that the United States Patent and Trademark Office treat any concurrent or future reply requiring a petition for an extension of time pursuant to §1.136 for its timely submission as incorporating therein a petition for an extension of time for the appropriate length of time.

Applicant authorizes the Commissioner of Patents and Trademarks to charge all required extension of time fees that have not otherwise been paid to Deposit Account No. 22-0350.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: October 19, 1999

By: _____
William E. Anderson, II
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Louis G. Ellis et al.
Application No.:	*Filed concurrently herewith*
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	*Not yet assigned*
Group Art Unit:	*Not yet assigned*

Box New App Fee
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-8619

PRELIMINARY AMENDMENT

Prior to calculation of fees and examination, please make the following amendments:

In the Title:

Please delete the title and insert therefor:

--STENT DELIVERY SYSTEM WITH STENT SECUREMENT MEANS--.

In the Specification:

page 1, line 2, please insert:

--

Related Applications

The present application is a continuation of U.S. Application serial number 08/702,150, filed on August 23, 1996, which is incorporated herein by reference in its entirety.--;

page 3, line 29, delete "22" and insert -- 24 --, and delete "24" and insert -- 22 --.

In the claims:

1. (Amended) A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:

[a radially expandable stent of generally cylindrical configuration, and]

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

4. (Amended) The stent delivery system of claim 2 wherein the material comprises [HDPE] high density polyethylene.

6. (Amended) The stent delivery system of claim 1 wherein the at least one mounting body [configuration] includes at least one separation whereby the flexibility of the body and catheter is increased.

9. (Once Amended) The stent delivery system of claim 1, wherein the stent has two opposite ends, the stent delivery system further including a pair of stops, each of which is respectively positioned at the opposite ends of the stent and carried by the shaft inside the inflatable means.

11. (Once Amended) The stent delivery system of claim 1 further including marker bands positioned proximally and distally of the stent.

12. The stent delivery system of claim 1 wherein the inflatable means comprises a balloon.

13. (Amended) The stent delivery system of claim 1 further including a stop [positioned at the distal end of the catheter and] carried by the shaft and positioned inside the inflatable means.

14. A stent delivery system comprising:

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent to be delivered upon expansion of the inflatable means, the mounting and retaining means including at

least one mounting body inside the inflatable means and carried and/or surrounding the shaft, and

a stent crimped to the inflatable means and the mounting body such that opposite end portions of the stent are deformed to a diameter less than that of the mounting body whereby the stent is interlocked with the mounting body until expansion of the stent and inflatable means to prevent accidental movement of the stent along the catheter during delivery.

14. (Once Amended) A stent delivery system comprising:

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, to be delivered upon expansion of the inflatable means, the mounting and retaining means including at least one mounting body inside the inflatable means and carried on and/or surrounding the shaft, the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent, and

[a] the stent crimped to the inflatable means and the at least one mounting body such that [opposite end] a portion[s] of the stent [are] is deformed to a diameter less than that of the at least one mounting body [whereby the stent is interlocked with the mounting body until expansion of the stent and inflatable means to prevent accidental movement of the stent along the catheter during delivery].

15. (Amended) The stent delivery system of claim 14 wherein the stent is generally tubular in shape and the at least one mounting body is generally cylindrical in shape.

16. (Amended) The stent delivery system of claim 14 wherein at least two spaced mounting bodies are included and a portion of the stent between the mounting bodies is additionally crimped to a lesser diameter than that of the mounting bodies and positioned between the mounting bodies.

18. (Amended) The stent delivery system of claim 14 wherein [at least] three

Sub C3 cont

A10 spaced mounting bodies are included and the stent is crimped to a lesser diameter between the bodies.

20. (Amended) A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, and means for inflating the balloon, the shaft including at least one[,] mounting body radially carried on the shaft inside the balloon whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon, the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent.

A11 B

23. (Amended) The catheter of claim 21 wherein the material is [HDPE] high density polyethylene.

A12

A13 27. (Amended) The catheter of claim 20 further including a pair of spaced stops.

A14 29. (Amended) The catheter of claim 20 further including spaced marker bands.

Please add the following claims:

35. A stent delivery system comprising:

B a radially expandable stent of generally cylindrical configuration, having a first length end and a second end and a contracted state and an expanded state, and

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon, and

A15 including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means, the at least one mounting body being at least ½ the length of the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable

means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

36. The stent delivery system of claim 35, wherein the at least one mounting body is at least 2/3 the length of the stent.

REMARKS

Prior to examination, please make the above amendments. Many of the above amendments are made to remain consistent with the previously filed priority application. Early examination is respectfully requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 19, 1999

By: _____
William E. Anderson, II
Registration No.: 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001
F:\WPWORK\WEA\8619-AMD.A19

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/420,249	10/19/99	ELLIS L	S6.2-8619

0242/1112

VIDAS ARRETT & STEINKRAUS P A
920 SECOND AVENUE SOUTH
SUITE 1540
MINNEAPOLIS MN 55402-4014

NOT ASSIGNED

3734

DATE MAILED: 11/12/99

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☑ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 1142.

☑ 1. The statutory basic filing fee is:
- ☑ missing.
- ☐ insufficient.

Applicant must submit $ 760 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☑ 2. The following additional claims fees are due:

$ 252 for 14 total claims over 20.

$ _____ for _____ independent claims over 3.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☐ is missing or unsigned.
- ☐ does not cover the newly submitted items.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. **A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).**

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application was filed in a language other than English.
Applicant must file a verified English translation of the application, the $130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)).

☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

FORM **PTO-1533** (REV. 9/98)

U.S. GPO 1999 450-5875

PART 1 - ATTORNEY/APPLICANT COPY

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/420,249	10/19/99	ELLIS	L S6.2-8519

0242/1210

WILLIAM E ANDERSON II ESQ
VIDAS ARRETT & STEINKRAUS
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA MN 55343

NOT ASSIGNED

3734

DATE MAILED: 12/10/99

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☑ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☑ non-small entity is $ 1142.

☑ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $ 760 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☑ 2. The following additional claims fees are due:

$ 252 for 1 total claims over 20.

$ _____ for _____ independent claims over 3.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☐ is missing or unsigned.
- ☐ does not cover the newly submitted items.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. **A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).**

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application was filed in a language other than English.
Applicant must file a verified English translation of the application, the $130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)).

☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

FORM **PTO-1533** (REV. 9/98) U.S. GPO 1999 450-5875

PART 3 - OFFICE COPY

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	not assigned yet
Group Art Unit:	3734

Application Processing Division
Customer Correction Branch
Assistant Commissioner for Patents
Washington, DC 20231

Docket No.: S63.2-8619

REQUEST FOR CORRECTION OF FILING RECEIPT

Upon reviewing the Official Filing Receipt for the above-identified application, an error was noted. A red-lined copy of the Filing Receipt is enclosed herewith showing the corrections.

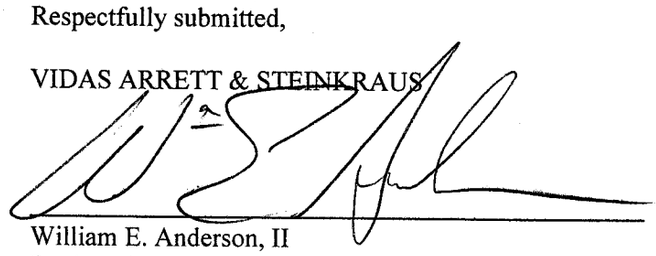
An inventor's first name listed on the filing receipt is spelled incorrectly. Please correct the inventor's name from "Andew J. Dusbabeki" to "Andrew J. Dusbabek".

Applicant respectfully requests issuance of a Corrected Filing Receipt.

Respectfully submitted,

VIDAS ARRETT & STEINKRAUS

Date: .January 5, 2000

By: 

William E. Anderson, II
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001
F:\WPWORK\WEA\8619-FIL.105

PTO-103X
(Rev. 6-99)

FILING RECEIPT

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/420,249	10/19/99	3734	$0.00	S6.2-8619	4	34	3

WILLIAM E ANDERSON II ESQ
VIDAS ARRETT & STEINKRAUS
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA MN 55343

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s) LOUIS G. ELLIS, ST. ANTHONY, MN; ~~ANDEW~~ ANDREW J. DUSBABEK, DAYTON, MN; CHRISTOPHER R. LARSON, ST. PAUL, MN; TERRY V. BROWN, FRIDLEY, MN.

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A CON OF 08/702,150 08/23/96

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 11/09/99
TITLE
STENT DELIVERY SYSTEM

PRELIMINARY CLASS: 604

DATA ENTRY BY: DIXON, DOROTHY L. TEAM: 04 DATE: 12/10/99

(See reverse for new important information)

PATENT

Receipt
FILE COPY
0350

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	not assigned yet
Group Art Unit:	3734

Application Processing Division
Customer Correction Branch
Assistant Commissioner for Patents
Washington, DC 20231

Docket No.: S63.2-8619

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
1 pg Request to Correct Filing Receipt; 1 pg redlined copy of filing receipt; VA&S Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☒ No additional fee is required.
   - ☐ Attached is check(s) in the amount of $_____.
   - ☐ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date: January 5, 2000

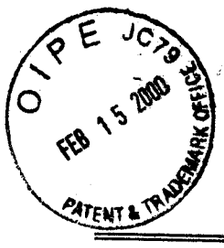
By: _____

William E. Anderson, II
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001

Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Application Processing Division Customer Correction Branch, Assistant Commissioner for Patents, Washington D.C. 20231, on January 5, 2000

_____
Jodi D. Nickel



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	not assigned yet
Group Art Unit:	3734

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-8619

RESPONSE TO NOTICE OF MISSING PARTS

In response to the Notice to File Missing Parts of Application--Filing Date Granted, mailed December 10, 1999, enclosed for filing please find:

1. A copy of the Notice to File Missing Parts of Application (Form PTO-1533) and a Check for $1142.00 to cover the filing and surcharge fees.

If any other fees are necessitated by this response, please charge or credit them to Deposit Account No. 22-0350.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 7, 2000

By: _____

William E. Anderson, II
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone No.: (612) 563-3000
Facsimile No.: (612) 563-3001
F:\WPWORK\WEA\8619-LTR.207

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/420,249	10/19/99	ELLIS L	S6.2-8619

0242/1210

WILLIAM E ANDERSON II ESQ
VIDAS ARRETT & STEINKRAUS
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA MN 55343

NOT ASSIGNED

3734

DATE MAILED: 12/10/99

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☑ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☑ non-small entity is $ 1142.

☑ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $ 760 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☑ 2. The following additional claims fees are due:

$ 252 for 14 total claims over 20.

$ _____ for _____ independent claims over 3.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☐ is missing or unsigned.
- ☐ does not cover the newly submitted items.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. **A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).**

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application was filed in a language other than English.
Applicant must file a verified English translation of the application, the $130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)).

☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

FORM PTO-1533 (REV. 9/98)

U.S. GPO: 1999-455-875

PART 2 - COPY TO BE RETURNED WITH RESPONSE

02/17/2000 SLUANG 00000106 09420249
01 C:101 760.00 OP
02 C:105 130.00 OP
03 C:103 252.00 OP

PATENT

Sector 5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	not assigned yet
Group Art Unit:	3734

Box Missing Parts
Assistant Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
1 pg Response to Notice to File Missing Parts; 1 pg PTO form 1533; check 1142.00;VA&S Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☐ No additional fee is required.
   - ☒ Attached is check(s) in the amount of $ 1142.00 .
   - ☐ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date:February 7, 2000

By: _____
William E. Anderson, II
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001

Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Box Missing Parts, Assistant Commissioner for Patents, Washington D.C. 20231, on February 7, 2000

_____
Jodi D. Nickel

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	*(Not yet assigned)*
Group Art Unit:	3734

Assistant Commissioner for Patent
Washington, D.C. 20231

Docket No.: S63.2-8619

#4
AMB 6/13/00

INFORMATION DISCLOSURE STATEMENT

Applicant submits herewith patents, publications or other information of which he is aware, and which he believes may be material to the examination of this application.

This Information Disclosure Statement is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" to the invention of the above-identified application, unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information exists.

The related co-pending application(s)that we are aware of are listed as follows:

Application No.: 08/702,150, filed August 23, 1996, now U.S. Patent 6,007,543.

Pursuant to MPEP §2001.06(b), no copies of cited art in a previous application(s) to which priority was claimed need be submitted.

This Information Disclosure Statement is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before receipt of a first Official Action on the merits, whichever occurs last.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: March 8, 2000

By: _____

William E. Anderson, II
Registration No.: 37,766

Suite 2000
6109 Blue Circle Drive
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001
F:\WPWORK\WEA\8619-IDS.308

09/420,249

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY DOCKET NO: ~~[illegible]~~ 6050	Serial No: ~~08/702,150~~
	APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown	
	FILING DATE: August 23, 1996	Group:

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JL	AA	5,378,237	1/3/95	Boussignac et al			
JL	AB	5,344,402	9/6/94	Crocker			
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR		
	AS		
	AT		

EXAMINER: [signature] DATE CONSIDERED: 8/4/00

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.

F:\WPWORK\FORMS\PTO-1449.FRM

MAIL DATE [illegible] F

08/702,150

FORM PTO-1449 (Modified)	ATTY DOCKET NO.: [illegible]050	SERIAL NO.: ~~08/702,150~~
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	APPLICANT: Louis G. ELLIS et al.	
	FILING DATE: August 23, 1996	GROUP: 3301

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JZ	AA	5,817,102	Oct. 6, 1998	Johnson et al.	606	108	4/21/97
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						

RECEIVED
DEC 23 1998
Group 3700

FOREIGN PATENT DOCUMENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OF PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	BA							
	BB							
	BC							
	BD							
	BE							
	BF							
	BG							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CA	
	CB	
	CC	
	CD	
	CE	

RECEIVED
DEC 10 1998
TECHNOLOGY CENTER 3700

EXAMINER	DATE CONSIDERED
[signature]	4/13/99

EXAMINER: Initial citation connsidered. Draw line through citation if not 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.

F:\WPWORK\FORMS\IDS-1449

FORM PTO-1449 (Modified)	ATTY DOCKET NO.: S63.2-6050	SERIAL NO.: ~~08/702,150~~
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	APPLICANT: Louis G. ELLIS et al.	
	FILING DATE: August 23, 1996	GROUP: 3301

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JJ	AA	5,653,691	8/5/97	Rupp et al.	604	96	4/25/96
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						

FOREIGN PATENT DOCUMENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OF PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	BA							
	BB							
	BC							
	BD							
	BE							
	BF							
	BG							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CA		
	CB		
	CC		
	CD		
	CE		

EXAMINER JJ — DATE CONSIDERED 10/12/00

EXAMINER: Initial citation connsidered. Draw line through citation if not 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.

F:\WPWORK\FORMS\IDS-1449

JJ 8/4/00

09/702,249

FORM PTO-1449 (Modified)
INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.: S63.2-6050	SERIAL NO.: ~~08/702,150~~
APPLICANT: Louis ELLIS et al.	
FILING DATE: August 23, 1996	GROUP: 3301

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						

FOREIGN PATENT DOCUMENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OF PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
JR	BA	0 266 957 A2	5/11/88	EP	—	—	X	
	BB							
	BC							
	BD							
	BE							
	BF							
	BG							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CA		
	CB		
	CC		
	CD		
	CE		

EXAMINER JR — DATE CONSIDERED 3/17/98

EXAMINER: Initial citation connsidered. Draw line through citation if not 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.

F:\WPWORK\FORMS\IDS-1449

8/4/04

/2223 U.S. PTO
01/10/97

C P E JC73
MAR 20 2000
PATENT & TRADEMARK OFFICE

09/702,029

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY DOCKET NO:S63.2-6050	Serial No: 08/702,150
	APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown	
	FILING DATE: August 23, 1996	Group: 3301

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JF	AA	4,328,056	05/04/1982	Snooks			
	AB	4,338,942	07/13/1982	Fogarty			
	AC	4,423,725	01/03/1984	Baran et al.			
	AD	4,608,984	09/02/1986	Fogarty			
	AE	4,733,665	03/29/1988	Palmaz			
	AF	B1 4,733,665	01/11/1994	Palmaz			
	AG	4,740,207	04/26/1988	Kreamer			
	AH	4,744,366	05/17/1988	Jang			
	AI	4,848,343	07/18/1989	Walstein et al.			
	AJ	4,875,480	10/24/1989	Imbert			
JF	AK	4,950,227	08/21/1990	Savin et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
JF	AL	0 257 091 B1	07/28/1993	EPO			X	
JF	AM	0 442 657 A2	09/21/1991	EPO			X	
JF	AN	0 553 960 A1	08/04/1993	EPO			X	
JF	AO	0 627 201 A1	12/07/1994	EPO			X	
JF	AP	0 699 451 A2	03/06/1996	EPO			X	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

JF	AR		Julio C. Palmaz et al., ***Expandable Intraluminal Graft: A Preliminary Study, Work in Progress***, From the Departments of Radioloty (J.C.P., R.R.S., S.R.R.) and Pathology (F.O.T.) University of Texas Health Science Center at Sanantonio and Memorial Medical Center (W.J.K.), Corpus Christi, Texas, ***RADIOLOGY***, Volume 356, Number 1, Pages 73-77.
	AS		
	AT		

EXAMINER JF — DATE CONSIDERED 8/7/97

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.

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JF 8/4/03

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PATENT & TRADEMARK OFFICE

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY DOCKET NO:S63.2-6050 — Serial No: 08/702,150 APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown FILING DATE: August 23, 1996 — Group:

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JZ	AA	5,007,926	04/16/1991	Derbyshire			
	AB	5,026,377	06/25/1991	Burton et al.			
	AC	5,037,392	08/06/1991	Hillstead			
	AD	5,049,132	09/17/1991	Shaffer et al.			
	AE	5,108,416	04/28/1992	Ryan et al.			
	AF	5,116,318	05/26/1992	Hillstead			
	AG	5,158,548	10/27/1992	Lau et al.			
	AH	5,226,880	07/13/1993	Martin			
	AI	5,226,889	07/13/1993	Sheiban			
	AJ	5,242,399	09/07/1993	Lau et al.			
JZ	AK	5,290,306	03/01/1994	Trotta et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
JZ	AL	0 707 837 A1	04/24/1996	EPO			X	
JZ	AM	WO 93/19703	10/14/1993	PCT			X	
JZ	AN	WO 96/03072	02/08/1996	PCT			X	
JZ	AO	WO 96/03092 A1	02/08/1996	PCT			X	
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER JZ — DATE CONSIDERED 8/7/97

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.

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Page 2 of 4

JZ 8/4/00

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY DOCKET NO:S63.2-6050	Serial No: ~~08/702,150~~
	APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown	
	FILING DATE: August 23, 1996	Group:

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JL	AA	5,342,305	08/30/1994	Shonk			
	AB	5,344,426	09/06/1994	Lau et al.			
	AC	5,358,487	10/25/1994	Miller			
	AD	5,403,341	04/04/1995	Solar			
	AE	5,405,380	04/11/1995	Gianotti et al.			
	AF	5,409,495	04/25/1995	Osborn			
	AG	5,415,664	05/16/1995	Pinchuk			
	AH	5,445,646	08/29/1995	Euteneuer et al.			
	AI	5,447,497	09/05/1995	Sogard et al.			
	AJ	5,453,090	09/26/1995	Martinez et al.			
JL	AK	5,458,615	10/17/1995	Klemm et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AL							
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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.

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Page 3 of 4

JL 8/4/00

08/702,249

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY DOCKET NO:S63.2-6050	Serial No: ~~08/702,150~~
	APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown	
	FILING DATE: August 23, 1996	Group:

REFERENCE DESIGNATION — U.S. PATENT DOCUMENTS

EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JR	AA	5,470,313	11/28/1995	Crocker et al.			
JR	AB	5,507,768	04/16/1996	Lau et al.			
JR	AC	5,512,051	04/30/1996	Wang et al.			
JR	AD	5,534,007	07/09/1996	St. Germain et al.			
JR	AE	5,536,252	07/16/1996	Imran et al.			
	AF						
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AL							
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EXAMINER JR — DATE CONSIDERED 8/7/97

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.

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JR 8/4/05

Notice of References Cited

09/470,244

Application No.	Applicant(s)		
~~08/702,150~~	Ellis et al		
Examiner	Group Art Unit	Page 1 of 1	
Justine Yu	3301		

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,108,416	Apr. 1992	Ryan et al	606	194
B	5,445,646	Aug. 1995	Euteneuer et al	606	198
C	5,304,198	Apr. 1994	Samson	606	194
D	5,632,760	May 1997	Sheiban et al	606	195
E	4,950,227	Aug. 1990	Savin et al	606	192
F	5,571,086	Nov. 1996	Kaplan et al	604	96
G	5,591,228	Jan. 1997	Edoga	606	194
H	5,441,515	Aug. 1995	Khosravi et al	606	194
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FOREIGN PATENT DOCUMENTS

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09/420,249

Notice of References Cited

Application No.	Applicant(s)		
~~08/702,150~~	Ellis et al		
Examiner	Group Art Unit	Page 1 of 1	
Justine Yu	3733		

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,409,495	4-1995	Osborn	606	108
B					
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
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Notice of References Cited

Application No.	Applicant(s)	
~~08/702,150~~ 09/420,249	Ellis et al	
Examiner: Justine Yu	Group Art Unit: 3301	Page 1 of 1

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,653,691	Aug. 1997	Rupp et al	604	96
B	5,571,089	Nov. 1996	Crocker	604	96
C					
D					
E					
F					
G					
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I					
J					
K					
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FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
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NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
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8/4/00

Gp 3734
#4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	not assigned yet
Group Art Unit:	3734

Assistant Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
2 pg Information Disclosure Statement; 8 pgs of 1449 forms; 3 pgs of 892 form; VA&S Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☒ No additional fee is required.
   - ☐ Attached is check(s) in the amount of $_____.
   - ☐ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date: March 9, 2000

By: _____

William E. Anderson, II
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9131
Telephone: (612) 563-3000
Facsimile: (612) 563-3001

Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Assistant Commissioner for Patents, Washington D.C. 20231, on March 16, 2000

Michelle R. Ricklefs

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,249	10/19/99	ELLIS L	S6.2-8619

QM32/0815

Oliver f Arrett
VIDAS ARRETT & STEINKRAUS
920 Second Avenue South
Suite 1540
minneapolis MN 55402-4014

EXAMINER	
YU, J	
ART UNIT	**PAPER NUMBER**
3764	5

DATE MAILED: 08/15/00

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

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

U.S. G.P.O. 2000 ; 465-188/25266

1- File Copy

Office Action Summary

Application No.	Applica[illegible]s)
09/420,249	Ellis et al
Examiner	**Group Art Unit**
Justine Yu	3764

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ 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.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

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

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

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

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

2. Claims 1-19 and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 6, the term "for radial expansion of the stent" is confusing because it is not clear which disclosed element performing the recited function, the inflatable means, or the mounting and retaining means.

In claim 14, lines 6-7 the term "on and/or surrounding the shaft, the at least one mounting body being positioned on the shaft" is indefinite because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

In claims 17, 19, 32, and 34, the term "like" is vague and indefinite.

In claim 35, lines 9-10, the term "the length of the stent" is vague and indefinite because the length of the stent is variable. Similar to the "length of the stent" in claim 36.

Claim Rejections - 35 USC § 102

3. 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.

4. Claims 1-3, 5, 6, 8, 12-17, 20-22, 24-25, and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryan et al (Pat. No. 5,108,416).

Figure 15 of Ryan shows a stent introducer system comprising two end cups 102 and 104 (cups are interpreted as the mounting means or bodies with separation in between, or one cup as the mounting body and the other one as the stop) located inside the balloon 20. The teaching in column 5, lines 42-53 of Ryan discloses that the end caps can be formed of any of a variety of resilient polymers including polyester elastomers and can be coated with silicone.

In regard to claim 15, column 11, lines 40-41 of Ryan teaches that the end cap can be formed from a segment of tubing having uniform diameter (cylindrical shape, ring-like).

5. Claims 14, 15, 20, and 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lau et al (Pat. No. 5,158,548).

Figures 1 and 2 of Lau show the marker (mounting body) being carried on the shaft inside the balloon and under the stent.

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.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al.

Ryan lacks a description of the end cups being made of high density polyethylene. However, the feature of choosing high density polyethylene is considered as an obvious design choice since such material is well known in the art.

8. Claims 11 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al in view of Euteneuer et al (Pat. No. 5,445,646).

Ryan lacks marker bands on the catheter. However, the feature of using marker bands is well known in the stent delivery art to identify the location. In addition, Euteneuer discloses two marker bands 20 in the stent delivery system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Ryan's system with a pair of marker bands as taught by Euteneuer, in order to identify the location of the stent during the delivery process.

9. Claims 1-10, 14, 16, 18-28, and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (Pat. No. 5,683,410) in view of Ryan et al.

Samson discloses an angioplasty balloon catheter comprises an inner member 114 (mounting and retaining means) having two ends 116 (stops or spaced mounting bodies) and a flexible coil 118 (mounting body) located inside of the balloon. Samson lacks a tubular stent mounted on the balloon. However, Ryan shows a stent introducer system having a tubular stent mounted on the balloon. Therefore, it would have been obvious to one of ordinary skill in the art

at the time the invention was made to provide Samson's catheter with a stent as taught by Ryan, since the balloon catheter is well known in the art for delivering the stent into the body.

In regard to claims 3-5, the teaching in column 6, lines 1-14 of Samson discloses the coil 118 may be made of any suitable material. Therefore, choosing a particular material such as elastomeric, high density polyethylene, or silicone is considered as an obvious design choice.

In regard to claims 9-10, figure 1A of Samson shows the pair of stops 116 in the cylindrical shaped but lacks in the conical shaped. However, having a conical shaped instead of cylindrical is considered as an obvious design choice since it appears that the modified Samson's stop would perform equally well with conical shaped stop.

In regard to claims 18 and 27, figure 1 of Samson shows three spaced mounting bodies which including two spaced stops 116 and a coil 118.

10. Claim 21-24, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al.

Lau does not explicitly disclose the specific material for the marker. However, the feature of choosing markers from a material which resiliently deforms under radial pressure such as elastomeric, high density polyethylene, silicone is considered as an obvious design choice because the recited materials are well known in the radiopaque marker art.

Regarding claims 31-34, Lau shows one ring shaped mounting body rather than two or three spaced mounting bodies. However, duplicating the components of a prior art device is a

design consideration within the skill of the art. Therefore, the feature of having two or three mounting bodies fails to patentably define over the prior art.

Regarding claims 35 and 36, Lau differs from the present invention in that the mounting body having the length of less than ½ the length of the stent. However, the feature of choosing a smaller or shorter stent such that the length of the mounting body being at least ½ or 2/3 the length of the stent is considered as an obvious design choice since the length of the stent is variable and it is necessary and inherent upon various applications.

11. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al in view of Walker et al (Pat. No. 5,364,354).

Lau's marker in a form of a tube rather than a spiral configuration. However, Walker teaches a resilient coiled marker 62. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of the Lau's marker with a coil configuration as taught by Walker, since it is a matter of design for art recognized equivalents.

12. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al in view of Euteneuer et al.

Regarding claims 27 and 28, Lau lacks a pair of stops. However, Euteneuer in figures 16 and 17 shows a pair of stops (206, 208; 206). Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to provide Lau's delivery system with a pair of stops as taught by Euteneuer, so as to further secure the stent on the position. Furthermore, the feature of choosing a particular shape for the stops such as conical in shape is considered as an obvious design choice since it appears that the Euteneuer's stops would perform equally well with both stops in conical shape.

Regarding claim 29, Lau has only one marker but lacks a plurality of markers. However, Euteneuer teaches an additional pair of markers 20 being located on the shaft, see figure 2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Lau's system with an addition pair of markers as taught by Euteneuer, in order to provide better assistance to the physician in positioning the system into the desire location within the body.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,007,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the patented claims and the proposed application claims are minor and obvious from each other. The instant claims are broader version of the patented claims (i.e. the instant claim 1 does not include the structural limitation such as the mounting body being substantially the same length as the stent as recited in the patented claim 1; and the instant claim 14 does not include the structural limitation such that the stent is interlocked with the mounting body as recited in the patented claim 13). And any infringement over the patent would also infringe over the instant claims. In the instant claims, the structural elements are included in the patented claims 1-33. Hence, the instant claims do not differ from the scope of the patented claims 1-33. In 214USPQ 761, In re Van Ornum and Stang, broad claims in the continuing application were held to be obvious double patenting over previously narrow claims.

15. should be directed to Justine Yu whose telephone number is (703) 308-2675. The examiner can normally be reached on Tuesday - Friday from 8:30 AM - 6:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Justine Yu

August 9, 2000

Notice of References Cited

Application No.	Applicant(s)		
09/420,249	Ellis et al		
Examiner	Group Art Unit	Page 1 of 1	
Justine Yu	3764		

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,364,354	11/1994	Walker et al	604	96
B					
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NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
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Attachment _____

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.

SUBSTITUTE PTO-948

376 By Atty

5-11-00 Refer copying

FILING RECEIPT

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: ASSISTANT SECRETARY AND
COMMISSIONER OF PATENT AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/420,249	10/19/1999	3734	1142	S6.2-8619	4	34	3

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minneapolis, MN 55402-4014

STE 3764

Date Mailed: 03/06/2000

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Applicant(s)

Louis g. ELLIS, ST. ANTHONY, MN ;
ANDREW j. DUSBABEK, DAYTON, MN ;
CHRISTOPHER r. LARSON, ST. PAUL, MN ;
TERRY v. BROWN, FRIDLEY, MN ;

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A CON OF 08/702,150 08/23/1996 PAT 6,007,543

Foreign Applications

Foreign filing license granted on 11/09/1999

Title

STENT DELIVERY SYSTEM

Preliminary Class

604

Data entry by : DIXON, DOROTHY **Team :** OIPE **Date:** 03/06/2000

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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FILING RECEIPT

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UNITED STATES DEPARTMENT OF COMMERCE
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ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/420,249	10/19/99	3734	$0.00	S6.2-8619	4	34	3

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Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s) LOUIS G. ELLIS, ST. ANTHONY, MN; ANDEW J. DUSBABEK, DAYTON, MN; CHRISTOPHER R. LARSON, ST. PAUL, MN; TERRY V. BROWN, FRIDLEY, MN.

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A CON OF 08/702,150 08/23/96

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 11/09/99
TITLE
STENT DELIVERY SYSTEM

PRELIMINARY CLASS: 604

DATA ENTRY BY: DIXON, DOROTHY L. TEAM: 04 DATE: 11/09/99

(See reverse for new important information)

7/B
EW-12-4-00

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J
Group Art Unit:	3764

Assistant Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

AMENDMENT

In response to the official action mailed August 15, 2000, please make the following amendments:

In the Claims:

Sub C1 B1

1. (Amended) A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving the stent on the expandable inflatable means [for radial expansion of] whereby the stent is radially expanded upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent and wherein, when the stent is mounted on the catheter, the at least mounting body is between the stent and the shaft.

Sub C2 B2

14. (Once Amended) A stent delivery system comprising:

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent, the stent

B

having a first end and a second end and a contracted state and an expanded state, to be delivered upon expansion of the inflatable means, the mounting and retaining means including at least one mounting body inside the inflatable means and carried on [and/or surrounding] the shaft, the at least one mounting body being positioned on the shaft such that, when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state, at least a portion of the at least one mounting body is under the stent, and

the stent crimped to the inflatable means and the at least one mounting body such that a portion of the stent is deformed to a diameter less than that of the at least one mounting body, thereby facilitating mounting and retaining of the stent .

17. The stent delivery system of claim 16 wherein the stent is generally tubular in shape and the mounting bodies are ring-[like]shaped.

19. The stent delivery system of claim 18 wherein the stent is generally tubular in shape and the mounting bodies are ring-[like]shaped.

20. (Amended) A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, and means for inflating the balloon, the shaft including at least one mounting body radially carried on the shaft inside the balloon whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon, the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent.

21. The catheter of claim 20 wherein the mounting body is of a material which resiliently deforms under radial pressure.

22. The catheter of claim 21 wherein the material is elastomeric.

23. (Amended) The catheter of claim 21 wherein the material is high density polyethylene.

24. The catheter of claim 21 wherein the material is silicone.

25. The catheter of claim 20 wherein the mounting body is configured with at least one separation whereby trackability of the catheter is improved.

26. The catheter of claim 25 wherein the separation is in a spiral configuration.

27. (Amended) The catheter of claim 20 further including a pair of spaced stops.

28. The catheter of claim 27 wherein the stops are conical in shape.

29. (Amended) The catheter of claim 20 further including spaced marker bands.

30. The catheter of claim 20 wherein the mounting body is cylindrical in shape.

31. The catheter of claim 20 wherein at least two spaced mounting bodies are included.

32. The catheter of claim 31 wherein the mounting bodies are ring-[like]shaped.

33. The catheter of claim 20 wherein at least three spaced mounting bodies are included.

34. The catheter of claim 33 wherein the mounting bodies are ring-[like]shaped.

35. A stent delivery system comprising:

a radially expandable stent of generally cylindrical configuration, having a length, a first end and a second end and a contracted state and an expanded state, and

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon, and including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means, the at least one mounting body being at least ½ the length of the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the

mounting and retaining of the stent.

36. The stent delivery system of claim 35, wherein the at least one mounting body is at least 2/3 the length of the stent.

Please add the following claims:

37. Balloon catheter for expansion of vessel stenoses and for simultaneous introduction of a deformable stent into the vessel which is to be expanded in order to stabilize it in the expanded condition, whereby the distal area of the catheter which is provided for receiving the stent has an interior tube which is surrounded by the unexpanded stent, a balloon is arranged between the stent and the interior tube, and the interior tube has at its ends two sleeves applied to it as x-ray markers which are composed of material opaque to X rays and are provided within the balloon on the interior tube, the catheter further comprising a intermediate tube which forms an additional plateau and which is composed of a flexible material is provided between interior tube and exterior balloon as an intermediate layer in such manner that it extends in longitudinal direction to the sleeves which form the x-ray markers.

38. Balloon catheter according to Claim 37, the intermediate tube forming the intermediate layer essentially has a thickness which corresponds to that of the sleeves forming the x-ray markers.

39. Balloon catheter according to claim 37, the interior tube, the balloon, the tube forming the intermediate layer, and the stent crimped onto this base forming a pre-assembled unit.

40. Balloon catheter according to claim 39, the tube forming the intermediate layer being composed of a soft and elastic material into which the stent presses during crimping.

41. Balloon catheter according to claim 39, wherein tube forming the intermediate layer is bonded at the distal end to the interior tube of the catheter.

REMARKS

The following is in response to the official action mailed August 15, 2000. Each

issue is discussed in detail below.

Rejections under §112

(2)

Claims 1-19 and 35-36 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specific items of the claims were addressed.

In response, Applicant has amended the claims to remove the asserted indefinite nature.

Rejection under §102

(4)

Claims 1-3, 5-6, 8, 12-17, 20-22, 24-25 and 30-32 are rejected under 35 U.S.C. §102(b) as being anticipated by Ryan et al. (5108416).

The claims are not anticipated by Ryan et al. because the end cups are not position under the stent when the stent is loaded, as required by independent claims 1, 14 and 20.

(5)

Claims 14-15, 20 and 30 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by Lau et al. (5158548).

Applicant respectfully traverses on multiple accounts. Firstly, the "marker band" in figure 1 does not qualify to one skilled in the art as a mounting body carried on the shaft inside the expandable means, whereby the diameter of the shaft and expandable means, when the expandable means is in its contracted state, are increased at the distal part of the shaft for facilitating the mounting and *retaining* of the stent.

In this particular situation, it is assumed that the unlabeled marker in figure 1 is indeed a marker band. The item is not labeled and I find no reference to a marker band in the patent. The only information we have is what can be seen in figure 1. Typically, marker bands are quite thin and would not increase the diameter of the shaft to facilitate mounting and

retaining of the stent, as claimed above and as understood in the specification. Even in figure 1, the marker band is shown as having no effect on the crimped stent. Neither the balloon or the stent is shown to have contact with the marker band. Figure 2 does not show the marker band and therefore we do not have enough clear evidence from Lau et al. on how the "marker band" would affect the retention of the stent. As such, the band of Lau cannot reliably be considered mounting bodies, as defined in the present specification. If the marker band of Lau would have had any appreciable effect on the diameter of the catheter shaft, and therefore the seating of the stent, it would have likely been commented on.

To the extent that figure 1 of Lau et al. is being relied upon as an accurate three dimensional representation of the size of the marker band, it follows that the spacial representation between the stent, balloon and the marker band should also be accepted. As mentioned above, Figure 1, which is the only disclosure of the marker band, represents that the marker band has no retention effect on the stent. It cannot be said that Lau clearly teaches a mounting body as claimed. Only in hindsight of Applicant's application can one skilled in the art make such a connection analysis. "Obviousness may not be established using hindsight, or in view of the teachings or suggestions of the inventor." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 303, 311, 312- 13 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Rejections under §103

(7)

Claims 4 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ryan et al.

As this rejection is dependent upon the rejection of paragraph 4 of the official action, for the reasons stated above in response thereto, it similarly fails. As shown above, Ryan et al. does not anticipate the claims except for the element of the high density polyethylene. Reconsideration is therefore requested.

(8)

Claims 11 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ryan et al. in view of Euteneuer et al. (5445646).

As this rejection is dependent upon the rejection of paragraph 4 of the official action, for the reasons stated above in response thereto, it similarly fails. As shown above, Ryan et al. does not anticipate the claims except for the element of the marker bands. Reconsideration is therefore requested.

(9)

Claims 1-10, 14, 16, 18-28 and 30-34 were rejected under 35 U.S.C. §103 as being unpatentable over Samson (5683410) in view of Ryan et al. It is asserted that Samson discloses all of the elements of the present claims, save a stent mounted on the catheter.

In response, the Applicant respectfully traverses. The asserted inner member 114 is not on and *surrounding* the shaft, as required. The construction and purpose of the presently claimed invention is distinctly different from the invention disclosed in Samson. Samson discloses a balloon catheter wherein the inner shaft is connected to a spring, which in turn is connected to another inner shaft portion which extends distally to the end of the catheter, wherein a balloon encloses the spring portion. The purpose of the spring appears to provide axial length stability to the balloon and maintain the lumen within the valve region in general co-linear relationship with the lumen, while allowing for slight flexibility and movement of the balloon inner member, as well as fluid accessability to expand the balloon.

The angioplasty catheter of Sampson is to be used for opening stenoses and can be used in very tight areas due to the fact the guide wire lumen and fluid lumen are one and the same, thus minimizing the balloon profile. The patent does not discuss whether it is designed for, or intended to accept, an expandable stent which would increase the profile, let alone to provide a raised inner shaft profile for better mounting and retaining of a loaded stent. In fact, Samson clearly teaches that the profile of the shaft, including the spring portion, should remain constant. Even Figures 3c and 3d, where the spring/mesh is loaded on a section of tubing, the

section of tubing is stepped down such the added thickness of the spring/mesh does not increase the profile of the balloon inner member beyond that of the inner shaft. This is consistent with the general goal in making catheters to reduce the overall profile as much as possible. The sections of tubing in Figures 3c and 3d provide holes to allow fluid flow such that the spring/mesh are optional (Col. 6, lines 25-27 and 38-39), further indicating that Samson does not teach increasing the profile of the inner shaft in the area of the balloon to provide for improved mounting and retaining a stent.

The purpose of the Sampson invention is to decrease the profile of the catheter. The patent does not discuss the use of a stent. In fact, it appears that it would not be desirable for a surgeon to add a stent onto the balloon of Sampson because a stent loaded on such a balloon may have a tendency to slip off or negatively effect the valve function. A crimped stent, after customary recoil, would have nothing substantial to hold onto and may be loosened by the movement of the spring/mesh. Such a slip could be disastrous and even fatal for the patient.

The present invention provides mounting bodies on the shaft in the region of the balloon specifically to raise the profile of the shaft in certain parts of that region to improve the retention and loading of the stent. Sampson clearly does not speak to this issue. Nor does Sampson teach any motivation or desirability to add a stent. In fact, as mentioned above, there are reasons not to.

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the <u>desirability</u> of the modification.

In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (CAFC 1992). As mentioned above, adding a stent to the catheter of Sampson would not be obvious because the references do not teach a desirability for the modification.

Absent hindsight, there is no desirability to make the combination. The references in and of themselves do not teach the combination and only using the Applicant's disclosure may a link be made. Furthermore, there is no cited teaching "reasonably pertinent to the particular problem with which the inventor was concerned", i.e., providing for a simple and efficient apparatus which more accurately controls the retention of a loaded stent. Sampson deals with the minimization of the profile of a balloon catheter and there is no suggestion that there would be a need, let alone a desire to add a stent for its purport use.

The Office Action fails to suggest any motivation for, or desirability of, the combination espoused, and it has not been shown that a person of ordinary skill, seeking to solve the problem addressed in Applicant's claims, would reasonably be expected or motivated to look to Sampson, let alone the cited combination. The combination of elements in a manner that reconstructs Applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (CAFC 1992). Reconsideration is respectfully requested.

(10)

Claim 21-24 and 31-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lau et al.

As this rejection is dependent upon the rejection of paragraph 5 of the official action, for the reasons stated above, it similarly fails. Lau et al. does not anticipate the claims, save the additional elements provided by the present claims.

Further, with regard to claim 21, it is asserted in the official action that the feature of choosing markers from a material which resiliently deforms under radial pressure such as elastomeric material, high density polyethylene or silicone is considered as an obvious design choice because, it is asserted, the recited materials are well known in the radiopaque marker art. This is not understood by Applicant. High density polyethylene and silicone are not inherently

B

radiopaque in nature. Such material would not be an obvious choice to one skilled in the art in view of Lau et al., which is being used to provide disclosure for the rejection. This lack of obviousness is understandable because Lau et al discloses a marker band, not a mounting body. As such, the teaching of Lau et al. would cause one skilled in the art to use traditional marker band material, such as relatively hard material such as platinum, tungsten, rhenium, ruthenium or alloys. Lau et al. provides no motivation to use an elastomeric material as claimed.

Further with regard to claims 31-34, which require multiple mounting bodies *under the stent*, a motivation is not articulated in the rejection for adding a second marker band, let alone an third, other than a statement that it would be an obvious design choice. The design choice assertion is not convincing because the cited reference is directed to a marker band and the present claims are directed to mounting bodies. They are dealing with two different elements. The design choice of marker bands cannot be substituted for the design choice of mounting bodies without further teaching. Such teaching is dreadfully lacking in Lau et al., which doesn't even reference the marker band.

With regard to the arguments in the rejection directed toward claims 35-36, it is asserted that although the marker band of Lau et al. is less than ½ the length of the stent, the feature of choosing a smaller or shorter stent such that the length of the mounting body being at least ½ or 2/3 the length of the stent is considered as an obvious design choice since the length of the stent is variable and it is necessary and inherent upon various applications.

The fact remains, Lau et al. discloses a marker band which is approximately 1/7 the size of the stent. It would not be an obvious design choice to increase it by 3 ½ times because it is a marker band. There is no cited motivation to do so. Once again, the design choices of marker bands can not replace the design choices of mounting bodies because they are different elements serving different purposes. Without any further teaching, the requirements of the claims cannot be seen as obvious without the benefit of hindsight. Reconsideration is respectfully requested.

(11)

Claims 25 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lau et al. in view of Walker et al. (5364354).

As this rejection is dependent upon the rejection of paragraph 5 of the official action, for the reasons stated above, it similarly fails. Lau et al. does not anticipate the claims, save the additional elements provided by the present claims.

(12)

Claims 27-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lau et al. in view of Euteneuer et al.

As this rejection is dependent upon the rejection of paragraph 5 of the official action, for the reasons stated above, it similarly fails. Lau et al. does not anticipate the claims, save the additional elements provided by the present claims.

With regard to claim 29, as discussed above in response to paragraph 10, there is no cited motivation to add additional mounting bodies/markers as claimed.

Double Patenting

Applicant wishes to postpone responding to the double patenting rejection until the application is otherwise allowed.

Conclusion

The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 15, 2000

By: _____
William E. Anderson, II
Attorneys of Record No. 37,766

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GP-3734

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3734

Box Non-Fee Amendment
Commissioner of Patents
Washington, DC 20231

Docket No.: 263.2-8619

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
12 pg amendment; check for excess claim fee $90.00; VA&S Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☐ No additional fee is required.
   - ☒ Attached is check(s) in the amount of $ 90.00 .
   - ☐ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date: November 15, 2000 By: _____

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Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Commissioner for Patents, Washington D.C. 20231, on November 15, 2000

Jodi D. Nickel

6

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,249	10/19/99	ELLIS	L 56.2-8619

EXAMINER	
YU,J	
ART UNIT	**PAPER NUMBER**
3764	8

DATE MAILED: 02/08/01

0M32/0208

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

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary	Application No. 09/420,249	Applicant(s) Ellis et al
	Examiner Justine Yu	Group Art Unit 3764

☒ Responsive to communication(s) filed on *Nov 20, 2000*.

☐ This action is **FINAL.**

☐ 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.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-41* is/are pending in the application.

Of the above, claim(s) *37-41* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-36* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

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

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This office action is responsive to the amendment filed on 11/20/00. As directed by the amendment, claims 1, 17, 19, 20, 32, and 34 were amended, no claim was canceled, and claims 37-41 were added. Thus, claims 1-41 are presently pending in this application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, drawn to a stent delivery system including mounting and retaining means, classified in class 606, subclass 108.

II. Claims 37-41, drawn to a balloon catheter having markers and intermediate tube, classified in class 606, subclass 194.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination of balloon catheter having an intermediate tube as claimed for patentability. The subcombination has separate utility such as reinforcing the inner tube of a balloon catheter.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Newly submitted claims 37-41 are directed to an invention that is independent or distinct from the invention originally claimed for the aforementioned reasons.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-41 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

7. Claim 1 is objected to because of the following informalities: the newly added term "at least mounting body" should be changed to --at least one mounting body-- . Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. 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 --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. Claims 1, 2, 4, 8, 11, 12, 20, 21, 23, 29, 30 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Rupp et al (Pat. NO. 5,653,691).

Rupp teaches a catheter for uniform stent expansion comprising a shaft 30, a stent 100, and a build up section (mounting and retaining means) (20, 210). Figure 1 of Rupp further shows the build up section (mounting body) being located between the stent and the shaft.

Regarding claims 2 and 21, it is inherent that the mounting body being made of material which resiliently deforms under radial pressure. See teaching in column 6, lines 11-12 of Rupp.

Regarding claim 4, Rupp teaches polyethylene in column 5, lines 65-69.

Regarding claim 11, notes the markers 65 in figure 10 of Rupp.

Regarding claim 30, figures 1 and 6 of Rupp show that the buildup section is generally cylindrical in shape.

Claim Rejections - 35 USC § 103

10. 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.

11. Claims 3, 5, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupp et al.

Rupp does not explicitly disclose that the mounting body being made of elastomeric material or silicone. However, the feature of choosing elastic material or silicon is considered as an obvious design choice since such materials are well known in the art.

12. Claims 6, 9, 10, 13, 25, 27, 28, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupp et al in view of Ryan et al (Pat. NO. 5,108,416).

Rupp lacks a pair of stops. However, Ryan teaches a pair of stops 102, 104(see figure 15) for retaining the stent in place (column 11, lines 61-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Rupp's catheter with a pair of stops as taught by Ryan, in order to hold the stent in place as the delivery catheter is guided to a selected location. Notes that the stops could be considered as part of the mounting and retaining means or the second and third mounting bodies since the stops being used to mount and retain the stent on the catheter.

Regarding claims 6 and 25, the modified Rupp's reference discloses the at least one mounting body comprising two stops and the buildup section. Thus, the separated mounting and retaining means forms sparations tween the stops and the buildup section.

Regarding claim 10, notes the conical stops in figure 15 of Ryan reference.

13. Claims 14, 15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rupp et al in view of Dirks et al.

Rupp has everything as claimed including crimping the stent onto the balloon except for the functional recitation that a portion of the stent being deformed to a diameter less than the at least one mounting body. However, since the mounting body has a thickness, it is inherent that a portion of the stent (both ends of the stent) would be able to deform to a diameter less than the mounting body which depends on the applied crimping force. In addition, Dirks shows the stent being tightly crimped to a balloon. Therefore, it would have been obvious to one of ordinary skill in the art at the invention was made to crimp Rupp's stent tightly to the balloon as taught by Dirks, since the way to crimp the stent to the catheter is a common practice and well known in the art.

Regarding claim 15, figures 1 and 6 of Rupp show the buildup section being generally cylindrical in shape.

14. Claims 16-19, 25, 27, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupp et al in view of Dirks et al (Pat. No. 5,846,246).

Rupp teaches a pair of marker bands located proximally and distally of the stent but does not explicitly disclose that the markers being part of the mounting bodies. However, Dirks teaches a pair of marker bands 114, 115 forming a pair of stops (column 4, lines 33-36, column 6, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Rupp's markers to a pair of stops as taught by Dirks, so as to provide additional advantageous benefit such as able to hold the stent on the balloon during delivery.

Regarding claims 18 and 19, the modified Rupp has three spaced mounting bodies and the mounting bodies are ring shaped (see figure 1 of Rupp and figure 5 of Dirks).

Regarding claim 25, the modified Rupp reference has the mounting body which including a central buildup section and two stops, and the mounting body is configured with at least one separation.

15. Claim 35 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rupp et al.

Rupp in figure 1 shows the buildup section being at least ½ the length of the stent but lacks a detail description that the buildup section being at least ½ the length of the stent. However, the feature of choosing such particular length of the buildup section is considered as an obvious design choice since the length of the stent is variable.

16. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rupp et al.

Rupp lacks detail description that the mounting body being at least 2/3 the length of the stent. However, the feature of choosing a mounting body with such a particular length is considered as an obvious design choice since it appears that the modified Rupp device would perform equally well with the selected length.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,007,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the patented claims and the proposed application claims are minor and obvious from each other. The instant claims are broader version of the patented claims (i.e. the instant

claim 1 does not include the structural limitation such as the mounting body being substantially the same length as the stent as recited in the patented claim 1; and the instant claim 14 does not include the structural limitation such that the stent is interlocked with the mounting body as recited in the patented claim 13). And any infringement over the patent would also infringe over the instant claims. In the instant claims, the structural elements are included in the patented claims 1-33. Hence, the instant claims do not differ from the scope of the patented claims 1-33. In 214USPQ 761, In re Van Ornum and Stang, broad claims in the continuing application were held to be obvious double patenting over previously narrow claims.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Justine Yu whose telephone number is (703) 308-2675. The examiner can normally be reached on Tuesday - Friday from 8:30 AM - 6:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Everett Williams whose telephone number is (703) 305-1708.

Justine Yu

February 1, 2001

Notice of References Cited

Application No.	Applicant(s)		
09/420,249	Ellis et al		
Examiner		Group Art Unit	Page 1 of 1
Justine Yu		3764	

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,846,246	12/1998	Dirks et al	606	108
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N						
O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U		
V		
W		
X		

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Serial No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3764

Box Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-8619

Dear Sir:

PETITION FOR AN EXTENSION OF TIME UNDER 37 CFR §1.136

Petitioner, Louis Ellis, et al., hereby requests a one month extension of time to respond to the Office Action mailed February 8, 2001. This petition is accompanied by $110.00 as set forth in 37 CFR §1.17 and is filed prior to or with the response.

Any outstanding fee for extension should be charged to our Deposit Account No. 22-0350.

Respectfully submitted,

Vidas, Arrett & Steinkraus, P.A.

Date: June 7, 2001 By: _____

William E. Anderson
Reg. No. 37,766
Attorneys of Record

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Minnetonka, MN 55343-9185
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J
Group Art Unit:	3764

Box Fee Amendment
Assistant Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

AMENDMENT

In response to the official action mailed February 8, 2001, please make the following amendments:

In the Claims:

Please cancel claims 37-41.

Please amend the claims as follows:

1. (Amended twice) A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving the stent on the expandable inflatable means whereby the stent is radially expanded upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body, the at least one mounting body having a length and an outer surface diameter and being carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft is increased at the distal part for facilitating the mounting and retaining of the stent and wherein, when the stent is mounted on the catheter, the at least one mounting body is between the stent and the shaft, the outer surface diameter of the at least one mounting body being

C1

15

substantially constant along its length.

14. (Amended twice) A stent delivery system comprising:

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, to be delivered upon expansion of the inflatable means, the mounting and retaining means including at least one mounting body, the at least one mounting body being inside the inflatable means and carried on the shaft, the at least one mounting body being positioned on the shaft such that, when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state, at least a portion of the at least one mounting body is under the stent, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length, and

C2

the stent crimped to the inflatable means and the at least one mounting body such that a portion of the stent is deformed to a diameter less than that of the at least one mounting body, thereby facilitating mounting and retaining of the stent.

15. (Amended twice) The stent delivery system of claim 14 wherein the stent is generally tubular in shape and the at least one mounting body is uniformly cylindrical in shape.

16. (Amended twice) The stent delivery system of claim 14 wherein at least two longitudinally spaced mounting bodies are included positioned between the stent and the shaft and a portion of the stent between the mounting bodies is additionally crimped to a lesser diameter than that of the mounting bodies and positioned between the mounting bodies.

18. (Amended twice) The stent delivery system of claim 14 wherein three longitudinally spaced mounting bodies are included between the stent and the shaft and the stent is crimped to a lesser diameter between the bodies.

C3

16

C

20. (Amended twice) A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, and means for inflating the balloon, the shaft including at least one mounting C4 body radially carried on the shaft inside the balloon, whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon, the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length.

C5 25. (Amended) The catheter of claim 20 wherein the mounting body comprises at least one separation whereby trackability of the catheter is improved.

C6 30. (Amended) The catheter of claim 20 wherein the mounting body is uniformly cylindrical in shape.

C7 31. (Amended) The catheter of claim 20 wherein at least two longitudinally spaced mounting bodies are included, wherein the at least two mounting bodies are positioned between the stent and the shaft.

C8 33. (Amended) The catheter of claim 20 wherein at least three longitudinally spaced mounting bodies are included positioned between the stent and the shaft.

Please add the following claim:

17 C

Sub D2 C9

42. (New) The stent delivery system of claim 35, the at least one mounting body comprising no more than one layer of the material.

Add D3

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

REMARKS

The following is in response to the official action mailed February 8, 2001. Each issue is discussed in detail below.

Election/Restriction

A restriction requirement was issued grouping the claims. Claims 1-36 were assigned to group I and claims 37-41 were assigned to group II. It is stated that group I containing claims 1-36 was constructively elected by original presentation for prosecution on the merits and 37-41 were withdrawn from consideration as being directed to a non-elected invention.

Although Applicant does not concur with the restriction requirement, claims 37-41 have been canceled. Applicant maintains the right to prosecute the claims in a continuation application.

Claim Objections

The minor error pointed out in paragraph 7 of the official action has been corrected in the amendments.

Rejection under §102

(9)

Claims 1, 2, 4, 8, 11-12, 20-21, 23, 29-30 and 33 (the official action says 23 instead of 33, however, Applicant assumes Examiner means 33) are rejected under 35 U.S.C. §102(b) as being anticipated by Rupp et al. (US 5653691).

In response, Applicant has amended independent claims 1 and 20, and therefore effectively the above mentioned dependent claims, to more clearly define the at least one mounting body. The amendments further distinguish the claims from the built up layer of Rupp et al. As such, Rupp et al. does not disclose or teach each and every element of the claimed invention. Although the dependent claims remain patentable for other reasons, no further discussion is needed to overcome the rejection. Withdrawal of the rejection is respectfully requested.

Claim 30 has been amended to more specifically describe the claimed shape of the mounting body to further distinguish it from the built up layer of Rupp et al.

Rejections Under §103

(11)

Claims 3, 5, 22 and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rupp et al.

The present rejection depends upon the rejection of paragraph 9 to independent claims 1 and 20. As discussed above, Applicant has amended claims 1 and 20 to overcome the rejection. Although the dependent claims remain patentable for other reasons, no further discussion is needed to overcome the rejection. As such, the present rejection should be withdrawn as well.

(12)

Claims 6, 9, 10, 13, 25, 27, 28 and 31-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rupp et al. in view of Ryan et al. (US 5108416).

The present rejection depends upon the rejection of paragraph 9 to independent

claims 1 and 20. As discussed above, Applicant has amended claims 1 and 20 to overcome the rejection. Although the dependent claims remain patentable for other reasons, no further discussion is needed to overcome the rejection. As such, the present rejection should be withdrawn as well.

Additionally, Rupp et al. and Ryan et al. do not teach a separation in the mounting body itself to increase the flexibility *of the body*, as required by claims 6 and 25. The claim language does not refer to the "mounting and retaining means", rather it refers specifically to the mounting body.

Claim 31 has been further amended to specify the positioning of the mounting bodies as being under the stent as well as their positioning relative to one another. Such requirements cannot be said to be disclosed or made obvious by the cited combination.

(13)

Claims 14-15 were rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Rupp et al. in view of Dirks et al.

Claim 14 has been amended similarly to claim 1. As such, it similarly is distinct over Rupp et al. Claim 15 has also been amended to further distinguish it from the references.

(14)

Claims 16-19, 25, 27 and 31-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rupp et al in view of Dirks et al. (US 5846246)

The present rejection depends upon the rejection of paragraph 9 to independent claims 1 and 20. As discussed above, Applicant has amended claims 1 and 20 to overcome the rejection. As such, the present rejection should be withdrawn as well.

Although the dependent claims remain patentable for other reasons, no further discussion is needed to overcome the rejection. However, claims 16, 18, 31, 33 have been further amended to specify the positioning of the mounting bodies as being under the stent as well as their positioning relative to one another. Such requirements can not be said to be

disclosed or made obvious by the cited combination.

Additionally, Rupp et al. and Dirks et al. do not teach a separation in the mounting body itself to increase the trackability, as required by claim 25. The claim language does not refer to the "mounting and retaining means", rather it refers specifically to the mounting body. Applicant has amended the claim to further clarify this.

(15)

Claim 35 was rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Rupp et al. It is asserted that figure 1 of Rupp shows the built-up section as being at least ½ the length of the stent, but lacks a detailed description of the lengths. However, it is asserted, the feature of choosing such a particular length is considered as an obvious design choice.

Figure 1 is not drawn to scale. As such, one cannot draw conclusions as to the relative lengths of the featured elements to illustrate disclosure. This is especially true when the specification teaches a specific measurement. Rupp specifically teaches that the built up section is approximately 1/3 of the length of the stent (col. 5, lines 1-9) and should be centered between the proximal and distal ends of the stent. The claimed invention requires a 50% increase. This is a significant increase. The built up section is meant to be substantially shorter than the stent so that the ends of the stent are tapered downward from the middle of the stent when the stent is mounted on the built up section to encourage even expansion of the stent. Rupp has quite clear teachings and guidance which diverge from the claimed invention. The claimed invention distinctly diverges from those teachings.

The rejection states that increasing the length of the built-up section by 50% is merely a design choice. Applicant disagrees. A design choice which ignores the specific recommended teachings of a reference which represents the prior art cannot be said to be an obvious design choice. Reconsideration is respectfully requested.

(16)

As to the rejection of claim 36 under 35 U.S.C. §103(a), for the above reasons in response to paragraph 15 of the official action, claim 36 is similarly not made obvious. The obviousness rejection of claim 36 is even less appropriate since the claimed invention requires a 100% increase to the recommended teachings of Rupp et al. As such reconsideration is respectfully requested.

Double Patenting

Claims 1-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of US 6007543.

Applicant wishes to postpone responding to this rejection until the claims are found to be otherwise allowable.

Conclusion

The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 7, 2001

By: _____
William E. Anderson, II
Attorneys of Record No. 37,766

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Phone: (952) 563-3000
Facsimile: (952) 563-3001
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 37-41.

Please amend the claims as follows:

1. (Amended twice) A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving the stent on the expandable inflatable means whereby the stent is radially expanded upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body, the at least one mounting body having a length and an outer surface diameter and being carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft [and inflatable portion are] is increased at the distal part for facilitating the mounting and retaining of the stent and wherein, when the stent is mounted on the catheter, the at least one mounting body is between the stent and the shaft, the outer surface diameter of the at least one mounting body being substantially constant along its length.

14. (Amended twice) A stent delivery system comprising:

a catheter having a shaft and expandable inflatable means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, to be delivered upon expansion of the inflatable means, the mounting and retaining means including at least one mounting body, the at least one mounting body being inside the inflatable means and carried on the shaft, the at least one mounting body being positioned on the shaft such that, when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state, at least a portion of the at least one mounting body is under the stent, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length, and

the stent crimped to the inflatable means and the at least one mounting body such that a portion of the stent is deformed to a diameter less than that of the at least one mounting body, thereby facilitating mounting and retaining of the stent.

15. (Amended twice) The stent delivery system of claim 14 wherein the stent is generally tubular in shape and the at least one mounting body is [generally] uniformly cylindrical in shape.

16. (Amended twice) The stent delivery system of claim 14 wherein at least two longitudinally spaced mounting bodies are included positioned between the stent and the shaft and a portion of the stent between the mounting bodies is additionally crimped to a lesser diameter than that of the mounting bodies and positioned between the mounting bodies.

18. (Amended twice) The stent delivery system of claim 14 wherein three longitudinally spaced mounting bodies are included between the stent and the shaft and the stent is crimped to a

lesser diameter between the bodies.

20. (Amended twice) A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, and means for inflating the balloon, the shaft including at least one mounting body radially carried on the shaft inside the balloon, whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon, the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length.

25. (Amended) The catheter of claim 20 wherein the mounting body [is configured with] comprises at least one separation whereby trackability of the catheter is improved.

30. (Amended) The catheter of claim 20 wherein the mounting body is uniformly cylindrical in shape.

31. (Amended) The catheter of claim 20 wherein at least two longitudinally spaced mounting bodies are included, wherein the at least two mounting bodies are positioned between the stent and the shaft.

33. (Amended) The catheter of claim 20 wherein at least three longitudinally spaced mounting bodies are included positioned between the stent and the shaft.

Please add the following claim:

42. The stent delivery system of claim 35, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length.

3734

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3734

Box Fee Amendment
Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
8 pg. Amendment; 2 pg. Marked Claims; 1 pg. Petition for Extension; Check $110.00; VA&S Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☐ No additional fee is required.
   - ☒ Attached is check(s) in the amount of $110.00 .
   - ☐ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date: June 7, 2001

By: _____
William E. Anderson, II
Registration No. 37,766

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Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Box Fee Amendment, Commissioner for Patents, Washington D.C. 20231, on June 7, 2001.

_____
Michelle R. Ricklefs

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,249	10/19/99	ELLIS L	S6.2-8619

OM32/0820

OLIVER F ARRETT
VIDAS ARRETT & STEINKRAUS
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNEAPOLIS MN 55343-9131

EXAMINER	
YU, J	
ART UNIT	**PAPER NUMBER**
3764	11

DATE MAILED: 08/20/01

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

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/420,249	ELLIS ET AL.	
	Examiner	Art Unit	
	Justine Yu	3764	

-- 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 *11 June 2001* .

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) *1-36 and 42* 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) *1-36 and 42* 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).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ 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.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This office action is responsive to the amendment filed on 6/11/01. As directed by the amendment, claims 1, 14-16, 18, 20, 25, 30, 31, and 33 were amended, claims 37-41 were canceled, and claim 42 was added. Thus, claims 1-36 and 42 are presently pending in this application.

Claim Rejections - 35 USC § 112

2. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "the material" lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. 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 --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

4. 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.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 35 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rupp et al.

Rupp in figure 1 shows the buildup section being at least ½ the length of the stent. Although Rupp in column 5, lines 1-5 states that the preferred length of the buildup section is equal to one-third of the length of the stent, however, it is the examiner's position that the length of the build up section is an obvious design choice upon the selected stents for various applications.

6. Claims 36 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupp et al.

Regarding claim 36, Rupp lacks detail description that the mounting body being at least 2/3 the length of the stent. However, the feature of choosing a mounting body with such a particular length is considered as an obvious design choice since it appears that the modified Rupp device would perform equally well with the selected length.

Regarding claim 42, figure 1 of Rupp shows the mounting body comprising no more than one layer of the buildup material 210.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-36 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,007,543. Although

the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the patented claims and the proposed application claims are minor and obvious from each other. The instant claims are broader version of the patented claims (i.e. the instant claim 1 does not include the structural limitation such as the mounting body being substantially the same length as the stent as recited in the patented claim 1; and the instant claim 14 does not include the structural limitation such that the stent is interlocked with the mounting body as recited in the patented claim 13). And any infringement over the patent would also infringe over the instant claims. In the instant claims, the structural elements are included in the patented claims 1-33. Hence, the instant claims do not differ from the scope of the patented claims 1-33. In 214USPQ 761, In re Van Ornum and Stang, broad claims in the continuing application were held to be obvious double patenting over previously narrow claims.

9. The examiner is not sure whether or not this application being assigned to the same assignee as in its parent application Serial No. 08/702,150, to SciMed Life Systems, Inc.. If the present application has the same assignee as in the parent application, claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,123,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the patented claims and the proposed application claims are minor and obvious from each other. The instant claims are broader version of the patented claims (i.e. the instant claim 1 does not include the

structural elements such as the tube component having a plurality of ribs as recited in the patented claim 1, and the recitation of "the outer surface diameter is substantially constant along the length" of the instant claim 1 is merely obvious variation over the "the tube component having a certain length and forming a continuous covering over the inner shaft along the tube's length" from the patented claim 1). Any infringement over the patent would also infringe over the instant claims. In the instant claims, the structural elements are included in the patented claims 1-7. Hence, the instant claims do not differ from the scope of the patented claims 1-7.

10. Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 36-45 of copending Application No. 09/387,179. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending application No. 09/387,179 claims and the proposed application claims are minor and obvious from each other. The instant claims are broader version of the copending application claims (i.e. the instant claim 1 does not include the structural limitation such as a sleeve as recited in the copending application claim 23). And any infringement over the copending application claims would also infringe over the instant claims. .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 6/11/01 have been fully considered but they are not persuasive.

Applicant on page 7, section (15) of the remarks argues that the increase of the buildup layer from a 1/3 of the length of the stent to ½ of the length of the stent is not a design choice. While Rupp in column 5, lines 1-9 states that the build up section is equal to 1/3 of the length of the stent, however, Rupp also teaches that it is merely "preferred" (column 5, line 3-5). In addition, figure 16 of Rupp clearly shows the length of the buildup section is greater than ½ of the length of a selected stent. Furthermore, applicant in his figure 6 clearly shows that the mounting bodies each having a length being less than ½ of the length of the stent. Therefore, it is the examiner's position that the length of the mounting body is not a criticality of the present invention. The feature of choosing a particular length of the mounting body with respect to the length of the stent is merely an obvious design choice.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Justine Yu whose telephone number is (703) 308-2675. The examiner can normally be reached on Tuesday - Friday from 8:30 AM - 6:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Everett Williams whose telephone number is (703) 305-1708.

Justine Yu

August 16, 2001

#3734

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3734

Box Fee Amendment
Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TRANSMITTAL LETTER

1. In regard to the above-identified application, we are submitting the attached:
2pgs Remarks; Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection Over a Pending Second Application; Check $110.00; VA&S Transmittal Letter; and Postcard.

2. With respect to fees:
   - ☐ No additional fee is required.
   - ☒ Attached is check(s) in the amount of $ 110.00 .
   - ☐ Charge additional fee to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

VIDAS, ARRETT & STEINKRAUS

Date: August 3, 2001

By: _____
William E. Anderson, II
Registration No. 37,766

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Telephone: (952) 563-3000
Facsimile: (952) 563-3001

Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Box Fee Amendment, Commissioner for Patents, Washington D.C. 20231, on August 3, 2001.

Ann Lowe

Ann Lowe

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J
Group Art Unit:	3764

Box Fee Amendment
Assistant Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

REMARKS

Applicant received a phone call from Examiner the week of July 30, 2001. Examiner stated that the application would be allowable if a terminal disclaimer were filed.

It was asserted by Examiner that claim 1 of the above mentioned file would be provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of US Application 09/387,179, which is commonly owned.

Applicant respectfully traverses the double patenting rejection. However, since the eventual patent which would issue from this application would expire on the same date as the eventual patent from US Application 09/387,179, Applicant is enclosing a terminal disclaimer to forward the prosecution of the instant application.

Conclusion

The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: August 3, 2001

By: _____
William E. Anderson, II
Attorneys of Record No. 37,766

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F:\WPWORK\WEA\8619-AMD.802

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420/249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3764

Commissioner for Patents
Washington, DC 20231

Docket No.: S63.2-8619

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING SECOND APPLICATION

The owner, SciMed Life Systems, Inc., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second Application Number 09/387,179 , filed on August 31, 1999, of any patent on the pending second application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the second application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of any patent granted on the second application, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

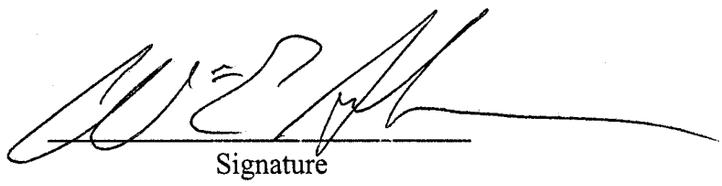
1. ☐ For submission on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf on the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all

statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney of record.

August 3, 2001
Date


Signature

William E. Anderson, II
Typed or printed name

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.
☒ PTO suggested wording for terminal disclaimer was

☒ unchanged ☐ changed (if changed, an explanation should be supplied).

10/10 EO - 11-28-01

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J
Group Art Unit:	3764

BOX Non-Fee Amendment
Assistant Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

AMENDMENT

In response to the official action mailed August 20, 2001, please make the following amendments:

In the Claims:

Please cancel claim 36.

Please amend the remaining claims as follows:

35. (Amended) A stent delivery system comprising:

a radially expandable stent of generally cylindrical configuration, having a length, a first end and a second end and a contracted state and an expanded state, and a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon, and including mounting and retaining means for receiving the stent on the expandable inflatable

means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means, the at least one mounting body being at least 2/3 the length of the stent and

18

D1 Cont'd

being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

D2

36 ~~42~~. (Amended) The stent delivery system of claim 35, the at least one mounting body comprising no more than one layer of material.

Please add the following claim: 36

D3

37 ~~43~~. The stent delivery system of claim ~~42~~, wherein the material comprises high density polyethylene.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

REMARKS

The following is in response to the official action mailed August 15, 2000. Claims 1-36 and 42 are pending in this case. Each issue of the official action is discussed in detail below.

Rejections under §112

(2)

Claim 42 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. It is asserted that the term "the material" lacks antecedent basis.

In response, Applicant has amended the claim to remove the asserted indefinite nature.

§102 & §103 Issues

(4)

The subject matter of the various claims was commonly owned at the time any inventions covered in the application were made.

(5)

Claim 35 was rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 3 USC §103(a) as obvious over Rupp et al. It is asserted that figure 1 of Rupp et al. shows the buildup section being at least ½ the length of the stent.

Claim 35 has been amended by incorporating claim 36, which was not seen as being anticipated. As such, the §102 rejection should be withdrawn.

Rejections under §103

(6)

Claims 36 and 42 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rupp et al. Regarding claim 36, it is asserted that Rupp et al. lack a detailed description that the mounting body is at least 2/3 the length of the stent, however, the feature of choosing a mounting body with such a particular length is considered as an obvious design choice.

Claim 36 has been incorporated into claim 35. As such, the rejection is discussed in terms of amended claim 35. Claim 36 has been canceled.

Amended claim 35 would not be obvious in light of Rupp et al. Even if, for argument's sake, one considers the comparison between the length of the stent and the built-up layer of figure 1 a teaching that the built-up layer can be approximately ½ the length of the stent, it cannot be said that the reference teaches that a built-up layer can be 2/3 the length of the stent. It further cannot be said that increasing the size of the built-up layer to 2/3 the length of the stent is obvious. Even if one were to give the disclosure of Rupp et al. a broad reading and consider figure 1 a teaching of the relative size of the built-up layer as compared to the stent, it still offers no teaching or suggestion to increase the relative size of the built-up layer by 33%.

If we consider the length of the built-up layer, as asserted in the rejection to be represented in figure 1, to be approximately ½ of the length of the stent a disclosed option, then, in light of the clear teaching in col. 5, lines 3-5, which states that the preferred length is 1/3, ½ should be considered to be the upper limit of the range. The preferred length is 1/3, which is less than ½. As such, it would be counterintuitive to the teachings of the reference to go beyond the indicated range to 2/3. The longer the built-up layer becomes, the higher it must be to maintain the asserted effectiveness of its sloping sides. As such, one would not be inclined to increase the length above that which is disclosed so as not to sacrifice a desired low profile. A low profile has always been a desired feature in catheters.

It is further not required to show a critical difference between ½ and 2/3 when the reference teaches away from increasing the length above ½, as discussed above. This point of law is discussed in *In re Wertheim, et al.*, 191 USPQ 90, 100 (CCPA 1976), wherein "[t]he examiner's comment about the lack of a showing of a critical difference is based on his failure to appreciate that Pfluger 1963 teaches away from increasing foam density." The rejection was reversed. As such, the rejection should be withdrawn because Rupp et al. does not teach or suggest increasing the length of the built-up layer beyond what is shown in the figures.

Regarding claim 42, it is asserted in the rejection that Rupp et al. shows a mounting body comprising no more than one layer of buildup material 210.

The rejection is irrelevant due to the dependency of claim 42 on claim 35, which has been amended and shown to be patentably distinct in the above discussion.

Double Patenting

(8)

Claims 1-36 and 42 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of US 6007543. Claims 1-34 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of US 6123712. And, claims 1-34 were

provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 36-45 of co-pending Application No. 09/387,179.

Applicant does not concur with the rejections and believe them to be improper. However, the term of the patent which would result from the present application would terminate on the same dates as the cited patents and application in any case. Therefore, in response, Applicant submits herewith terminal disclaimers to overcome the rejection. Withdrawal of the rejection is requested.

Miscellaneous

(9)

In response to Examiner's query regarding the assignment of the present invention, Applicant is filing herewith a copy of the parent application's assignment and recordation sheet. The present application was properly filed as a continuation of App. No. 08/702,150, now US 6007543.

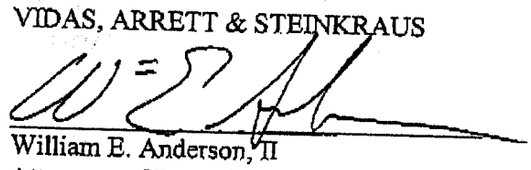
Conclusion

The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 20, 2001

By: 

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F:\WPWORK\WEA\8619-AMD.A25

Version with markings to show changes made

In the Claims:

Please cancel claim 36.

Please amend the remaining claims as follows:

35. (Amended) A stent delivery system comprising:

a radially expandable stent of generally cylindrical configuration, having a length, a first end and a second end and a contracted state and an expanded state, and

a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon, and including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means, the at least one mounting body being at least [½] 2/3 the length of the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

42. (Amended) The stent delivery system of claim 35, the at least one mounting body comprising no more than one layer of [the] material.

Please add the following claim:

43. The stent delivery system of claim 42, wherein the material comprises high density polyethylene.

UNITED ST..ES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

FEBRUARY 28, 1997

PTAS

100331187A

VIDAS, ARRETT & STEINKRAUS, P.A.
OLIVER F. ARRETT
1540 KINNARD FINANCIAL CENTER
920 SECOND AVENUE SOUTH
MINNEAPOLIS, MN 55402-4014

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, NORTH TOWER BUILDING, SUITE 10C35, WASHINGTON, D.C. 20231.

RECORDATION DATE: 11/14/1996 REEL/FRAME: 8281/0720
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
ELLIS, LOUIS G. DOC DATE: 10/30/1996

ASSIGNOR:
DUSBABEK, ANDREW J. DOC DATE: 10/30/1996

ASSIGNOR:
LARSON, CHRISTOPHER R. DOC DATE: 11/04/1996

ASSIGNOR:
BROWN, TERRY V. DOC DATE: 10/30/1996

ASSIGNEE:
SCIMED LIFE SYSTEMS, INC.
ONE SCIMED PLACE
MAPLE GROVE, MINNESOTA 55311-1566

SERIAL NUMBER: 08702150 FILING DATE: 08/23/1996
PATENT NUMBER: ISSUE DATE:

B281/0720 PAGE 2

DOROTHY RILEY, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

40.581

Form PTO-1595
1-31-92

NOV 14 1996

01-02-1997

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

HEET

100331187

To the Honorable Commissioner of Pat... Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):
Louis G. Ellis; Andrew J. Dusbabek; Christopher R. Larson; Terry V. Brown

11-14-96

Additional name(s) of conveying party(ies) attached? ☐ yes ☒ no

2. Name and address of receiving party(ies):
Name: SCIMED LIFE SYSTEMS, INC.
Internal Address:

Street Address: One SCIMED Place, Maple Grove, Minnesota 55311-1566

City State Zip

Additional name(s) & address(es) attached? ☐ Yes ☒ No

3. Nature of Conveyance:
☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Other _____
Execution Date: 10/30/96 and 11/4/96

4. Application number(s) or patent number(s):
If this document is being filed with a new application, the execution date of the application is:

6277 U.S. PTO
12/31/96

A. Patent Application No.(s)
08/702,150

B. Patent No.(s)

Additional numbers attached? ☐ yes ☒ no

5. Name and address of party to whom correspondence concerning document should be mailed:

Oliver F. Arrett
Vidas, Arrett & Steinkraus, P.A.
1540 Kinnard Financial Center
920 Second Avenue South
Minneapolis, MN 55402-4014

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): $40.00
☒ Enclosed
☐ Authorized to be charged to deposit account

8. Deposit Account Number: 22-0350
(Attach duplicate of this page if paying by deposit account)

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Oliver F. Arrett

Signature

11/14/96
Date

Total number of pages including cover sheet, attachments, and document: 2

OMB No. 0651-011 (exp. 4/94)

Do not detach this portion

260 FC 11/29/96 08702150
1 391 40.00 CK

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents and Trademarks
Box Assignments
Washington, D.C. 20231

F:\WPWORK\FORMS\PA-ASSGN.CVR

UTILITY/DESIGN PATENT

Docket No. S63.2-6050

ASSIGNMENT

WHEREAS, I(we), Louis G. Ellis; Andrew J. Dusbabek; Christopher R. Larson; Terry V. Brown residing at, 3004 Armour Terrace, St. Anthony, MN 55418; 13750 Jonquil Lane North, Dayton, MN 55327; 523 Desnoyer Avenue, St. Paul, MN 55104; 6231 Trinity Drive Northeast, Fridley, MN 55432 have invented and own the entire United States right, title and interest in an invention for

STENT DELIVERY SYSTEM

disclosed in my application for United States Letter Patent filed

☐ concurrently herewith
☒ on 8/23/1996 and assigned Serial No. 08/702,150 ; and

I hereby authorize and request any attorney of Vidas, Arrett & Steinkraus, P.A., 1540 Kinnard Financial Center, 920 2nd Ave. S., Minneapolis, MN 55402-4014, to insert the filing date and application number of said application above when known.

WHEREAS, **SCIMED LIFE SYSTEMS, INC.** ("Assignee"), a corporation organized and existing under and by virtue of the laws of the State of Minnesota, and having its principal place of business at One SCIMED Place, Maple Grove, Minnesota 55311-1566, is desirous of acquiring the entire right, title, and interest in and to said invention, to said application for any and all countries, to any and all Letters Patent, and to any and all Design Letters Patent of any and all countries which may be granted thereon;

NOW, THEREFORE, Be It Known that for good and valuable consideration, the receipt of all of which is hereby acknowledged, I(we) hereby sell, assign, and transfer unto Assignee, its successors, and assigns, the entire right, title and interest, legal and equitable, in and to said invention, to said application for any and all countries, to any and all Letters Patent, and to any and all Design Letters Patent of any and all countries which may be granted thereon; and the Commissioner of Patents and Trademarks is hereby authorized and requested to issue all Letters Patent and all Design Letters Patent which may be granted to said invention to Assignee.

Dated: 10-30-96 First Inventor's Signature: Louis G. Ellis
First Inventor's Name: Louis G. Ellis

Dated: 10-30-96 Second Inventor's Signature:
Second Inventor's Name: Andrew J. Dusbabek

Dated: 11/4/96 Third Inventor's Signature:
Third Inventor's Name: Christopher R. Larson

Dated: 30 Oct 96 Fourth Inventor's Signature: Terry V Brown
Fourth Inventor's Name: Terry V. Brown

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3764

Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

FACSIMILE TRANSMITTAL LETTER

TO: Examiner: Yu, J.
FACSIMILE NO.: (703) 872-9302
GROUP ART UNIT: 3764

DATE: November 20, 2001
TIME: _____

TOTAL NUMBER OF PAGES (including cover letter): 15

Dear Examiner:

Enclosed please find the following documents for your filing:
6 Pg. Amendment; Assignment Documents from Parent Case; Terminal Disclaimer...A Pending Second Application; Terminal Disclaimer...Over A Prior Patent;; and 1 pg. VAS Transmittal.

Please charge the two $110.00 fees and any additional fees or credit any overpayment associated with this communication to Deposit Account No. 22-0350.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

By: _____
William E. Anderson, II
Registration No.

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

Certificate of Transmission
I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (703) 872-9302 on November 20, 2001.
Typed or printed name of person signing this certificate:

Signature: _____
Robin Poddieson

#14

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3734

Box Fee Amendment
Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING SECOND APPLICATION

The owner, Scimed Life Systems, Inc. of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second Application No. 09/387,179, filed on August 31, 1999 of any patent on the pending second application. The owner hereby agrees that any patent so granted on the second instant application shall be enforceable only for and during such period that it, and any patent granted on the second application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

01 FC:140 11/20/2001 EWILLIS 00000001 09420249
118.00 CH

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C.154 to 156 and 173 of any patent granted on the second application as shortened by any terminal disclaimer filed prior to the patent garnt, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or

terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

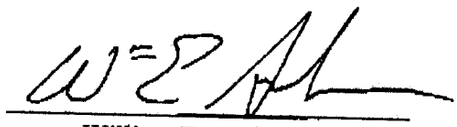
Check either box 1 or 2 below, if appropriate.

1. ☐ For submission on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf on the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney of record.

November 20, 2001
Date



William E. Anderson, II

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.
☒ PTO suggested wording for terminal disclaimer was

☒ unchanged ☐ changed (if changed, an explanation should be supplied).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	STENT DELIVERY SYSTEM
Examiner:	Yu, J.
Group Art Unit:	3734

Box Fee Amendment
Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

The owner, Scimed Life Systems, Inc. of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior patent No's 6,007,543, 6,123,712. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it, and the prior patents are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C.154 to 156 and 173 of any of the prior patents as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submission on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf on the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney of record.

November 20, 2001
Date

William E. Anderson, II

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.
☒ PTO suggested wording for terminal disclaimer was

☒ unchanged ☐ changed (if changed, an explanation should be supplied).

Notice of Allowability	Application No.	Applicant(s)	
	09/420,249	ELLIS ET AL.	
	Examiner	Art Unit	
	Denise Pothier	3764	

-- 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 *the Amendment filed 11/20/01*.
2. ☒ The allowed claim(s) is/are *1-35,42 and 43*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
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. _____ .
      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: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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.**

7. ☐ 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.

8. ☒ CORRECTED DRAWINGS 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. ____.
   (b) ☒ including changes required by the proposed drawing correction filed *19 October 1999*, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ 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 Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No.____ .
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6☐ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

Everett R. Williams

Everett R. Williams
Patent Analyst
for Justine Yu
Primary Examiner

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 12/17/2001

Oliver f Arrett
VIDAS ARRETT & STEINKRAUS
6109 Blue Circle Drive
Suite 2000
Minneapolis, MN 55343-9131

EXAMINER	
YU, JUSTINE ROMANG	
ART UNIT	**CLASS-SUBCLASS**
3764	606-108000

DATE MAILED: 12/17/2001

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,249	10/19/1999	Louis g. ELLIS	S6.2-8619	2556

TITLE OF INVENTION: STENT DELIVERY SYSTEM WITH STENT SECUREMENT MEANS

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
37	nonprovisional	NO	$1280	$0	$1280	03/18/2002

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.

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 changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

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 the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. 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.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box 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.

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and mail this form, together with applicable fee(s), to:

Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 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: Legibly mark-up with any corrections or use Block 1)

7590 12/17/2001

Oliver f Arrett
VIDAS ARRETT & STEINKRAUS
6109 Blue Circle Drive
Suite 2000
Minneapolis, MN 55343-9131

Note: The certificate of mailing below 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.

Certificate of Mailing

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 Box Issue Fee address above on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,249	10/19/1999	Louis g. ELLIS	S6.2-8619	2556

TITLE OF INVENTION: STENT DELIVERY SYSTEM WITH STENT SECUREMENT MEANS

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
37	nonprovisional	NO	$1280	$0	$1280	03/18/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
YU, JUSTINE ROMANG	3764	606-108000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

☐ 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) attached.

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. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. 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 enclosed:

☐ Issue Fee

☐ Publication Fee

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.

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

☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____(enclose an extra copy of this form).

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee and Publication Fee (if any) to the application identified above.

(Authorized Signature) (Date)

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.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, United States Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington, D.C. 20231

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.

TRANSMIT THIS FORM WITH FEE(S)

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004. OMB 0651-0033 U.S. 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 OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,249	10/19/1999	Louis g. ELLIS	S6.2-8619	2556

7590 12/17/2001

Oliver f Arrett
VIDAS ARRETT & STEINKRAUS
6109 Blue Circle Drive
Suite 2000
Minneapolis, MN 55343-9131
UNITED STATES

EXAMINER	
YU, JUSTINE ROMANG	
ART UNIT	**PAPER NUMBER**
3764	

DATE MAILED: 12/17/2001

Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension 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) system. (http://pair.uspto.gov)

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004.

#16 MR TD

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
Filed:	October 19, 1999
For:	Stent Delivery System
Examiner:	Yu, J.
Group Art Unit:	3764

Attn: Official Draftsman
Commissioner of Patents
Washington, DC 20231

Docket No.: S63.2-8619

TRANSMITTAL OF FORMAL DRAWINGS

In response to the Notice of Allowability mailed on December 11, 2002, attached please find the formal drawings for this application with each sheet indicating the application number and Title on the front side of the drawings - Number of Sheets: 4.

Respectfully submitted,

Vidas, Arrett & Steinkraus, P.A.

Date: February 6, 2002

By: _____
William E. Anderson, II Esq.
Registration No. 37,766

Suite 2000
6109 Blue Circle Drive
Minnetonka, MN 55343-9185
Phone: (952) 563-3000
Facsimile: (952) 563-3001

12/01

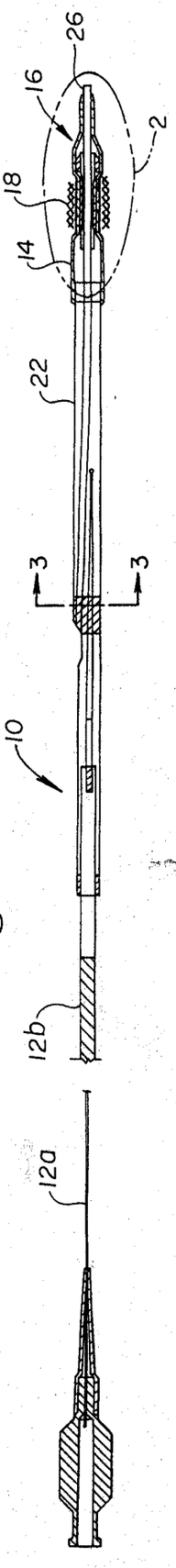


Fig. 1

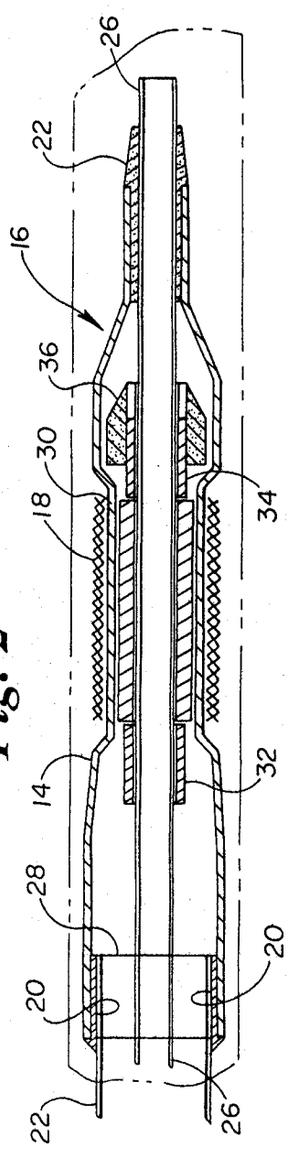


Fig. 2

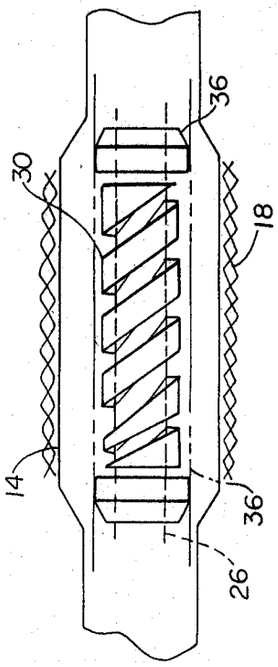


Fig. 4

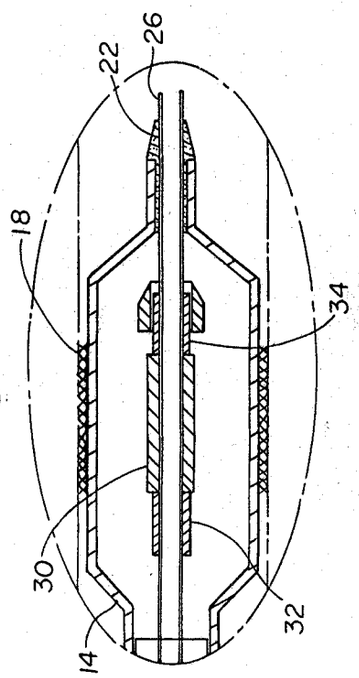


Fig. 3

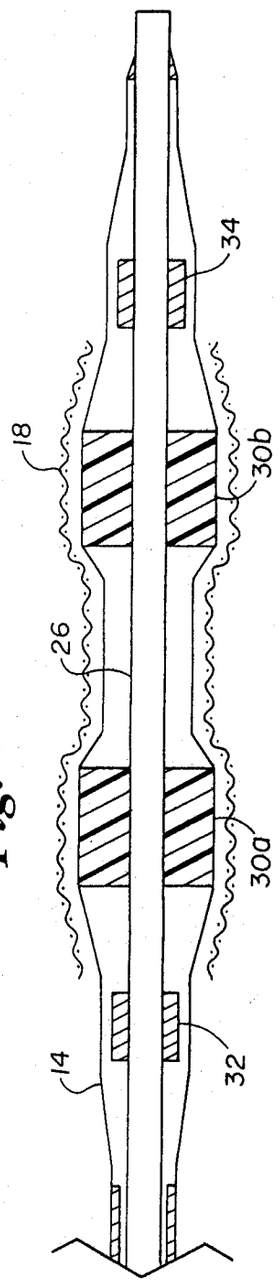


Fig. 6

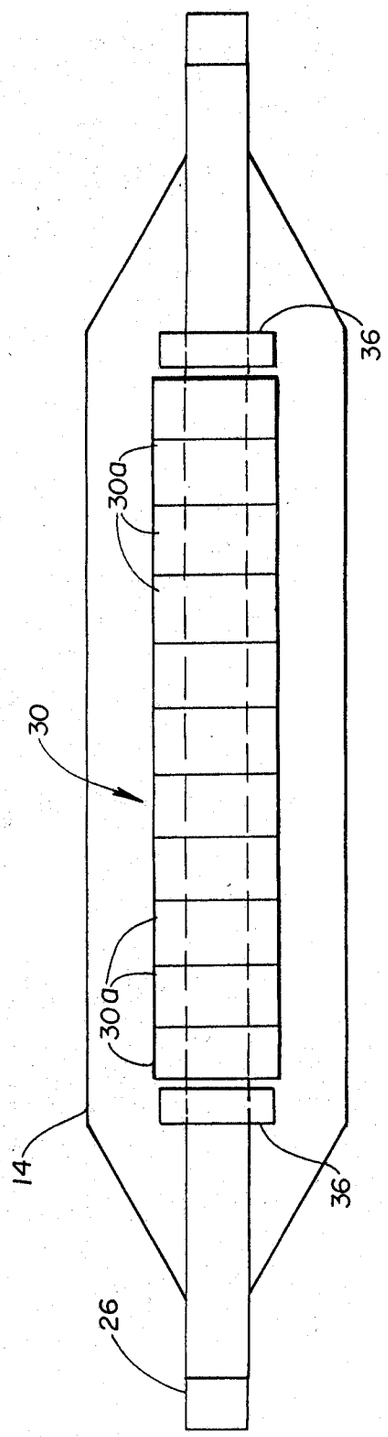


Fig. 5

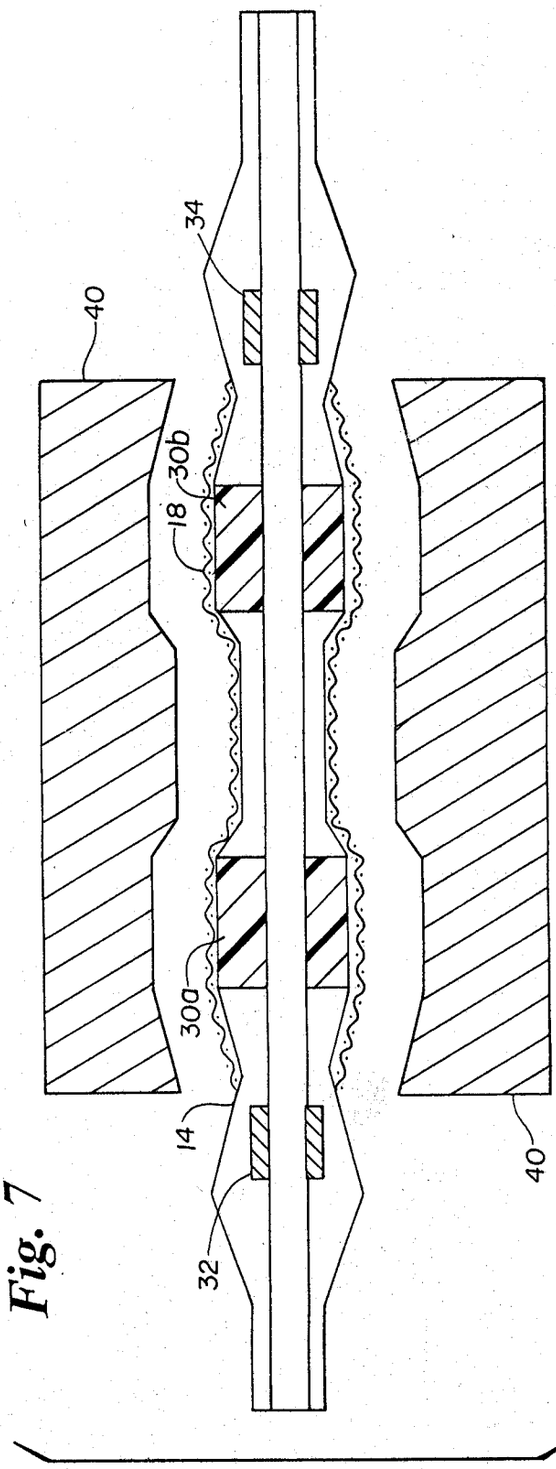


Fig. 7

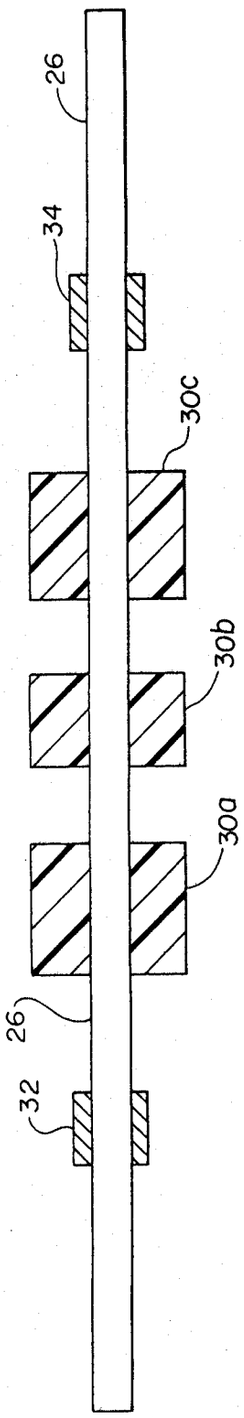


Fig. 8

B2

PART B - FEE(S) TRANSMITTAL

Complete and mail this form, together with applicable fee(s), to: **Box ISSUE FEE**
Assistant Commissioner for Patents
Washington, D.C. 20231

PTO FEB 26 2002

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 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: Legibly mark-up with any corrections or use Block 1)

7590 12/10/2001

Oliver f Arrett
VIDAS ARRETT & STEINKRAUS
6109 Blue Circle Drive
Suite 2000
Minneapolis, MN 55343-9131

Note: The certificate of mailing below 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.

Certificate of Mailing

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 Box Issue Fee address above on the date indicated below.

Robin Peddieson	(Depositor's name)
	(Signature)
February 6, 2002	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,249	10/19/1999	Louis g. ELLIS	S6.2-8619	2556

TITLE OF INVENTION: STENT DELIVERY SYSTEM

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
37	nonprovisional	NO	$1280	$0	$1280	03/11/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
YU, JUSTINE ROMANG	3764	606-108000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

☐ 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) attached.

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 Vidas, Arrett & Steinkraus
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. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. 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 enclosed:

☑ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☑ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee and Publication Fee (if any) to the application identified above.

(Authorized Signature) _____ (Date) 2/6/02

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.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, United States Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington, D.C. 20231

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.

03/04/2002 CV0222 00000164 09420249
01 FC:142 1280.00 OP

TRANSMIT THIS FORM WITH FEE(S)

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD
Effective November 10, 1998

Application or Docket Number: 09/450,249

CLAIMS AS FILED - PART I

	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
FOR		
BASIC FEE		
TOTAL CLAIMS	34 minus 20=	* 14
INDEPENDENT CLAIMS	3 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
	380.00	OR		760.00
X$ 9=		OR	X$18=	252
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL		OR	TOTAL	1012

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

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	* 39	Minus	** 34	= 5
Independent	* 6	Minus	*** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=	99	OR	X$18=	90
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(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=	
X39=		OR	X78=	
+130=		OR	+260=	
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=	
X39=		OR	X78=	
+130=		OR	+260=	
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.

ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	AH	72192	10/26/99
O.I.P.E. CLASSIFIER		48	10/29
FORMALITY REVIEW		65918	11-9-99

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
— (Through numeral) Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date										
		8/8/00	1/1/01	8/15/01	11/13/01							
1	(1)	✓	✓	✓	=							
2	2		✓									
3	3		✓									
4	4		✓									
5	5		✓									
6	6		✓									
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Claim Final	Claim Original	Date
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If more than 150 claims or 10 actions
staple additional sheet here

[redacted]

SEARCHED

Class	Sub.	Date	Exmr.
606	194 195 198 108	8/4/00	JR
updated search		1/30/01	JR
Updated Search		8/15/01	JR

See 09/387,179 for D.P.

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.
East	8/4/00	JR

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.