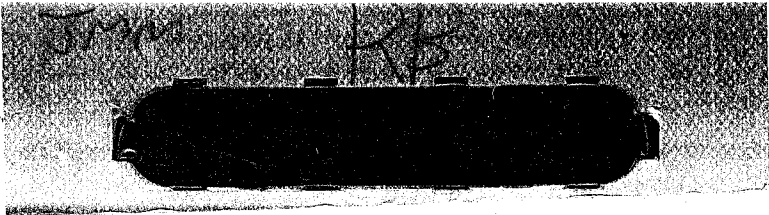


1542 U.S. PTO  
09/420249



606	108
Class	Subclass
ISSUE CLASSIFICATION	



PATENT NUMBER

6371962



6371962

### U.S. UTILITY PATENT APPLICATION

O.I.P.E. <i>R/M</i> SCANNED <i>AG. DQA. KLOI</i>	PATENT DATE <b>APR 16 2002</b>
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SECTOR	CLASS <i>606</i> <del>604</del>	SUBCLASS <i>108</i>	ART UNIT <i>3764</i>	EXAMINER <i>J. Yu</i>
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FILED WITH:  DISK (CRF)  FICHE  
(Attached in pocket on right inside flap)

*Con of 10/19/99*  
*Con Yu*

### PREPARED AND APPROVED FOR ISSUE

### ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)			
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)		
<i>606</i>	<i>108</i>	<i>606</i>	<i>19A</i>		
INTERNATIONAL CLASSIFICATION					
<i>A61F</i>	<i>11/00</i>				

Continued on Issue Slip Inside File Jacket

<input checked="" type="checkbox"/> <b>TERMINAL DISCLAIMER</b>	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg. <i>4</i>	Figs. Drwg. <i>8</i>	Print Fig. <i>1,2</i>	Total Claims <i>37</i>	Print Claim for O.G. <i>1</i>
<input type="checkbox"/> a) The term of this patent subsequent to _____ (date) has been disclaimed.	_____ (Assistant Examiner)			NOTICE OF ALLOWANCE MAILED	
<input checked="" type="checkbox"/> b) The term of this patent shall not extend beyond the expiration date of U.S. Patent No. <i>6,207,543</i> <i>6,123,712</i>	<i>JR</i> <b>JUSTINE R. YU</b> PRIMARY EXAMINER (Primary Examiner)			<i>12/10/01</i>	
<input type="checkbox"/> c) The terminal _____ months of this patent have been disclaimed.	<i>Ernest Williams</i> (Legal Instruments Examiner)			Amount Due <i>\$1280</i>	Date Paid <i>AH</i> <i>2-26-02</i>
WARNING:			ISSUE BATCH NUMBER		

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.

Form PTO-436A (Rev. 10/97)

ISSUE FEE IN FILE (LABEL AREA) *Formal Drawings (1 sheet) 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	
2. <del>Amend A</del>	11/12/99	
3. <del>Amend</del>	12-10-99	
4. <del>DS</del>	03/20/00	
5. <del>Key (ms)</del>	8-15-00	
6. Returned filing receipt	3-7-00	
7. Amndt B	11-20-00	
8. Ref (3)	02/08/01	
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10. Amndt C	6-11-01	
11. REJECTION	08-20-01	
12. Terminal Disclaimer	8-6-01	
13. Amndt D	11-20-01	
14. Terminal Disclaimer	11-20-01	
15. Notice of Allowability	12/10/01	
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Bib Data Sheet



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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<b>SERIAL NUMBER</b> 09/420,249	<b>FILING DATE</b> 10/19/1999 <b>RULE</b> -	<b>CLASS</b> 604	<b>GROUP ART UNIT</b> 3734	<b>ATTORNEY DOCKET NO.</b> S6.2-8619
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**APPLICANTS**

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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

**\*\* FOREIGN APPLICATIONS \*\*\*\*\***

*yes, j*  
*none, j*

**IF REQUIRED, FOREIGN FILING LICENSE GRANTED \*\***

\*\* 11/09/1999

Foreign Priority claimed <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	<b>STATE OR COUNTRY</b> MN	<b>SHEETS DRAWING</b> 4	<b>TOTAL CLAIMS</b> 34 36	<b>INDEPENDENT CLAIMS</b> 3
35 USC 119 (a-d) conditions met <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> Met after Allowance				
Verified and Acknowledged Examiner's Signature <i>[Signature]</i> Initials				

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**TITLE**

**STENT DELIVERY SYSTEM**

*Ins. A1*

<b>FILING FEE RECEIVED</b> 1142	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees
		<input type="checkbox"/> 1.16 Fees ( Filing )
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<b>SERIAL NUMBER</b> 09/420,249	<b>FILING DATE</b> 10/19/1999 <b>RULE</b> -	<b>CLASS</b> 604	<b>GROUP ART UNIT</b> 3734	<b>ATTORNEY DOCKET NO.</b> S6.2-8619
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 TERRY v. BROWN, FRIDLEY, MN ;

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

**\*\* FOREIGN APPLICATIONS \*\*\*\*\***

**IF REQUIRED, FOREIGN FILING LICENSE GRANTED \*\* 11/09/1999**

Foreign Priority claimed <input type="checkbox"/> yes <input type="checkbox"/> no	<b>STATE OR COUNTRY</b> MN	<b>SHEETS DRAWING</b> 4	<b>TOTAL CLAIMS</b> 34	<b>INDEPENDENT CLAIMS</b> 3
35 USC 119 (a-d) conditions met <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance				
Verified and Acknowledged Examiner's Signature _____ Initials _____				

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 Minneapolis ,MN 55343-9131

**TITLE**  
 STENT DELIVERY SYSTEM

<b>FILING FEE RECEIVED</b> 1142	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees
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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

66/19/99  
JCS45 U.S. PTO

JCS42 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 CLAIMS					
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
<b>BASIC FEE</b>					\$760.00
<b>TOTAL FILING FEE</b>					\$1,012.00

*continued on next page.....*

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

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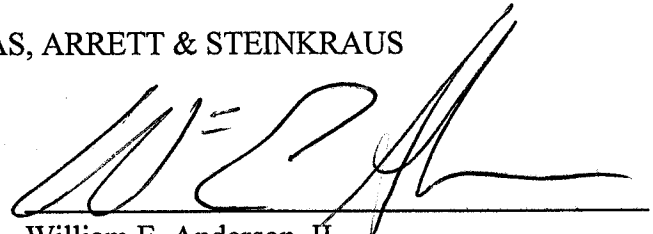
<b>NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity)</b> <i>(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))</i>	Docket No. S63.2-8619
	Total Pages in this Submission <i>(including checks and postcard)</i> 30

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

By:



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

Date: October 19, 1999

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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

**ATTORNEYS:** William E. Anderson, II, Esq.  
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EL440581335US

## STENT DELIVERY SYSTEM

### Background of the Invention

*Trs. A2* *AP*  
5 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  
10 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  
15 compress the atherosclerotic 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  
20 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  
25 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  
30 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  
5 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  
10 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  
15 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  
20 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.

#### 25 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  
30 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;

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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  
5 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

10 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  
15 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  
20 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  
25 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  
A adhesive 20 and <sup>24</sup>22, respectively to the outer member <sup>24</sup>24 of the catheter and to the  
30 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

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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.

5 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  
10 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  
15 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.

20 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  
25 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  
30 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

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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

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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-  
5 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  
10 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  
15 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.

20

7





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

5 *Sub A8* 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.

10 *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

15 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 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.

20 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 *Shaped* ring-like.

25 *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 *Shape* ring-like.

30 *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.
- 5 22. The catheter of claim 21 wherein the material is elastomeric.
- Sub C5 23. The catheter of claim 21 wherein the material is HDPE.
- Sub C5 24. The catheter of claim 21 wherein the material is silicone.
- 10 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.
- Sub C5 27. The catheter of claim 20 including a pair of spaced stops.
- 15 28. The catheter of claim 27 wherein the stops are conical in shape.
- Sub C5 29. The catheter of claim 20 including spaced marker bands.
- Sub C5 30. The catheter of claim 20 wherein the mounting body is cylindrical in shape.
- 20 31. The catheter of claim 20 wherein at least two spaced mounting bodies are included.
- B 32. The catheter of claim 31 wherein the mounting bodies are ring-like<sup>shape</sup>.
- Sub C8 33. The catheter of claim 20 wherein at least three spaced mounting bodies are included.
- 25 B 34. The catheter of claim 33 wherein the mounting bodies are ring-like<sup>shape</sup>.

Add A15  
Add B3

Add C9

30

Abstract of the Disclosure

**STENT DELIVERY SYSTEM**

5 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  
10 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.

15

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OK  
11/28/01

Fig. 1

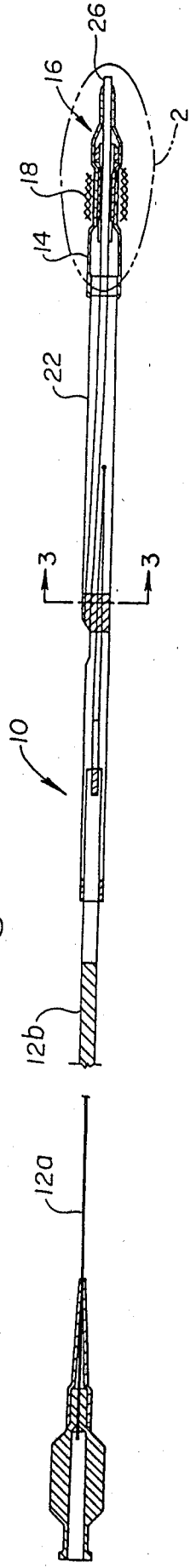
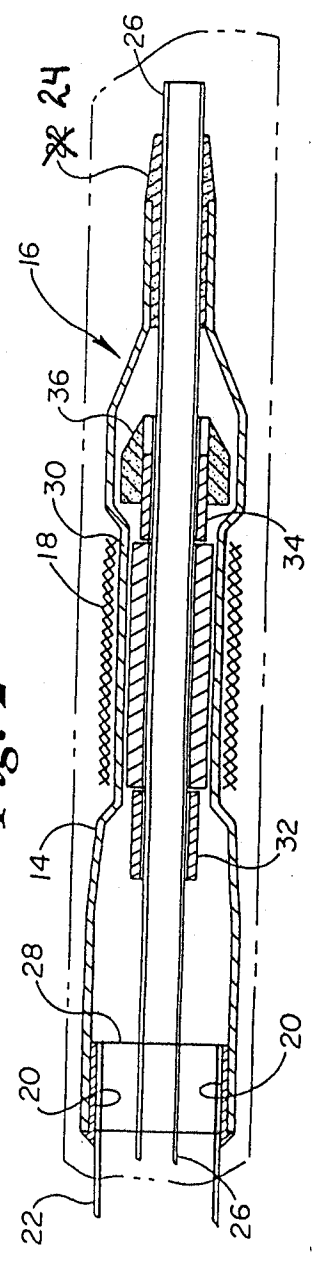
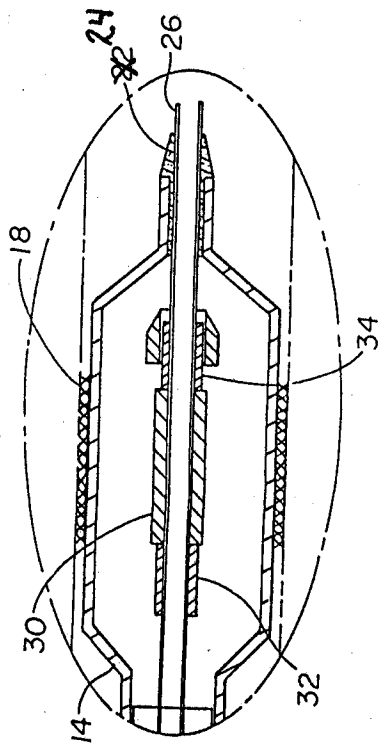


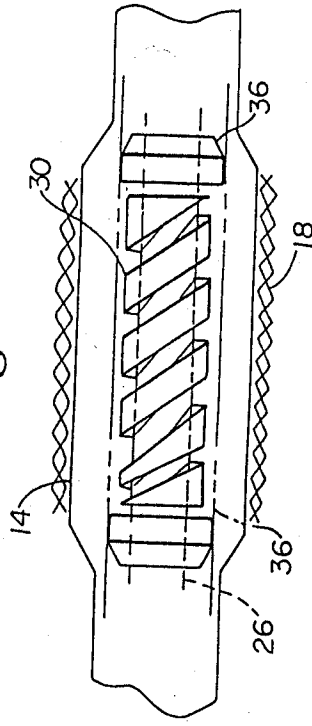
Fig. 2



**Fig. 3**



**Fig. 4**



**Fig. 6**

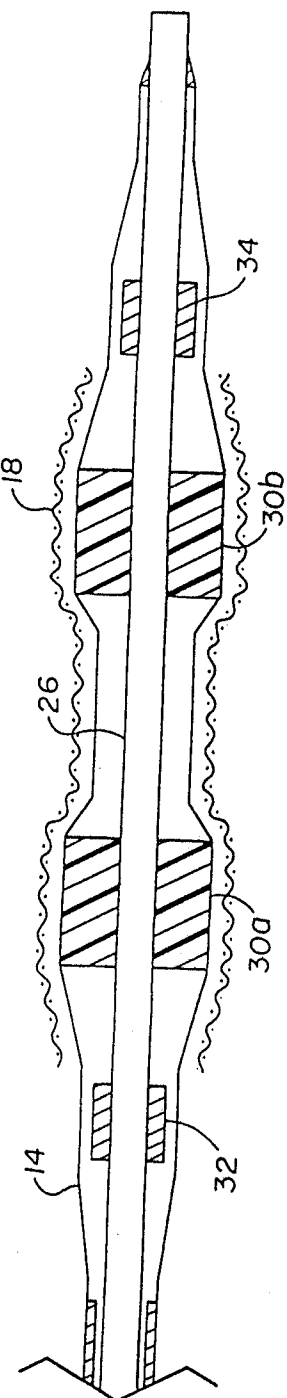


Fig. 5

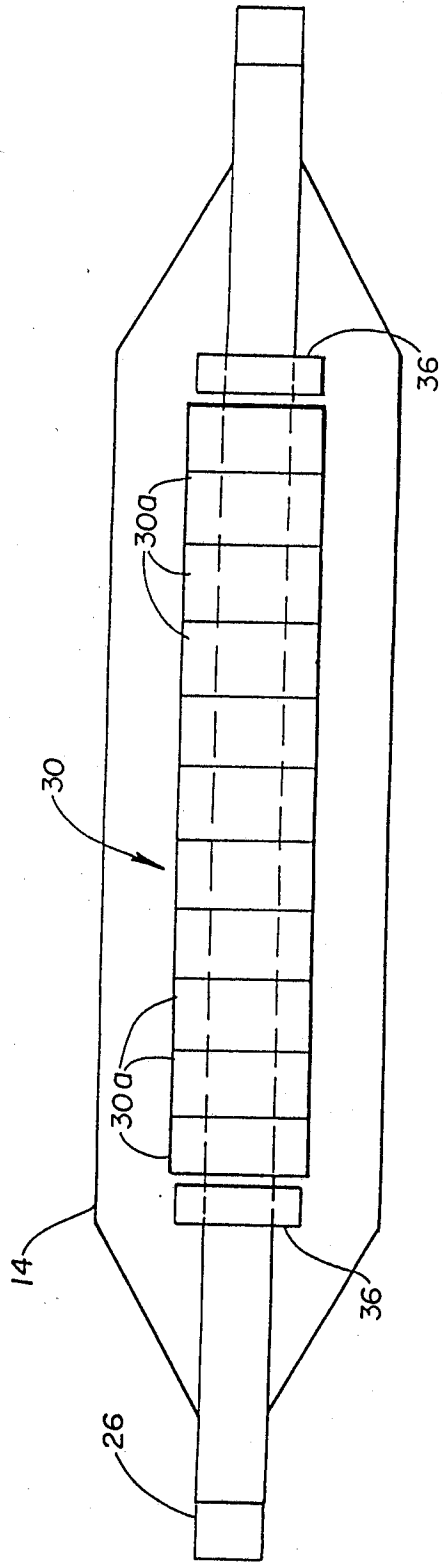


FIG. 7

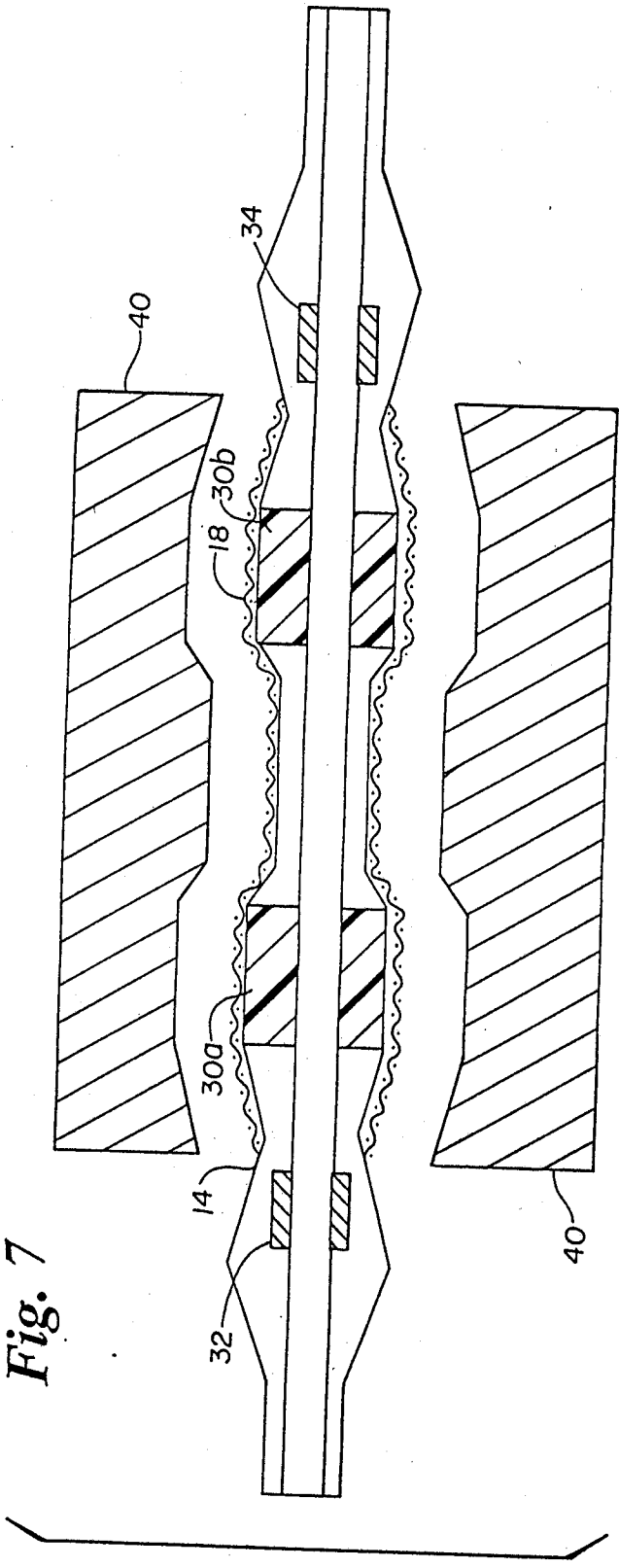
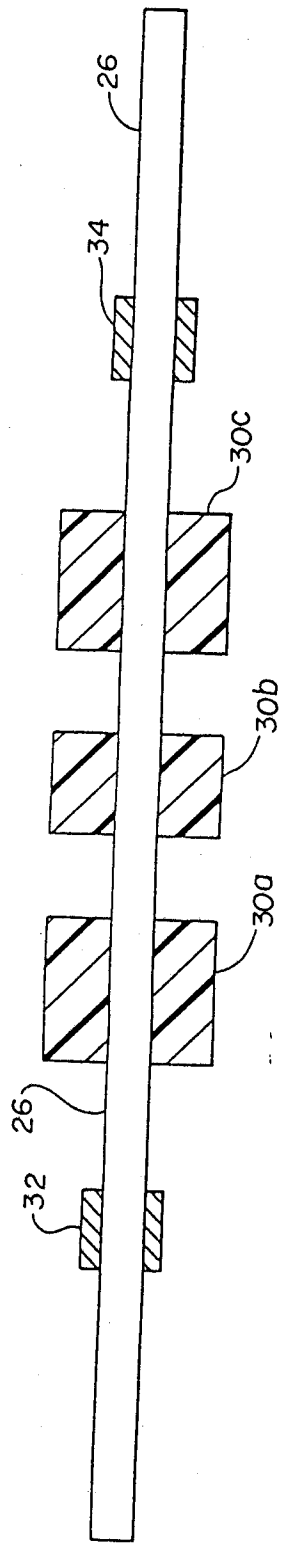


Fig. 7

Fig. 8



606  
108

14  
3700

Fig. 1

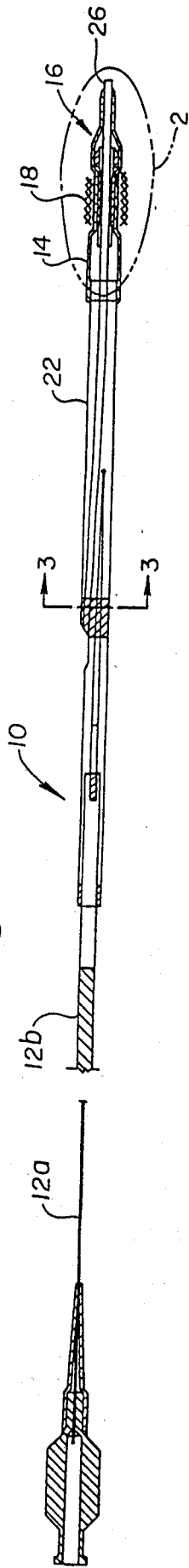
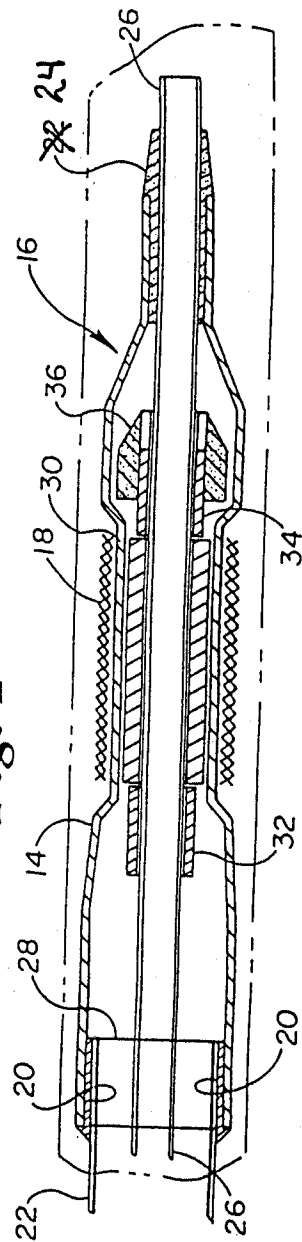


Fig. 2





Edwards Lifesciences Corporation

Fig. 3

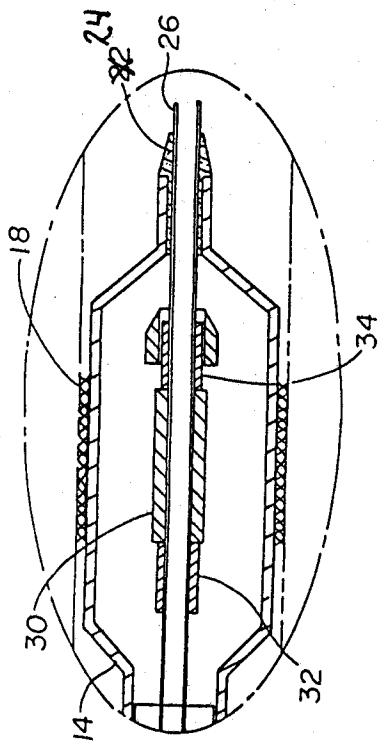


Fig. 4

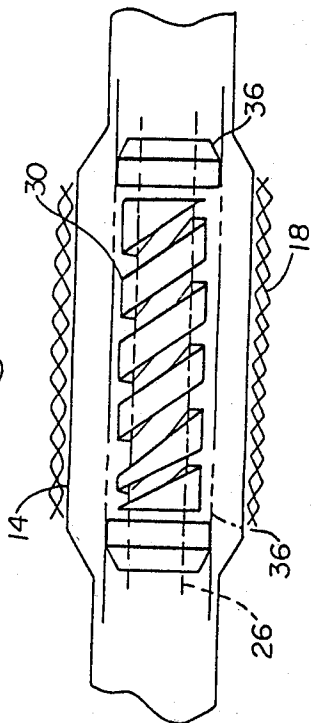
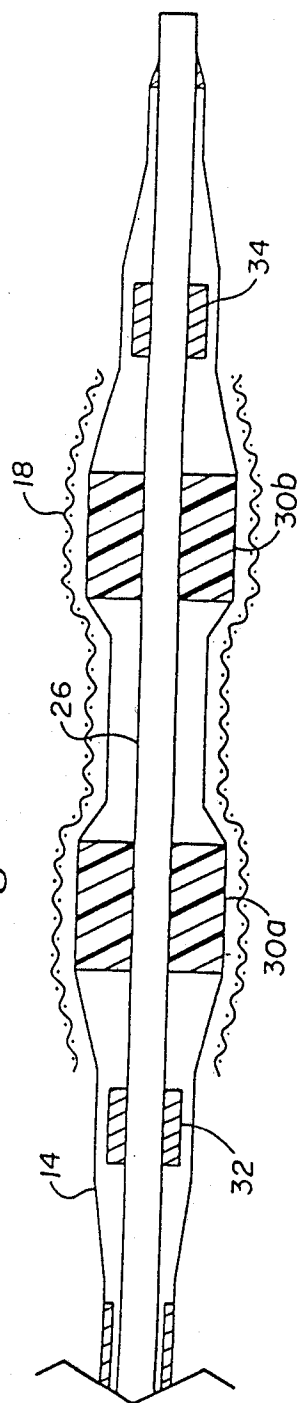
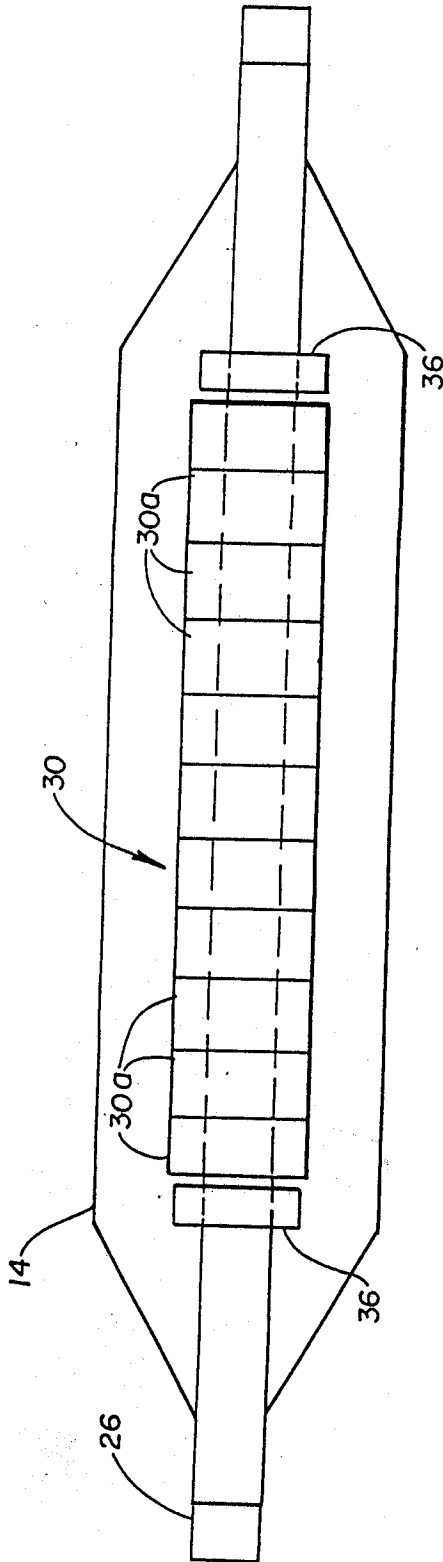


Fig. 6



U.S. PATENT AND TRADEMARK OFFICE

Fig. 5



U.S. PATENT AND TRADEMARK OFFICE

Fig. 7

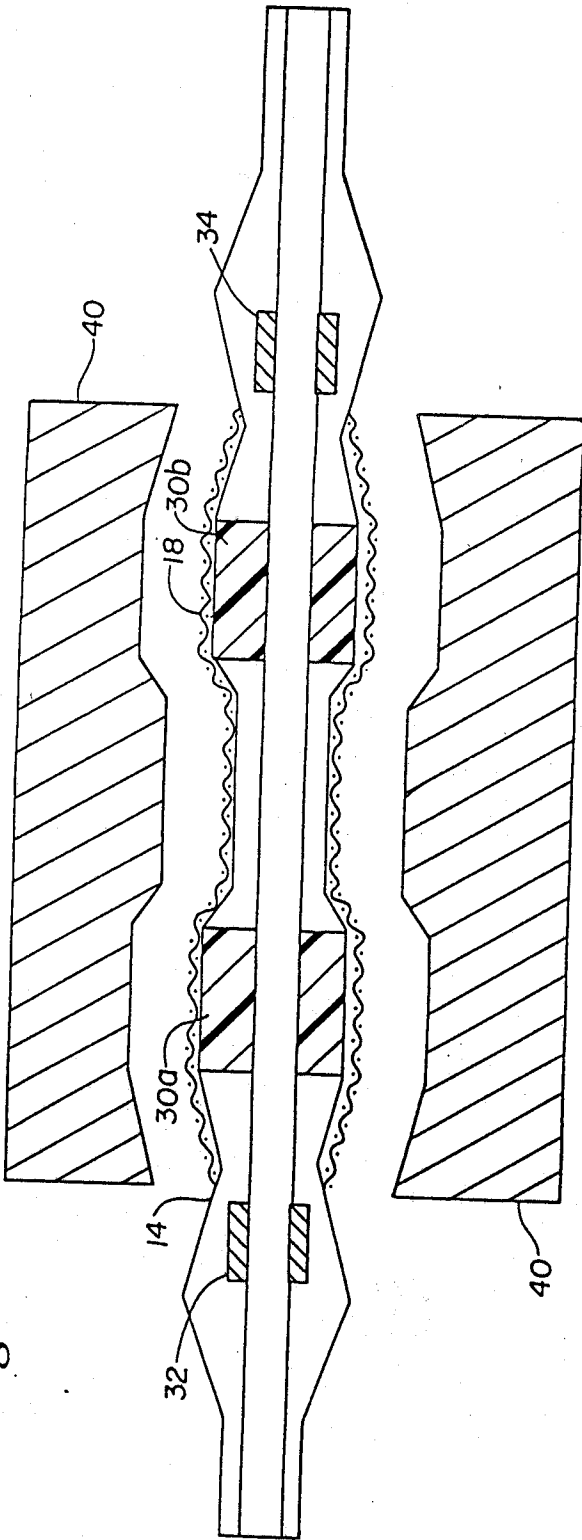
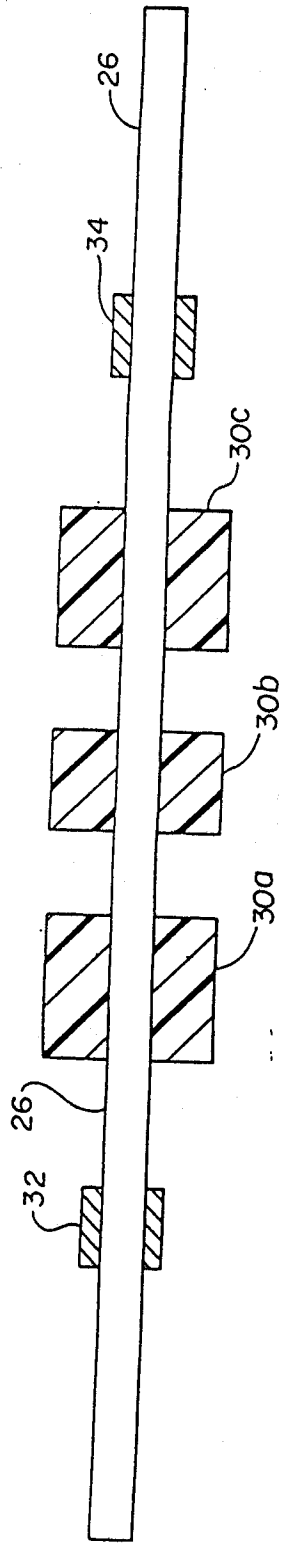


Fig. 8



DECLARATION

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

TYPE OF DECLARATION

This declaration is of the following type:

- 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)  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
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> 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.

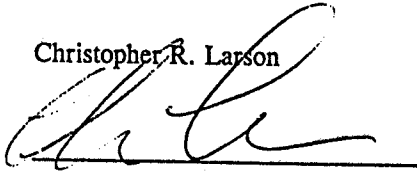
**First Inventor**

Full name: Louis G. Ellis  
 Inventor's signature: *Louis G. Ellis*  
 Date: 10-30-96  
 Citizenship: United States of America  
 Post office Address: 3004 Armour Terrace  
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 Residence: \_\_\_\_\_  
 (If different than above)

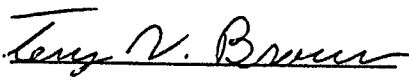
**Second Inventor**

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  
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 (If different than above)

**Third Inventor**

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Inventor's signature:   
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(If different than above)

**Fourth Inventor**

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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:	<input type="checkbox"/> concurrently herewith <input checked="" type="checkbox"/> on <u>8/23/96</u> and assigned Serial No. <u>08/702,150</u>

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 21<sup>st</sup> day of October, 19 96.

(Company Name)

SCIMED LIFE SYSTEMS, INC.

(Signature)

By [Signature]

(typed name)

John A. Rissman

(title)

Its: Vice President and Chief  
Intellectual Property Counsel

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



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

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:

A handwritten signature in black ink, appearing to read "W. E. Anderson, II", written over a horizontal line.

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



#12/A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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:

Sub  
01  
cont  
A3

[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.

A4

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

A5

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.

A6

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.

A7

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.

A8

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

12

A

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:

Sub C2 A9  
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].

Sub C2 A9  
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.

Sub C3 A10  
18. (Amended) The stent delivery system of claim 14 wherein [at least] three

Sub  
3  
cont  
A 10

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

A11

B

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 <sup>and retaining</sup> 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.

A12

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

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:

A15

35. A stent delivery system comprising:  
B a radially expandable stent of generally cylindrical configuration, having a first end and a second end and a contracted state and an expanded state, and <sup>length</sup>  
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 1/2 the length of the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable

A

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**

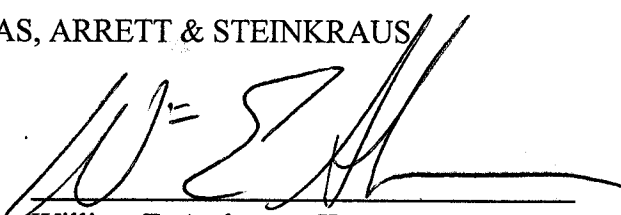
Prior to examination, please make the above amendments. Many of the above amendments are made to remain consistent with the previously filed priority application. Early examination is respectfully requested.

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 56.2-8619

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



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 56.2-8619
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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.**

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



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



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).

*ANDREW*

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

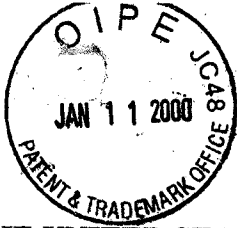
PRELIMINARY CLASS: 604

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



(See reverse for new important information)

*170  
12/5*



Receipt  
FILE COPY  
0300

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

Docket No.: S63.2-8619

TRANSMITTAL LETTER

- 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.**
- 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.
- 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.
- 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

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

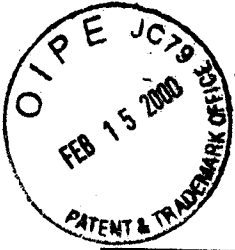
Date: January 5, 2000

By:

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**

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

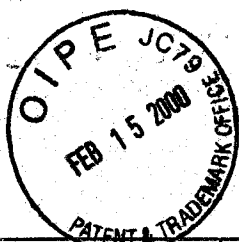
VIDAS, ARRETT & STEINKRAUS

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    86.2-8619

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:

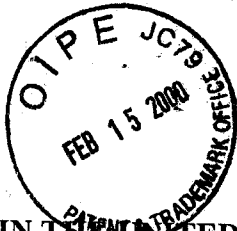
Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

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

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

02/17/2000 5LWANG 00000106 09420249  
 760.00 OP  
 130.00 OP  
 252.00 OP  
 01 C:101  
 02 C:105  
 03 C:103  
 U.S. GPO 1999-456-5875

PATENT



*See for [initials]*

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

- 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.**
- 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.
- 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.
- 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

By:

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

Date: February 7, 2000

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

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

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MAR 22 2000  
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Assistant Commissioner for Patent  
Washington, D.C. 20231

Docket No.: S63.2-8619

INFORMATION DISCLOSURE STATEMENT

#4  
AUS  
6/13/00

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.

*Information Disclosure Statement*  
*Application No. 09/420,249*  
*Page 2*



Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: March 8, 2000

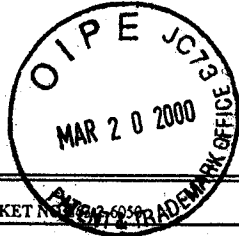
By:

A handwritten signature in black ink, appearing to read "W. E. Anderson, II", written over a horizontal line.

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

RECEIVED  
MAR 22 2000  
TC 5700 MAIL ROOM



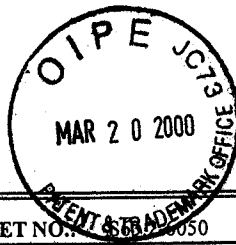
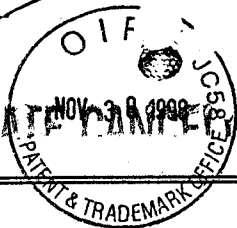
09/420,249

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			ATTY DOCKET NUMBER: 09/420,249			Serial No. 08/702,130		
APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown						FILING DATE: August 23, 1996		
REFERENCE DESIGNATION						U.S. PATENT DOCUMENTS		
EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
<i>JE</i>	AA	5,378,237	1/3/95	Boussignac et al				
	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	NO
	AL							
	AM							
	AN							
	AO							
	AP							
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AR							
	AS							
	AT							
EXAMINER: <i>Justin</i>				DATE CONSIDERED: <i>8/4/00</i>				
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.								

RECEIVED  
 MAR 22 2000  
 TRADEMARK OFFICE



MAIL DATE ~~NOV 23 1998~~



01420299

FORM PTO-1449 (Modified)	ATTY DOCKET NO.: 568,9050	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
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

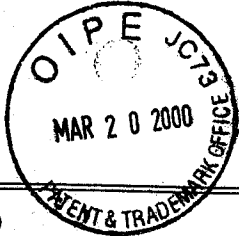
FOREIGN PATENT DOCUMENT OR PUBLISHED FOREIGN PATENT APPLICATION								
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OF PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
BA								
BB								
BC								
BD								
BE								
BF								
BG								

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
CA		
CB		
CC		
CD		
CE		

RECEIVED  
DEC 10 1998  
TECHNOLOGY CENTER 3700  
TO STENO HALL ROOM  
MAR 22 1999  
PROTECTED

EXAMINER <i>J. H. ...</i>	DATE CONSIDERED <i>4/13/89</i>
---------------------------	--------------------------------

EXAMINER: Initial citation considered. 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.



01/20/96

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								
72	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	NO		
	BA									
	BB									
	BC									
	BD									
	BE									
	BF									
	BG									

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
CA		
CB		
CC		
CD		
CE		

EXAMINER <i>J. J. J.</i>	DATE CONSIDERED <i>10/12/98</i>
--------------------------	---------------------------------

EXAMINER: Initial citation considered. 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.

FWPWORKFORMSIDS-1449

*J. J. J.* *8/4/00*



09/720,249

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	NO
<i>JL</i>	BA	0 266 957 A2	5/11/88	EP	<del>    </del>		X	
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	BC							
	BD							
	BE							
	BF							
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EXAMINER *JL* DATE CONSIDERED *3/17/98*

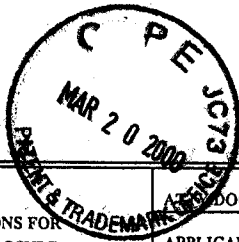
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*JL* *8/4/04*

12223 U.S. PTO



01/10/97



09/100,245

FORM PTO-1449 (Modified)	ATTORNEY DOCKET NO: S63.2-6050	Serial No: 08/702 150
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	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
Jr	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			
Jr	AK	4,950,227	08/21/1990	Savin et al.			

		FOREIGN PATENT DOCUMENTS						
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							YES	NO
Jr	AL	0 257 091 B1	07/28/1993	EPO			X	
Jr	AM	0 442 657 A2	09/21/1991	EPO			X	
Jr	AN	0 553 960 A1	08/04/1993	EPO			X	
Jr	AO	0 627 201 A1	12/07/1994	EPO			X	
Jr	AP	0 699 451 A2	03/06/1996	EPO			X	

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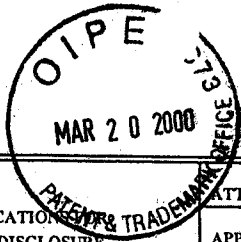
Julio C. Palmaz et al., *Expandable Intraaluminal Graft: A Preliminary Study, Work in Progress*, From the Departments of Radiology (J.C.P., R.R.S., S.R.R.) and Pathology (F.O.T.) University of Texas Health Science Center at San Antonio and Memorial Medical Center (W.J.K.), Corpus Christi, Texas, RADIOLOGY,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

EXAMINER: Jr	DATE CONSIDERED: 8/7/97
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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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FORM PTO-1449 (Modified)		ATTY DOCKET NO: S63.2-6050			Serial No: 08/702,150			
LIST OF PATENTS AND PUBLICATIONS		APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown						
APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		FILING DATE: August 23, 1996			Group:			
REFERENCE DESIGNATION U.S. PATENT DOCUMENTS								
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<i>Jr</i>	AA	5,007,926	04/16/1991	Derbyshire				
<i>Jr</i>	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	5,168,548	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.				
<i>Jr</i>	AK	5,290,306	03/01/1994	Trotta et al.				
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<i>Jr</i>	AL	0 707 837 A1	04/24/1996	EPO			X	
<i>Jr</i>	AM	WO 93/19703	10/14/1993	PCT			X	
<i>Jr</i>	AN	WO 96/03072	02/08/1996	PCT			X	
<i>Jr</i>	AO	WO 96/03092 A1	02/08/1996	PCT			X	
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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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09/12/2019

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: 08/902,150				
		APPLICANT: Louis G. Ellis, Andrew J. Dusbabek, Christopher R. Larson, Terry V. Brown						
		FILING DATE: August 23, 1996		Group:				
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<i>JL</i>	AA	5,342,305	08/30/1994	Shonk				
<i>↑</i>	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.				
<i>↓</i>	AJ	5,453,090	09/26/1995	Martinez et al.				
<i>JL</i>	AK	5,458,615	10/17/1995	Klemm et al.				
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EXAMINER <i>JL</i>			DATE CONSIDERED 8/7/99					
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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MAR 22 1999  
FEDERAL BUREAU OF INVESTIGATION

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094720,249

FORM PTO-1449 (Modified)		ATTY DOCKET NO: S63.2-6050		Serial No: 08/702,150				
LIST OF PATENTS AND PUBLICATIONS APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		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						
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<i>JL</i>	AA	5,470,313	11/28/1995	Crocker et al.				
<i>JL</i>	AB	5,507,768	04/16/1996	Lau et al.				
<i>JL</i>	AC	5,512,051	04/30/1996	Wang et al.				
<i>JL</i>	AD	5,534,007	07/09/1996	St. Germain et al.				
<i>JL</i>	AE	5,536,252	07/16/1996	Imran et 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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**Notice of References Cited**

09/420, 244

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

U.S. PATENT DOCUMENTS

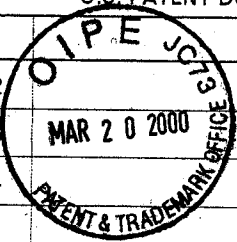
DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	Apr. 1992	Ryan et al	606	194
B	Aug. 1995	Euteneuer et al	606	198
C	Apr. 1994	Samson	606	194
D	May 1997	Sheiban et al	606	195
E	Aug. 1990	Savin et al	606	192
F	Nov. 1996	Kaplan et al	604	96
G	Jan. 1997	Edoga	606	194
H	Aug. 1995	Khosravi et al	606	194
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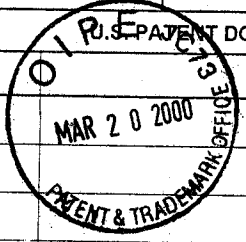
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09/420,249

<b>Notice of References Cited</b>	Application No. <del>08/702,150</del>	Applicant(s) Ellis et al
	Examiner Justine Yu	Group Art Unit 3733

Page 1 of 1



U.S. PATENT DOCUMENTS					
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**Notice of References Cited**

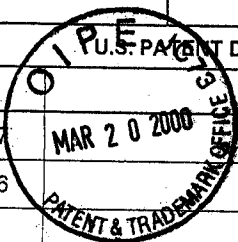
Application No. <sup>09/420,249</sup>  
~~08/702,150~~ Applicant(s)

Ellis et al

Examiner  
 Justine Yu

Group Art Unit  
 3301

Page 1 of 1



*Handwritten initials*

	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
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**FOREIGN PATENT DOCUMENTS**

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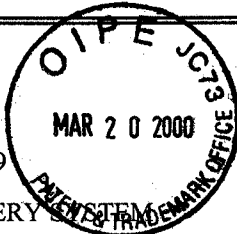
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Cap 3734  
#4

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

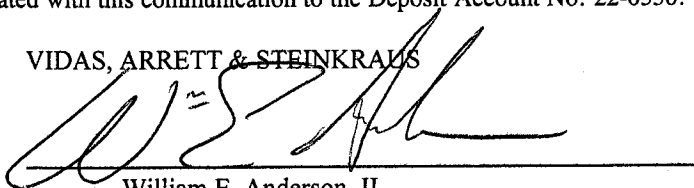
Docket No.: S63.2-8619

TRANSMITTAL LETTER

- 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.**
- 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.
- 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.
- 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.

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VIDAS, ARRETT & STEINKRAUS



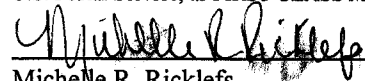
Date: March 9, 2000

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 10, 2000

  
Michelle R. Ricklefs



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

*sc*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,249	10/19/99	ELLIS	L 86.2-8619

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

3764


DATE MAILED: 08/15/00

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

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No. <b>09/420,249</b>	Applicant(s) <b>Ellis et al</b>
Examiner <b>Justine Yu</b>	Group Art Unit <b>3764</b>



- 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 ---

Art Unit: 3764

## 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.

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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).

Art Unit: 3764

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 negated 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.



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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

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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

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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  $\frac{1}{2}$  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  $\frac{1}{2}$  or  $\frac{2}{3}$  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

Art Unit: 3764

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).

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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.

Application/Control Number: 09/420,249

Page 10

Art Unit: 3764

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. <b>09/420,249</b>	Applicant(s) <b>Ellis et al</b>
Examiner <b>Justine Yu</b>	Group Art Unit <b>3764</b>
Page 1 of 1	

**U.S. PATENT DOCUMENTS**

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

Attachment \_\_\_\_\_

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

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

SUBSTITUTE PTO-948



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**FILING RECEIPT**



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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

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

376  
 3764

Date Mailed: 03/06/2000

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" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

**Applicant(s)**

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 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



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Title 37, Code of Federal Regulations, 5.11 & 5.15**

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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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**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

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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Assistant Commissioner of Patents  
Washington, DC 20231

Docket No.: S63.2-8619

11/22/2000 WKORDMA 00000043 09420249

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AMENDMENT

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

*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 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.

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

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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.

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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.

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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:
- Seals DI

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  $\frac{1}{2}$  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

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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 positioned 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

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*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)

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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 accessibility 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

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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 Sampson 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 desirability 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.

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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

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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  $\frac{1}{2}$  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  $\frac{1}{2}$  or  $\frac{2}{3}$  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  $\frac{1}{7}$  the size of the stent. It would not be an obvious design choice to increase it by  $3\frac{1}{2}$  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.

B

(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.

B

*Application No. 09/420,249*  
*Page 12*

*Amendment*

***Conclusion***

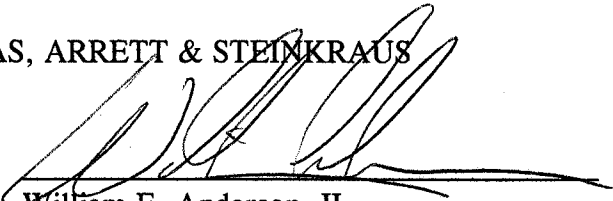
The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 15, 2000

By:

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

Suite 2000  
6109 Blue Circle Drive  
Minnetonka, MN 55343-9185  
Phone: (952) 563-3000  
Facsimile: (952) 563-3001  
FAWPWORK\WEA\8619-AMD.A29



QP-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

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

Docket No. 2003-063.2-8619

TRANSMITTAL LETTER

- 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.
- 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.
- 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.
- 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:

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

6109 Blue Circle Drive, Suite 2000  
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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 Commissioner for Patents, Washington D.C. 20231, on November 15, 2000

Jodi D. Nickel

B





**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.
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09/420,249	10/19/99	ELLIS	L 56.2-8619
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EXAMINER

QM32/0208

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

ART UNIT	PAPER NUMBER
----------	--------------

3764

DATE MAILED:  
02/08/01


8

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

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No. <b>09/420,249</b>	Applicant(s) <b>Ellis et al</b>
Examiner <b>Justine Yu</b>	Group Art Unit <b>3764</b>



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 ---

Art Unit: 3764

### 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.

Art Unit: 3764

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.

Art Unit: 3764

***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.

Art Unit: 3764

*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 negated 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.

Art Unit: 3764

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 separations between 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.

Art Unit: 3764

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  $\frac{1}{2}$  the length of the stent but lacks a detail description that the buildup section being at least  $\frac{1}{2}$  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.



Art Unit: 3764

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

Art Unit: 3764

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.

Art Unit: 3764

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. <b>09/420,249</b>	Applicant(s) <b>Ellis et al</b>
Examiner <b>Justine Yu</b>	Group Art Unit <b>3764</b>
Page 1 of 1	

**U.S. PATENT DOCUMENTS**

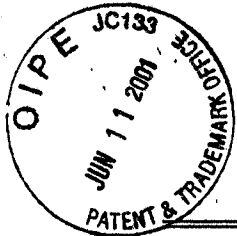
	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,846,246	12/1998	Dirks et al	606	108
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

**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		



9#

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

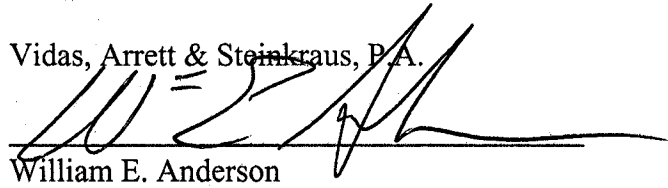
Any outstanding fee for extension should be charged to our Deposit Account No. 22-0350.

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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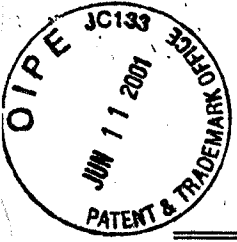
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EW-6-19-01



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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JUN 15 2001  
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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

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C

substantially constant along its length.

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C2

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 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.

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C3

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.

---

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C

C4 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.

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:

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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  $\frac{1}{2}$  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  $\frac{1}{3}$  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.

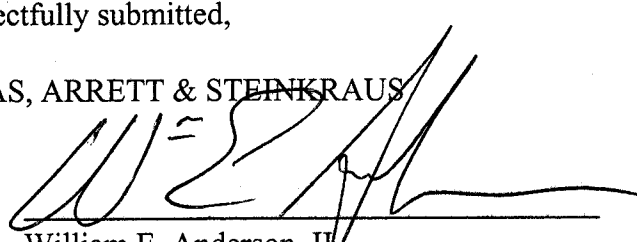
***Conclusion***

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

By:

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

Date: June 7, 2001

Suite 2000  
6109 Blue Circle Drive  
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Phone: (952) 563-3000  
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F:\WPWORK\WEA\8619-AMD.420

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.

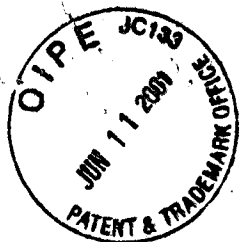
30. (Amended) The catheter of claim 20 wherein the mounting body is uniformly cylindrical in shape.

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

RECEIVED JUN 15 2001 TECHNOLOGY CENTER 3700

Box Fee Amendment  
Commissioner of Patents  
Washington, DC 20231

Docket No.: S692-8619

TRANSMITTAL LETTER

- 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.**
- 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.
- 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.
- 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.

Michèle 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.
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09/420,249	10/19/99	ELLIS	L 56.2-8619
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OLIVER F ARRETT  
VIDAS ARRETT & STEINKRAUS  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNEAPOLIS MN 55343-9131

QM32/0820

EXAMINER

ART UNIT	PAPER NUMBER
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3764

DATE MAILED:

08/20/01

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

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	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) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 3764

### 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*

Art Unit: 3764

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 negated 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  $\frac{1}{2}$  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.

Art Unit: 3764

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

Art Unit: 3764

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

Art Unit: 3764

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.

Art Unit: 3764

***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 1/2 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 1/2 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 1/2 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.



Application/Control Number: 09/420,249

Page 8

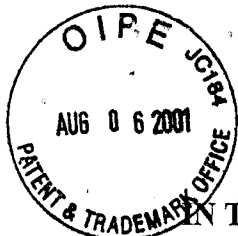
Art Unit: 3764

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  
#1234

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

- 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.**
- 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.
- 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.
- 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

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

Date: August 3, 2001

By:

6109 Blue Circle Drive, Suite 2000  
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Facsimile: (952) 563-3001

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AUG 10 2001  
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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 August 3, 2001.

Ann Lowe



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

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

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AUG 10 2001  
TC 3700 MAIL ROOM

*Application No.: 09/420,249*  
*Page 2*

*Amendment*

***Conclusion***

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

Respectfully submitted,

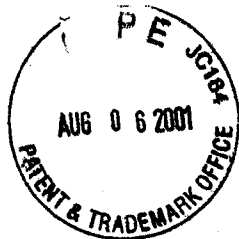
VIDAS, ARRETT & STEINKRAUS

By: 

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

Date: August 3, 2001

Suite 2000  
6109 Blue Circle Drive  
Minnetonka, MN 55343-9185  
Phone: (952) 563-3000  
Facsimile: (952) 563-3001  
FAWPWORK\WEA\8619-AMD.802



Application No.:  
Page 1

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

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AUG 10 2001  
TO 3700 MAIL ROOM

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.

- 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

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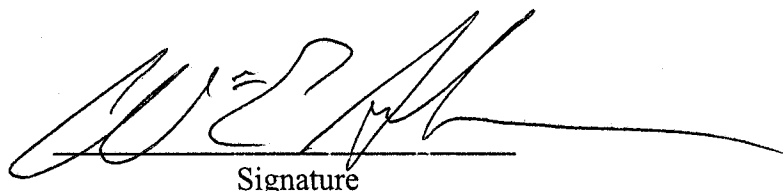
Application No.:

Page 2

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).

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EW  
11-28-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

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NOV 21 2001

GROUP 3700

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

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18

D

Application No. 09/420,249  
Page 2

Amendment

D1  
cont

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~~ (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:

D3

~~37~~ <sup>36</sup> 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.

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*Application No. 09/420,249*  
*Page 3*

*Amendment*

***§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  $\frac{1}{2}$  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  $\frac{2}{3}$  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  $\frac{1}{2}$  the length of the stent, it cannot be said that the reference teaches that a built-up layer can be  $\frac{2}{3}$  the length of the stent. It further cannot be said that increasing the size of the built-up layer to  $\frac{2}{3}$  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%.

*Application No. 09/420,249*  
*Page 4*

*Amendment*

If we consider the length of the built-up layer, as asserted in the rejection to be represented in figure 1, to be approximately  $\frac{1}{2}$  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  $\frac{1}{3}$ ,  $\frac{1}{2}$  should be considered to be the upper limit of the range. The preferred length is  $\frac{1}{3}$ , which is less than  $\frac{1}{2}$ . As such, it would be counterintuitive to the teachings of the reference to go beyond the indicated range to  $\frac{2}{3}$ . 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  $\frac{1}{2}$  and  $\frac{2}{3}$  when the reference teaches away from increasing the length above  $\frac{1}{2}$ , 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

*Application No. 09/420,249*  
*Page 5*

*Amendment*

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*

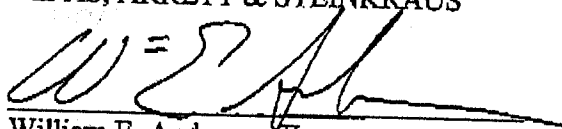
The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 20, 2001

By:



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

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6109 Blue Circle Drive  
Minnetonka, MN 55343-9185  
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Application No. 09/420,249  
Page 6

Amendment

*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  $[\frac{1}{2}] \frac{2}{3}$  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.

11/20/01 18:11 FAX 952 563 3009

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FEBRUARY 28, 1997

PTAS

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



\*100331187A\*

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

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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:

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DOROTHY RILEY, EXAMINER  
ASSIGNMENT DIVISION  
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Patent and Trademark Office



HEET

To the Honorable Commissioner of Patents

100331187

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

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

11-14-96

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

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

City State Zip

3. Nature of Conveyance:  
 Assignment  Merger  
 Security Agreement  Change of Name  
 Other

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

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:

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

B. Patent No.(s)

6277 U.S. PTO



12/31/96

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  
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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

*Oliver F. Arrett*  
Signature

11/4/96  
Date

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Washington, D.C. 20231

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

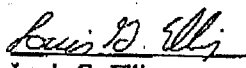
disclosed in my application for United States Letter Patent filed

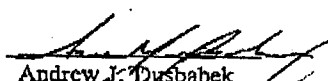
- concurrently herewith
- on 8/23/1996 and assigned Serial No. 08/702,150; and

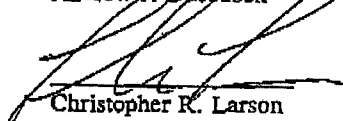
I hereby authorize and request any attorney of Vidas, Arrett & Steinkraus, P.A., 1540 Kimbark Financial Center, 920 2nd Ave. S., Minneapolis, MN 55402-4014, to insert the filing date and application number of said application above when known.

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:   
 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:   
 Fourth Inventor's Name: Terry V. Brown



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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

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GROUP 3700

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

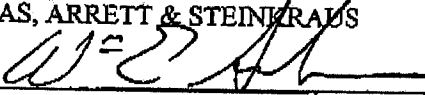
Dear Examiner:

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 & STEINRAUS

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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ellis et al.
Application No.:	09/420,249
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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.

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

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1/29/2001  
EMILY L  
09/420,249  
09/420,249

Application No.: 09/420,249

Page 2

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).

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**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.

Received from <952 563 3009> at 11/20/01 4:12:49 PM [Eastern Standard Time]

Application No.: 09/420,249  
Page 2

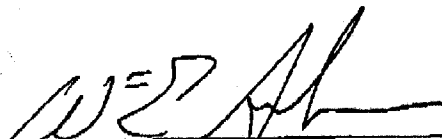
Check either box 1 or 2 below, if appropriate.

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).

<b>Notice of Allowability</b>	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 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input type="checkbox"/> Other   |

  
 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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Values: 09/420,249, 10/19/1999, Louis g. ELLIS, S6.2-8619, 2556

TITLE OF INVENTION: STENT DELIVERY SYSTEM WITH STENT SECUREMENT MEANS

Table with 7 columns: TOTAL CLAIMS, APPLN. TYPE, SMALL ENTITY, ISSUE FEE, PUBLICATION FEE, TOTAL FEE(S) DUE, DATE DUE. Values: 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.

**PART B - FEE(S) TRANSMITTAL**

**Complete and mail this form, together with applicable fee(s), to: Box ISSUE FEE  
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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

<p>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.</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.</p>	<p>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.</p> <p>1 _____</p> <p>2 _____</p> <p>3 _____</p>
--	---

**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

<p><b>4a. The following fee(s) are enclosed:</b></p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p><b>4b. Payment of Fee(s):</b></p> <p><input type="checkbox"/> A check in the amount of the fee(s) is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> 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).</p>
--	--

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) \_\_\_\_\_

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**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

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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		EXAMINER YU, JUSTINE ROMANG	
Oliver f Arrett VIDAS ARRETT & STEINKRAUS 6109 Blue Circle Drive Suite 2000 Minneapolis, MN 55343-9131 UNITED STATES			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>)



#16  
MR TD

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>In Re Application of:</b>	Ellis et al.
<b>Application No.:</b>	09/420,249
<b>Filed:</b>	October 19, 1999
<b>For:</b>	Stent Delivery System
<b>Examiner:</b>	Yu, J.
<b>Group Art Unit:</b>	3764

Attn: Official Draftsman  
Commissioner of Patents  
Washington, DC 20231

**Docket No.:** S63.2-8619

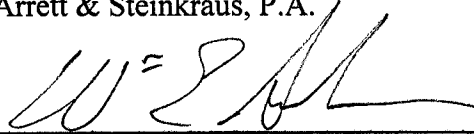
**TRANSMITTAL OF FORMAL DRAWINGS**

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

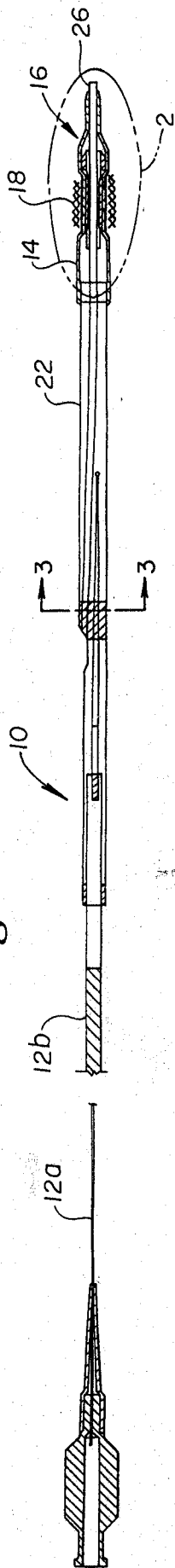
By:   
William E. Anderson, II Esq.  
Registration No. 37,766

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

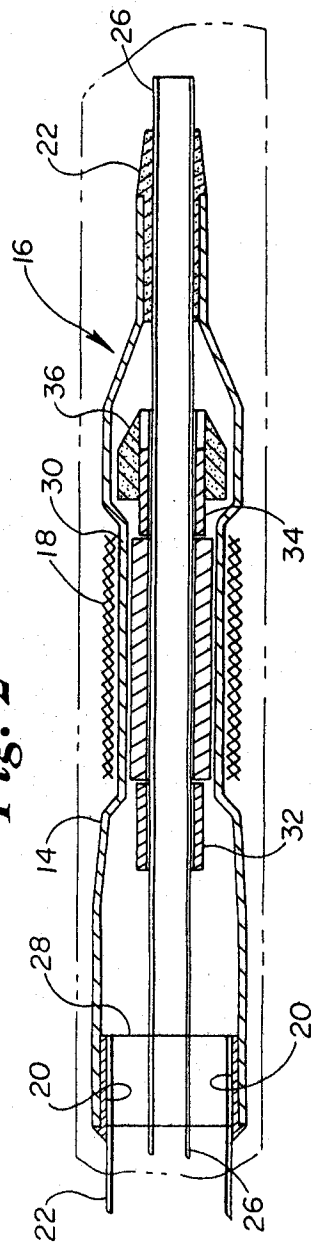
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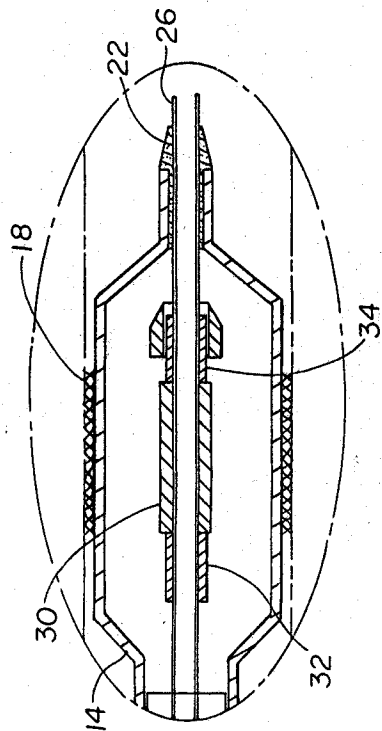
**Fig. 1**



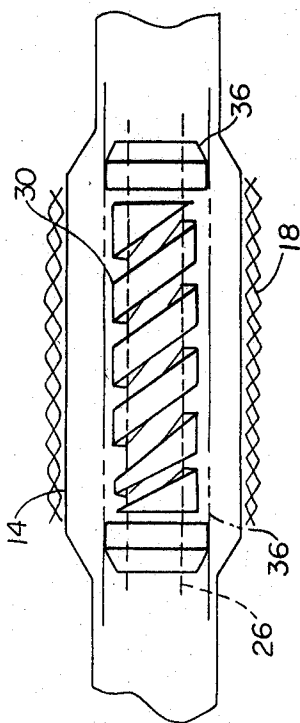
**Fig. 2**



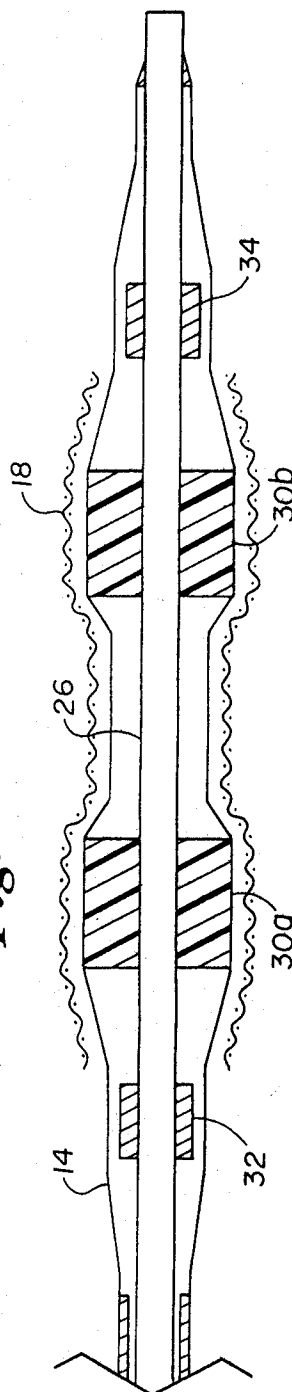
**Fig. 3**



**Fig. 4**

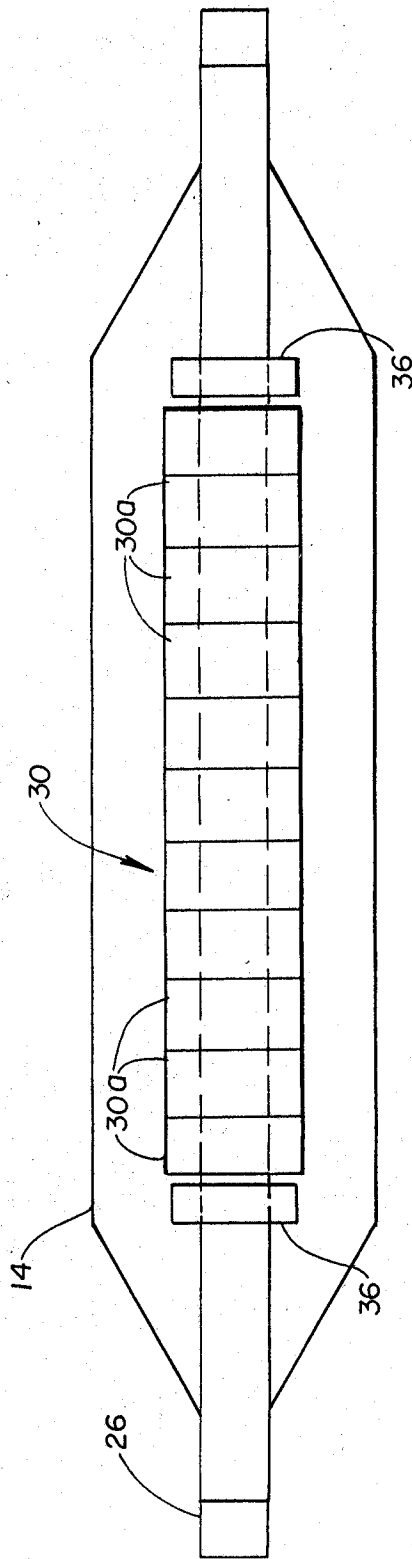


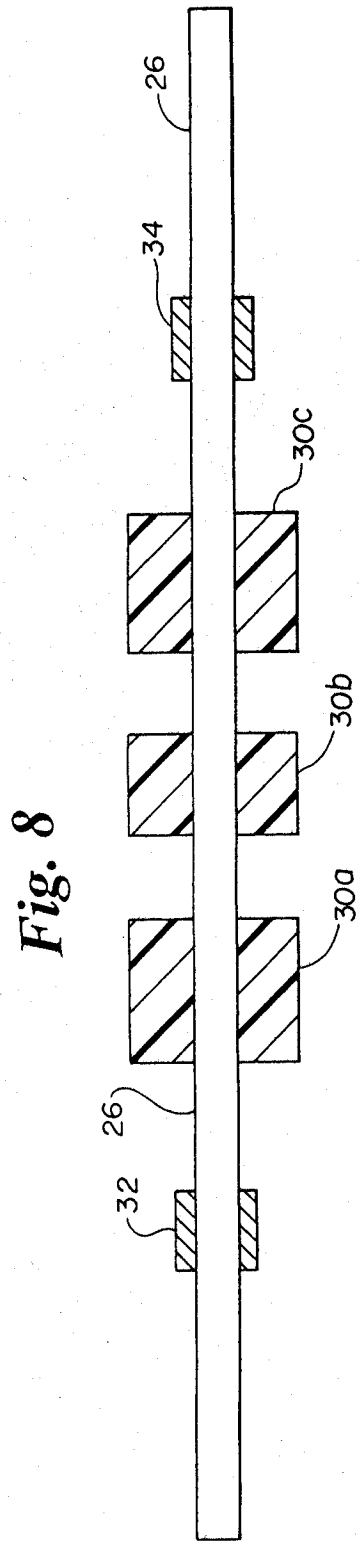
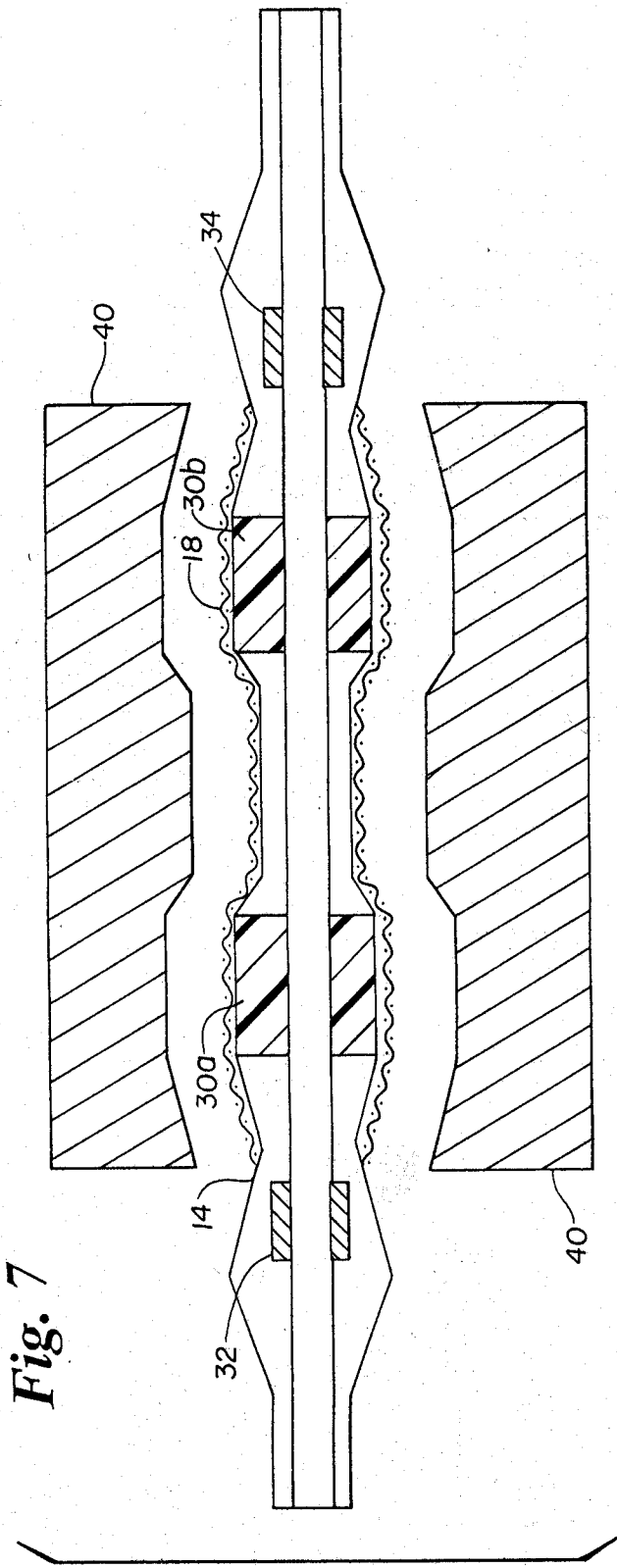
**Fig. 6**



Inventor: Ellis et al.  
Application No.: 09/420,249  
Docket No.: S63.2-8619  
Title: Stent Delivery System  
Page 3 of 4

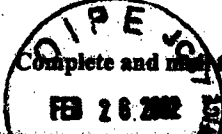
**Fig. 5**





02

PART B - FEE(S) TRANSMITTAL



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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

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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) [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

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TRANSMIT THIS FORM WITH FEE(S)

Page 2 of 3

03/04/2002 CIVE22 00000164 09420249 1280.00 01 FC:142

**PATENT APPLICATION FEE DETERMINATION RECORD**  
Effective November 10, 1998

Application or Docket Number

09/420,209

**CLAIMS AS FILED - PART I**

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
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	OR	RATE	FEE
	380.00			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**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT A				
Total	* 39	Minus	** 34	= 5
Independent	* 3	Minus	*** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY OR

OTHER THAN SMALL ENTITY

RATE	ADDI-TIONAL FEE	OR	RATE	ADDI-TIONAL FEE
X\$ 9=	90	OR	X\$18=	90
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

RATE ADDI-TIONAL FEE

RATE ADDI-TIONAL FEE

RATE	ADDI-TIONAL FEE	OR	RATE	ADDI-TIONAL FEE
X\$ 9=		OR	X\$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

RATE ADDI-TIONAL FEE

RATE ADDI-TIONAL FEE

RATE	ADDI-TIONAL FEE	OR	RATE	ADDI-TIONAL 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	<i>AA</i>	<i>22192</i>	<i>10/26/99</i>
O.I.P.E. CLASSIFIER		<i>48</i>	<i>10/29/</i>
FORMALITY REVIEW		<i>65918</i>	<i>11-9-99</i>

INDEX OF CLAIMS

- ✓ ..... Rejected
- = ..... Allowed
- (Through numeral) Canceled
- ÷ ..... Restricted
- N ..... Non-elected
- I ..... Interference
- A ..... Appeal
- O ..... Objected

Claim	Final	Original	Date
1	1	✓	
2	2	✓	
3	3	✓	
4	4	✓	
5	5	✓	
6	6	✓	
7	7	✓	
8	8	✓	
9	9	✓	
10	10	✓	
11	11	✓	
12	12	✓	
13	13	✓	
14	14	✓	
15	15	✓	
16	16	✓	
17	17	✓	
18	18	✓	
19	19	✓	
20	20	✓	
21	21	✓	
22	22	✓	
23	23	✓	
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25	25	✓	
26	26	✓	
27	27	✓	
28	28	✓	
29	29	✓	
30	30	✓	
31	31	✓	
32	32	✓	
33	33	✓	
34	34	✓	
35	35	✓	
36	36	✓	
37	37	N	
38	38	N	
39	39	N	
40	40	N	
41	41	N	
42	42	✓	
43	43	✓	
44	44		
45	45		
46	46		
47	47		
48	48		
49	49		
50	50		

Claim	Final	Original	Date
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Claim	Final	Original	Date
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If more than 150 claims or 10 actions  
staple additional sheet here

# SEARCHED

# SEARCH NOTES (INCLUDING SEARCH STRATEGY)

Class	Sub.	Date	Exmr.
606	194 195 198 108	8/4/00	<i>JL</i>
updated search		1/30/01	<i>JL</i>
updated search		8/15/01	<i>JL</i>
			see 09/307,179 for D.P.

Date	Exmr.
8/4/00	<i>JL</i>

## INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.