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APPLICANTS
ROBERT L. HESS, PORTOLA VALLEY, CA.

CONTINUING DATA***
VERIFIED *none*

FOREIGN/PCT APPLICATIONS***
VERIFIED *no*

***** SMALL ENTITY *****

Foreign priority claimed 35 USC 119 conditions met	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
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TITLE
METHOD AND APPARATUS FOR RESTENOSIS TREATMENT

U.S. DEPT. of COMM. Pat. & TM Office - PTO-436L (rev. 10-78)

ISSUE FEE IN FILE

PARTS OF APPLICATION FILED SEPARATELY

NOTICE OF ALLOWANCE MAILED	PREPARED FOR ISSUE	CLAIMS ALLOWED
11-26-93	11-29	Total Claims: 6, Print Claim: 1
ISSUE FEE	LEE S. COHEN ART UNIT	DRAWING
Amount Due: 285.00, Date Paid: 12-28-93	Primary Examiner	Sheets Drwg: 4, Figs. Drwg: 9, Print Fig: 1
Label Area	ISSUE CLASSIFICATION	ISSUE BATCH NUMBER
	Class: 600, Subclass: 003	583
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PATENT
011683-004

ROBERT L. HESS
(Typed or printed name of person mailing paper or fee)

Signature of person mailing: METHOD AND APPARATUS FOR RESTENOSIS TREATMENT

Background of the Invention

This invention relates generally to angioplasty and more particularly to a method and apparatus for preventing restenosis after angioplasty or other stenosis treatment.

Background Description

In the past, catheters have been developed which may be effectively inserted into blood vessels and maneuvered through a vascular tree. A balloon may be used with such catheters to expand in the vessel and open blockages found therein. In a typical percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA) procedure, a guiding catheter is percutaneously introduced into the vascular system of a patient through an artery and advanced therein until the distal tip of the guiding catheter is appropriately positioned. A dilation catheter having a balloon on the distal end thereof and a guide wire are slidably disposed and introduced through the guiding catheter. The guide wire is first advanced through the distal tip of the guiding catheter until the distal end of the guide wire crosses the lesion to be dilated. The dilation catheter is then advanced over the previously introduced guide wire until the dilation balloon on the distal extremity of the dilation catheter is properly positioned inside the lesion. The balloon portion of the dilation catheter is then inflated to a

predetermined size to radially compress the
atherosclerotic plaque of the lesion against the inside
of the artery wall to thereby reduce the annular
stenosed area. After a period of time, the balloon is
5 deflated so that blood flow is resumed, allowing the
dilation catheter to be removed.

A major problem encountered in a significant
number of patients treated by this procedure is the
subsequent narrowing of the artery after the expansion
10 treatment. Various methods and apparatus have been
developed to address the restenosis problem including
multiple inflations of the balloon during the original
procedure, atherectomy, hot balloons, and lasers. Even
the installation of permanent stents has been thought
15 to potentially have some value in reducing restenosis
rates. See, for example, U.S. Patent No. 5,019,075 to
Spears et al. wherein the region surrounding the
balloon utilized in the angioplasty procedure is heated
by means within the balloon, or within the skin of the
20 balloon, upon inflation of the balloon in order to
ideally fuse together fragmented segments of tissue.
F6 U.S. Patent No. 4,733,655 to Palmaz discloses an
expandable vascular graft which is expanded within a
blood vessel by an angioplasty balloon to dilate and
25 expand the lumen of the blood vessel. The Palmaz
method and apparatus leaves the expandable vascular
graft in place to ideally prevent recurrence of
stenosis in the body passageway.

However, recent data seems to indicate that
30 the prior art methods described above do not
significantly reduce restenosis rates of occurrence.
In restenosis, a proliferation of cells following
angioplasty is believed to cause the lesion to reform.
The rate of occurrence of restenosis is generally

6 considered to be about 33 percent. It would therefore
be desirable to have a method and apparatus to treat a
lesion in order to reduce the restenosis rate of
occurrence. The present invention is believed to
5 provide a unique method and apparatus to reduce the
restenosis rate of occurrence following an angioplasty
or like-intended procedure.

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Summary of the Invention

10 The purpose of the invention is to provide
method and apparatus to significantly reduce restenosis
rates of occurrence following an angioplasty procedure.
To accomplish this purpose, there is provided method
and apparatus for exposing the dilated lesion to a
radiation dose that will affect smooth muscle cell
15 growth. There is provided a catheter which has at its
distal end a radioactive source, the source being
maneuverable to the site of a lesion which has been
dilated or removed, the apparatus allowing the site to
be exposed to the radiation dose that will affect
20 smooth muscle cells such that the rapid growth of such
cells can be prevented, thereby controlling restenosis.

In one aspect of the invention there is
provided a method for treatment and post-treatment of
the stenosed region of an artery comprising the steps
25 of:

reducing the annular stenosed area within an
artery; and

applying a radioactive dose to the area of
reduced stenosis.

30 In another aspect of the invention there is
provided a method for treatment and post-treatment of
the stenosed region of an artery after reduction of

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said region by angioplasty or other means comprising the step of applying a radioactive dose to said reduced region of the artery.

5 In yet another aspect of the invention there is provided apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means; and
10 positioning means operatively connected to said dose means to position said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means.

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Description of the Drawing

15 FIG. 1 is a partial cross-sectional view of an embodiment of the invention wherein said dose applying means is a radioactive element contained within a wire wound housing for radioactive containment, the housing having a window cut-out. A larger wire wound sheath covers the window during
20 insertion and removal, the sheath being withdrawn to expose the radioactive element at the lesion site.

25 FIG. 2 is a partial perspective view of an alternate embodiment having a radioactive dose means positioned upon the balloon of an expandable balloon catheter, said balloon catheter being provided with a means or perfusion to allow blood flow during the time the balloon is inflated.

FIG. 3 is an enlarged partial cross-sectional view of a portion of the apparatus shown in FIG. 2.

FIG. 4 is a partial perspective view of the apparatus shown in FIGS. 2 and 3 upon expansion of the balloon portion of the apparatus.

5 FIG. 5 is a partial perspective view of another embodiment of the invention wherein the radioactive dose means is an element that may be contained within a complementary containment means provided with a remotely actuated window.

10 FIG. 6 is a partial perspective cross-sectional view of a catheter tip containing radioactive dose means showing the remotely actuated window.

15 FIG. 7 is a partial perspective cross-sectional view of an alternate embodiment further including a stent wherein said radioactive dose means is in the form of a coating of radioactive material on the stent.

FIG. 8 is a partial cross-sectional view of the device shown in FIG. 7 after expansion of the stent shown in FIG. 7.

20 FIG. 9 is a partial perspective view of the stent illustrated in FIGS. 7 and 8 wherein the stent is implanted within the artery.

Description of the Preferred Embodiments

25 With continued reference to the drawing, FIG. 1 illustrates the apparatus and method for preventing restenosis of an artery that has been enlarged by angioplasty or other procedure. Specifically, apparatus, shown generally at 10, is positioned within artery segment 12 having lesion site 14 which has

previously been enlarged by angioplasty or other procedure such that atherosclerotic plaque 16 has been radially compressed by expansion of the balloon portion of an angioplasty device (not shown) or removed by
5 other means. Device 10 having distal end 18 with tip 20 and wire wound housing 22 is positioned such that housing 22 is positioned within the lesion site 14. Housing 22 contains radioactive dose means 30 and is provided with window cut-out 32. Device 10 includes a
10 wire wound retractable sheath 24 and catheter shaft 26 with guide wire and guide wire port 28. A radioactive dose means 30 is moveable by advancing or retracting catheter shaft 26 which may be referred to as a positioning means. Sheath 24 is drawn back when the
15 radioactive dose means is positioned directly proximate the lesion site 14 such that window cut-out 32 is opened to expose the lesion site 14, which has been previously dilated, to a radiation dose that will affect the smooth muscle cells/plaque.

20 In FIG. 2 there is illustrated a device shown generally at 34 which is an alternate embodiment of the invention further including an angioplasty balloon 36 with dose means in the form of radioactive elements 38 attached thereto. Device 34 includes catheter shaft 40
25 having perfusion capabilities provided by holes 41 positioned proximately and distally to the balloon portion.

FIG. 3 shows in expanded view details of balloon 36 of FIG. 2 positioned about catheter shaft 40
30 having two main lumens 42 and 44. Lumen 42 makes provision for guide wire capability and contains perfusion holes. Lumen 44 is the lumen which provides the passage to inflate the balloon from the inflation port 45 shown in FIG. 2 at the proximal end of the

device 34. The radioactive elements 38 are not shown in FIG. 3.

FIG. 4 illustrates the device 34 of FIGS. 2 and 3 wherein the balloon 36 is expanded in the vicinity of the lesion site 46, and the radioactive elements 38 are forced into contact with the lesion.

It is understood that the various embodiments of the subject invention are useful in the treatment of a lesion site within an artery. "Lesion site" includes those lesions which have been treated with balloon angioplasty, those lesions that have been treated by an atherectomy or laser angioplasty, those lesions that have been treated by rotational atherectomy or any other means of compressing or removing the material of the lesion which may cause trauma to the artery. It is this trauma which causes the proliferation of smooth muscle cells which method and apparatus of the subject invention is intended to inhibit.

With regard to all embodiments of the subject invention, "radioactive dose" means bombardment by particles emitted from radioactive materials including, but not limited to, materials such as Radon 222, Gold 198, Strontium 90, Radium 192, and Iodine 125. These materials may be incorporated into or delivered in a solid, liquid, or gaseous form, and the delivery of such forms is considered to be within the scope of the subject invention.

FIG. 5 illustrates an alternate embodiment of the subject invention in the form of apparatus shown generally at 48. Sheath 50 of said device is preferably made from a helically wire wound member to provide a measure of shielding for the radioactive dose

means. Device 48 includes positioning means 52 which is a motion wire providing slidable motion of the radioactive dose means 54 within the sheath.

Radioactive dose means 54 is thus positionable
5 proximate to the lesion site 56 of artery segment 58 and retractable within sheath 50 for insertion and removal within the artery segment 58.

FIG. 6 illustrates yet another embodiment of the subject invention in the form of the device shown
10 generally at 60, similar to the device 10 shown in FIG. 1. In FIG. 6, device 60 is comprised of the shaft portion 62 and contains at its distal end a canister 64 containing the radioactive dose means. This canister 64 has a remotely actuated window 66 which can be
15 actuated through port 68 to expose the radioactive dose means to the lesion 70.

FIGS. 7, 8, and 9 illustrate yet another embodiment of the subject invention wherein a device shown generally at 72 is an inflatable stent delivery
20 balloon system for delivery and expansion of stent 74. Stent 74 may be removable or may be a permanent implant. In the case of a permanently implanted stent, the radioactive dose means has to be carefully chosen in terms of dose level and half-life in order to limit
25 the total radiation dose. In this embodiment, the radioactive dose means is associated with stent 74 and may be included as a cladding, a coating, an additive within the basic stent material itself, or an attachment by other means to the stent. In FIG. 7 the
30 device 72 includes an inflatable balloon dilation catheter to position stent 74 within lesion 76.

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FIG. 8 shows the expanded balloon of the stent delivery system 78 having dilated stent 74 in close proximal contact with lesion 76.

5 FIG. 9 shows the stent 74 in place within lesion 76 with the stent delivery system having been removed from the artery.

The foregoing description of the drawing illustrates various methods of the invention. It should be understood that the methods of the invention include the treatment and post-treatment of an annularly stenosed region of an artery. Most methods of treatment currently available cause some trauma to the artery. The artery in response to this trauma proliferates the growth of smooth muscle cells in many cases, and this results in restenosis at the site of the original stenosis -- usually within a six-month period. The post-treatment consists of exposing the treated region of the stenosis to a radiation dose which is sufficient to retard or halt the proliferation of smooth muscle cells. It should also be pointed out that both the treatment and post-treatment could occur simultaneously if the device which removes or compresses the stenosis material also contains the radioactive dose means.

25 Having indicated above preferred embodiments of the present invention, it will occur to those skilled in the art that modification and alternatives can be practiced within the spirit of the invention. It is accordingly intended to define the scope of the invention only as indicated in the following claims.

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On what is claimed is

What Is Claimed Is:

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1. A method for treatment and post-treatment of the stenosed region of an artery comprising the steps of:
reducing the annular stenosed area within an artery; and
applying a radioactive dose to the area of reduced stenosis.
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2. A method as defined in Claim 1 wherein the step of applying the radioactive dose is sufficient to affect smooth muscle cells within the area of reduced stenosis to inhibit rapid growth of such cells, thereby preventing restenosis of the artery.
- 1
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3. A method as defined in Claim 1 further including ^athe step of continuing to reduce the annular stenosed area while applying a radioactive dose to said area.
- 1
2
3
4. A method as defined in Claim 1 including ^a~~the~~ step of allowing blood flow through the area of reduced stenosis while applying the radioactive dose.
- 1
2
3
5. A method as defined in Claim 1 including the contacting of the tissue of the area of reduced stenosis with ^{the}~~a~~ radioactive ^{dose}~~material~~.
- 1
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6. A method as defined in Claim 1 further including ^a~~the~~ step of containing a source of radioactive dose before and after exposure to said area of reduced stenosis.
- 1
2
7. A method for treatment and post-treatment of the stenosed region of an artery after

3 reduction of said region by angioplasty or other means
4 comprising the step of applying a radioactive dose to
5 said reduced region of the artery.

1 8. A method as defined in Claim 1 wherein
2 the step of applying the radioactive dose is sufficient
3 to affect smooth muscle cells within the area of
4 reduced stenosis, thereby inhibiting rapid growth of
5 such cells and preventing restenosis of the artery.

1 *Sub A27* 9. Apparatus for post-treatment of a
2 stenosed region of an artery that has been reduced by
3 angioplasty or other means comprising:
4 radioactive dose means; and
5 positioning means operatively connected to
6 said dose means to position said dose means within the
7 stenosed region of an artery that has been reduced by
8 angioplasty or other means.

1 10. Apparatus as in Claim 9 wherein the
2 positioning means includes a retractable sheath which
3 may be removably positioned over said radioactive dose
4 means.

1 11. Apparatus as in Claim 9 wherein the
2 positioning means further includes an angioplasty
3 balloon and said radioactive dose means is connected to
4 said balloon and is positioned in the stenosed region
5 by expansion of said balloon.

1 12. Apparatus as in Claim 9 wherein the
2 positioning means includes a stent and said radioactive
3 dose means is associated with said stent.



Abstract of the Disclosure:

Method and apparatus for treatment and post-treatment of the stenosed region of an artery after reduction of the region by angioplasty or other means by applying a radioactive dose to said reduced region of the artery by positioning a radioactive dose to the reduced region is disclosed.

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**COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION**

Attorney Docket No.

011683-004

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

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

I BELIEVE I AM THE ORIGINAL, FIRST AND SOLE INVENTOR (if only one name is listed below) OR AN ORIGINAL, FIRST AND JOINT INVENTOR (if more than one name is listed below) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION

ENTITLED: Method and Apparatus for Restenosis Treatment

the specification of which

(check one)

is attached hereto;

was filed on _____ as

Application Serial No. _____

and was amended on _____ ;
(if applicable)

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, Sec. 1.56 (a) which states: "A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.";

I do not know and do not believe the said invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application; that said invention was not in public use or on sale in the United States of America more than one year prior to said application; that said invention has not been patented or made the subject of an inventor's certificate issued before the date of said application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than twelve months prior to said application;

I hereby claim foreign priority benefits under Title 35, United States Code Sec. 119 and/or Sec. 365 of any foreign application(s) for patent or inventor's certificate as indicated below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application(s) on which priority is claimed:

COMBINED DECLARATION AND POWER OF ATTORNEY		Attorney Docket No. 011683-004	
COUNTRY/INTERNATIONAL	APPLICATION NUMBER	DATE OF FILING <small>(day, month, year)</small>	PRIORITY CLAIMED
///			YES__ NO__
///			YES__ NO__

I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

William L. Mathis	301 17,337	Regis E. Slutter	26,999	Tereaa Stanek Rea	30,427
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Joel M. Freed	302 25,101	E. Joseph Gess	28,510	T. Gene Dillahunty	25,423
Norman H. Stepno	22,716	David D. Reynolds	29,273	Patrick C. Keane	32,858
Ronald L. Grudziecki	24,970	R. Danny Huntington	27,903	Peter K. Skiff	31,917
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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.

401-00	FULL NAME OF SOLE OR FIRST INVENTOR	SIGNATURE	DATE
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	POST OFFICE ADDRESS	same	
	FULL NAME OF SECOND JOINT INVENTOR, IF ANY	SIGNATURE	DATE
	///		
	RESIDENCE	CITIZENSHIP	
	POST OFFICE ADDRESS		
	FULL NAME OF THIRD JOINT INVENTOR, IF ANY	SIGNATURE	DATE
	///		
	RESIDENCE	CITIZENSHIP	
	POST OFFICE ADDRESS		

Please see attached continuation page for additional inventors.



Applicant or Patentee: Robert L. Hess Attorney's Docket No.: 011683-004
 Serial or Patent No.: Unknown
 Filed or Issued: September 5, 1991
 For: Method and Apparatus for Restenosis Treatment

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9 (f) and 1.27 (b)) — INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9 (c) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled Method and Apparatus for Restenosis Treatment described in

- the specification filed herewith
- application serial no. _____, filed _____.
- patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9 (c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- no such person, concern, or organization
- persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME ///
 ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME ///
 ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

FULL NAME ///
 ADDRESS _____

INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

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, any patent issuing thereon, or any patent to which this verified statement is directed.

Robert L. Hess	///	///
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of Inventor	Signature of Inventor	Signature of Inventor
September 5, 1991		
Date	Date	Date

(January 1984)

NC 000016

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Date of Deposit SEPTEMBER 1991

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" account under 37 C.F.R. 1.16 in the date indicated above and in accordance with the Commission on Patents and Trademarks Washington, D.C. 20231.

PATENT
Attorney's Docket No. 011683-004

ROBERT L. HESS IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Type or printed name of person mailing)

UTILITY PATENT
APPLICATION TRANSMITTAL LETTER

Signature of person mailing paper or fee:



Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the utility patent application
of Robert L. Hess
for Method and Apparatus for Restenosis Treatment

Enclosed are:

- 4 sheet(s) of [] formal [x] informal drawing(s).
- [] A claim for foreign priority under 35 U.S.C. 119/365 in
[] a separate document [] the declaration.
- [] A certified copy of the priority document.
- [] An Associate Power of Attorney.
- 1 verified statement(s) of small entity status.
- []

The declaration of the inventor(s) [x] is enclosed [] will follow.
The fee has been calculated as follows:

A. Basic Application Fee	\$630.00
B. Total Claims <u>12</u> minus 20 = <u>0</u> x \$20.00 = \$ <u>0</u>	
C. Independent Claims <u>3</u> minus 3 = <u>0</u> x \$60.00 = \$ <u>0</u>	
D. If multiple dependent claims present, add \$200.00 = \$ <u>0</u>	
E. Total Application Fee (Total A, B, C, & D)	= \$ <u>630.00</u>
F. If verified statement of small entity status is enclosed, fifty percent reduction of Total Application Fee (50% x E)	= \$ <u>315.00</u>
G. Application Fee Due (E minus F)	= \$ <u>315.00</u>
H. Assignment Recording Fee of \$8.00 if assignment document enclosed.	= \$ <u>0</u>
I. TOTAL FEE (G plus H)	= \$ <u>315.00</u>

- A check in the amount of \$ 315.00 is attached.
- [] Charge \$ _____ to Deposit Account No. 02-4800.

The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 02-4800. A duplicate copy of this

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September 5, 1991

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS

By James W. Peterson
James W. Peterson
Reg. No. 26,057

424

As Originally Filed

011683-004
114

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~~22~~
330

600/3

#7 755480

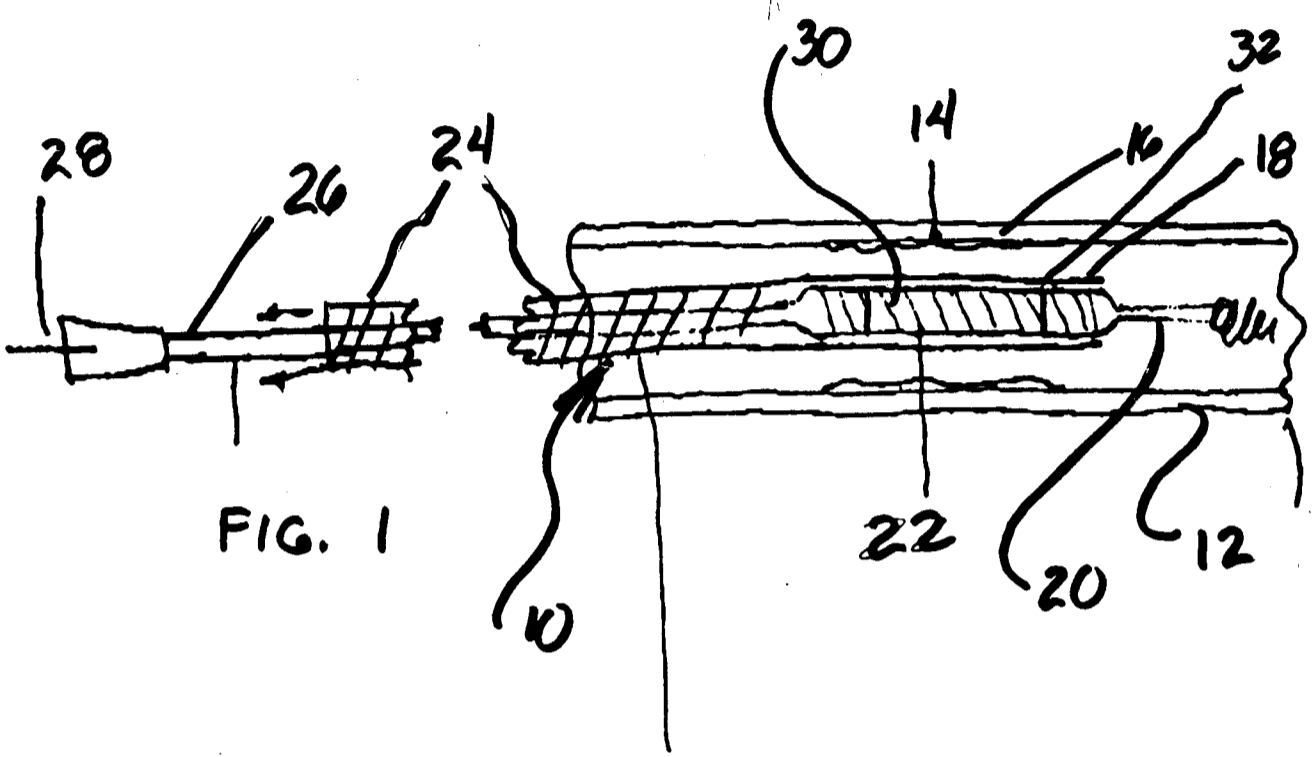


FIG. 1

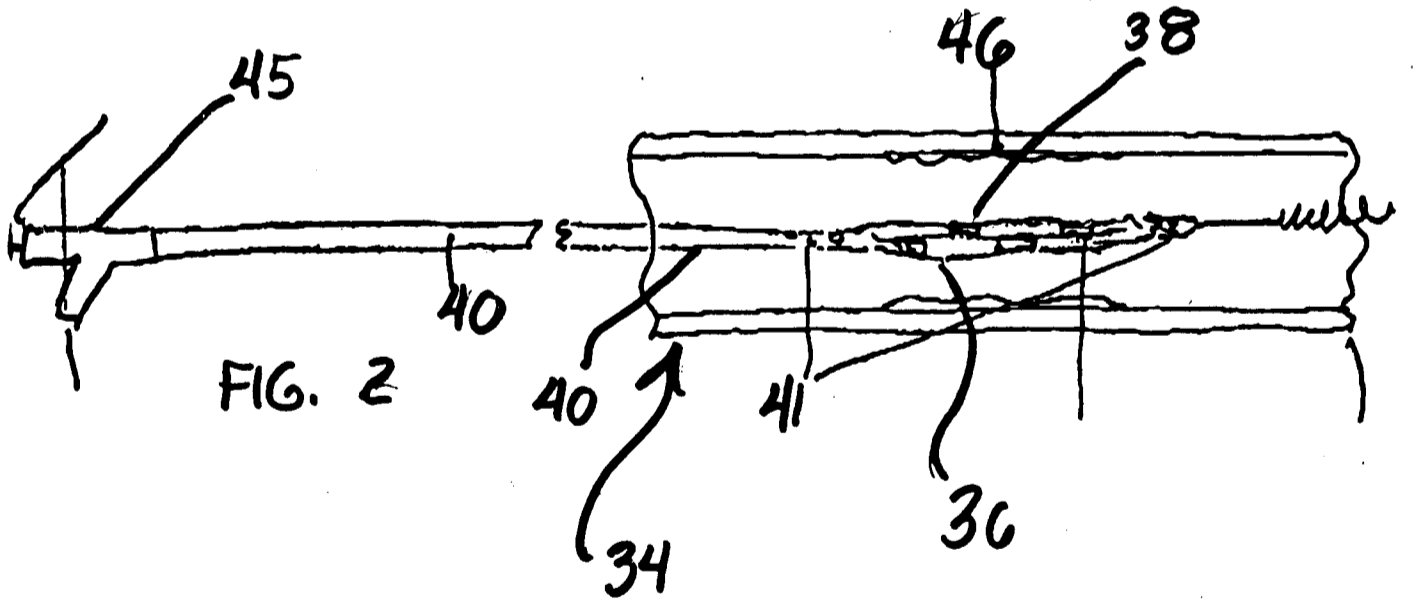


FIG. 2

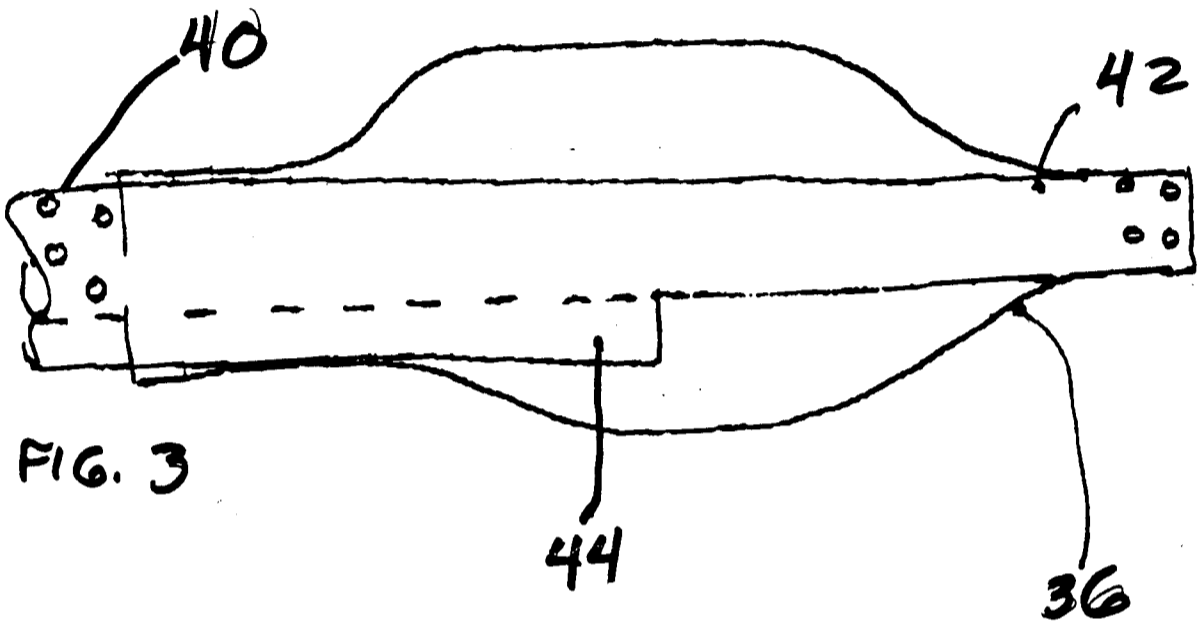


FIG. 3

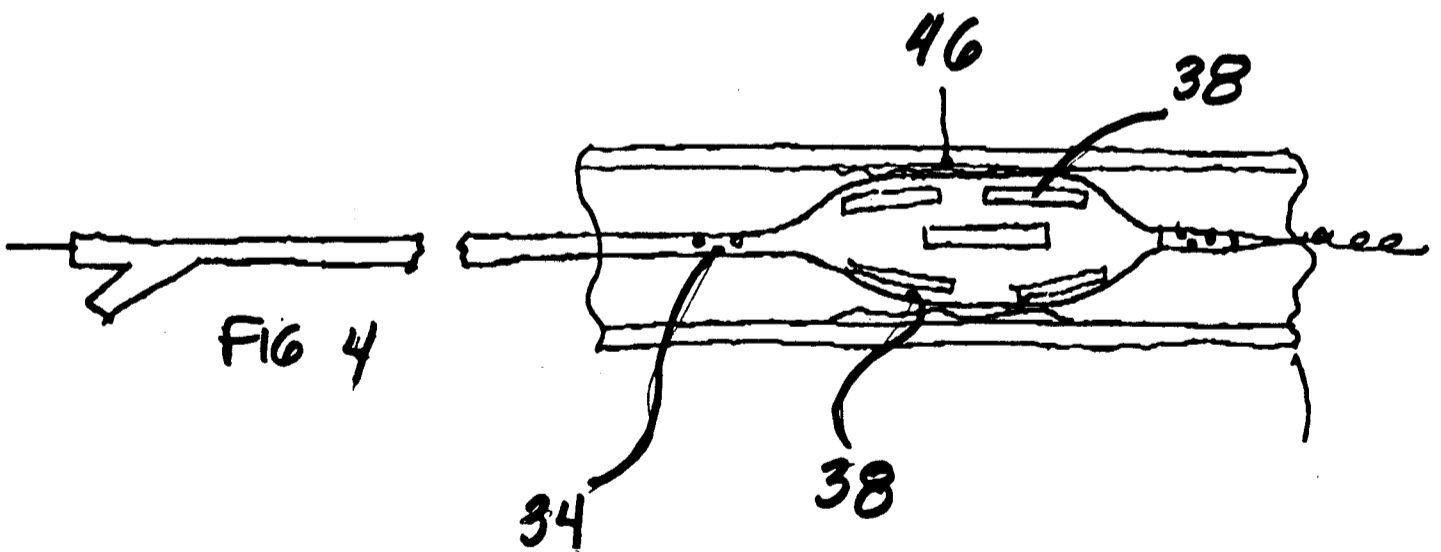
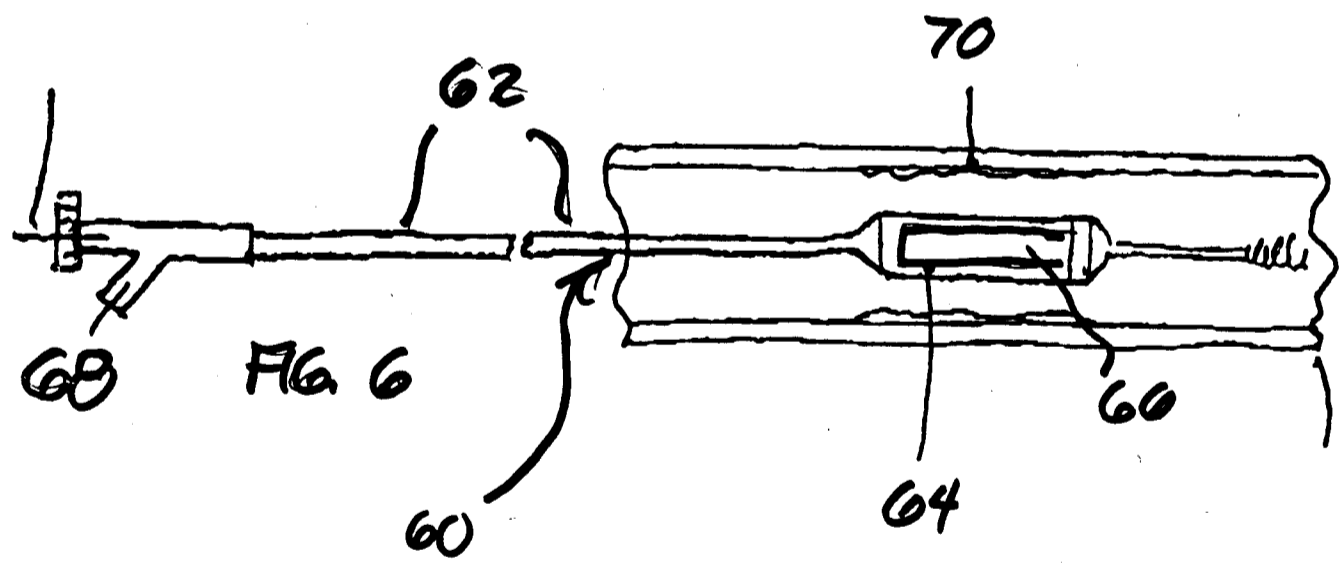
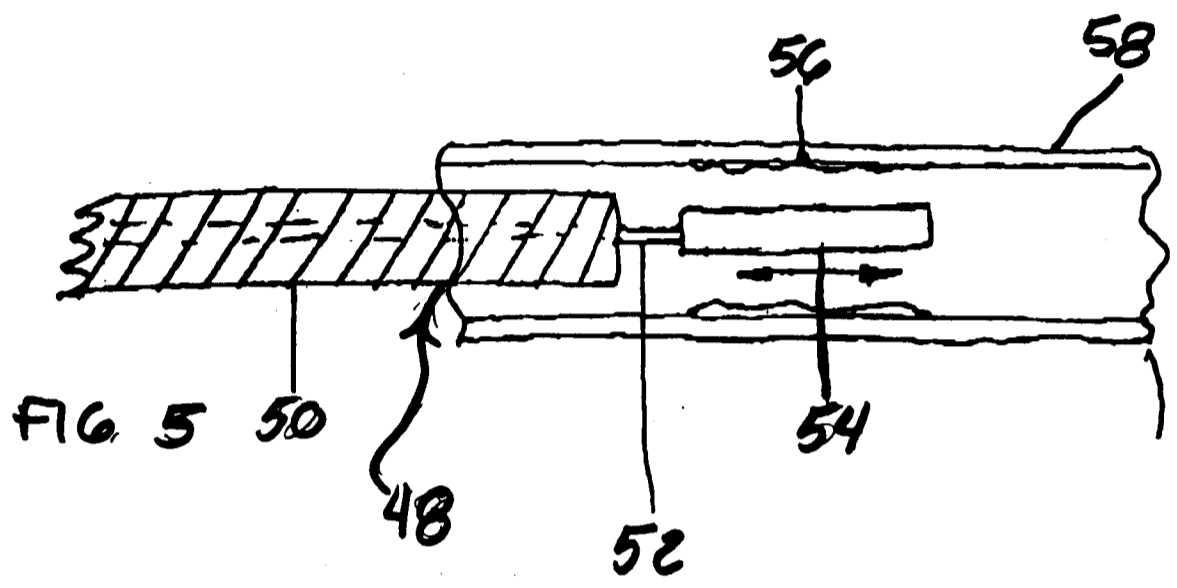


FIG 4

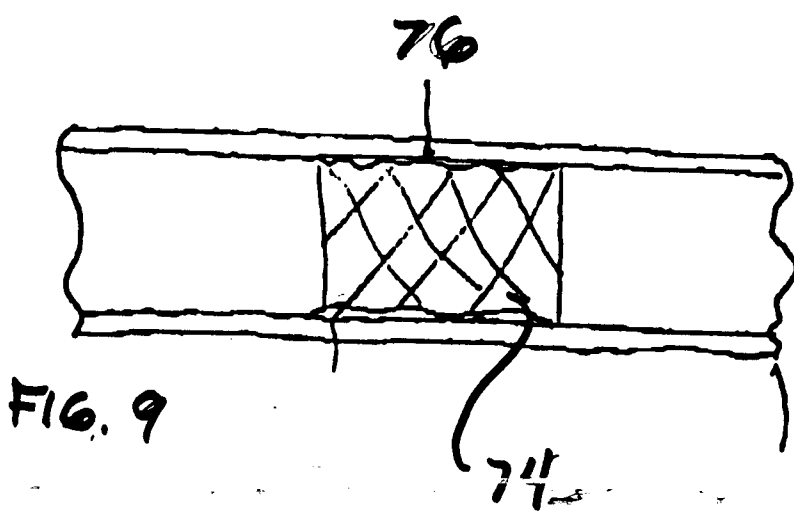
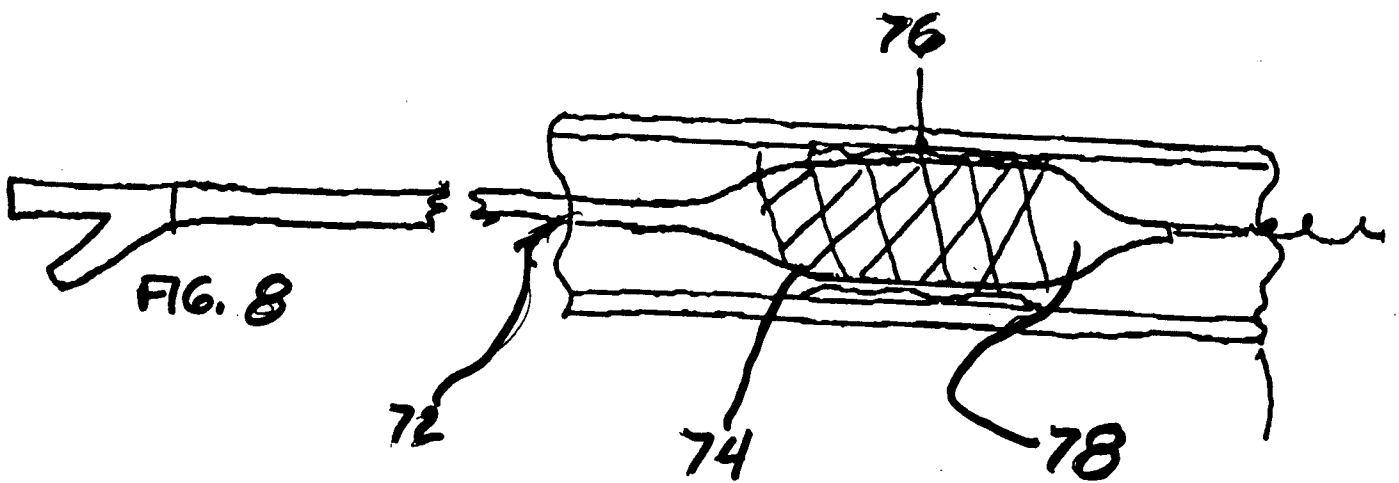
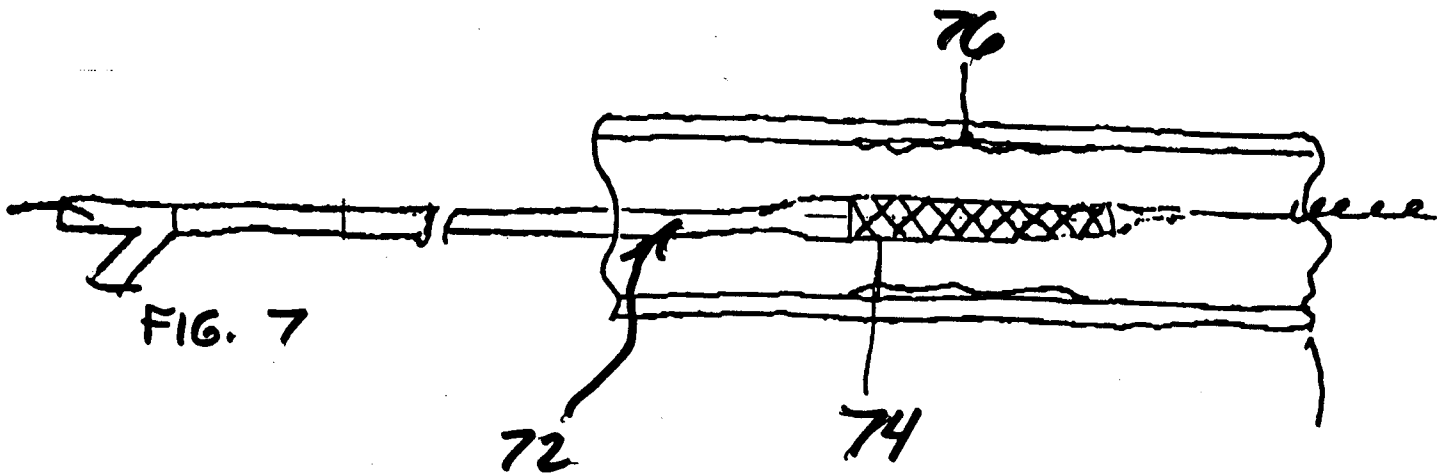
011683-004
3/4

Ø1 755480



011683-004
4/4

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

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

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
07/755,480	09/05/91	ROBERT L. HESS	011683-004

JAMES W. PETERSON
 BURNS, DOANE, SWECKER & MATHIS
 GEORGE MASON BUILDING
 WASHINGTON AND PRINCE STREETS
 P.O. BOX 1404
 ALEXANDRIA, VA 22313-1404

EXAMINER	
ART UNIT	PAPER NUMBER
	2

DATE MAILED: SEPT. 23, 1991

**IF NO RESPONSE TO THIS NOTICE IS RECEIVED WITHIN FORTY-FIVE DAYS, A
FORMAL REQUIREMENT WILL BE ISSUED**

The subject matter of this application appears to:

- be "useful in the production or utilization of special nuclear material or atomic energy" as recited in 42 U.S.C. 2182 (Department of Energy (DOE)).
- "have significant utility in the conduct of aeronautical and space activities" as recited in 42 U.S.C. 2457 (National Aeronautics and Space Administration (NASA)).

Accordingly, no patent can issue on this application unless applicant(s) file a statement (under oath or in the form of a declaration as provided by 37 CFR 1.68) setting forth (1) the full facts concerning the circumstances under which the invention was made and conceived and (2) the relationship (if any) of the invention to the performance of any work under any contract or other arrangement with the Agency (ies) noted above. On the reverse side of this form is an example of an acceptable format for this statement. The language appearing in paragraphs III and/or IV of the example *must* appear if applicant is attempting to establish that no relationship (under item 2 above) exists.

If the invention disclosed in this application was developed under a contract, grant or cooperative agreement between the Agency indicated above and a person, small business or non-profit organization and rights to the invention have been determined by specific reference to 35 U.S.C. 202 in the contract, grant or cooperative agreement, then applicant need not submit the statement described above. Instead, applicant may file a verified statement (under oath or in the form of a declaration, 37 CFR 1.68) setting forth the information required by 35 U.S.C. 202(c)(6).

IF NO STATEMENT HAS BEEN RECEIVED WITHIN FORTY-FIVE DAYS OF THE MAIL DATE INDICATED ABOVE, a formal requirement for statement will then be issued. No provision is made for extension of the statutory thirty-day period for response to the formal requirement and the penalty for failure to file an acceptable and timely statement is abandonment of the application. Therefore, applicants are strongly encouraged to submit a statement at this time in order to avoid the issuance of a formal requirement.

IT IS IMPORTANT TO NOTE that the statement must accurately represent the property rights-situation of the claimed invention if and when the application is found allowable. Thus, if during prosecution before the examiner, the claimed invention is so altered or the property rights situation so changed as to impact the accuracy of a statement submitted earlier, a supplemental statement must be filed. Failure to submit such additional information where appropriate may be considered a false representation of material facts and render the patent owner vulnerable to loss of patent rights and other sanctions as set forth in the statutes. The PTO will not review allowed applications for this possibility. The responsibility for complying with the statutes rests with the applicants.

Any questions regarding this requirement should be directed to Licensing and Review at (703) 557-3011.

**PLEASE DIRECT ALL COMMUNICATIONS RELATING TO THIS MATTER TO THE
ATTENTION OF LICENSING AND REVIEW**



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

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

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
07/755,480	09/05/91	ROBERT L. HESS	011683-004

JAMES W. PETERSON
 BURNS, DOANE, SWECKER & MATHIS
 GEORGE MASON BUILDING
 WASHINGTON AND PRINCE STREETS
 P.O. BOX 1404
 ALEXANDRIA, VA 22313-1404

RECEIVED
 NOV 12 1991
LICENSING & REVIEW

EXAMINER	
ART UNIT	PAPER NUMBER
	2

DATE MAILED: SEPT. 23, 1991

**IF NO RESPONSE TO THIS NOTICE IS RECEIVED WITHIN FORTY-FIVE DAYS, A
FORMAL REQUIREMENT WILL BE ISSUED**

The subject matter of this application appears to:

- be "useful in the production or utilization of special nuclear material or atomic energy" as recited in 42 U.S.C. 2182 (Department of Energy (DOE)).
- "have significant utility in the conduct of aeronautical and space activities" as recited in 42 U.S.C. 2457 (National Aeronautics and Space Administration (NASA)).

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If the invention disclosed in this application was developed under a contract, grant or cooperative agreement between the Agency indicated above and a person, small business or non-profit organization and rights to the invention have been determined by specific reference to 35 U.S.C. 202 in the contract, grant or cooperative agreement, then applicant need not submit the statement described above. Instead, applicant may file a verified statement (under oath or in the form of a declaration, 37 CFR 1.68) setting forth the information required by 35 U.S.C. 202(c)(6).

IF NO STATEMENT HAS BEEN RECEIVED WITHIN FORTY-FIVE DAYS OF THE MAIL DATE INDICATED ABOVE, a formal requirement for statement will then be issued. No provision is made for extension of the statutory thirty-day period for response to the formal requirement and the penalty for failure to file an acceptable and timely statement is abandonment of the application. Therefore, applicants are strongly encouraged to submit a statement at this time in order to avoid the issuance of a formal requirement.

IT IS IMPORTANT TO NOTE that the statement must accurately represent the property rights situation of the claimed invention if and when the application is found allowable. Thus, if during prosecution before the examiner, the claimed invention is so altered or the property rights situation so changed as to impact the accuracy of a statement submitted earlier, a supplemental statement must be filed. Failure to submit such additional information where appropriate may be considered a false representation of material facts and render the patent owner vulnerable to loss of patent rights and other sanctions as set forth in the statutes. The PTO will not review allowed applications for this possibility. The responsibility for complying with the statutes rests with the applicants.

Any questions regarding this requirement should be directed to Licensing and Review at (703) 557-3011.

**PLEASE DIRECT ALL COMMUNICATIONS RELATING TO THIS MATTER TO THE
ATTENTION OF LICENSING AND REVIEW**



UNITED STATES DEPARTMENT OF COMMERCE
 Patent and Trademark Office
 ASSISTANT SECRETARY AND COMMISSIONER
 OF PATENTS AND TRADEMARKS
 (20, 2007)

#3

PTO-103c (rev. 6-79) SECURITY FILE

SERIAL NO. (SERIES OF 1970) 755480

FILING DATE 9/5/91

APPLICANT INVENTION

DRAWINGS	TOTAL CL'S	IND CL'S	FILING FEE REC.	TRANSACTION	ATTY DK.
(DOE)					

SCREENED BY

LICENSE

DATE

DARCOM

NAVY

AF

CE

DOE

NASA

NSA

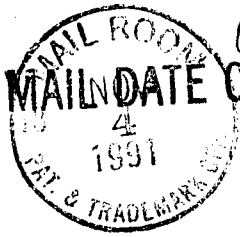
ACCESS ACKNOWLEDGEMENT

As Required by

Title 35, United States Code (1952) Section 181

I hereby acknowledge that I have inspected the disclosure of the above identified application for patent in the administration of the law cited above, on behalf of the department or agency which I represent, and promise that any information acquired from said application will not be divulged, disclosed or used for any purpose other than in the administration of the cited law.

NAME	DATE	AGENCY REPRESENTED
SNR - V. Caron	10-21-91	DOE



074



#4

Statement (152)
PATENT

Attorney Docket No.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Robert L. Hess

RECEIVED

Attention: LICENSING
AND REVIEW

Serial No.: 07/755,480

NOV 12 1991

Group Art Unit: 223

Filed: Sept. 5, 1991

LICENSING & REVIEW

Examiner: not assigned yet

For: METHOD AND APPARATUS
FOR RESTENOSIS TREATMENT

LETTER

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231
Sir:

In Paper No. Two dated September 23, 1991, a Statement regarding the full facts concerning the circumstances under which the present invention was made and conceived and its relationship, if any to the performance of any work under any contract or any arrangement with the Department of Energy, was required.

Enclosed herewith is a Declaration of Robert L. Hess which sets forth that to the best of his knowledge and belief the invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

It is respectfully submitted that the Declaration fully satisfies the requirement set forth in Paper No. Two.

In view of the foregoing, early and favorable consideration of Claims 1-12 is respectfully requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

The George Mason Building
Washington and Prince Sts.
Post Office Box 1404
Alexandria, VA 22313-1404
(703) 836-6620

By: James W. Peterson
James W. Peterson
Registration No. 26,057

Dated: November 6, 1991

RECEIVED

Serial No. 07/755,480
Attorney Docket No. 011683-004

NOV 12 1991

LICENSING & REVIEW



PATENT

Attorney Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
Robert L. Hess)	Attention: LICENSING
)	AND REVIEW
Serial No.: 07/755,480)	
)	Group Art Unit: 223
Filed: Sept. 5, 1991)	
)	Examiner: not assigned yet
For: METHOD AND APPARATUS FOR)	
RESTENOSIS TREATMENT)	

DECLARATION

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

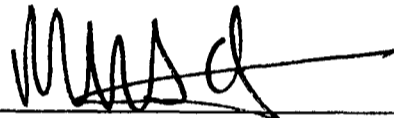
I, Robert L. Hess, a citizen of the United States of America, having the following mailing address: 222 Wyndham Drive, Portola Valley, CA 94025, declare that I made and conceived the invention described and claimed in patent application Serial No. 07/755,480, filed in the United States of America on September 5, 1991, and entitled, "Method and Apparatus for Restenosis Treatment."

OK
H

To the best of my knowledge and belief the invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy. The invention was independently made and conceived by me with my own resources.

Serial No. 07/755,480
Attorney Docket No. 011683-004

The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are 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 issuing thereon.



Robert L. Hess

Date:

5 NOVEMBER 1991



GP.
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ENC
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#5
Prorated

Patent Attorney's Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
ROBERT L. HESS)
)
Serial No.: 07/755,480)
)
Filed: SEPTEMBER 5, 1991)
)
For: METHOD AND APPARATUS)
FOR RESTENOSIS TREATMENT)

Group Art Unit: 223
Examiner: Unassigned

RECEIVED
MAR 20 1992
GROUP 220

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, applicant discloses to the Office information set forth below, which could be deemed material to the examination of the application, but which is believed not to be a bar to the patentability of any claims in this application. Accompanying this Disclosure are duplicate copies of form PTO-1449 listing the items whose relevance is discussed below. The Examiner is requested to consider the listed items and to return an initialed copy of the form to the applicants.

Listed are U.S. Patent Nos. 3,168,092, 3,324,847, 4,588,395, 4,733,655, 4,815,449, 4,878,492, 5,019,075. U.S. Patent Nos. 4,733,655 and 5,019,075 are discussed in Applicant's Background of the Invention.

U.S. Patent No. 3,168,092 discloses an instrument for inserting a capsule of radioactive material into the body.

U.S. Patent No. 3,324,847 discloses a radioactive balloon catheter for treatment of body organs.

U.S. Patent No. 4,588,395 discloses a catheter for insertion of radioactive material into the body, e.g., gamma treatment.

U.S. Patent No. 4,733,655 discloses an expandable intratuminal vascular graft.

U.S. Patent No. 4,815,449 discloses radioactive seeds in a conduit that is inserted into the body.

U.S. Patent No. 4,878,492 discloses a laser-type angioplasty catheter which acts to treat restenosis.

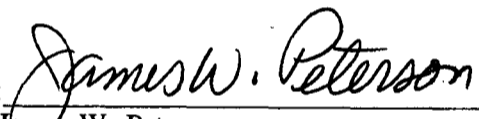
U.S. Patent No. 5,019,075 discloses another example of treating restenosis of blood vessels with heat.

Copies of all of the references are enclosed for the Examiner's convenience. Applicant submits that none of the references discloses, teaches or suggests Applicant's devices, articles or method of manufacture as set forth in the claims of the application.

The Examiner is asked to consider the references and to make them of record in the application.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 
James W. Peterson
Registration No. 26,057

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: March 13, 1992

MAR 16 1992

INFORMATION DISCLOSURE CITATION PTO-1449	PATTY. DOCKET NO. 011683-004	SERIAL NO. 07/755,480
	APPLICANT ROBERT L. HESS	
	FILING DATE September 5, 1991	GROUP 223

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
<i>JM</i>	3,168,092	2/2/65	SILVERMAN	128	1.2	6/15/61
	3,324,847	6/13/67	ZOUMBOULIS	128	1.2	10/16/64
	4,588,395	5/13/86	LEMELSON	604	59	10/28/80
	4,733,665	3/29/88	PALMAZ	128	343	11/7/85
	4,815,449	3/28/89	HOROWITZ	600	7	3/20/87
	4,878,492	11/7/89	SINOFKY	128	303.1	10/8/87
<i>sh</i>	5,019,075	5/28/91	SPEARS	606	7	6/31/90

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No

RECEIVED
 MAR 20 1992
 GROUP 220

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

EXAMINER <i>[Signature]</i>	DATE CONSIDERED 6/25/92
--------------------------------	----------------------------

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.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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

SERIAL NUMBER 077755,480	FILING DATE 09/05/91	FIRST NAMED INVENTOR HESS	ATTORNEY DOCKET NO. 011655-004
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LACYK, J EXAMINER

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
GEORGE MASON BUILDING, P.O. 1404
WASHINGTON AND PRINCE STS.
ALEXANDRIA, VA 22313-1404

ART UNIT 3305	PAPER NUMBER 6
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07/21/92

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on _____ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- Claims 1-12 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- Claims _____ have been cancelled.
- Claims _____ are allowed.
- Claims 1-12 are rejected.
- Claims _____ are objected to.
- Claims _____ are subject to restriction or election requirement.
- This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- Formal drawings are required in response to this Office action.
- The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).
- The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).
- Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.
- Since this application appears to be 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.
- Other

NC 000031

EXAMINER'S ACTION

Serial No. 755,480

-2-

Art Unit 335

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(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, 4-5, 7-9 and 12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Fischell et al.

Fischell discloses a device to be used after an angioplasty procedure has been performed to prevent restenosis. A radioactive stent is positioned at the site where the procedure was performed. Once the stent is in placed the radioactive material contacts the tissue to prevent restenosis and allows the blood to flow through.

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

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

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same

NC 000032

Serial No. 755,480

-3-

Art Unit 335

person or subject to an obligation of assignment to the same person.

Claims 3 and 11 are rejected under 35 U.S.C. § 103 as being unpatentable over Fischell et al in view of Palmaz.

Palmaz discloses a stent that is used to expand the inside of a blood vessel. Palmaz discloses that it is well known to use a balloon catheter to direct the stent to the proper position and be inflated to expand the stent in position and then be withdrawn. Therefore it would have been obvious to use a balloon catheter to properly place the radioactive stent of Fischall since Palmaz teaches that this is a well known way to place a stent.

Claims 6 and 10 are rejected under 35 U.S.C. § 103 as being unpatentable over Fischell et al in view Lemelson.

Fischell further teaches (column 2 lines 48-52) that placement of a radioactive source at the site of the vessel wall trauma by a wire with a radioactive tip can also be used.

Lemelson discloses a catheter used to administer medication or a source of radiation, etc to a selected site. Once the catheter is in positioned the source (37) is pushed out of a protective sheath (32) to treat the body portion and can be withdrawn back into the sheath ^{when} finished for proper removal. One of ordinary skill would have been motivated to use the catheter device of Lemelson for the wire and tip embodiment disclose in Fischell since this is a type of wire and tip assembly that

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Serial No. 755,480

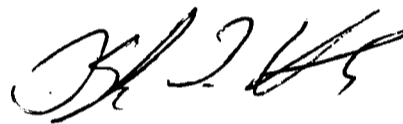
-4-

Art Unit 335

further adds a sheath to protect the source (32) while being inserted and removed.

Any inquiry concerning this communication should be directed to John P. Lacyk at telephone number (703) 308-2995.


John Lacyk:bhw
July 11, 1992



KYLE L. HOWELL
SPE
GROUP 330

GROUP 335

755480

NOTICE OF DRAFTSMAN'S PATENT DRAWING REVIEW

The PTO Draftsmen review all originally filed drawings regardless of whether they were designated as informal or formal.

The drawings filed 9/5/91

A. are approved.

B. are objected to under 37 CFR 1.84 for reason(s) checked below. The examiner will require submission of new, corrected drawings at the appropriate time. Corrected drawings must be submitted according to the instructions listed on the back of this Notice.

1. Paper and ink. 37 CFR 1.84(a)

- Poor Quality Paper. Must Be White. Transparent Paper Not Allowed. Sheet(s) _____

2. Size of Sheet and Margins. 37 CFR 1.84(b)

Acceptable Paper Sizes and Margins

Margin	Paper Size		
	8 1/2 by 14 inches	8 1/2 by 13 inches	DIN size A4 21 by 29.7 cm.
Top	2 inches	1 inch	2.5 cm.
Left	1/4 inch	1/4 inch	2.5 cm.
Right	1/4 inch	1/4 inch	1.5 cm.
Bottom	1/4 inch	1/4 inch	1.0 cm.

- Proper Size Paper Required. All Sheets Must be Same Size. Sheet(s) _____

- Proper Margins Required. Sheet(s) 1-4
 - Top Right
 - Left Bottom

3. Character of Lines. 37 CFR 1.84(c)

- Lines Pale, Rough and Blurred, or Jagged. Fig(s) 1-9
- Solid Black Shading Not Allowed. Fig(s) _____

4. Photographs Not Approved. _____

Comments:

5. Hatching and Shading. 37 CFR 1.84(d)

- Shade Lines are Required. Fig(s) _____
- Criss-Cross Hatching Not Allowed. Fig(s) _____
- Double Line Hatching Not Allowed. Fig(s) _____
- Parts in Section Must be Hatched Properly. Fig(s) _____

6. Reference Characters. 37 CFR 1.84(f)

- Reference Characters Poor or Rough and Blurred. Fig(s) 1-9
- Minimum 1/8 inch (3.2 mm.) in height is required. Fig(s) _____
- Figure Legends Poor or Placed Incorrectly. Fig(s) _____

7. Views. 37 CFR 1.84(i) & (j)

- Figures Must be Numbered Separately. _____
- Figures Must Not be Connected. Fig(s) _____

8. Identification of Drawings. 37 CFR 1.84(l)

- Extraneous Matter or Copy Machine Marks Not Allowed. Fig(s) _____

9. Changes Not Completed from Prior PTO-948 dated _____

Telephone inquiries concerning this review should be directed to the Chief Draftsman at telephone number (703) 557-6404.

Reviewing Draftsman WS

Date 9/27/91

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 3-78)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO. 755480	GROUPART UNIT 339	ATTACHMENT TO PAPER NUMBER 6
NOTICE OF REFERENCES CITED		APPLICANT(S) HESS		

U.S. PATENT DOCUMENTS																	
*	A	B	C	D	E	F	G	H	I	J	K	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A											5059166	10/22/91	FISCHER et al	600	3	12/11/89
	B																
	C																
	D																
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	I																
	J																
	K																

FOREIGN PATENT DOCUMENTS														
*	L	M	N	O	P	Q	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG.	PP. SPEC.
	L													
	M													
	N													
	O													
	P													
	Q													

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)	
R	
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T	
U	

EXAMINER 	DATE 6/25/92
---	------------------------

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)



Patent
Attorney's Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. HESS)	
)	
Application No.: 07/755,480)	
)	
Filed: September 5, 1991)	Group Art Unit: 3305
)	
For: METHOD AND APPARATUS FOR)	Examiner: J. Lacyk
RESTENOSIS TREATMENT)	

7
R
12/29/92

SUBMISSION OF DECLARATION UNDER 37 CFR §1.131

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

The Amendment filed December 21, 1992 included a facsimile copy of a Declaration Under 37 CFR §1.131 signed by the inventor, Robert L. Hess. Attached hereto is the original of the Hess Declaration.

In view of the foregoing, it is submitted that the present application is in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: Peter K. Skiff
Peter K. Skiff
Registration No. 31,917

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: December 22, 1992

(BDSM 20)
(10/92)

NC 000037



PATENT
Attorney Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
)	
Robert L. HESS)	
)	
Serial No.: 07/755,480)	
)	Group Art Unit: 3305
Filed: September 5, 1991)	
)	Examiner: J. Lacyk
For: METHOD AND APPARATUS FOR)	
RESTENOSIS TREATMENT)	

DECLARATION UNDER 37 CFR §1.131

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Robert L. Hess, declare that:

1. I am the inventor of the subject matter claimed in U.S. Patent Application Serial No. 07/755,480.

2. Exhibit A attached hereto discloses a method for treatment and post-treatment of the stenosed region of an artery. The method includes steps of reducing the annular stenosed area within an artery and advancing a radioactive dose means within the artery to the area of reduced stenosis. The radioactive dose means is operatively connected to positioning means and the advancing step is performed by moving the positioning means. The method also includes steps of applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means and removing the dose means from the artery by moving the positioning means. Exhibit A also discloses apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means. The apparatus includes radioactive dose

means and positioning means operatively connected to the dose means for advancing the dose means and positioning the dose means within the stenosed region of an artery that has been reduced by angioplasty or other means. The positioning means is also operatively connected to the dose means for withdrawing the dose means from the artery. Exhibit A was prepared in the United States prior to December 11, 1989.

3. Work performed by me or under my direction relating to guide wires and catheters for use with radioactive dose means to be used for treatment and post-treatment of the stenosed region of an artery has been ongoing in the United States from prior to December 11, 1989 through the September 5, 1991 filing date of U.S. Patent Application Serial No. 07/755,480.

The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are 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 issuing thereon.

16 Dec 1992
Date

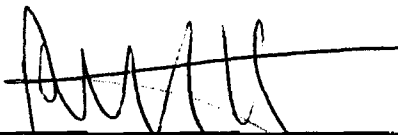
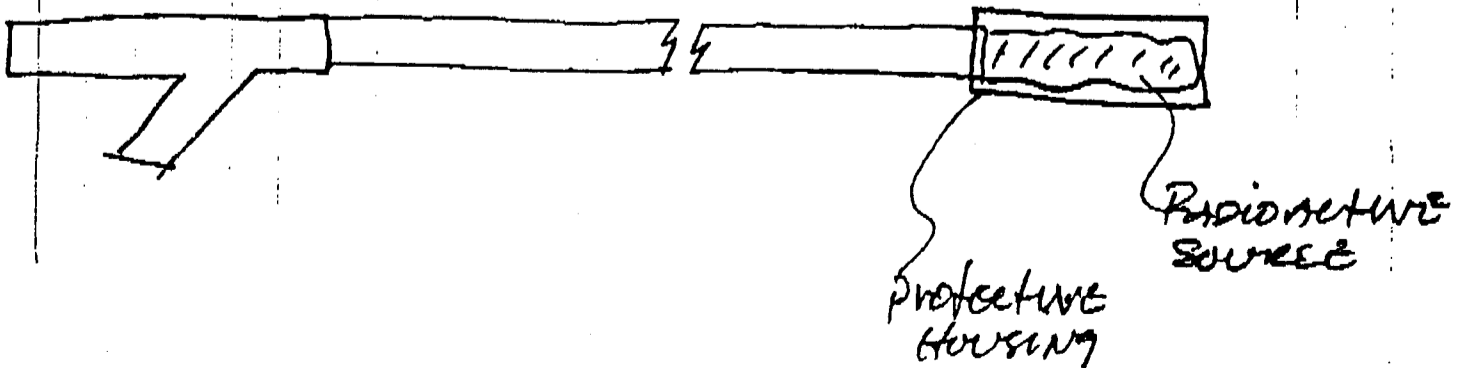
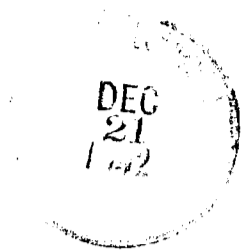

Robert L. Hess

EXHIBIT A

ATHEROSCLEROSIS, HOT BALLOONS (LASER; OTHERS) AND THE USE OF STENTS HAVE BEEN THOUGHT TO POTENTIALLY HAVE SOME VALUE IN REDUCING RESTENOSIS RATES. HOWEVER, THE DATA WHICH IS NOW COMING IN SEEMS TO INDICATE THAT THESE METHODS DO NOT SIGNIFICANTLY REDUCE RESTENOSIS RATES. IN RESTENOSIS A PROLIFERATION OF CELLS FOLLOWING ANGIOPLASTY IN ATHEROSCLEROSIS CAUSES THE LESION TO REFORM - THE RATE OF RESTENOSIS IS GENERALLY CONSIDERED TO BE ABOUT 33%. THEREFORE IT WOULD BE DESIRABLE TO HAVE A MEANS AND A METHOD TO TREAT LESIONS WITH A REDUCED RESTENOSIS RATE - I PROPOSE A CATHETER WHICH HAS, AT ITS DISTAL END, A RADIOACTIVE SOURCE. THE SOURCE WOULD BE MANEUVERED TO THE SITE OF A LESION WHICH HAS BEEN DILATED OR REMOVED AND THE SITE WOULD BE EXPOSED TO A RADIATION DOSE THAT WOULD KILL SMOOTH MUSCLE CELLS. IF THIS CAN BE DONE IN A CONTROLLED MANNER, IT IS POSSIBLE THAT THE RAPID GROWTH OF CELLS COULD BE PREVENTED AND RESTENOSIS CONTROLLED.





Patent
Attorney's Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. HESS)	
)	
Application No.: 07/755,480)	
)	
Filed: September 5, 1991)	Group Art Unit: 3305
)	
For: METHOD AND APARATUS FOR)	Examiner: J. Lacyk
RESTENOSIS TREATMENT)	

#8
1/23/93

SUBMISSION OF FORMAL DRAWINGS

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231


ATTN: OFFICIAL DRAFTSMAN

Sir:

Enclosed please find five sheets of formal drawings for review by the Patent and Trademark Office. Should the enclosed drawings require changes, it is respectfully requested that the Patent and Trademark Office notify the undersigned attorney of same.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 
Peter K. Skiff
Registration No. 31,917

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: December 21, 1992

(BDSM 20)
(10/92)

NC 000041

5302168

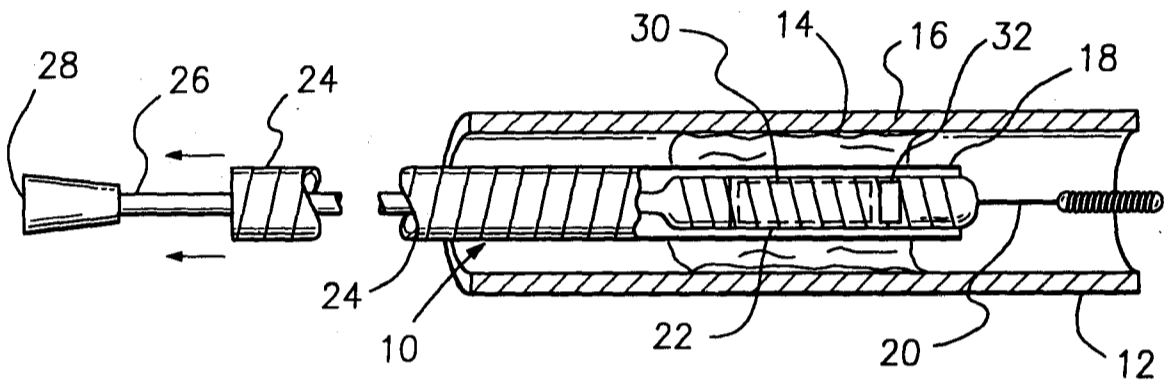


FIG. 1

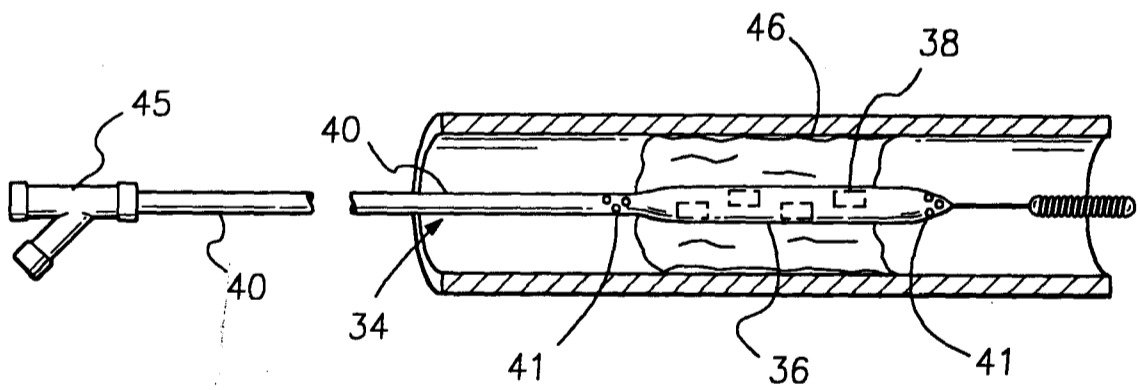


FIG. 2

1
600 003

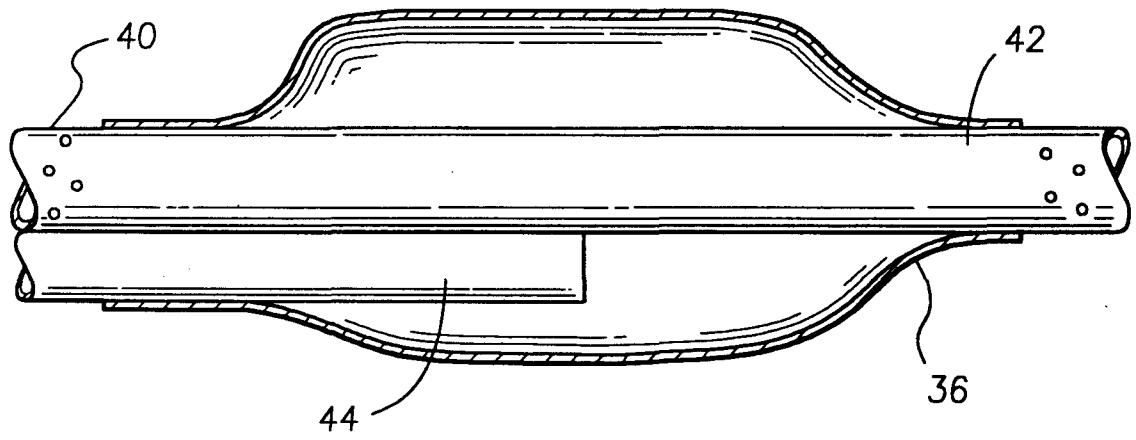


FIG. 3

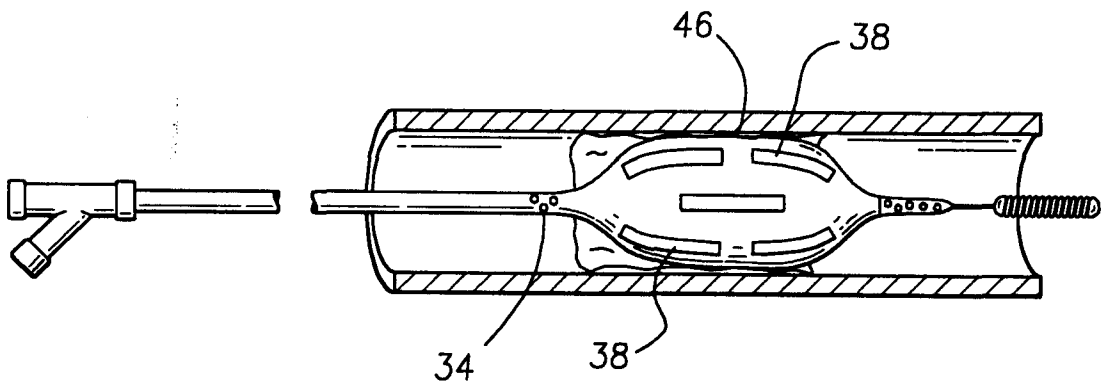


FIG. 4

1
600,000

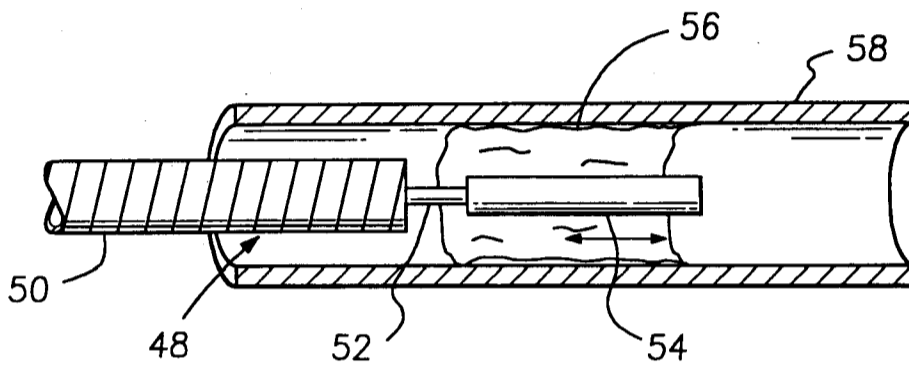


FIG. 5

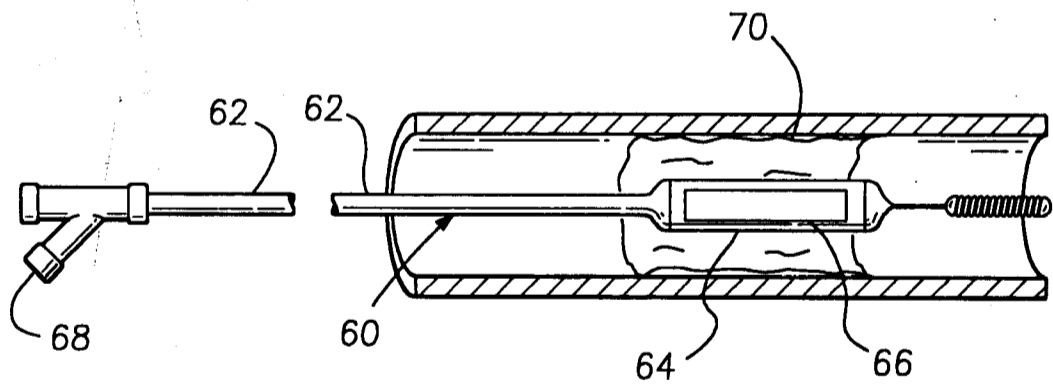


FIG. 6

1
600 003

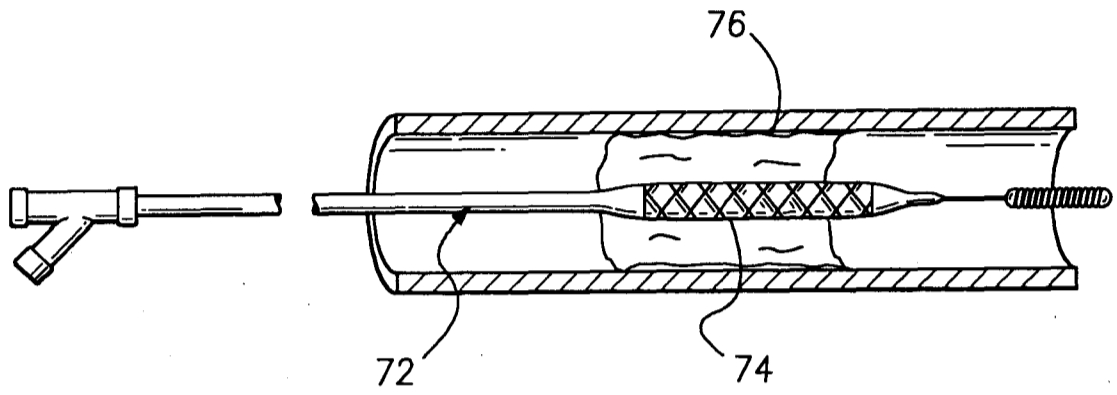


FIG. 7

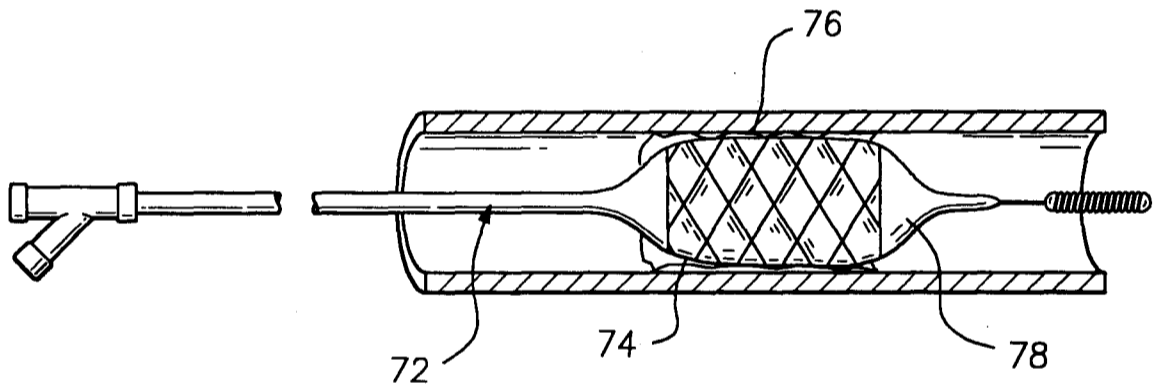


FIG. 8

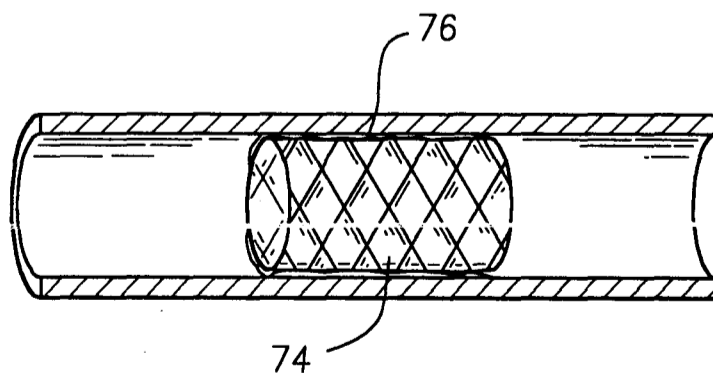


FIG. 9

9

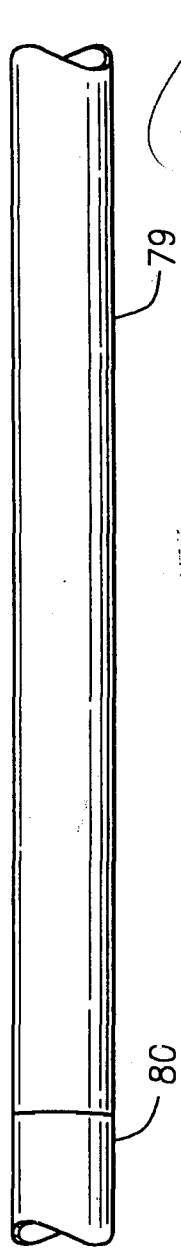


FIG. 17A

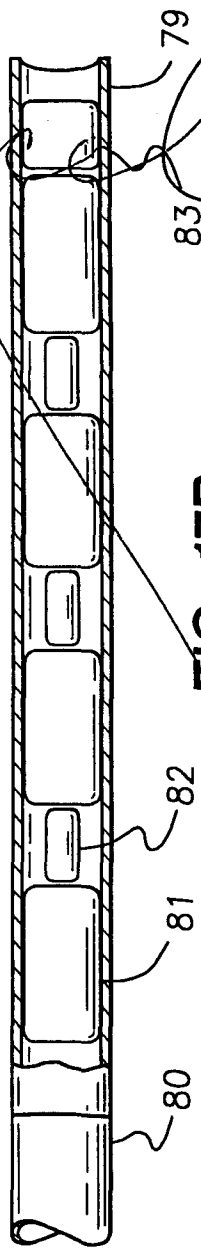


FIG. 17B

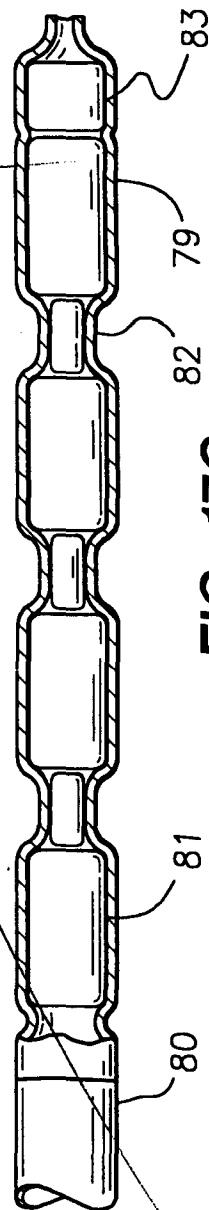


FIG. 17C

180 20-216 CR335

DEC 21 1992

Patent Attorney's Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of Robert L. HESS Application No.: 07/755,480 Filed: September 5, 1991 For: METHOD AND APPARATUS FOR RESTENOSIS TREATMENT Group Art Unit: 3305 Examiner: J. Lacyk

#9 1/21/93

PETITION FOR EXTENSION OF TIME

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

The following extension of time is requested to respond to the Office Action of July 21, 1992:

two months to December 21, 1992; the extension fee is [X] \$ 180.00 [] \$ 360.00

[] The shortened statutory period has been reset by an Advisory Action dated

[X] A check in the amount of \$ 180.00 is enclosed.

[] Charge \$ to Deposit Account No. 02-4800.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

I. O. P. □

CLERK, Group 350

REQUEST FOR PROVISION OF TIME IS GRANTED BY AUTHORITY OF THE PRINCIPAL EXAMINER FOR

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

The George Mason Building Washington & Prince Streets P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620

By: Peter K. Skiff Registration No 31,017

Date: December 21, 1992

040 TD 01/05/93 07755480

1 216 180.00 CK

(BDSM 25) (10/92)

NC 000047



PATENT
Attorney Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
)
Robert L. HESS)
)
Serial No.: 07/755,480)
)
Filed: September 5, 1991)
)
For: METHOD AND APPARATUS FOR)
RESTENOSIS TREATMENT)

Group Art Unit: 3305
Examiner: J. Lacyk

10/a
1/28/93
JL

AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In response to the Official Action dated July 21, 1992, the period for response having been extended until December 21, 1992 by a Petition for a Two-Month Extension of Time submitted herewith, please amend the above-identified application as follows.

IN THE CLAIMS:

Please cancel claims 7 and 12, and amend claims 1 and 9 as follows.

1. (Amended) A method for treatment and post-treatment of the stenosed region of an artery comprising the steps of:
- reducing the annular stenosed area within an artery; [and]
 - [applying] advancing a radioactive dose means within the artery to the area of reduced stenosis[.], the radioactive dose means being operatively connected to positioning means and the advancing step being performed by moving the positioning means;

ai

A1 cont.
applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means; and
removing the dose means from the artery by moving the positioning means.

A2
9. (Amended) Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means; and

positioning means operatively connected to said dose means [to position] for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery.

REMARKS

Reconsideration of the Official Action dated July 21, 1992 is respectfully requested.

The sole grounds of rejection set forth in the Official Action are prior art rejections based on U.S. Patent No. 5,059,166 ("Fischell"). In particular, claims 1, 2, 4, 5, 7-9 and 12 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Fischell, claims 3 and 11 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Fischell in view of U.S. Patent No. 4,733,665 ("Palmaz") and claims 6 and 10 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Fischell in view of U.S. Patent No. 4,588,395 ("Lemelson"). These rejections are respectfully

traversed on the basis that Fischell is not available as a reference against the claims of the present application. As such, all of the rejections based on Fischell should be withdrawn.

Claims 1 and 9 are the only independent claims. Claim 1 has been revised to recite a method for treatment and post-treatment of the stenosed region of an artery comprising the steps of reducing the annular stenosed area within an artery, advancing a radioactive dose means within the artery to the area of reduced stenosis, the radioactive dose means being operatively connected to positioning means and the advancing step being performed by moving the positioning means, applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means, and removing the dose means from the artery by moving the positioning means.

Claim 9 has been revised to recite an apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means comprising radioactive dose means and positioning means operatively connected to the dose means for advancing the dose means and positioning the dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, the positioning means also being operatively connected to the dose means for withdrawing the dose means from the artery. Claims 1 and 9, and the claims dependent thereon are clearly patentable over the cited references for the following reasons.

Fischell relates to intra-arterial stents which are used to maintain patency of an arterial lumen typically subsequent to balloon angioplasty or atherectomy (column 1, lines 6-9 of Fischell). All of Fischell's claims are directed to an intra-arterial stent or a method of using an intra-arterial stent. Fischell discloses that the stent is fabricated from a metal or alloy which has been irradiated so that it has become radioactive and that the radioisotope used for this purpose would have a half-life between ten hours and 100 days

(column 1, lines 65-68 and column 2, lines 11-13 of Fischell). Figure 1 of Fischell shows a stent embedded within a human artery (column 1, lines 43-46 of Fischell). Fischell does not disclose any means for removing the stent. As such, the stent of Fischell is apparently meant to remain in the human body indefinitely.

Claim 1 recites a method wherein a radioactive dose means is temporarily exposed to an area of reduced stenosis and the dose means is removed from the artery by moving a positioning means operatively connected to the radioactive dose means. Claim 9 recites apparatus for carrying out the method of claim 1. The disclosure of Fischell relating to the stent clearly fails to disclose or suggest the method of claim 1 or the apparatus of claim 9. It is noted, however, that Fischell also discloses a thin wire having a radioactive tip for temporary placement of a radioactive source within an arterial lumen (column 2, lines 44-52 of Fischell). There are no claims in Fischell directed to the thin wire having the radioactive tip.

Fischell matured from an application filed on December 11, 1989. In order to remove Fischell as a reference against the claims of the present application, submitted herewith is a Declaration Under 37 C.F.R. §1.131. The Rule 131 Declaration is signed by the inventor, Robert L. Hess, and establishes that the claimed method and claimed apparatus was conceived in the United States prior to December 11, 1989. In addition, the Hess Declaration establishes that the inventor has been diligent in reducing the invention to practice from prior to the December 11, 1989 filing date of Fischell until filing of the present application on September 5, 1991. It should be noted that the Hess Declaration does not bear an original signature. As such, the original thereof will be filed in due course.

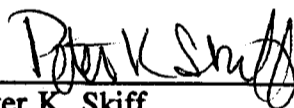
From the foregoing, it should be clear that Fischell is not available as a reference against the claims of the present application. See MPEP §715.07. In addition, the claims of the present application and the claims of Fischell are not directed to the same invention. As such, an interference between the present application and Fischell should not be declared.

In view of the removal of Fischell as a reference against the claims of the present application, it is submitted that the rejections based on Fischell in view of Palmaz and Fischell in view of Lemelson should also be withdrawn.

In view of the foregoing, it is submitted that the present application is in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 
Peter K. Skiff
Registration No. 31,917

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: December 21, 1992



PATENT
Attorney Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
)
Robert L. HBSS)
)
Serial No.: 07/755,480)
)
Filed: September 5, 1991)
)
For: METHOD AND APPARATUS FOR)
RESTENOSIS TREATMENT)

Group Art Unit: 3305
Examiner: J. Lacyk

DECLARATION UNDER 37 CFR §1.131

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Robert L. Hess, declare that:

1. I am the inventor of the subject matter claimed in U.S. Patent Application Serial No. 07/755,480.
2. Exhibit A attached hereto discloses a method for treatment and post-treatment of the stenosed region of an artery. The method includes steps of reducing the annular stenosed area within an artery and advancing a radioactive dose means within the artery to the area of reduced stenosis. The radioactive dose means is operatively connected to positioning means and the advancing step is performed by moving the positioning means. The method also includes steps of applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means and removing the dose means from the artery by moving the positioning means. Exhibit A also discloses apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means. The apparatus includes radioactive dose

means and positioning means operatively connected to the dose means for advancing the dose means and positioning the dose means within the stenosed region of an artery that has been reduced by angioplasty or other means. The positioning means is also operatively connected to the dose means for withdrawing the dose means from the artery. Exhibit A was prepared in the United States prior to December 11, 1989.

3. Work performed by me or under my direction relating to guide wires and catheters for use with radioactive dose means to be used for treatment and post-treatment of the stenosed region of an artery has been ongoing in the United States from prior to December 11, 1989 through the September 5, 1991 filing date of U.S. Patent Application Serial No. 07/755,480.

The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are 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 issuing thereon.

16 Dec 1992
Date

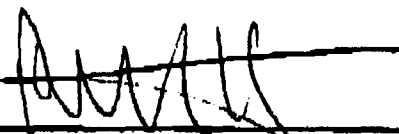
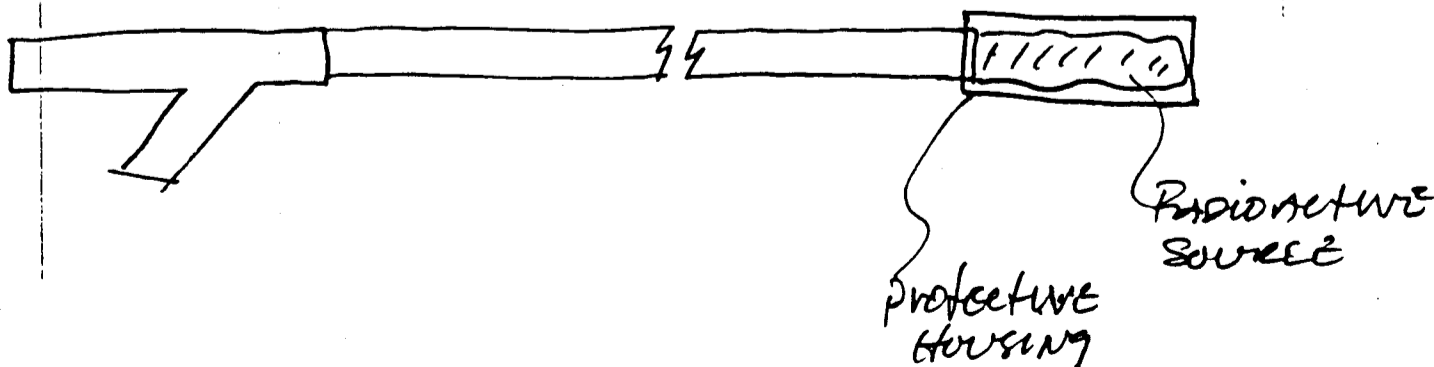

Robert L. Hess

EXHIBIT A

ATHERECTOMY, HOT BALLOONS (LASER; OTHERS) AND THE USE OF STENTS HAVE BEEN THOUGHT TO POTENTIALLY HAVE SOME VALUE IN REDUCING RESTENOSIS RATES. HOWEVER, THE DATA WHICH IS NOW COMING IN SEEMS TO INDICATE THAT THESE METHODS DO NOT SIGNIFICANTLY REDUCE RESTENOSIS RATES. IN RESTENOSIS A PROLIFERATION OF CELLS, FOLLOWING ANGIOPLASTY OR ATHERECTOMY CAUSES THE LESION TO REFORM - THE RATE OF RESTENOSIS IS GENERALLY CONSIDERED TO BE ABOUT 33%. THEREFORE IT WOULD BE DESIRABLE TO HAVE A MEANS AND A METHOD TO TREAT LESIONS WITH A REDUCED RESTENOSIS RATE - I PROPOSE A CATHETER WHICH HAS, AT ITS DISTAL END, A RADIOACTIVE SOURCE. THE SOURCE WOULD BE MANEUVERED TO THE SITE OF A LESION WHICH HAS BEEN DILATED OR REMOVED AND THE SITE WOULD BE EXPOSED TO A RADIATION DOSE THAT WOULD KILL SMOOTH MUSCLE CELLS. IF THIS CAN BE DONE IN A CONTROLLED MANNER, IT IS POSSIBLE THAT THE RAPID GROWTH OF CELLS COULD BE PREVENTED AND RESTENOSIS CONTROLLED.





Patent
Attorney's Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Robert L. HESS)
)
Application No.: [REDACTED])
)
Filed: September 5, 1991)
)
For: METHOD AND APARATUS FOR)
RESTENOSIS TREATMENT)

Group Art Unit: 3305

Examiner: J. Lacyk

#11
FD
2/24

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56,
Applicant hereby submits the following information made of record in a search report
(copy enclosed) for a corresponding PCT application.

U.S. Patent No. 4,434,788

U.S. Patent No. 4,202,323


The undersigned certifies that each item of information contained herein was cited
in a communication from a foreign patent office in a counterpart foreign application not
more than three months prior to the filing of this Information Disclosure Statement.

To assist the Examiner, the documents are listed on the attached form PTO-1449.
It is respectfully requested that an initialled copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

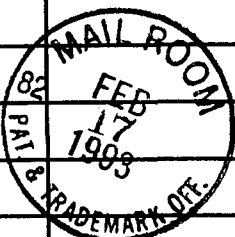
By:


Peter K. Skiff
Registration No. 31,917

The George Mason Building
Washington and Prince Streets
Post Office Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: February 17, 1993

INFORMATION DISCLOSURE CITATION				ATTY. DOCKET NO. 011683-004		SERIAL NO. 07/755,480	
PTO-1449				APPLICANT Robert L. HESS			
				FILING DATE September 5, 1991		GROUP 3305	
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
<i>ML</i>	4,202,323	5/80	Zweig et al	—	—		
<i>ML</i>	4,434,788	3/84	Nakatsugawa	—	—		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
EXAMINER	<i>ML</i>			DATE CONSIDERED 4/1/93			



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.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

07/755,480 09/05/91 HESS

R 011683-004

EXAMINER
LACYK, J

33M1

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
GEORGE MASON BUILDING, P.O. 1404
WASHINGTON AND PRINCE STS.
ALEXANDRIA, VA 22313-1404

ART UNIT PAPER NUMBER

3305

12

DATE MAILED: 05/05/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 2/17/93 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- Claims 1-6 AND 8-11 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- Claims 7, 12 have been cancelled.
- Claims _____ are allowed.
- Claims 1-6 AND 8-11 are rejected.
- Claims _____ are objected to.
- Claims _____ are subject to restriction or election requirement.
- This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- Formal drawings are required in response to this Office action.
- The corrected or substitute drawings have been received on _____ Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).
- The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).
- Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____
- Since this application appears to be 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.
- Other

EXAMINER'S ACTION

NC 000059

Serial No. 755,480

-2-

Art Unit 3305

Claims 1-6, 8 and 10 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 1, it appears that "the stenosed region" should be --A stenosed region--; also on line 3, "stenoses area" should be --stenosed region-- to remain consistent with language previously used. In claims 3, 4 and 6 on line 2, "the step" should be --a step--. In claim 5, it is unclear if "a radioactive material" is different from the radioactive does or if it is the same element; if it is the same element consistent terminology should be used. Claim 8 is the same as claim 2. In claim 10, line 3, the use of "may be removably positioned" is indefinite in that it is unclear whether the sheath is positioned over the radioactive does means or not.

The declaration under 37 CFR 1.131 has not been considered in that an originally signed copy of the declaration has not been presented. Further it should be noted that the declaration and exhibit a only show the embodiment of Figure 1 and fail to show embodiments using a stent or balloon catheter.

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.

NC 000060

Serial No. 755,480

-3-

Art Unit 3305

(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(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, 4-5 and 8-9 are rejected under 35 U.S.C.

§ 102(e) as being anticipated by Fischell et al.

Fischell discloses a device to be used after an angioplasty procedure has been performed to prevent restenosis. A radioactive stent is positioned at the site where the procedure was performed. Once the stent is in place the radioactive material contacts the tissue to prevent restenosis and allows the blood to flow through.

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

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

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 3 and 11 are rejected under 35 U.S.C. § 103 as being

NC 000061

Serial No. 755,480

-4-

Art Unit 3305

unpatentable over Fischell et al in view of Palmaz.

Palmaz discloses a stent that is used to expand the inside of a blood vessel. Palmaz discloses that it is well known to use a balloon catheter to direct the stent to the proper position and be inflated to expand the stent in position and then be withdrawn. Therefore it would have been obvious to use a balloon catheter to properly place the radioactive stent of Fischell since Palmaz teaches that this is a well known way to place a stent.

Claims 6 and 10 are rejected under 35 U.S.C. § 103 as being unpatentable over Fischell et al in view of Lemelson.

Fischell further teaches (column 2 lines 48-52) that placement of a radioactive source at the site of the vessel wall trauma by a wire with a radioactive tip can also be used.

Lemelson discloses a catheter used to administer medication or a source of radiation, etc to a selected site. Once the catheter is in positioned the source (37) is pushed out of a protective sheath (32) to treat the body portion and can be withdrawn back into the sheath when finished for proper removal. One of ordinary skill would have been motivated to use the catheter device of Lemelson for the wire and tip embodiment disclose in Fischell since this is a type of wire and tip assembly that further adds a sheath to protect the source (32) while being inserted and removed.

NC 000062

Serial No. 755,480

-5-

Art Unit 3305


Claim 9 is rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Liprie.

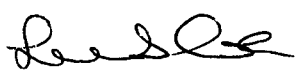
Liprie discloses a radioactive means (12) and a positioning means (14) to position the radioactive means within the body and withdraw the radioactive means when treatment is complete.

Claims 9-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lemelson.

Lemelson discloses a source of radiation (37) that uses a positioning means (30) to positioning the source within the body. Lemelson also teaches using a protective sheath (32) such that the source is pushed out of the protective sheath once the device is at the desired location. The source can be withdrawn back into the sheath when treatment is completed and withdrawn from the body.

Any inquiry concerning this communication should be directed to John P. Lacyk at telephone number (703) 308-2995.


J.P. Lacyk/pw
April 20, 1993


IFF S. COHEN
PRIMARY EXAMINER
ART UNIT 335

NC 000063

FORM PTO-892 (REV. 3-78)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO. 755480	GROUPART UNIT 3305	ATTACHMENT TO PAPER NUMBER 12
NOTICE OF REFERENCES CITED		APPLICANT(S) HESS		

U.S. PATENT DOCUMENTS							
*	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE	
A	5084002	1/29/92	LIPRIE	6000	3	8/4/88	
B							
C							
D							
E							
F							
G							
H							
I							
J							
K							

FOREIGN PATENT DOCUMENTS									
*	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG. PP. SPEC.		
L									
M									
N									
O									
P									
Q									

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)	
R	
S	
T	
U	

EXAMINER <i>Mack</i>	DATE 4/1/93
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* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

420.00 217 Gp. 3305



PATENT
ATTORNEY'S DOCKET NO. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. Hess)	Group Art Unit: 3305
)	
Application No.: 07/755,480)	Examiner: J. Lacyk
)	
Filed: September 5, 1991)	
)	
For: METHOD AND APPARATUS FOR)	
RESTENOSIS TREATMENT)	

13 / PJ
#19

PETITION FOR EXTENSION OF TIME

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

The following extension of time is requested to respond to the Office Action of May 5, 1993:

three months to November 5, 1993; the extension fee is \$ 420.00 \$ 840.00.

The shortened statutory period has been reset by an Advisory Action dated _____.

A check in the amount of \$420.00 is attached.

Charge \$ _____ to Deposit Account No. 02-4800.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

By: Peter K. Skiff
Peter K. Skiff
Registration No. 31,917

Date: November 3, 1993

050 AT 11/12/93 07755480

1 217 420.00 CK

(BDSM 26)
(2/93)

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GROUP 330

OFFICE OF THE
PRIMARY EXAMINER FOR
GROUP 330
Clerk, Group 330

ATTY Notified

C. P.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Robert L. HESS)
Serial No.: 07/755,480)
Filed: September 5, 1991)
For: METHOD AND APPARATUS FOR)
RESTENOSIS TREATMENT)

Group Art Unit: 3305

Examiner: J. Lacyk

#14 / B
FD
11-19
fee OK

AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In response to the Official Action dated May 5, 1993, the period for response having been extended until November 5, 1993 by a Petition for a Three-Month Extension of Time submitted herewith, please amend the above-identified application as follows.

IN THE CLAIMS:

Please cancel Claims 8-11 without prejudice or disclaimer of the subject matter thereof and amend Claims 1 and 3-6 as follows.

1. (Twice Amended) A method for treatment and post-treatment of [the] a stenosed [region] area of an artery comprising the steps of:
 - B' P reducing the annular stenosed area within an artery;
 - P1 advancing a radioactive dose means within the artery to the area of reduced stenosis, the radioactive dose means being operatively connected to positioning means and the advancing step being performed by moving the positioning means;

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B' pl
cont. fl

applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means; and
removing the dose means from the artery by moving the positioning means.

2
Claim 3, line 2, change "the step" to --a step--.

Claim 4, line 2, change "the step" to --a step--.

Claim 5, line 3, change "a radioactive material" to --the radioactive dose--.

Claim 6, line 2, change "the step" to --a step--.

REMARKS

Reconsideration of the Official Action dated May 5, 1993 is respectfully requested.

Claims 1 and 3-6 have been amended and Claims 8-11 have been cancelled without prejudice or disclaimer of the subject matter thereof. The amendments to Claims 1 and 3-6 incorporate the suggestions made at page 2 of the Official Action except "region" was changed to --area-- in line 1 of Claim 1 to be consistent with terminology in the dependent claims. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

At page 2 of the Official Action, it is stated that the signed Declaration under 37 C.F.R. §1.131 had not been received. However, the original of that Declaration was filed on December 22, 1992 (See "Submission of Declaration Under 37 C.F.R. §1.131" filed December 22, 1992, copy enclosed).

12

Claims 1, 2, 4, 5, 8 and 9 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,059,1666 ("Fischell"), Claims 3 and 11 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Fischell in view of U.S. Patent No. 4,733,665 ("Palmaz") and Claims 6 and 10 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Fischell in view of U.S. Patent No. 4,588,395 ("Lemelson"). These rejections are respectfully traversed on the basis that Fischell is not available as a reference against the claims of the present application. As such, all of the rejections based on Fischell should be withdrawn.

Claim 1 (the only independent claim) recites a method for treatment and post-treatment of a stenosed area of an artery comprising the steps of reducing the annular stenosed area within an artery, advancing a radioactive dose means within the artery to the area of reduced stenosis, the radioactive dose means being operatively connected to positioning means and the advancing step being performed by moving the positioning means, applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means, and removing the dose means from the artery by moving the positioning means.

Fischell relates to intra-arterial stents which are used to maintain patency of an arterial lumen typically subsequent to balloon angioplasty or atherectomy (column 1, lines 6-9 of Fischell). All of Fischell's claims are directed to an intra-arterial stent or a method of using an intra-arterial stent. Fischell discloses that the stent is fabricated from a metal or alloy which has been irradiated so that it has become radioactive and that the radioisotope used for this purpose would have a half-life between ten hours and 100 days (column 1, lines 65-68 and column 2, lines 11-13 of Fischell). Figure 1 of Fischell

shows a stent embedded within a human artery (column 1, lines 43-46 of Fischell). Fischell does not disclose any means for removing the stent. As such, the stent of Fischell is apparently meant to remain in the human body indefinitely.

Claim 1 recites a method wherein a radioactive dose means is temporarily exposed to an area of reduced stenosis and the dose means is removed from the artery by moving a positioning means operatively connected to the radioactive dose means. The disclosure of Fischell relating to the stent clearly fails to disclose or suggest the method of Claim 1. It is noted, however, that Fischell also discloses a thin wire having a radioactive tip for temporary placement of a radioactive source within an arterial lumen (column 2, lines 44-52 of Fischell). There are no claims in Fischell directed to the thin wire having the radioactive tip.

Fischell matured from an application filed on December 11, 1989. In order to remove Fischell as a reference against the claims of the present application, the original of a Declaration Under 37 C.F.R. §1.131 was filed on December 22, 1992. The Rule 131 Declaration is signed by the inventor, Robert L. Hess, and establishes that the claimed method was conceived in the United States prior to December 11, 1989. In addition, the Hess Declaration establishes that the inventor was diligent in reducing the invention to practice from prior to the December 11, 1989 filing date of Fischell until filing of the present application on September 5, 1991.



PATENT
ATTORNEY'S DOCKET NO. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Robert L. Hess)
)
Application No.: 07/755,480) Group Art Unit: 3305
)
Filed: September 5, 1991) Examiner: J. Lacyk
)
For: METHOD AND APPARATUS FOR)
RESTENOSIS TREATMENT)

15
20
11-19

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. A copy of the document cited is enclosed.

U.S. Patent No. 4,697,575

To assist the Examiner, the document is listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialled copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: Peter K. Skiff
Peter K. Skiff
Registration No. 31,917

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, VA 22313-1404
Phone: (703) 836-6620

Date: November 3, 1993

From the foregoing, it should be clear that Fischell is not available as a reference against the claims of the present application. See MPEP §715.07. In addition, the claims of the present application and the claims of Fischell are not directed to the same invention. As such, an interference between the present application and Fischell should not be declared.

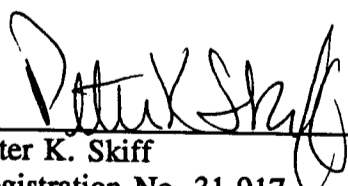
In summary, since the Rule 131 Declaration of Mr. Hess removes Fischell as a reference against the claims of the present application, it is submitted that the rejections based on Fischell in view of Palmaz and Fischell in view of Lemelson should also be withdrawn.

The remaining rejections of Claim 9 under 35 U.S.C. §102(e) over U.S. Patent No. 5,084,002 ("Liprie") and Claims 9 and 10 under 35 U.S.C. §102(b) over U.S. Patent No. 4,588,395 ("Lemelson") are moot in view of the cancellation of Claims 9 and 10.

In view of the foregoing, it is submitted that the present application is in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 
Peter K. Skiff
Registration No. 31,917

The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: November 3, 1993

INFORMATION DISCLOSURE CITATION PTO-1449			ATTY. DOCKET NO. 011683-004	SERIAL NO. 07/755,480			
			APPLICANT Robert L. Hess				
			FILING DATE September 5, 1991	GROUP 3305			
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
<i>rh</i>	4,697,575	10/87	HOROWITZ	—	—		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
EXAMINER	<i>[Signature]</i>			DATE CONSIDERED	<i>11/24/93</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.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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07/755,480 09/05/91 HESS

R 011683-004

EXAMINER
LACYK, J

33M1/1126

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
GEORGE MASON BUILDING, P.O. 1404
WASHINGTON AND PRINCE STS.
ALEXANDRIA, VA 22313-1404

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

3305

16

DATE MAILED: 11/26/93

NOTICE OF ALLOWABILITY

PART I.

- This communication is responsive to Amendment Filed 11/3/93
- All the 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 And Issue Fee Due or other appropriate communication will be sent in due course.
- The allowed claims are 1-6
- The drawings filed on 12/21/92 are acceptable.
- Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [-] been received. [-] not been received. [-] been filed in parent application Serial No. _____, filed on _____.
- Note the attached Examiner's Amendment.
- Note the attached Examiner Interview Summary Record, PTOL-413.
- Note the attached Examiner's Statement of Reasons for Allowance.
- Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
 - Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
 - The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
 - Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
 - Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- Examiner's Amendment
- Examiner Interview Summary Record, PTOL-413
- Reasons for Allowance
- Notice of References Cited, PTO-892
- Information Disclosure Citation, PTO-1449
- Notice of Informal Application, PTO-152
- Notice re Patent Drawings, PTO-948
- Listing of Bonded Draftsmen
- Other

LEE S. COHEN
PRIMARY EXAMINER
ART UNIT 3305



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

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

33M1/1126

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
GEORGE MASON BUILDING, P.O. 1404
WASHINGTON AND PRINCE STS.
ALEXANDRIA, VA 22313-1404

**NOTICE OF ALLOWANCE
AND ISSUE FEE DUE**

- Note attached communication from the Examiner
- This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/755,480	09/05/91	006	LACYK, J	3305 11/26/93
First Named Applicant: HESS, ROBERT L.				

TITLE OF INVENTION: METHOD AND APPARATUS FOR RESTENOSIS TREATMENT

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 011683-004	600-003,000	583	UTILITY	YES	\$585.00	02/28/94

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE 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.

HOW TO RESPOND 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 twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by a charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees.



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

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

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/755,480	09/05/91	HESS	R 011683-004

OF RECORD:

07M2/1203 7

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
GEORGE MASON BUILDING, P.O. 1404
WASHINGTON AND PRINCE STS.
ALEXANDRIA, VA 22313-1404

LACYK, J	
EXAMINER	
ART UNIT	PAPER NUMBER
3305	17

DATE MAILED: 12/03/93

A statement under Section 152 of Public Law 703 (83rd Congress, 2nd Session), concerning the making of the invention or discovery described therein, has been filed in the above-identified application. A copy of the application and a copy of the statement are forwarded herewith.

A statement of the date of receipt in the U.S. Department of Energy of the copy of the statement and the copy of the application is requested to determine the starting of the 90-day period recited in paragraph 2 of Section 152. An endorsed copy of this letter is provided for this purpose.

By direction of the Commissioner

For 
Special Laws Administration Group

Encl: Photo statement
Photo application
Receipt copy of this letter

Receipt in the U.S. Department of Energy is acknowledged of a copy of the above letter and its enclosure.

Date _____
THIS CORRESPONDENCE TO:

Signed _____

Assistant General Counsel
for Patents, GC-42
U.S. Department of Energy
1000 Independence Ave.
MS 6F-067
Washington, D.C. 20585



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

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

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

OF RECORD:

JAMES M. FREEDSON
 ENGINEER, SUPPLIER & INVENTOR
 GEORGE WASHINGTON BUILDING, P.O. BOX
 WASHINGTON AND BRIDGE STS.
 ALEXANDRIA, VA 22303-1404

EXAMINER	
ART UNIT	PAPER NUMBER
	418

DATE MAILED: 12/07/93

A statement under Section 152 of Public Law 703 (83rd Congress, 2nd Session), concerning the making of the invention or discovery described therein, has been filed in the above-identified application. A copy of the application and a copy of the statement are forwarded herewith.

A statement of the date of receipt in the U.S. Department of Energy of the copy of the statement and the copy of the application is requested to determine the starting of the 90-day period recited in paragraph 2 of Section 152. An endorsed copy of this letter is provided for this purpose.

By direction of the Commissioner

Special Laws Administration Group

Encl: Photo statement
Photo application
Receipt copy of this letter

This application has been reviewed and from the information at hand you are hereby advised that the U.S. Department of Energy will not file a directive in this case.

AKR

Receipt in the U.S. Department of Energy is acknowledged of a copy of the above letter and its enclosure. DEC 07 1993

DEC 06 1993

Date
THIS CORRESPONDENCE TO:

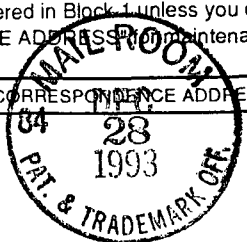
Assistant General Counsel for Patents, GC-42 U.S. Department of Energy 1000 Independence Ave. MS 6F-067 Washington, D.C. 20585

Anne L. Remsburg
 Signed Office of the Assistant General
 Counsel for Intellectual Property

PART B - ISSUE FEE TRANSMITTAL

585-242
39-56 A19B

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advanced orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**



1. CORRESPONDENCE ADDRESS JAMES W. PETERSON BURNS, DOANE, SWECKER & MATHIS GEORGE MASON BUILDING, P.O. 1404 WASHINGTON AND PRINCE STS. ALEXANDRIA, VA 22313-1404	2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
	INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	CO-INVENTOR'S NAME
	Street Address
City, State and ZIP Code	
<input type="checkbox"/> Check if additional changes are on reverse side	

921101
7560
3341/1126
12-10
AA

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/755,481	09/05/91	006	LADYK. J	3065 11/26/93
First Named Applicant	ROBERT L. HENSE			

TITLE OF INVENTION: METHOD AND APPARATUS FOR RESTENOSIS TREATMENT

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
011083-004	500-003,000	583	UTILITY	YES	\$300.00	03/28/94

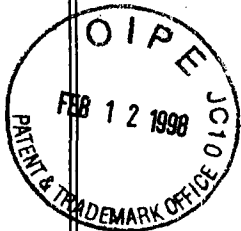
3. Further correspondence to be mailed to the following:	4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.
	1 Burns, Doane, Swecker & Mathis
	2 _____
	3 _____

DO NOT USE THIS SPACE

0970 BA 02500 07755481	1 240	235.00 CR
0970 BA 02500 07755481	1 561	39.00 CR

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)	6a. The following fees are enclosed:
(1) NAME OF ASSIGNEE:	<input checked="" type="checkbox"/> Issue Fee <input checked="" type="checkbox"/> Advanced Order - # of Copies <u>13</u>
(2) ADDRESS: (City & State or Country)	(Minimum of 10)
(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION	6b. The following fees should be charged to:
	DEPOSIT ACCOUNT NUMBER <u>02-4800</u>
	(Enclose Part C)
	<input type="checkbox"/> Issue Fee <input type="checkbox"/> Advanced Order - # of Copies _____
	<input checked="" type="checkbox"/> Any Deficiencies in Enclosed Fees (Minimum of 10)
A. <input checked="" type="checkbox"/> This application is NOT assigned.	The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.
<input type="checkbox"/> Assignment previously submitted to the Patent and Trademark Office.	(Signature of party in interest of record)
<input type="checkbox"/> Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.	James W. Peterson
PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.	(Date)
	James W. Peterson, 26,057 12/27/93
	NOTE: The Issue Fee 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 Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE



PAIC #21

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert L. Hess

Patent No.: 5,302,168

7/755480

Filed: April 12, 1994

Docket: 1944 (203-2201)

Date: February 9, 1998

For: APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

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FEB 10 1998
OFFICE OF PETITIONS
AC PATENTS

LETTER

Sir:

Enclosed herewith for filing with respect to the above-identified

application are the following:

1. Notification of Loss of Entitlement to Small Entity Status under 37 C.F.R. §1.28(b)
2. Power of Attorney by Assignee of Entire Interest (Revocation of Prior Powers); and
3. Certificate under 37 C.F.R. §3.73(b) Establishing Right of Assignee to take action.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to the: Assistant Commissioner for Patents Washington D C 20231 on February 9, 1998.

Dated: February 9, 1998

David M. Carter
David M. Carter

Practitioner's Docket No. 1944 (203-2201)

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTEE(S) : Robert L. Hess
PATENT NO. : 5,302,168
ISSUED : April 12, 1994
FOR : METHOD AND APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

NOTIFICATION OF LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
(37 C.F.R. 1.28(b))



Applicant hereby notifies the Patent and Trademark Office that it is no longer entitled to status as a small entity, and that the claim for small entity status, set forth in the verified statement filed on September 5, 1991 is hereby withdrawn.

Date 12-15-97

Thomas R. Bremer
(print or type name of person signing)

Thomas R. Bremer
Signature

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail, postpaid in an envelope, addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

on February 9, 1998
Dated: 2-9-98

David M. Carter
David M. Carter

P.O. Address of signatory **UNITED STATES SURGICAL CORPORATION**
150 Glover Avenue
Norwalk, Connecticut 06856

Inventor(s)

Assignee of Complete interest

Person authorized to sign on behalf of assignee

Practitioner of record

Filed under Rule 34(a)

Registration No.

(if applicable)

Telephone No. ()

Reg. No.

Customer No.

(complete the following, if applicable)

UNITED STATES SURGICAL CORPORATION
(type name of assignee)

150 Glover Avenue
Address of assignee

Norwalk, Connecticut 06856

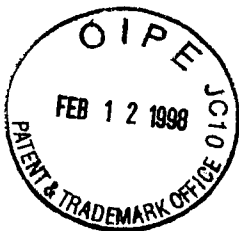
Sr. **Vice President and General Counsel**
Title of person authorized to sign on behalf of assignee

Assignment recorded in PTO _____

Reel _____ Frame _____

Note: A statement under 37 CFR 3.73(b) is not required to be submitted when the assignee signs a small entity declaration. Notice of April 30, 1993, 1150 O.G. 62-64.

NC 000080



PATENT

Practitioner's Docket No. 1944 (203-2201)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: **Robert L. Hess**

Patent No.: **5,302,168**

Issued: **April 12, 1994**

For: **METHOD AND APPARATUS FOR
RESTENOSIS TREATMENT**

Patent No.: **Listed Above**

*NOTE: Insert name(s) of inventor(s) and title also for patent.

**Assistant Commissioner for Patents
Washington, D.C. 20231**

**POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE INTEREST
(REVOCATION OF PRIOR POWERS)**

As assignee of record of the entire interest of the above identified

application,

patent,

REVOCATION OF PRIOR POWERS OF ATTORNEY

all powers of attorney previously given are hereby revoked and

**RECEIVED
1998 OCT -6 PM 12: 12
DSD/PTCS**

NEW POWER OF ATTORNEY

the following attorney(s) and/or agent(s) are hereby appointed to prosecute and transact all business in the Patent and Trademark Office connected therewith.

PETER G. DILWORTH, Reg. No. 26,450; **ROCCO S. BARRESE**, Reg. No. 25,253; **DAVID M. CARTER**, Reg. No. 30,949; **PAUL J. FARRELL**, Reg. No. 33,494; **PETER DELUCA**, Reg. No. 32,978; **FRANK CHAU**, Reg. No. 34,136; **ADRIAN T. CALDERONE**, Reg. No. 31,746; **GEORGE M. KAPLAN**, Reg. No. 28,375; **JEFFREY S. STEEN**, Reg. No. 32,063; **JOSEPH W. SCHMIDT**, Reg. No. 36,920; **RAYMOND E. FARRELL**, Reg. No. 34,816; **RUSSELL R. KASSNER**, Reg. No. 36,183; **CHRISTOPHER G. TRAINOR**, Reg. No. 39,517; **GEORGE LIKOUREZOS**, Reg. No. 40,067, **JAMES M. LOEFFLER**, Reg. No. 37,873; **WILLIAM E. LEWIS**, Reg. No. 39,274, **JAMES J. BITETTO**, Reg. No. 40,513, **JOHN G. TUTUNJIAN**, Reg. No. 39,405, and **MARK S. LEONARDO**, Reg. No. 41,433, each of them of **DILWORTH & BARRESE**, 333 Earle Ovington Boulevard, Uniondale, New York 11553 and; **JOHN C. ANDRES**, Reg. No. 30,931; **BASAM E. NABULSI**, Reg. No. 31,645; **NEIL D. GERSHON**, Reg. No. 32,225; **NEIL Y. GILBERT**, Reg. No. 35,156, and **CAROLYN BLANKENSHIP**, Reg. No. 35,449 each of them of **UNITED STATES SURGICAL CORPORATION**, 150 Glover Avenue, Norwalk, Connecticut 06856.

(check the following item, if applicable)

- Attached as part of this power of attorney, is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

John C. Andres, Esq.
UNITED STATES SURGICAL CORPORATION
150 Glover Avenue
Norwalk, Connecticut 06856

DIRECT TELEPHONE CALLS TO:

John C. Andres, Esq.
(203) 845-4018

UNITED STATES SURGICAL CORPORATION
(type or print identity of assignee of entire interest)

150 Glover Avenue
Address

Norwalk, CT 06856

Recorded in PTO on _____

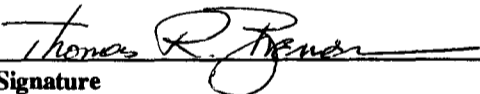
Reel _____

Frame _____

Recorded herewith

ASSIGNEE CERTIFICATION

Attached to this power is a "CERTIFICATE UNDER 37 C.F.R. 3.73(B)."


Signature

Date: 12-15-97

Thomas R. Bremer
(type or print name of person authorized to
sign on behalf of assignee)

Sr. Vice President and General Counsel
United States Surgical Corporation
Title

Note: The assignee of the entire interest may revoke previous powers and be represented by attorney of his or her selection. 37 C.F.R. 1.36.
(check the following item, if it forms a part of this power of attorney)

Added page - Authorization of attorney(s) to accept and follow instructions from representative.

Practitioner's Docket No. 1944 (203-2201)

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTEE(S) : Robert L. Hess
PATENT NO. : 5,302,168
ISSUED : April 12, 1994
FOR : METHOD AND APPARATUS FOR
RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE UNDER 37 C.F.R. 3.73(b)
ESTABLISHING RIGHT OF ASSIGNEE TO TAKE ACTION

1. The assignee(s) of the entire right, title and interest hereby seek(s) to take action in the PTO in this matter.

IDENTIFICATION OF ASSIGNEE

2. UNITED STATES SURGICAL CORPORATION

Name of assignee

Corporation

Type of assignee, e.g., corporation, partnership, university, government agency, etc.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

on February 9, 1998

Dated: 2-9-98

David M. Carter
David M. Carter

PERSON AUTHORIZED TO SIGN

3. Thomas R. Bremer
(type name of person authorized to sign on behalf of assignee)
- Senior Vice President and General Counsel
Title of person authorized to sign

I, the person signing below, aver that I am empowered to sign this statement on behalf of the assignee.

BASIS OF ASSIGNEE'S INTEREST

Ownership by the assignee is established as follows:

- A.
- An assignment from the inventor(s) of the matter identified above, which was recorded in the PTO at
Reel _____, Frame _____.
 - An assignment (document) separately being submitted for recordal herewith.

AND/OR

- B. A chain of title from the inventor(s) to the current assignee as shown below:
- From: _____
Name of inventor(s)
To: _____
Recorded in PTO: Reel _____, Fame _____
 - From: _____
Name of inventor(s) or assignee
To: _____
Recorded in PTO: Reel _____, Fame _____

3. From: _____
Name of inventor(s) or assignee

To: _____

Recorded in PTO: Reel _____, Page _____

COPIES OF DOCUMENTS IN CHAIN OF TITLE

Copies of the assignment(s) or other document(s) in the chain of title are attached as follows:

A 1 2

B 1 2 3

DECLARATIONS

I, the undersigned, have reviewed all the documents in the chain of title of the

patent application patent

reexamination or reissue

matter identified above and, to the best of my knowledge and belief, title is in the assignee identified above.

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 are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



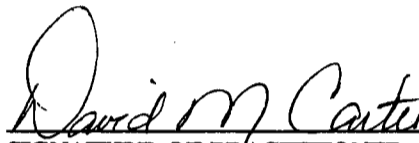
(Signature of authorized person)

Thomas R. Bremer

(type or print name of authorized person)

Sr. **Vice President and General Counsel**

Title of authorized person



SIGNATURE OF PRACTITIONER

David M. Carter

(type or print name of practitioner)

333 Earle Ovington Boulevard

P.O. Address

Uniondale, New York 11553

Reg. No. 30.949

Tel. No. (516) 228-8484

Customer No.:

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	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/755480	09/05/91	HESS	011683-004

JAMES W. PETERSON
 BURNS, DOANE, SWECKER & MATHIS
 GEORGE MASON BUILDING, P.O. 1404
 WASHINGTON AND PRINCE STS.
 ALEXANDRIA VA 22313-1404

EXAMINER
LACYK, JOHN

ART UNIT	PAPER NUMBER
3305	21

DATE MAILED: 10/06/98

PATENT NUMBER: 5302168

This is a communication from
 the Patent & Trademark Office

This is in response to the Power of Attorney filed 02/12/98

- 1. The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record. 37 CFR 1.33.
- 2. The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record. (37 CFR 1.33).
- 3. The withdrawal as attorney in this application has been accepted. Future correspondence will be mailed to the new address of record. 37 CFR 1.33.
- 4. The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the below-noted address as provided by 37 CFR 1.33.
- 5. The Power of Attorney in this application is not accepted for the reason(s) checked below:
 - a. The Power of Attorney is from an assignee and the Certificate required by 37 CFR 3.73(b) has not been received.
 - b. The person signing for the assignee has omitted their empowerment to sign on behalf of the assignee.
 - c. The inventor(s) is without authority to appoint attorneys since the assignee has intervened as provided by 37 CFR 3.71.
 - d. The signature of _____, a co-inventor in this application, has been omitted. The Power of Attorney will be entered upon receipt of confirmation signed by said co-inventor.
 - e. The person(s) appointed in the Power of Attorney is not registered to practice before the U.S. Patent & Trademark Office.
 - f. The revocation is not signed by the applicant, the assignee of the entire interest, or one particular principal attorney having the authority to revoke.

JOHN C. ANDRES, ESQ.
 UNITED STATES SURGICAL CORPORATION
 150 GLOVER AVENUE
 NORWALK CT 06856



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

Paper No. 22

John C. Andres, Esq.
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

COPY MAILED

SEP 30 1998

SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS

In re Application of :
Robert L. Hess :
Serial No. 07/755,480 : LETTER
Filed: September 5, 1991 :
Attorney Docket No. 011683-004 :

This is in response to the paper filed February 12, 1998 under 37 CFR 1.28(b) requesting that status as a Small Entity be removed.

In accordance with the request of February 12, 1998, status as a Small Entity has been removed.

The file is being forwarded to Files Repository.

Janice Ford

Janice Ford
Legal Instruments Examiner
Office of Petitions
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

NC 000089



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CHANGE OF ADDRESS/POWER OF ATTORNEY

LOCATION 9200 SERIAL NUMBER 07755480 PATENT NUMBER 5302168

THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 21839

ON 12/14/99 THE ADDRESS OF RECORD FOR CUSTOMER NUMBER 21839 IS:

BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

PTO INSTRUCTIONS: PLEASE TAKE THE FOLLOWING ACTION WHEN THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER NUMBER: RECORD, ON THE NEXT AVAILABLE CONTENTS LINE OF THE FILE JACKET, 'ADDRESS CHANGE TO CUSTOMER NUMBER'. LINE THROUGH THE OLD ADDRESS ON THE FILE JACKET LABEL AND ENTER ONLY THE 'CUSTOMER NUMBER' AS THE NEW ADDRESS. FILE THIS LETTER IN THE FILE JACKET. WHEN ABOVE CHANGES ARE ONLY TO FEE ADDRESS AND/OR PRACTITIONERS OF RECORD, FILE LETTER IN THE FILE JACKET.

PTO UTILITY GRANT

Paper Number 20

The
United
States
of
America

The Commissioner of Patents
and Trademarks

*Has received an application for a patent
for a new and useful invention. The title
and description of the invention are en-
closed. The requirements of law have
been complied with, and it has been de-
termined that a patent on the invention
shall be granted under the law.*

Therefore, this

United States Patent

*Grants to the person or persons having
title to this patent the right to exclude
others from making, using or selling the
invention throughout the United States
of America for the term of seventeen
years from the date of this patent, sub-
ject to the payment of maintenance fees
as provided by law.*



Bruce Lehman

Commissioner of Patents and Trademarks

Priscilla A. Keller

Attest

PTO-1584

NC 000091

Staple Issue Slip Here

POSITION	INIT.	DATE
CLASSIFIER	10	9-16-91
EXAMINER	297	9-25-91
TYPIST		
VERIFIER	035 JAL	9-29-91
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SPEC. HAND		
FILE MAINT.		

INDEX OF CLAIMS

Claim	Final	Original	Date
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SYMBOLS
 ✓ Rejected
 - Allowed
 (Through numeral) Canceled
 → Restricted
 N Non-elected
 I Interference
 A Appeal
 O Objected

Claim	Final	Original	Date
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SEARCHED

Class	Sub.	Date	Exmr.
600	1-8		
606	7	4/29/92	sh
updated		2/1/93	sh
updates		11/24/93	sh

94

SEARCH NOTES

	Date	Exmr.

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
600	1-8		
606	7	11/24/93	sh

APPROVED FOR LICENSE

INITIALS _____

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Entered
or
Counted

CONTENTS

Received
or
Mailed

LICENSING & REVIEW

OCT 07 1991

RECEIVED

	1. Application <u>4 parts</u> papers.	
	2. <u>45 Day Letter (152)</u>	27 SEP 1991
	3. <u>Access Acknowledgement</u>	10-22-91
	4. <u>Statement (152)</u>	NOV. 6, 1991 OK
	5. <u>Prior Art</u>	3-16-92
4/29	6. <u>Req 3 no</u>	9/24/92 1992
	7. <u>Declaration</u>	10/22/92
	8. <u>Formal Drawings</u>	12/21/92
	9. <u>Extension 2 no.</u>	12/21/92 ^{cor} 12/21
1/21	10. <u>Amdt A</u>	12/21/92
2/24	11. <u>Prior Art</u>	2-17-93
4-8	12. <u>Req 3 no</u>	May 5 1993
	13. <u>Extension 3 no.</u>	11-3-93 ^{off} 11-5
11/19	14. <u>Amdt B</u>	11-3-93
	15. <u>Prior Art</u>	11-3-93
	16. <u>Fee 3 allowed</u>	11-26-93
	17. <u>90 Day Statement - Doc</u>	12/3/93
	18. <u>Fee 3 claimer</u>	12/8/93
	19. <u>Issue Fee</u>	12-28-93
	20. <u>PTOGRANT APR 12 1994</u>	
	21. <u>Change In Status</u>	2-12-98
	22. <u>Letter Entity</u>	9/30/98
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