ISSUE CLASSIFICATION	Class	Subclass
	600	

SCANNED 6

UTILITY SERIAL NUMBER	PATENT DATE	PATENT NUMBER

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
08/850,073 ✓ REISSUE	05/02/97	600		3309 3311	Lamb

APPLICANTS

ROBERT L. HESS, PORTOLA VALLEY, CA.

CONTINUING DATA********

VERIFIED

THIS APPLN IS A RE OF 08/219,179 03/28/94 PAT 5,411,466
WHICH IS A CON OF 07/755,480 09/05/91 PAT 5,302,168

FOREIGN/PCT APPLICATIONS********

VERIFIED no

FOREIGN FILING LICENSE GRANTED 09/23/97

Foreign priority claimed 35 USC 119 conditions met	Verified and Acknowledged	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
☐ yes ☒ no ☐ yes ☒ no	Examiner's initials	→	CA	4	19	5	$930.00	016565-049

ADDRESS

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TITLE

APPARATUS FOR RESTENOSIS TREATMENT

U.S. DEPT. OF COMM./ PAT. & TM—PTO-436L (Rev.12-94)

PARTS OF APPLICATION FILED SEPARATELY	Applications Examiner

NOTICE OF ALLOWANCE MAILED	Assistant Examiner	CLAIMS ALLOWED: Total Claims	Print Claim
		42	6

ISSUE FEE: Amount Due	Date Paid	Primary Examiner	DRAWING: Sheets Drwg.	Figs. Drwg.	Print Fig.
			4	9	1

Label Area

PREPARED FOR ISSUE

ISSUE BATCH NUMBER

Form PTO-436A (Rev. 8/92)

NC 000095

SCANNED QC

(FACE)

109-160.02

PATENT
Attorney Docket No. 016565-049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)
U.S. Patent No. 5,411,466	)
Robert L. HESS	)
Issued: May 2, 1995	)
Serial No.: 08/219,179	)
Filed: March 28, 1994	)
Title: APPARATUS FOR RESTENOSIS TREATMENT	)

TRANSMITTAL LETTER FOR APPLICATION FOR REISSUE OF UNITED STATES UTILITY PATENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for fling is an application for reissue of United States Letters Patent No. 5,411,466 issued to Robert L. Hess on May 2, 1995.

Enclosed are the following documents:

- The reissue application in the form of a copy of the original Letters Patent No. 5,411,466, along with new Claims 6-19;
- A Declaration as required by 37 C.F.R. §1.172(a);
- An Order for a Title Report (including a request that the required fee be charged to Deposit Account No. 02-4800);
- An Offer to Surrender Original Patent.
- Statement

Also enclosed is the basic filing fee of $770.

It is requested that all future correspondence relating to this application for reissue of United States Letters Patent No. 5,411,466 be addressed to:

James W. Peterson
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
Post Office Box 1404
Alexandria, Virginia 22313-1404

Address all telephone calls to :

Peter K. Skiff at (703) 836-6620

The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §§1.16, 1.17 and 1.19 which may be required, and to credit any overpayment, to our Deposit Account No. 02-4800. A duplicate copy of this letter is attached.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Peter K Skiff

Peter K. Skiff
Registration No. 31,917

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Date: 5-2-97

United States Patent [19]

Hess

[11] **Patent Number: 5,411,466**

[45] **Date of Patent: May 2, 1995**

[54] **APPARATUS FOR RESTENOSIS TREATMENT**

[75] Inventor: **Robert L. Hess**, 222 Wyndham Dr., Portola Valley, Calif. 94025

[73] Assignee: **Robert L. Hess**, Menlo Park, Calif.

[21] Appl. No.: **219,179**

[22] Filed: **Mar. 28, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 755,480, Sep. 5, 1991, Pat. No. 5,302,168.

[51] **Int. Cl.**[6] **A61N 5/00**

[52] **U.S. Cl.** **600/3; 606/7**

[58] **Field of Search** 600/1-8; 606/7

[56] **References Cited**

U.S. PATENT DOCUMENTS

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Primary Examiner—Lee S. Cohen
Assistant Examiner—John P. Lacyk
Attorney, Agent, or Firm—Burns, Doane, Swecker & Mathis

[57] **ABSTRACT**

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.

5 Claims, 4 Drawing Sheets

770-101 A/Reissue

APPARATUS FOR RESTENOSIS TREATMENT

This application is a continuation of application Ser. No. 07/755,480, filed Sep. 5, 1991, now U.S. Pat. No. 5,302,168.

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 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 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 to potentially have some value in reducing restenosis rates. See, for example, U.S. Pat. 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 balloon, upon inflation of the balloon in order to ideally fuse together fragmented segments of tissue. U.S. Pat. No. 4,733,655 to Palmaz discloses an expansible vascular graft which is expanded within a blood vessel by an angioplasty balloon to dilate and 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 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 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 provide a unique method and apparatus to reduce the restenosis rate of occurrence following an angioplasty or like-intended procedure.

SUMMARY OF THE INVENTION

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 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 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 of:

reducing the annular stenosed area within an artery; and

applying a radioactive dose to the area of reduced stenosis.

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

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

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.

DESCRIPTION OF THE DRAWING

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 insertion and removal, the sheath being withdrawn to expose the radioactive element at the lesion site.

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.

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.

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

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.

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

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 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 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 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.

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 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 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 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 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 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 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 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 device 72 includes an inflatable balloon dilation catheter to position stent 74 within lesion 76.

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

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.

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.

What is claimed is:

1. Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means for emitting radiation; and

positioning means operatively connected to said dose means 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, the positioning means further including an angioplasty balloon, said radioactive dose means being connected to said balloon and moveable into contact with the stenosed region by expansion of said balloon.

2. The apparatus of claim 1, wherein the radioactive dose means comprises a plurality of radioactive sources distributed around the balloon.

3. Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means for emitting radiation; and

positioning means operatively connected to said dose means 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, the positioning means including a retractable sheath which may be removably positioned over said radioactive dose means and the dose means being located in a housing having a cut-out in a sidewall thereof, the dose means being exposed to the stenosed region by moving the sheath from a first position wherein the cut-out is covered by the sheath to a second position wherein the cut-out is not covered by the sheath.

4. The apparatus of claim 3, wherein the housing is a wirewound housing.

5. Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means for emitting radiations; and

positioning means operatively connected to said dose means 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, the positioning means including a retractable remotely activated cover which may be removably positioned over said radioactive dose means and the dose means being located in a housing having an opening therein, the dose means being exposed to the stenosed region by moving the remotely activated cover from a first position wherein the opening is covered by the remotely activated cover to a second position wherein the opening is not covered by the remotely activated cover.

SUB B1 A1

6. Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

radioactive dose means for emitting radiation; and

positioning means operatively connected to said dose means for advancing said dose means and removably positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery after said radioactive dose means is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

7. The apparatus of Claim 6, wherein the dose means is in solid form.

8. The apparatus of Claim 6, wherein the dose means is in liquid form.

9. The apparatus of Claim 6, wherein the dose means is in gaseous form.

10. Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

a radiation source; and

a catheter adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to withdraw said radiation source from the artery after said radiation source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

11. The apparatus of Claim 10, wherein the radiation source is in solid form.

12. The apparatus of Claim 10, wherein the radiation source is in liquid form.

13. The apparatus of Claim 10, wherein the radiation source is in gaseous form.

14. The apparatus of Claim 10, wherein the catheter includes a balloon.

15. The apparatus of Claim 14, wherein the catheter includes a first lumen in fluid communication with the balloon.

16. The apparatus of Claim 15, wherein the catheter includes a second lumen in fluid communication with perfusion holes which allow perfusion of blood in the artery during inflation of the balloon.

17. The apparatus of Claim 10, wherein the radiation source provides a radiation dose to the stenosed region sufficient to retard proliferation of smooth muscle cells at the stenosed region.

18. The apparatus of Claim 10, wherein the catheter comprises a balloon catheter capable of performing angioplasty and the post-treatment.

SUB A4 E1-5

19. The apparatus of Claim 10, wherein the catheter is capable of reducing the stenosed region and performing the post-treatment.

add A5

add B7

Add C3

add E7

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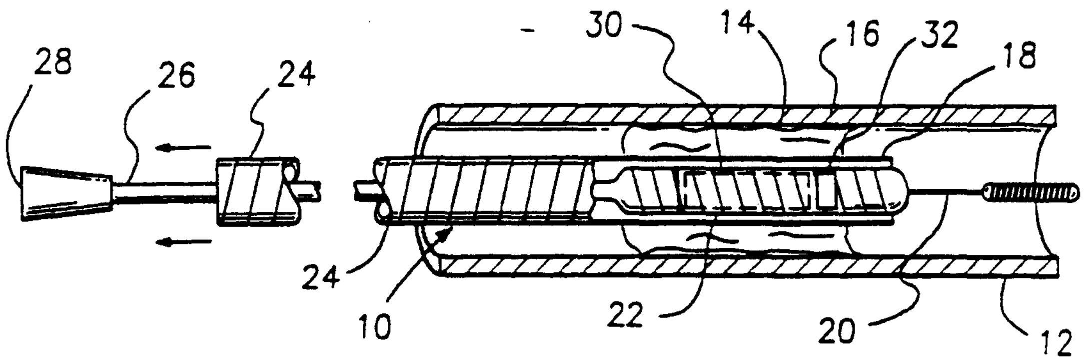

FIG. 1

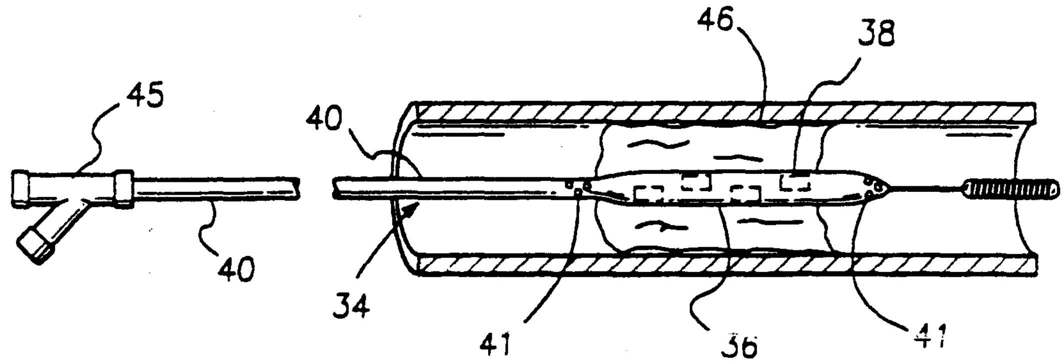

FIG. 2

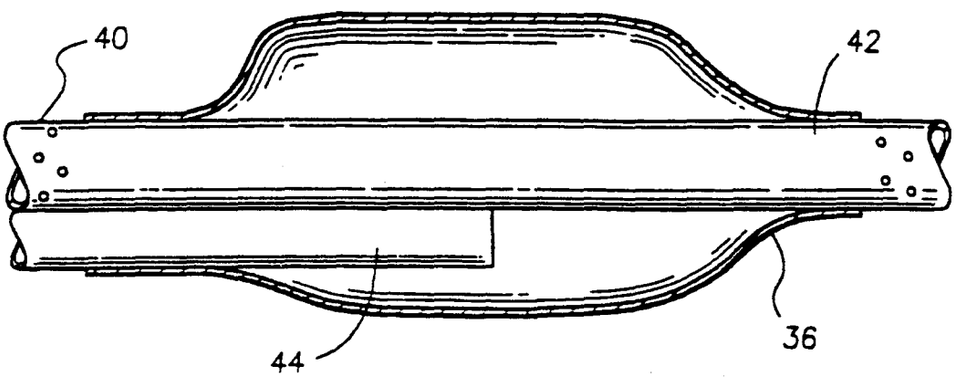

FIG. 3

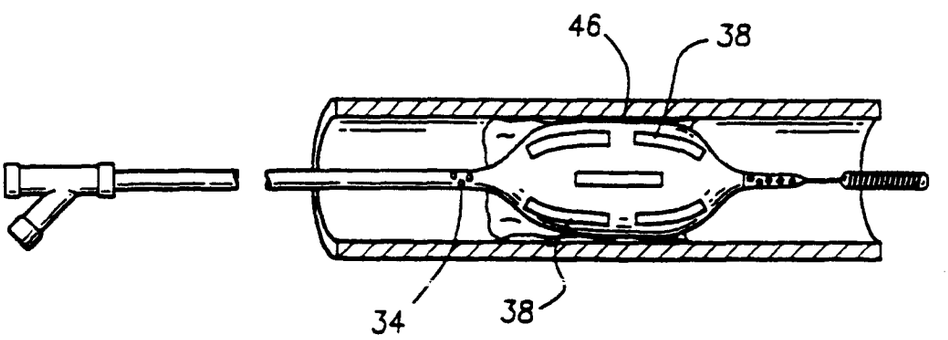

FIG. 4

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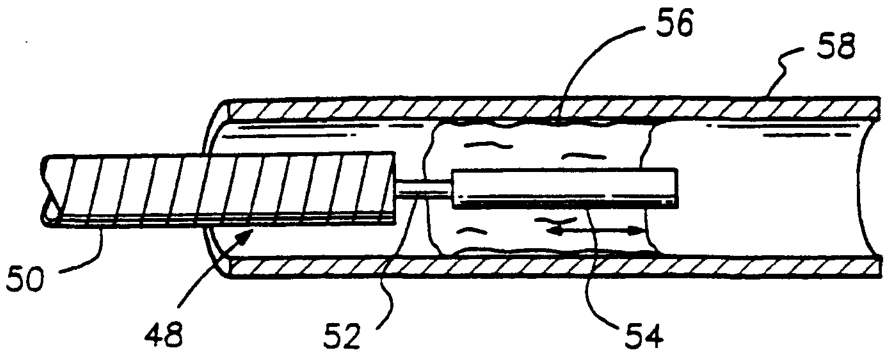

FIG. 5

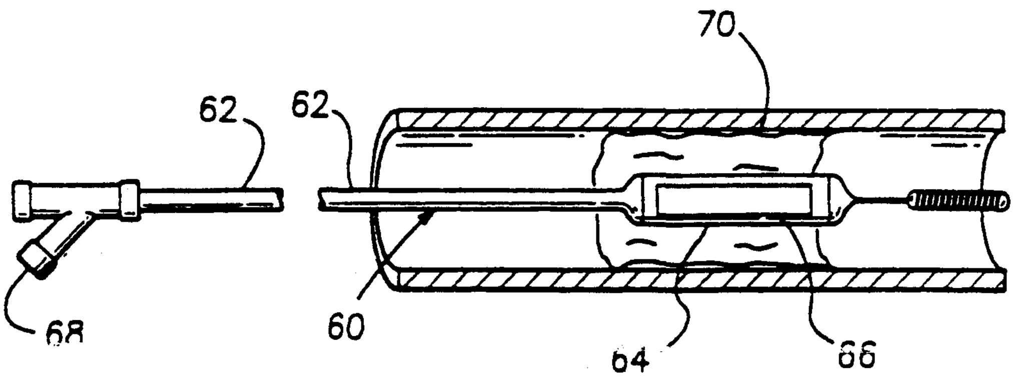

FIG. 6

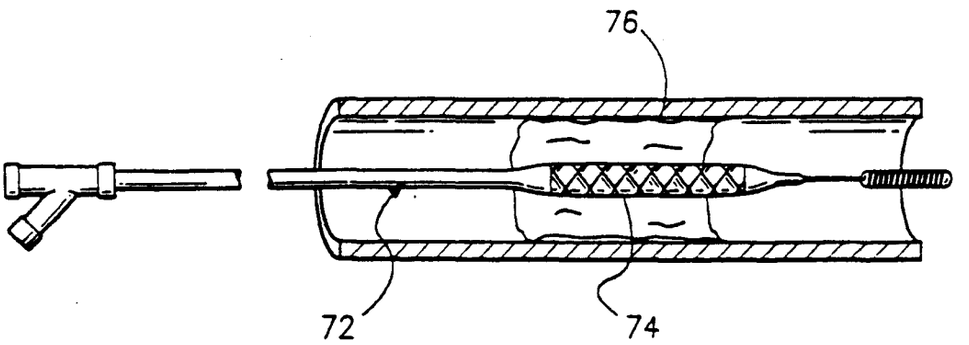

FIG. 7

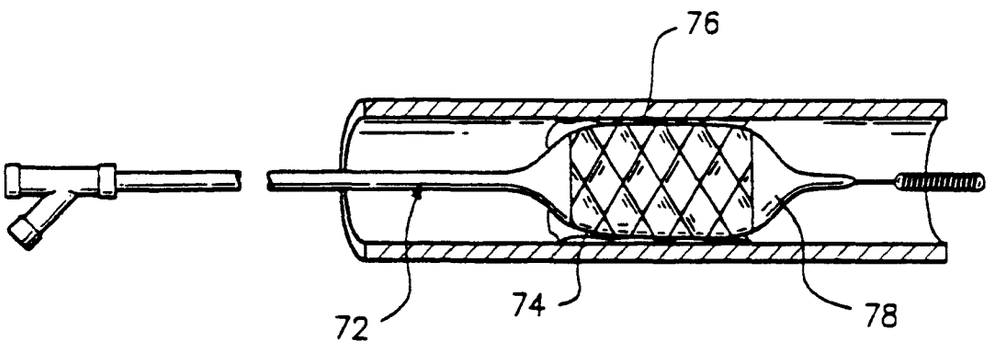

FIG. 8

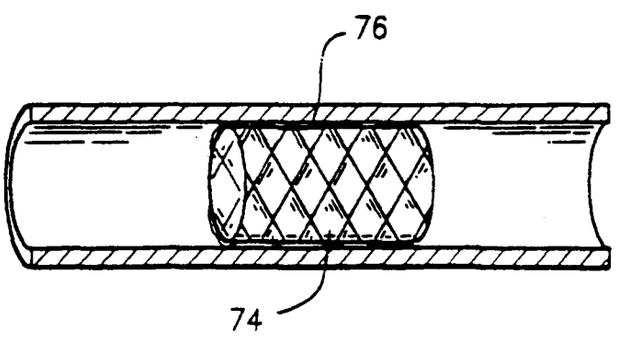

FIG. 9

PATENT
Attorney Docket No. 016565-049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)
	)
U.S. Patent No. 5,411,466	)
	)
Robert L. HESS	)
	)
Issued: May 2, 1995	)
	)
Serial No.: 08/219,179	)
	)
Filed: March 28, 1994	)
	)
Title: APPARATUS FOR RESTENOSIS TREATMENT	)

DECLARATION AND POWER OF ATTORNEY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Robert L. HESS, the above-named inventor, hereby declare that:

I am a citizen of the United States, and my residence is 35 Tages Court, Portola Valley, California 94025.

I verily believe myself to be the original, first inventor of the invention described and claimed in U.S. Letters Patent No. 5.411.466 ("the '466 patent") and for which invention I solicit a Reissue Patent.

I have reviewed and understand the contents of the specification and the claims of the Reissue Application. I have also reviewed and understand the contents of the original

specification of Serial No. 08/219,179, filed March 28, 1994 as a continuation of Serial No. 07/755,480 filed September 5, 1991.

I do not know and do not believe that said invention was ever known or used in the United States of America before my invention thereof.

I acknowledge my duty to disclose all information known to me which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

PETITIONER further declares the following:

I verily believe the '466 patent may be at least partly inoperative or invalid for the reason that I claimed less than I had a right to claim in the '466 patent.

The error in claiming less than I had a right to claim in the '466 patent was discovered as a result of discussions between myself and my attorney, Peter K. Skiff, during April and May of 1997. During these discussions, it was discovered that Claim 1 of the '466 patent may be unduly limiting by reciting in lines 12-13 that the positioning means includes an angioplasty balloon. Petitioner now realizes that it was error not to include in the original patent, claims which are not limited to a positioning means including an angioplasty balloon. Petitioner also now realizes that it was error to not specifically claim various advantageous aspects of the disclosed invention.

New Claim 6 is similar to Claim 1 of the '466 patent but omits the feature of the angioplasty balloon. New Claims 7-9 recite that the dose means is in solid form, liquid form and gaseous form, respectively, features disclosed at column 4, lines 4-12 of the '466 patent. New Claim 10 is similar to Claim 1 of the '466 patent but omits the feature of the angioplasty balloon, recites --a radiation source-- rather than "radioactive dose means for emitting radiation" and recites --a catheter-- rather than "positioning means". New Claims 11-13 recite that the radiation source is in solid form, liquid form and gaseous form, respectively, as disclosed at column 4, lines 4-12 of the '466 patent. New Claim 14 recites that the catheter includes a balloon as disclosed at column 3, lines 41-59 of the '466 patent. New Claim 15 recites that the catheter includes a first lumen in fluid communication with the balloon as disclosed at column 3, lines 45-54 of the '466 patent. New Claim 16 recites that the catheter includes a second lumen in fluid communication with perfusion holes which allow perfusion of blood in the artery during inflation of the balloon as disclosed at column 2, lines 53-58 and column 3, lines 45-51 of the '466 patent. New Claim 17 recites that the radiation source provides a radiation dose to the stenosed region sufficient to retard proliferation of smooth muscle cells at the stenosed region as disclosed at column 2, lines 13-20 and column 4, lines 54-66 of the '466 patent. New Claim 18 recites that the catheter comprises a balloon catheter capable of performing angioplasty and the post-treatment as disclosed at column 2, lines 53-58 and column 4, line 55 through column 5, line 2 of the '466 patent. New Claim 19 recites that the catheter is capable of reducing the stenosed region and performing the post-treatment as disclosed at column 4, line 55 through column 5, line 2 of the '466 patent.

After becoming aware of the aforementioned errors, the present application for reissue of the '466 patent was promptly prepared.

2 I hereby appoint James W. Peterson, Registration No. 26,057 and Peter K. Skiff, Registration No. 31,917 as my principal attorneys, with full power of substitution and revocation, to appoint other principal and associate attorneys, to prosecute this application, and to transact all business in the Patent and Trademark Office connected with this application.

Please address all correspondence to:

James W. Peterson
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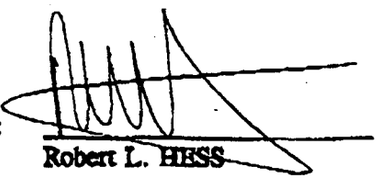
Post Office Box 1404
Alexandria, Virginia 22313-1404

Address all telephone calls to :

Peter K. Skiff at (703) 836-6620

I further 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 statement may jeopardize the validity of the application or any patent issuing thereon.

Dated: 21 July 97

By: 
Robert L. HESS

A/D

PATENT
Attorney Docket No. 016565-049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of		)
U.S. Patent No. 5,411,466		)
Robert HESS		)
Issued:	May 2, 1995	)
Serial No.:	08/219,179	)
Filed:	March 28, 1994	)
Title:	APPARATUS FOR RESTENOSIS TREATMENT	)

REQUEST FOR TITLE REPORT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please prepare and file a title report on U.S. Patent No. 5,411,466 in this Reissue Application. Please charge the costs for this service to our Deposit Account No. 02-4800 in the name of BURNS, DOANE, SWECKER & MATHIS, L.L.P., P.O. Box 1404, Alexandria, Virginia, 22313.

06/23/1997 MVILLARI 00000028 DA#102480 08850073
03 FC:570 25.00 CH

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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

P.O. Box 1404
Alexandria, Virginia 22313-1404
Phone No.: (703) 838-6620

Dated: May 2, 1997

PATENT
Attorney Docket No. 016565-049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)
	)
U.S. Patent No. 5,411,466	)
	)
Robert HESS	)
	)
Issued: May 2, 1995	)
	)
Serial No.: 08/219,179	)
	)
Filed: March 28, 1994	)
	)
Title: APPARATUS FOR RESTENOSIS TREATMENT	)

OFFER TO SURRENDER ORIGINAL LETTERS PATENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant hereby offers to surrender Original U.S. Letters Patent No. 5,411,466.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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

P.O. Box 1404
Alexandria, Virginia 22313-1404
Phone No.: (703) 838-6620

Dated: May 2, 1997

PATENT
Attorney Docket No. 016565-049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)
	)
U.S. Patent No. 5,411,466	)
	)
Robert HESS	)
	)
Issued: May 2, 1995	)
	)
Serial No.: 08/219,179	)
	)
Filed: March 28, 1994	)
	)
Title: APPARATUS FOR RESTENOSIS TREATMENT	)

REQUEST FOR TRANSFER OF DRAWINGS
FROM PATENT FILE OF U.S. PATENT NO. 5,411,466

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please transfer the formal drawings (Figures 1-9) from the patent file of U.S. Patent No. 5,411,466 to the present Reissue Application.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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

P.O. Box 1404
Alexandria, Virginia 22313-1404
Phone No.: (703) 838-6620

Dated: May 2, 1997

PATENT
Attorney Docket No. 016565-049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)
	)
U.S. Patent No. 5,411,466	)
	)
Robert L. HESS	)
	)
Issued: May 2, 1995	)
	)
Serial No.: 08/219,179	)
	)
Filed: March 28, 1994	)
	)
Title: APPARATUS FOR RESTENOSIS TREATMENT	)

STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The Examiner is advised that the reissue application filed herewith includes new Claims 8 and 12 which recite that a radioactive dose means (Claim 8) or radiation source (Claim 12) is in liquid form. Reissue Claims 8 and 12 are thus directed to subject matter which corresponds to at least the subject matter of Claim 1 of U.S. Patent No. 5,616,114 issued to Thornton et al. on April 1, 1997.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Peter K Skiff

Peter K. Skiff
Registration No. 31,917

Post Office Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: 5-2-97

FORM PTO-122
(REV. 12-87)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

TITLE REPORT

PAPER NO. 2

A. APPLICATION FILE DATA

1. SERIAL NO. 08/850073

2. FILED 5-2-97

3. INVENTOR(S)—FULL NAME(S)

Robert L. Hess

4. DIVISION OF

5. CONTINUATION OF

6. REISSUE OF 5,411,466

7. SUBSTITUTE OF

B. ASSIGNMENT RECORD DATA

The assignment records reveal that the Title appears to be vested in:

☐ (1.) Inventor(s)

☐ (2.) As endorsed

☐ (3.) As the record now stands, the patent, when granted, will issue in the name of the inventor(s).

☐ (4.) Other

EXAMINED UP TO AND INCLUDING	THIS CERTIFICATE DATED ➧	9-18-97

BRANCH CHIEF OF ASSIGNMENT SEARCH BRANCH Joanne Rawls

#3

DAC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert L. Hess

Serial No.: 08/850,073

Filed: May 2, 1997 Docket: 1944 CON RE (203-2201 CON RE)

Date: February 9, 1998

For: APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

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 CON Re. (203-2201 CON Re.) PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S)	:	Robert L. Hess
SERIAL NO.	:	08/850,073
ISSUED	:	May 2, 1997
FOR	:	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

[ ] Inventor(s)

[ ] Assignee of Complete interest

[X] 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.

#4

PATENT

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

[X] In re patent of: **Robert L. Hess**

Serial No.: **08/850,073**

Filed: **May 2, 1997**

For: **APPARATUS FOR RESTENOSIS TREATMENT**

[ ] Patent No.*:

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

Assistant Commissio. 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

[X] application,

[ ] patent,

REVOCATION OF PRIOR POWERS OF ATTORNEY

all powers of attorney previously given are hereby revoked and

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
333 Earle Ovington Boulevard
Uniondale, New York 11553

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 _____

[X] Recorded herewith

ASSIGNEE CERTIFICATION

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

Thomas R. Bremer
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 CON Re. (203-2201 CON Re.) PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S)	:	Robert L. Hess
SERIAL NO.	:	08/850,073
FILED	:	May 2, 1997
FOR	:	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

[X] 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.

1. [ ] An assignment from the inventor(s) of the matter identified above, which was recorded in the PTO at

Reel _____, Frame _____.

2. [X] 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:

1. From:_____
Name of inventor(s)

To:_____

Recorded in PTO: Reel _____, Fame _____

2. 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 _____, Fame _____

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

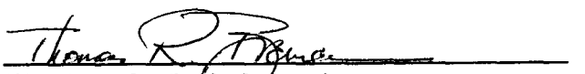
I, the undersigned, have reviewed all the documents in the chain of title of the

[X] 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

Reg. No. 30.949

David M. Carter
(type or print name of practitioner)

Tel. No. (516) 228-8484

333 Earle Ovington Boulevard
P.O. Address

Customer No.:

Uniondale, New York 11553

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

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/850072	05/02/97	HESS	U06565-049

EXAMINER	
LACYK, JOHN P	
ART UNIT	**PAPER NUMBER**
3736	5

JAMES W PETERSON
BURNS DOANE SWECKER & MATHIS
POST OFFICE BOX 1404
ALEXANDRIA VA 22313-1404

DATE MAILED: 11/10/98

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.

This is a communication from the
Patent and Trademark Office

☑ 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
333 EARLE OVINGTON BOULEVARD
UNIONDALE, NY 11553

This is a communication from the
Patent and Trademark Office

NC 000131

PTOL-305 (REV. 10-94) RETAIN THIS COPY IN THE APPLICATION FILE COPY A

FORM PTO 948 (REV. 01-97) U.S. DEPARTMENT OF COMMERCE-Patent and Trademark Office Application No. 850073

NOTICE OF DRAFTPERSON'S PATENT DRAWING REVIEW

The drawing filed (insert date) 5/2/97. are:

A. _____ not objected to by the Draftperson under 37 CFR 1.84 or 1.152.

B. ✓ objected to by the Draftperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings whe necessary. Corrected drawings must be submitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - _____ Color drawing are not acceptable until petition is granted. Fig.(s) _____
   - _____ Pencil and non black ink is not permitted. Fig(s)_____
2. PHOTOGRAPHS. 37 CFR 1.84(b)
   - _____ Photographs are not acceptable until petition is granted,
   - _____ 3 full-tone sets are required. Fig(s)_____
   - _____ Photographs not properly mounted (must brystol board or photographic double-weight paper). Fig(s)_____
   - _____ Poor quailty (half-tone). Fig(s)_____
3. TYPE OF PAPER. 37 CFR 1.84(e)
   - _____ Paper not flexible, strong, white and durable. Fig.(s)_____
   - ✓ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not acceptable. (~~too thin~~)
   - _____ Mylar, vellum paper is not acceptable (too thin). Fig(s)_____
4. SIZE OF PAPER. 37 CFR 1.84(F): Acceptable sizes:
   - _____ 21.0 cm by 29.7 cm (DIN size A4)
   - _____ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - _____ All drawings sheets not the same size. Sheet(s)_____
5. MARGINS. 37 CFR 18.4(g): Acceptable margins:
   - Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size
   - Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11
   - _____ Margins not acceptable. Fig(s)_____
   - _____ Top (T) _____ Left (L)
   - _____ Right (R) _____ Bottom (B)
6. VIEWS. CFR 1.84(h)
   REMINDER: Specification may require revision to correspond to drawing changes.
   - _____ Views connected by projection lines or lead lines. Fig.(s)_____

   Partial views. 37 CFR 1.84(h)(2)
   - _____ Brackets needed to show figure as one entity. Fig.(s)_____
   - _____ Views not labeled separately or properly. Fig.(s)_____
   - _____ Enlarged view not labeled separately or properly. Fig.(s)_____
7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3)
   - _____ Hatching not indicated for sectional portions of an object. Fig.(s)_____
   - _____ Sectional designation should be noted with Arabic or Roman numbers. Fig.(s)_____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - _____ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned, so that the top becomes the right side, except for graphs. Fig.(s)_____
   - _____ Views not on the same plane on drawing sheet. Fig.(s)_____
9. SCALE. 37 CFR 1.84(k)
   - _____ Scale not large enough to show mechansim with crowding when drawing is reduced in size to two-thirds in reproduction. Fig.(s)_____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
    - _____ Lines, numbers & letters not uniformly thick and well defined, clean, durable and black (poor line quality). Fig.(s)_____
11. SHADING. 37 CFR 1.84(m)
    - _____ Solid black areas pale. Fig.(s)_____
    - _____ Solid black shading not permitted. Fig.(s)_____
    - _____ Shade lines, pale, rough and blurred. Fig.(s)
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.48(p)
    - _____ Numbers and reference characters not plain and legible. Fig.(s)_____
    - _____ Figure legends are poor. Fig.(s)_____
    - _____ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(3) Fig.(s)_____
    - _____ Engligh alphabet not used. 37 CFR 1.84(p)(3) Fig.(s)_____
    - _____ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig.(s)_____
13. LEAD LINES. 37 CFR 1.84(q)
    - _____ Lead lines cross each other. Fig.(s)_____
    - _____ Lead lines missing. Fig.(s)_____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.48(t)
    - _____ Sheets not numbered consecutively, and in Ababic numerals beginning with number 1. Fig.(s)_____
15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
    - _____ Views not numbered consecutively, and in Abrabic numerals, beginning with number 1. Fig.(s)_____
16. CORRECTIONS. 37 CFR 1.84(w)
    - _____ Corrections not made from PTO-948 dated _____
17. DESIGN DRAWINGS. 37 CFR 1.152
    - _____ Surface shading shown not appropriate. Fig.(s)_____
    - _____ Solid black shading not used for color contrast. Fig.(s)_____

COMMENTS

REVIEWER Tavel DATE 9/25/97 TELEPHONE NO. 703 305 8404

ATTACHMENT TO PAPER NO. 6

PTO COPY

NC 000132

☆ U.S. GOVERNMENT PRINTING OFFICE: 1996-411-896

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

FORM PTO-892 (REV. 2-92)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
NOTICE OF REFERENCES CITED		08/850,073	3736	
		APPLICANT(S) HESS		

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	3165092	2/65	SILVERMAN	—	—	
	B	4202323	5/80	ZWICK et al	—	—	
	C	4434795	3/84	NAKATSUGAWA	—	—	
	D	4697575	10/87	HOROWITZ	—	—	
	E	4733665	3/88	PALMAZ	—	—	
	F	4815449	3/89	HOROWITZ	—	—	
	G	4878492	11/89	SINOFSKY	—	—	
	H	5019075	5/91	SPEARS	—	—	
	I	5059166	10/91	FISCHELL et al	—	—	
	J						
	K						

FOREIGN PATENT DOCUMENTS

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

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

R	
S	
T	
U	

EXAMINER	DATE	
		NC 000133

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

BET
7.16.99
#7 CHANGE OF ADDRESS

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Robert L. Hess EXAMINER:

SERIAL NO.: 08/850,073 GROUP ART UNIT: 3750

FILED: May 2, 1997 DOCKET: 203-2201 CON RE (1944 CON RE)

FOR: APPARATUS FOR RESTENOSIS TREATMENT DATED: May 5, 1999

RECEIVED
MAY 25 1999
Group 3700

Assistant Commissioner for Patents
Washington, D.C. 20231

CHANGE OF ATTORNEY'S ADDRESS IN APPLICATION

Sir:

FAX RECEIVED
MAY 05 1999
Group 3700

Please send all correspondence for this application to:

John C. Andres, Esq.
Vice President and General Counsel
United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

Respectfully submitted,

Christopher G. Trainor

DILWORTH & BARRESE
333 Earle Ovington Blvd.
333 Earle Ovington Boulevard
Uniondale, NY 11553
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Attorney for Applicant(s)

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below. Total Number of Pages Sent: 1.

Christopher G. Trainor
Type or Print Name of Person Signing Certification

Christopher G. Trainor
Signature

May 5, 1999
Date

UNITED STATE)EPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Jn

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/850,073	05/02/97	HESS	R 016565-049

QM12/0407

John C. Andres
Vice President and General Counsel
150 Glover Avenue
Norwalk CT 06856

EXAMINER	
LACYK,J	
ART UNIT	**PAPER NUMBER**
3736	8

DATE MAILED: 04/07/00

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

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

U.S. G.P.O. 1999 460-693

1- File Copy

NC 000135

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

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

65

DATE MAILED:

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

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

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

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

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☒ Claim(s) 1-5 is/are allowed.
☒ Claim(s) 6-19 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

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

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

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

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

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

NC 000136

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Claims 14-19 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 16, line 3, "perfusion holes" lacks positive antecedent basis. Claim 17 is directed to the intended use of the radioactive dose and fails to further limit the apparatus. In claims 18-19 the use of "capable of" is indefinite in that it is unclear whether the function is performed or not. Claims 14 and 18-19 appear to add the balloon into the claim, however as discussed in the declaration and looking at the claims this merely appears to be adding back in what was removed from the claims for these new claims, thereby making it unclear how these are not duplicates of the existing independent claims.

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

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Van't Hooft.

4. Claims 6-7, 10-11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Liprie.

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

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

6. Claims 8-9,12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie in view of Zoumboulis.

Liprie discloses the claimed device except for the specific use of the radioactive dose in a liquid or gaseous form. Zoumboulis teaches that it is well known to use a radioactive substance in a form other than solid, i.e. liquid. Therefore a modification of Liprie such that the radioactive dose is in any well known and conventionally used form would have been obvious to one skilled in the art.

7. Claims 1-5 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (703) 308-2995.

J.P.Lacyk

April 4, 2000

JOHN P. LACYK
PRIMARY EXAMINER

Notice of References Cited

Application No.	Applicant(s)		
08/550,073	Hess		
Examiner	**Group Art Unit**	**Page**	
LACyk	3736	1 of 1	

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
	A	5084002	1/28/92	LIPKE	600	3
	B	4881 938	11/21/89	VANTHOFF	600	3
	C	3324847	6/13/67	ZOUMBOULIS	600	3
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

* A copy of this reference is not being funished with this Office action.
(See Manual of Patent Examining Procedure, Section 707.05(a).)

#9/A

PATENT

Atty. Docket No. 1944 CON RE (203-2201 CON RE)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Robert L. Hess	**GROUP ART UNIT:**	3736
SERIAL NO. :	08/850,073	**EXAMINER:**	John P. Lacyk
FILED:	May 2, 1997	**Dated:**	June 22, 2000

FOR: APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT UNDER C.F.R. § 1.111

Sir:

In response to the Office Action of the U.S. Patent and Trademark Office mailed April 7, 2000, please amend the above-identified application as follows:

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 June 22, 2000

Dated: June 22, 2000

Harold G. Furlow

Harold G. Furlow

06/30/2000 JADD01 00000010 08850073
01 FC:103 126.00 OP

IN THE CLAIMS:

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

radioactive dose means for emitting radiation;

a device positioned in spaced relation to the dose means; and

positioning means operatively connected to said device [dose means] for advancing said device and dose means [and removably positioning said dose means] within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein in the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery, said positioning means being operatively connected to said device and dose means for withdrawing said device and dose means from the artery after said radioactive dose means is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

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

a radiation source; and

a catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said

A2

catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

A3

14. (Amended) The apparatus of Claim 10, wherein the catheter includes a balloon, the catheter defining at least one hole distal to the balloon and at least one hole proximal to the balloon.

16. (Amended) The apparatus of Claim 15, wherein the catheter defines a plurality of perfusion holes and includes a second lumen in fluid communication with perfusion holes which allow perfusion of blood in the artery during inflation of the balloon.

A4

17. (Amended) The apparatus of Claim 10, wherein the radiation source provides a radiation dose to the stenosed region through a window in the catheter [sufficient to retard proliferation of smooth muscle cells at the stenosed region].

18. (Amended) The apparatus of Claim 10, wherein the radiation source is repositioned relative to the catheter to position the radiation source for treatment [comprises a balloon catheter capable of performing angioplasty and the post-treatment].

19. (Amended) The apparatus of Claim 10, wherein the catheter includes a balloon for repositioning a stent, the stent including the radiation source [is capable of reducing the stenosed region and performing the post-treatment].

20. The apparatus of claim 6, wherein the radioactive dose means for emitting radiation is positioned within the device, the device defining a housing, wherein in the first position the dose means is at least partially enclosed within the housing and shielded from treating the stenosed region and in a second position the housing is deployed to at least partially expose the dose means to the stenosed region of the artery.

21. The apparatus of claim 20, wherein in the second deployed position the housing is withdrawn relative to the dose means positioned in the stenosed region to expose the stenosed region to the dose means.

22. The apparatus of claim 20, wherein the housing defines a window and in the second position the housing is repositioned within the artery relative to the dose means positioned in the stenosed region to position the window in proximity to expose the stenosed region to the dose means through the window.

23. The apparatus of claim 20, wherein the housing defines a window and a cover for the window and the positioning means includes a remote actuation mechanism for the cover such that in the second position the window is open and exposing the stenosed region to the dose means.

24. The apparatus of claim 6, wherein a portion of the device containing radioactive dose means for emitting radiation is expanded in the second position to a deployed configuration positioning the dose means at least partially in contact with the stenosed region of the artery.

25. The apparatus of claim 24, wherein the portion of the device that is expanded includes a balloon with the dose means positioned on the surface of the balloon.

A5

26. The apparatus of claim 24, wherein at least one portion of the device that is expanded includes a stent and the stent includes the dose means.

27. The apparatus of claim 26, wherein the dose means included with the stent is selected from the group consisting of cladding, coating, an additive to the stent material, and attached to the stent.

REMARKS

This application has been reviewed in light of the Office Action mailed April 7, 2000 (hereinafter "Office Action"). Claims 1-5 are allowed by the Office Action. Claims 6-19 are pending in this application with claims 6-19 being rejected by the Office Action. By this amendment, independent Claims 6 and 10 as well as dependent Claims 14 and 16-19 have been amended. New dependent Claims 20-27 have been added. Support for the afore-mentioned amendment is found through this specification and figures. In view of the amendments above and remarks that follow, reconsideration and allowance of this application has been respectfully

requested. The claims have been amended in a manner which is believed to overcome the rejections contained in the Office Action. No new matter or issues are believed to be introduced by this amendment.

CLAIMS REJECTIONS UNDER 35 U.S.C. § 112

Claims 14 -19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out into and distinctly claim the subject matter which applicant regards as the invention. The Office Action states:

> *In Claim 16, line 3, "perfusion holes" lacks positive antecedent basis. Claim 17 is directed to the intended use of the radioactive dose and fails to further limit the apparatus. In Claims 18-19 the use of "capable of" is indefinite in that it is unclear whether the function is performed or not. Claims 14 and 18-19 appear to add the balloon into the claim, however as discussed in the declaration and looking at the claims this merely appears to be adding back in what was removed from the claims for these new claims, thereby making it unclear how these are not duplicates of the existing independent claims.*

It is respectfully submitted that amended Claims 14 and 16-19 are now in compliance with 35 U.S.C. § 112, second paragraph. Claim 15 depends from amended Claim 14 and is now also believed to be in compliance with 35 U.S.C. § 112. It is respectfully submitted Claims 14-19 are definite and in particular point out and distinctly claim the subject matter which the applicant regards as the invention.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 6-7 stand rejected under 35 U.S.C. § 102 over U.S. Patent No. 4,881,938 to *van't Hooft* (hereinafter "*van't Hooft*"). The Office Action states that Claims 6 and 7 are rejected as being clearly anticipated by *van't Hooft*.

It is respectfully submitted that amended Claim 6 is neither disclosed nor suggested by *van't Hooft*. *van't Hooft* discloses each implant needle is connected to the cart by means of a patient transfer tube having a patient connector and a machine connector connected with a plurality of external tubes, from which cart tubes are selectively inserted into the needle or needles already introduced. The positioning can take place by means of a transport thread movable in the patent transfer tubes and the final position can be detected pneumatically by shutting off an air passage bounded by a shoulder, by means of a control head attached to each tube. See col. 1, lines 23-40; col. 3, line 15 to col. 4, line 33; and FIGS. 1 and 6 below. This structure positions tubes filled with a radioactive material in a final position at which point treatment is performed.

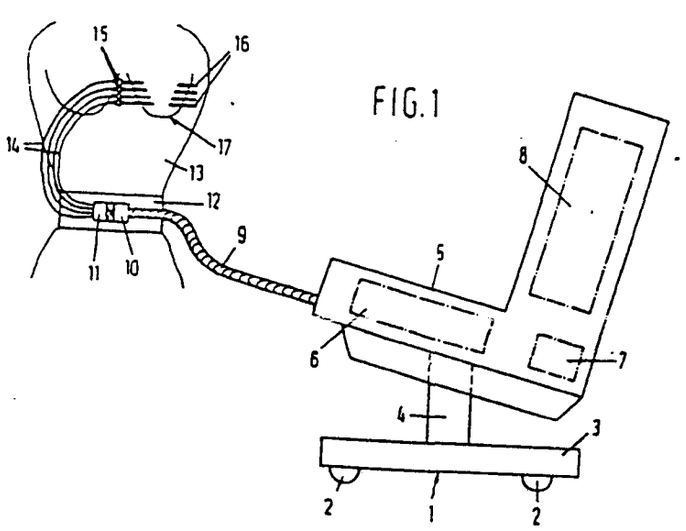
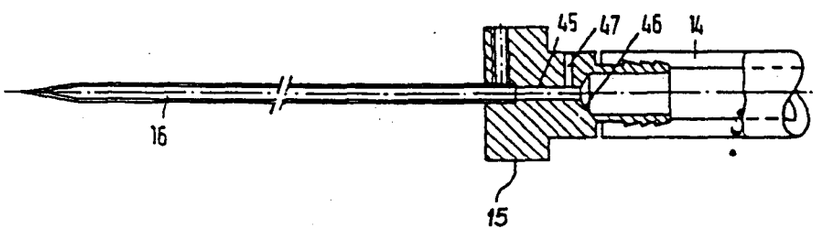


FIG.1

FIG.6



In regard to amended Claim 6, *van't Hooft* fails to teach or suggest, ***inter alia***, the newly recited positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position, wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery. When positioned, this configuration is used to move from a non-deployed configuration to a deployed treatment configuration in which the patient is being actively exposed to the radiation.

It is respectively submitted that dependent Claim 7 is at least patentable for the reasons that independent Claim 6 from which it directly depends is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

It is respectively submitted that amended Claim 6 is neither disclosed nor suggested by *van't Hooft* and is allowable thereover. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 6-7 and 10-11 stand rejected under 35 U.S.C. § 102 (e) over U.S. Patent No. 5,084,002 by *Liprie* (hereinafter "*Liprie*"). The Office Action states that the above-identified claims were clearly anticipated by *Liprie*.

It is respectfully submitted that amended independent Claims 6 and 10 are neither disclosed nor suggested by *Liprie*. Referring to FIG. 1 of *Liprie*, below, a partial cross-sectional view is shown of a relatively pure iridium core member or seed 12 form in the end of the unitary elongate relatively pure platinum delivery wire 14. See col. 4, lines 18-21 and FIG. 1, below. Thus, the device and the dose means of *Liprie* are fixedly positioned together.

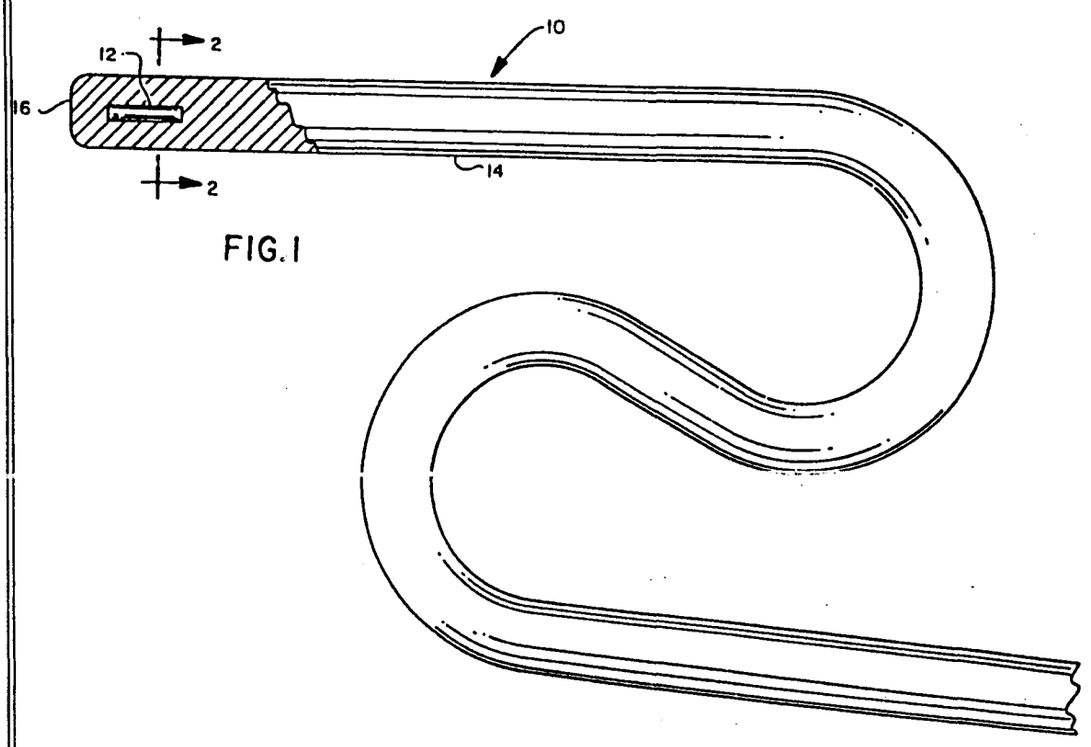


FIG. 1

In regard to amended Claim 6, *Liprie* fails to teach or suggest, *inter alia*, the newly recited positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position, wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery. When positioned, this configuration is used to move from a non-deployed configuration to a deployed treatment configuration in which the patient is being actively exposed to the radiation.

It is respectively submitted that dependent Claim 7 is at least patentable for the reasons that independent Claim 6 from which it directly depends is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

It is respectively submitted that amended Claim 6 is neither disclosed or suggested by *Liprie* and is allowable thereover. Accordingly, withdrawal of this rejection is respectfully requested.

In regard to amended independent Claim 10, *Liprie* fails to teach or suggest, *inter alia*, the newly recited catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation

source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region. This configuration is used to control the amount of exposure of the stenosed region of the artery to the radiation and allows movement between two configurations to control that level of exposure.

It is respectfully submitted that dependent Claim 11 is at least patentable for the reasons that independent Claim 10 from which it directly depends is patentable. Accordingly, withdrawal of this rejection is respectfully requested. It is respectfully submitted that amended independent Claims 6 and 10 are neither disclosed nor suggested by *Liprie* and are allowable thereover. Accordingly, withdrawal of this rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103:

In the Office Action, Claims 8-9 and 12-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Liprie* in view of U.S. Patent No. 3,324,847 by *Zoumboulis* (hereinafter "*Zoumboulis*"). The Office Action states:

> *Claims 8-9, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie in view of Zoumboulis.*
> *Liprie discloses the claimed device except for the specific use of the radioactive dose in a liquid or gaseous form. Zoumboulis teaches that it is well known to use a radioactive substance in a form other than solid, i.e. liquid. Therefore a modification of Liprie such that the radioactive dose is in any well known and conventionally used form would have been obvious to one skilled in the art.*

It is respectfully submitted that amended independent Claims 6 and 10 are distinguishable and non-obvious when *Liprie* is viewed in light of *Zoumboulis*. For example, in

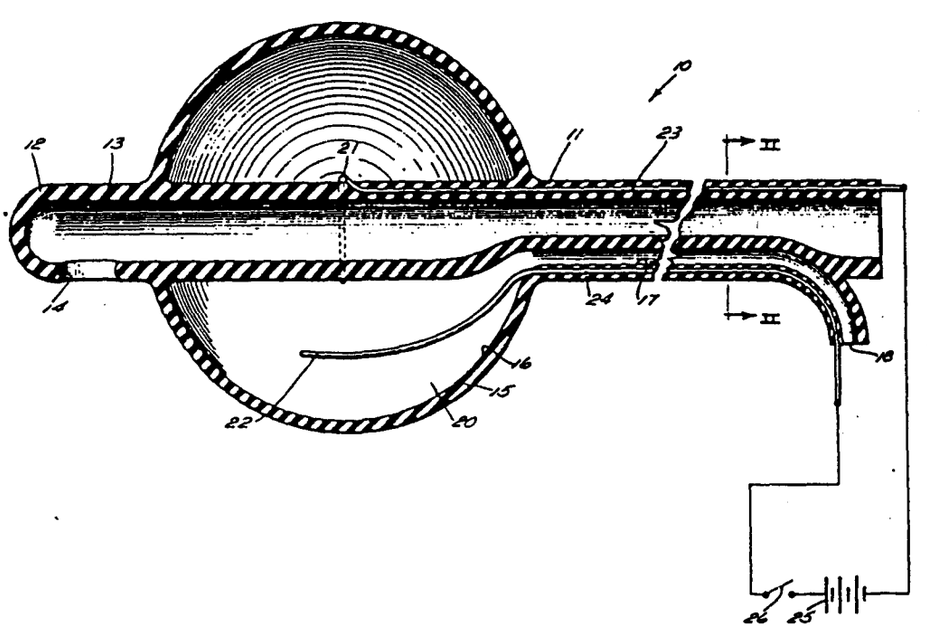
regard to independent Claim 6, the combination of *Liprie* in view of *Zoumboulis* fails to teach or suggest, *inter alia*, applicant's newly recited positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position, wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery. When positioned, this configuration is used to move from a non-deployed configuration to a deployed treatment configuration in which the patient is being actively exposed to the radiation.

In amended independent Claim 10, the combination of *Liprie* in view of *Zoumboulis* fails to teach or suggest, inter alia, applicant's newly recited a catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

In contrast, *Liprie* teaches a source 10 that includes a relatively pure iridium core member or seed 12 formed in the end of a unitary elongated pure platinum delivery wire 14. See col. 4, lines 16-21 and FIG. 1, above. *Zoumboulis* discloses the use of electrodes in combination

with this solution containing a radioactive isotope that is particularly advantageous in that ions are formed in the solution and migrate to one of the electrodes in acceptance with laws of iontophoresis to accumulate a solid radioactive source. See col.1, lines 20-48 and FIG. 1, below.

FIG. 1



Thus, neither *Liprie* nor *Zoumboulis* teach or suggest, *inter alia,* positioning means operatively connected to said device that is movable when positioned between a first non-deployed configuration and a second deployed configuration. Further, neither *Liprie* nor *Zoumboulis* teach or suggest, *inter alia*, an arrangement where a catheter is adapted to at least partially reposition relative to the radiation source for treatment. Accordingly, withdrawal of this rejection is respectfully requested.

It is respectfully submitted that amended independent Claims 6 and 10 are patentably distinguishable when *Liprie* is reviewed in light of *Zoumboulis* and therefore allowable thereover. It is respectfully submitted that dependent Claims 8-9 and 12-13 are at least patentably

distinguishable for the reason amended independent Claims 6 and 10 from which they respectively depend are patentable. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

It is respectfully submitted that none of the references of record disclose or suggest the present invention is claimed in the claims as amended considered or in combination with themselves considered in whole or in part. Accordingly, withdrawal of this rejection is respectfully requested. In view of the foregoing amendments and remarks, reconsideration of the rejections and allowance of the claims are earnestly solicited.

Respectfully submitted,

David M. Carter

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Attorney for Applicant

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GAU 3736

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robert L. Hess

DOCKET: 1944 CON RE (203-2201 CON RE)

SERIAL NO.: 08/850,073

Group: 3736

FILED: May 2, 1997

Examiner: John P. Lacyk

#9

FOR: APPARATUS FOR RESTENOSIS TREATMENT

Dated: June 22, 2000

Assistant Commissioner for Patents
Washington, DC 20231

AMENDMENT TRANSMITTAL FORM

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] Small entity status of this application under 37 C.F.R. §§1.9 and 1.27 has been established by a verified statement previously submitted.

[ ] A verified statement to establish small entity under 37 C.F.R. §§1.9 and 1.27 is enclosed.

[ ] No additional fee is required.

	(Col. 1)		(Col. 2)		(Col. 3)	SMALL ENTITY			OTHER THAN SMALL ENTITY		
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR		PRESENT EXTRA	RATE	ADDIT. FEE	OR	RATE	ADDIT. FEE	
TOTAL	*27	MINUS	**20	=	7	X $ 9		X	18	$ 126.00	
INDEP.	*3	MINUS	***3	=	0	X 39	$	X	78	$ 0	
☐ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM						X 130	$	X	260	$ 0	
						TOTAL	$	OR	TOTAL	$ 126.00	
									ADDIT. FEE	$	

* If the entry in Col. 1 is less than entry in Col. 2, write "0" in Col. 3.
** If the "Highest No. Previously Paid for" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The Highest No. Previously Paid For" (Total or indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

[ ] Please charge Deposit Account No. 04-1121 in the amount of $____. Two (2) copies of this sheet are enclosed.

[X] A check in the amount of $ 126.00 is enclosed.

[X] Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §§1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 04-1121. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 04-1121 therefor. TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,

David M. Carter

David M. Carter
Reg No. 30,949
Attorney for Applicant

DILWORTH & BARRESE, LLP
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(516) 228-8484

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 June 22, 2000.

Dated: June 22, 2000

Harold G. Furlow

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/850,073	05/02/97	HESS	R 016565-049

QM12/0915

John C. Andres
Vice President and General Counsel
150 Glover Avenue
Norwalk CT 06856

EXAMINER	
LACYK, J	
ART UNIT	**PAPER NUMBER**
3736	9

DATE MAILED: 09/15/00

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

Commissioner of Patents and Trademarks

NC 000155

Office Action Summary

Application No.	Applicant(s)
08/850,073	Hess
Examiner	**Group Art Unit**
John P. Lacyk	3736

☒ Responsive to communication(s) filed on *Jun 29, 2000*.

☒ This action is **FINAL.**

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

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

Disposition of Claims

☒ Claim(s) *1-27* is/are pending in the application.

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

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

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

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

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

☐ The specification is objected to by the Examiner.

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

Priority under 35 U.S.C. § 119

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

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

☐ received.

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

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

*Certified copies not received: _____.

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

Attachment(s)

☒ Notice of References Cited, PTO-892

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

☐ Interview Summary, PTO-413

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

☐ Notice of Informal Patent Application, PTO-152

NC 000156

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

1. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

2. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-27 are rejected as being based upon a defective declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

The supplemental oath/declaration should also state an error that is relied upon to support the reissue application since the claims have been amended thereby obviating the reasons submitted in the original oath/declaration.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide support for the dose means being in a non-deployed configuration and a deployed configuration.

4. Claims 18-19, 26-27 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.

It appears that the limitations of claim 18 were placed in claim 10 in the most recent amendment to the claims. Therefore claim 18 fails to further define the device. Claims 6 and 10 both have claimed language such that the device and dose means are withdrawn from the body. Claims 19 and 26-27 are therefore confusing since they recite the dose means being a stent. It is unclear how the dose means is withdrawn with the device. After the stent is deployed it stays in the body.

5. 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.

6. Claims 6-7,10-11,19-21,24-27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Weinstein et al.

Weinstein et al discloses a device that positions a radioactive source within a stenosed area where a shielding means is "repositioned" to expose the radioactive source for the treatment and the device and the radioactive source are withdrawn after treatment. A further embodiment shows the use of a stent to provide the selected treatment.

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

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

8. Claims 8-9, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al.

Although Weinstein et al only discloses the use of a solid form, it is well known to use radioactive elements in liquid and gas forms to treat the body. Therefore a modification of Weinstein et al such that any desired form is chosen would have been obvious to one skilled in the art since it is well known to use any of these forms based upon the suitability for the intended use.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (703) 308-2995.

JOHN P. LACYK
PRIMARY EXAMINER

J.P. Lacyk

September 11, 2000

Notice of References Cited

Application No.	Applicant(s)		
08/850,073	Hess		
Examiner		Group Art Unit	Page 1 of 1
John P. Lacyk		3736	

U.S. PATENT DOCUMENTS

		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
	A	5,213,561	5/1993	Weinstein et al	600	3
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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PTO/SB/30 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.
See The American Inventors Protection Act of 1999 (AIPA).

Application Number	08/850,073
Filing Date	May 2, 1997
First Named Inventor	Robert L. Hess
Group Art Unit	3736
Examiner Name	J. Lacyk
Attorney Docket Number	1944CON RE (203-2201 CON RE)

1.53(d) #11

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

NOTE: *37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA.* See *Changes to Application Examination and Provisional Application Practice*, Final Rule, 65 *Fed. Reg.* 50092 (Aug. 16, 2000); Interim Rule, 65 *Fed. Reg.* 14865 (Mar. 20, 2000), 1233 *Off. Gaz. Pat. Office* 47 (Apr. 11, 2000), which established RCE practice.

1. Submission required under 37 C.F.R. § 1.114
   - a. ☐ Previously submitted
     - i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on _____ (Any unentered amendment(s) referred to above will be entered).
     - ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
     - iii. ☐ Other _____
   - b. ☒ Enclosed
     - i. ☒ Amendment/Reply
     - ii. ☐ Affidavit(s)/Declaration(s)
     - iii. ☐ Information Disclosure Statement (IDS)
     - iv. ☐ Other _____

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2. Miscellaneous
   - a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)
   - b. ☐ Other _____

3. Fees — The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed.
   - a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 04-1121
     - i. ☐ RCE fee required under 37 C.F.R. § 1.17(e)
     - ii. ☐ Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)
     - iii. ☐ Other _____
   - b. ☒ Check in the amount of $ 710.00 enclosed
   - c. ☐ Payment by credit card (Form PTO-2038 enclosed)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	David M. Carter	Registration No. (Attorney/Agent)	30,949
Signature		Date	December 5, 2000

CERTIFICATE UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence and the documents referred to as enclosed are being deposited with the United States Postal Service on date below in an envelope as "Express Mail Post Office to Addresse" Mail Label Number _____ addressed to: Assistant Commissioner for Patents, Box Provisional Application, Washington, D.C. 20231.

Name (Print/Type)	Harold G. Furlow		
Signature	Harold G. Furlow	Date	December 5, 2000

12/12/2000 CV0111 00000050 08850073
01 FC:172 710.00 OP

1-3-1

PATENT

Atty. Docket No. 1944 CON RE (203-2201 CON RE)

12/B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robert L. Hess **GROUP ART UNIT:** 3736

SERIAL NO. : 08/850,073 **EXAMINER:** J. Lacyk

FILED: May 2, 1997 **Dated:** December 5, 2000

FOR: APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

In response to the Office Action of the U.S. Patent and Trademark Office mailed September 15, 2000, please amend the above-identified application as follows:

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 December 5, 2000

Dated: December 5, 2000

Harold G. Furlow

Harold G. Furlow

12/12/2000 CV0111
02 FC:103

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54.00 OP

NC 000163

IN THE SPECIFICATION

Please amend the specification as follows:

At col. 4, line 10 after "form" revise the text as follows:

Insert --in a deployed configured for treatment--

At col. 4, line 10 after "forms" revise the text as follows:

Insert --in a non-deployed configuration--

IN THE CLAIMS

Please amend the claims as set forth herein below:

Cancel claims 22, 26, and 27 without prejudice.

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

radioactive dose means for emitting radiation; and

a device having a cut-out positioned in spaced relation to the dose means; and

positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein in the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position wherein the dose means is exposed to the stenosed region of the artery through the cut-out defined in the device in a deployed configuration for treating at least a portion of the stenosed region of the artery, said positioning means being operatively connected to said device and dose means for withdrawing said device and dose means

from the artery after said radioactive dose means is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

B1

10. (Twice Amended) Apparatus for post treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

a radiation source; and

a catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery <u>to position a portion of the catheter in contact with the stenosed region and the radiation source in close proximity to, but not in contact with the stenosed region of the artery</u>, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

B2

B3

17. (Twice Amended) The apparatus of Claim <u>6</u> [10] wherein the radiation source provides a radiation dose to the stenosed region through a window in the catheter.

19. (Twice Amended) The apparatus of Claim 10, wherein the catheter includes a balloon [for repositioning a stent, the stent including a radiation source is] capable of reducing the stenosed region and <u>simultaneously</u> performing the post-treatment <u>by forcing a balloon into contact with a lesion, the balloon being inflated by a fluid having the radiation dose means incorporated therein</u>.

B4

B5

20. (Amended) The apparatus of claim 6, wherein the radioactive dose means for emitting radiation is positioned within the device, the device defining a housing wherein in the first position

the dose means is [at least partially enclosed within the housing and] shielded from treating the stenosed region and in a second position the housing is deployed to at least partially expose the dose means to the stenosed region of the artery.

21. (Amended) The apparatus of claim 20, wherein in the second deployed position a sheath [the housing] is withdrawn relative to the dose means positioned in the stenosed region to expose the stenosed region to the dose means.

23. (Amended) The apparatus of claim 20, wherein the housing defines a window and a cover for the window [and the positioning means includes a remote actuation mechanism for the cover] such that in the second position the window is open and exposing the stenosed region to the dose means.

24. (Amended) The apparatus of claim 10 [6] wherein the catheter includes a balloon with [a portion of the device containing] radioactive dose means for emitting radiation incorporated into and enclosed within the material of the balloon and the balloon is expanded in the second deployed configuration positioning the balloon [dose means] at least partially in contact with the stenosed region of the artery.

Please add the following new claims:

28. (New) The apparatus for post treatment of a stenosed region of claim 17, wherein the dose means is a liquid.

29. (New) The apparatus for post treatment of a stenosed region of claim 17, wherein the dose means is a gas.

30. (New) The apparatus for post treatment of a stenosed region of claim 24, wherein the dose means incorporated into the balloon material is a solid.

31. (New) The apparatus for post treatment of a stenosed region of claim 24, wherein the dose means incorporated into the balloon material is a liquid.

32. (New) The apparatus for post treatment of a stenosed region of claim 24, wherein the dose means incorporated into the balloon material is a gas.

B7

33. (New) The apparatus for post treatment of a stenosed region of claim 6, wherein the apparatus controls the exposure of the dose means by controlling the radial direction and axial position of the cut out.

REMARKS

This application has been reviewed in light of the Office Action mailed September 15, 2000 (hereinafter "Office Action"). Claims 1-27 are pending in this application with claims 1-27 being rejected by the Office Action. By this amendment, independent claims 6 and 10 are amended as well as dependent claims 17 and 19-24. New dependent claims 28-29 and 33 depend from claim 6. New dependent claims 30-32 depend from independent claim 10. Claims 22 and 26-27 are canceled without prejudice.

New claims 28-33 submitted herein are believed to be in condition for allowance.

Upon notice of allowance applicant will provide an offer to surrender in accordance with 37 C.F.R. 1.178 and a reissue oath/declaration in accordance with 37 C.F.R. 1.175(b)(1).

It is respectfully submitted that amended Claims 18-19 are now in compliance with 35 U.S.C. § 112, second paragraph.

Support for the foregoing amendment is found through this specification and figures. In view of the amendments above and remarks that follow, reconsideration and allowance of this application has been respectfully requested. The claims have been amended in a manner which is

believed to overcome the rejections contained in the Office Action. No new matter or issues are believed to be introduced by this amendment.

CLAIMS REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 6-7, 10-11, 19-21, 24-27 stand rejected under 35 U.S.C. § 102(b) over *Weinstein et al.* (U.S. Patent No. 5,213,561).

It is respectfully submitted that amended independent claims 6 and 10 are neither disclosed nor suggested by *Weinstein et al.* With regard to amended independent claim 6, *Weinstein et al.* discloses an outer sleeve 3 of a guidewire 1 slidable over an inner wire 5 for a distance sufficient to cover and uncover radioactive material 9, so that the shielding section 11 of the outer sleeve can be moved away from the radioactive material 9 to expose the angioplasty site to radiation. See col. 3, lines 47-56, and FIG. 1, below. Thus, *Weinstein et al.* deploys and treats the entire exposed surrounding area for restenosis upon the shifting of outer sleeve 3 and exposing of the radioactive material 9.

In regard to amended claim 6, *Weinstein et al.* fails to teach or suggest, *inter alia*, the recited dose being exposed to the stenosed region of the artery through a cut-out defined in a housing in a deployed configuration. Thus, amended claim 6 has structure that includes a device defining a cut-out through which treatment of the stenosed region is conducted. See col. 3, lines 20-40, and FIG. 1., below. Thus, amended claim 6 includes a device structure having a window for selectively treating the vascular portions that have developed restenosis at the angioplasty site, a device that is neither contemplated nor suggested by *Weinstein et al.* Accordingly, withdrawal of this rejection is requested.

It is respectfully submitted that dependent claims 7, 20, and 21 are patentable for at least the reasons that independent Claim 6 from which they ultimately depend is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

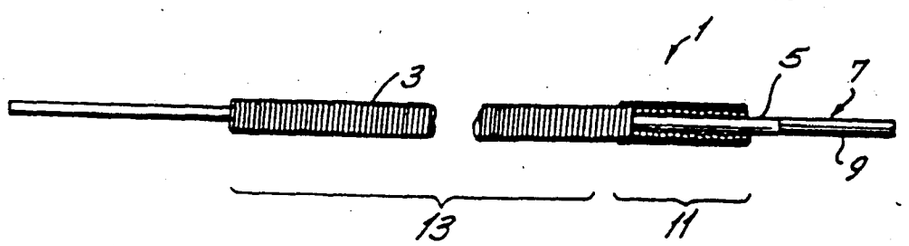


FIG. 1

FIG. 1 of *Weinstein et al.*

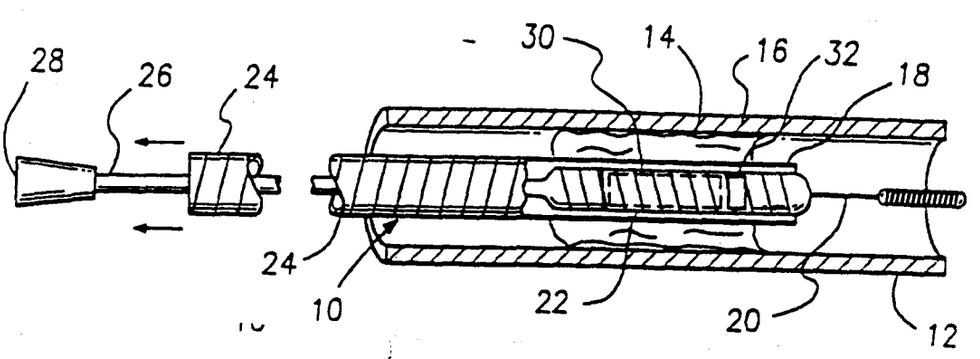


FIG. 1

FIG. 1 of present disclosure

With respect to amended claim 10, *Weinstein et al.* discloses a second embodiment wherein radioactive material 25 is embedded in or mounted on a tube 17 inside a balloon 19. A retractable radiation shielding sleeve 27 is slidable along tube 17 and covers source 25, blocking

exposure to radiation until it is shifted away. Note sleeve 27 is in a fixed positioned inside of balloon 19. See col 3 line 57-col. 4 line 5, and FIG. 2, below.

In regard to amended claim 10, *Weinstein et al.* fails to teach or suggest, *inter alia*, the newly recited positioning a portion of the catheter in contact with the stenosed region and the radiation source in close proximity to, but not in contact with the stenosed region of the artery. See col. 4, lines 4-12; col. 3, lines 41-59, and FIGS. 2 and 4, below. Thus, amended claim 10 includes positioning the catheter in contact with the stenosed region and the radiation source in close proximity to, but not in contact with the stenosed region of the artery to provide angioplasty and restenosis treatment and withdrawing the radiation source from the artery, a device that is neither contemplated or suggest by *Weinstein et al.*. Accordingly, withdrawal of this rejection is requested.

It is respectively submitted that dependent claims 11, 19, 24 and 25 are patentable for at least the reasons that independent claim 10 from which they ultimately depend is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

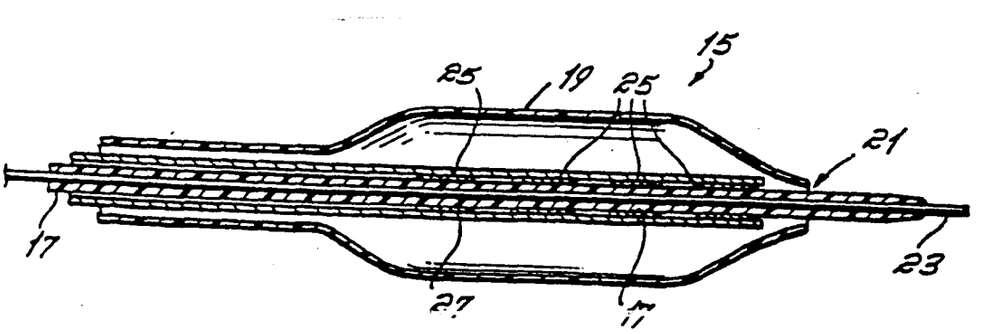


FIG. 2

FIG. 2 of *Weinstein et al.*

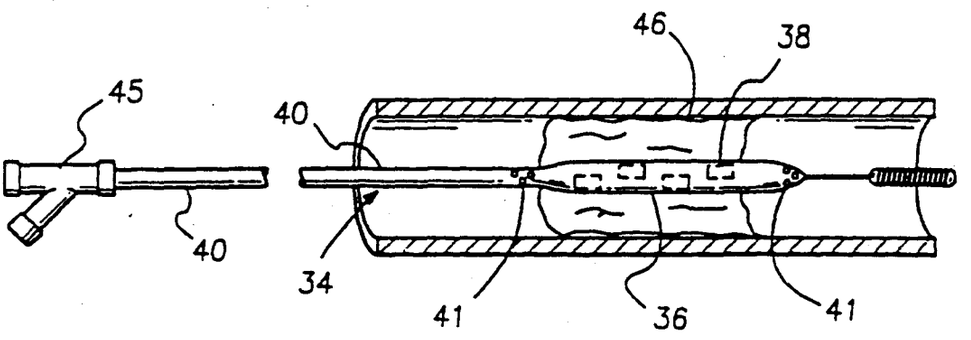


FIG. 2

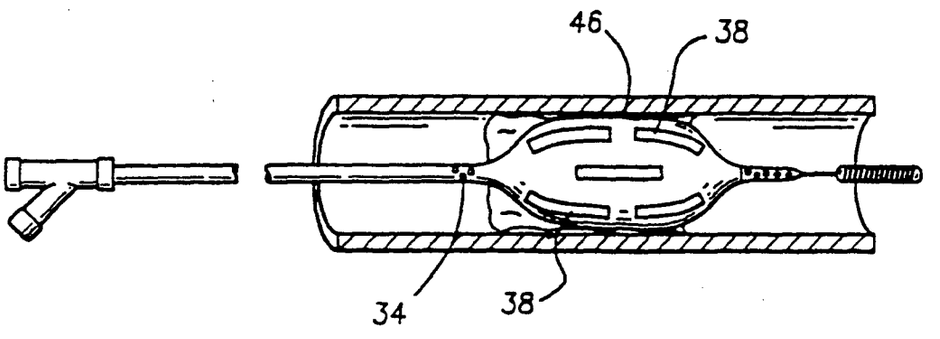


FIG. 4

FIGS. 2 and 4 of present disclosure

CLAIM REJECTIONS UNDER U.S.C. §103

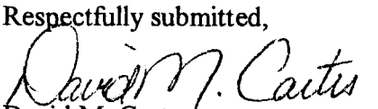
In the Office Action, claims 8-9 and 12-13 stand rejected under 35 U.S.C. § 103(a) over *Weinstein et al.* It is respectfully submitted that amended independent claims 6 and 10 are distinguishable and non-obvious over *Weinstein et al.* as noted above and therefore claims 8-9 and 12-13 are patentable for at least the reasons that independent claims 6 and 10, from which

they respectively depend, are patentable. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

It is respectfully submitted that none of the references of record disclose or suggest the present invention as claimed in claims 6-21 and 23-25 as amended and new claims 28-33. Accordingly, withdrawal of this rejection is respectfully requested. In view of the foregoing amendments and remarks, reconsideration of the rejections and allowance of the claims are earnestly solicited.

Respectfully submitted,



David M. Carter
Registration No. 30, 949
Attorney for Applicant

DILWORTH & BARRESE, LLP
333 Earle Ovington Boulevard
Uniondale, New York 11553
(516) 228-8484

PATENT

Attorney Docket **1944 CON RE (203-2201 CON RE)**

In re application of:	Robert L. Hess	Group Art Unit:	3736
Serial No.:	08/850,073	Examiner:	J. Lacyk
Filed:	May 2, 1997	Dated:	December 5, 2000

For: APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT TRANSMITTAL FORM

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] Small entity status of this application under 37 C.F.R. § 1.9 and 1.27 has been established by a verified statement previously submitted.

[ ] A verified statement to establish small entity under 37 C.F.R. § 1.9 and 1.27 is enclosed.

[ ] No additional fee is required.

The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)	SMALL ENTITY			OTHER THAN SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE	OR	RATE	ADDIT. FEE
TOTAL	30	MINUS	27**	=3	X 9	$0		X 18	$54.00
INDEP.	2	MINUS	3***	=2	X 39	$0		X 80	$0
☐ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					X 135	$0		X 270	$0
					TOTAL		OR	TOTAL ADDIT. FEE	$54.00

* If the entry in Co. 1 is less than entry in Col. 2, write "0" in Col. 3.
** If the "Highest No. Previously Paid for" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The Highest No. Previously Paid For" (Total or indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

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.

Dated: December 5, 2000

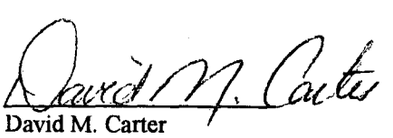
Harold G. Furlow

[ ] Please charge Deposit Account No. 04-1121 in the amount of $___. Two (2) copies of this sheet are enclosed.

[ ] A check in the amount of $0.00 is enclosed.

[x] Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 04-1121. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 04-1121 therefor. **TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.**

Respectfully submitted,



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Attorney for Applicant

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/850,073	05/02/97	HESS	R 016565-049

EXAMINER	
LACYK, J	
ART UNIT	PAPER NUMBER
3736	13

DATE MAILED: 04/11/01

QM12/0411

John C. Andres
Vice President and General Counsel
150 Glover Avenue
Norwalk CT 06856

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

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

NC 000175

Office Action Summary

Application No.	Applicant(s)
08/850,073	Hess
Examiner	**Group Art Unit**
John P. Lacyk	3736

☒ Responsive to communication(s) filed on *Dec 8, 2000* .

☐ This action is **FINAL**.

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

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

Disposition of Claims

☒ Claim(s) *1-21, 23-25, and 28-33* is/are pending in the application.

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

☒ Claim(s) *1-5* is/are allowed.

☒ Claim(s) *6-21, 23-25, and 28-33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

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

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

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

☐ The specification is objected to by the Examiner.

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

Priority under 35 U.S.C. § 119

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

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

☐ received.

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

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

*Certified copies not received: _____ .

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

Attachment(s)

☐ Notice of References Cited, PTO-892

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

☐ Interview Summary, PTO-413

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

☐ Notice of Informal Patent Application, PTO-152

JOHN P. LACYK
PRIMARY EXAMINER

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

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/00 has been entered.

2. The amendment filed 12/8/00 is improper. The amendment to the specification does not include underlining of the additions; also the new claims 28-33 lack the proper underlining. See M.P.E.P. 1453.

3. In view of the fact that additional errors in the original patent have been corrected through amendments to the claims, a new/supplemental oath or declaration complying with 37 CFR 1.175 (a) is required.

4. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

5. Claims 10 and 18 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.

Claim 18 still fails to further define the device. In claim 10, line 8, "in close proximity" is indefinite in that it is unclear what the limitations of such language are.

6. 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.

7. Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstein et al. Weinstein et al discloses a device that positions a radioactive source within a stenosed area where a shielding means is "repositioned" to expose the radioactive source for the treatment and the device and the radioactive source are withdrawn after treatment.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (703) 308-2995.

JOHN P. LACYK
PRIMARY EXAMINER

John P. Lacyk

March 14, 2001

Patent
Attorney's Docket No. 011683-012

6-24-01
#15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
Robert L. HESS	)	Group Art Unit: 3736
	)	
Application No.: 08/850,073	)	Examiner: J. Lacyk
	)	
Filed: May 2, 1997	)	
	)	
For: APPARATUS FOR RESTENOSIS TREATMENT	)	

REVOCATION AND NEW POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE INTEREST

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

As the Assignee of the entire interest in the above-identified application, all powers of attorney previously given are hereby revoked, and James W. Peterson, Reg. No. 26,057, Mary Ann Dillahunty, Reg. No. 34,576, T. Gene Dillahunty, Reg. No. 25,423, Robert E. Krebs, Reg. No. 25,885, Gerald F. Swiss, Reg. No. 30,113, Anthony T. Cascio, Reg. No. 29,904, Charles H. Jew, Reg. No. 34,192, Kirk M. Nuzum, Reg. No. 38,983, Cindy A. Lynch, Reg. No. 38,699, Kelly J. McCrystle, Reg. No. 46,257, Anthony J. Josephson, Reg. No. 45,742, Alan E. Kopecki, Reg. No. 25,813 and Peter K. Skiff, Reg. No. 31,917, are hereby appointed to prosecute and transact all business in the Patent and Trademark Office connected with the above-identified application. The Assignee has reviewed documentary evidence of the chain of title from the original owner to the Assignee (copy of Assignment as filed June 18, 2001) and certifies that to the best of its knowledge and belief it is the owner of the entire right, title and interest in and to the above-identified application.

Please direct all telephone calls and correspondence to:

James W. Peterson, Esquire
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

21839

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.

Date: 06/15/01 Signature: _____

Name: Robert L. Hess
Title: Managing Member / Officer
Company: Calmedica, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/850,073	05/02/1997	ROBERT L. HESS	016565-049

CONFIRMATION NO. 4543

OC000000006228998

John C. Andres
Vice President and General Counsel
150 Glover Avenue
Norwalk, CT 06856

Date Mailed: 06/26/2001

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/19/2001.

- 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).

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

OFFICE COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/850,073	05/02/1997	ROBERT L. HESS	016565-049

CONFIRMATION NO. 4543

OC000000006229069

JAMES W. PETERSON, ESQ.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

Date Mailed: 06/26/2001

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/19/2001.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

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

OFFICE COPY

BURNS DOANE

BURNS DOANE SWECKER & MATHIS LLP

ALEXANDRIA, VIRGINIA
REDWOOD SHORES, CALIFORNIA
DURHAM, NORTH CAROLINA

REPLY TO:

Suite 700
333 Twin Dolphin Drive
Redwood Shores, California 94065-1418

TELEPHONE: +1.650.622.2300

FACSIMILE: +1.650.622.2499

DATE: September 4, 2001

RECIPIENT INFORMATION		SENDER INFORMATION	
To:	**Examiner Lacyk**	From:	**Cindy A. Lynch**
Voice Tel. No.:	**703-308-2995**	Voice Tel. No.:	**650-622-2331**
Fax Tel. No.:	**703-746-3334**	Sent By:	
Your Ref.:	**08/850,073**	Our Ref.:	**011683-012**
		Total Pages (Incl. Cover Page):	**4**

RE: Serial No. 08/850,073 (Reissue)

MESSAGE:

is relied upon to support the reissue application **if**:

(A) an error to support a reissue has been previously and properly stated in a reissue oath/declaration in the application; and

(B) that error is still being corrected in the reissue application.

If applicant chooses to state any further error at this point (even though such is not needed), the examiner should not review the statement of the further error.

The supplemental reissue oath/declaration must state an error which is relied upon to support the reissue application only where one of the following is true:

(A) the prior reissue oath/declaration failed to state an error;

(B) the prior reissue oath/declaration attempted to state an error but did not do so properly; or

(C) all errors under 35 U.S.C. 251 stated in the prior reissue oath(s)/declaration(s) are no longer being corrected in the reissue application.

WHEN A SUPPLEMENTAL OATH/DECLARATION MUST BE SUBMITTED

The supplemental oath/declaration in accordance with 37 CFR 1.175(b)(1) must be submitted before allowance. See MPEP § 1444 for a discussion of the action to be taken by the examiner to obtain the supplemental oath/declaration in accordance with 37 CFR 1.175(b)(1), where such is needed.

Where applicant seeks to correct an error after allowance of the reissue application, a supplemental reissue oath/declaration must accompany the requested correction stating

See MPEP § 1414.01 for a discussion of the requirements for a supplemental reissue oath/declaration.

1414.01 Supplemental Reissue Oath/ Declaration

If additional defects or errors are corrected in the reissue after the filing of the application, a supplemental reissue oath/declaration must be filed, unless all errors corrected are spelling, grammar, typographical, editorial or clerical errors which are not errors under 35 U.S.C. 251 (see MPEP § 1402). In other words, a supplemental oath/declaration is required where any "error" under 35 U.S.C. 251 has been corrected and the error was not identified in the original reissue oath/declaration.

The supplemental reissue oath/declaration must state that every error which was corrected in the reissue application not covered by the prior oath(s)/declaration(s) submitted in the application arose without any deceptive intention on the part of the applicant.

An example of acceptable language is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by the prior declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

WHEN AN ERROR MUST BE STATED IN THE SUPPLEMENTAL OATH/DECLARATION

In the supplemental reissue oath/declaration, there is **no need to state an error** which

BURNS DOANE

BURNS DOANE SWECKER & MATHIS LLP

ALEXANDRIA, VIRGINIA
REDWOOD SHORES, CALIFORNIA
DURHAM, NORTH CAROLINA

REPLY TO:

Suite 700
333 Twin Dolphin Drive
Redwood Shores, California 94065-1418

TELEPHONE: +1.650.622.2300

FACSIMILE: +1.650.622.2499

DATE: September 4, 2001

RECIPIENT INFORMATION		SENDER INFORMATION	
To:	**Examiner Lacyk**	From:	**Cindy A. Lynch**
Voice Tel. No.:	**703-308-2995**	Voice Tel. No.:	**650-622-2331**
Fax Tel. No.:	**703-746-3334**	Sent By:	
Your Ref.:	**08/850,073**	Our Ref.:	**011683-012**
		Total Pages (Incl. Cover Page):	**4**

RE: Serial No. 08/850,073 (Reissue)

MESSAGE:

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.

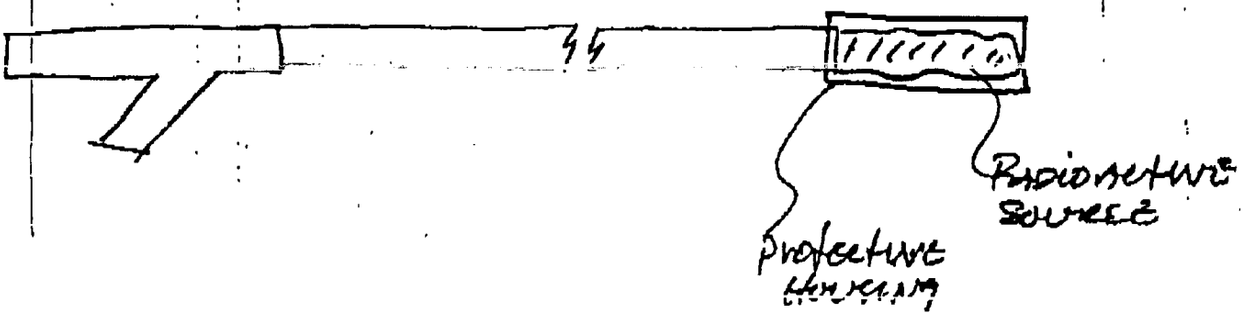
The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable 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.

6 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 REGROW - THE RATE OF RESTENOSIS IS GENERALLY CONSIDERED TO BE ABSENT 33%. THERE FOR 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 MANUVERED 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. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of)
)
Robert L. HESS) Group Art Unit: 3736
)
Serial No.: 08/850,073) Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466))
)
Filed: May 2, 1997)
)
For: APPARATUS FOR RESTENOSIS)
TREATMENT)

#17

DECLARATION OF ROBERT L. HESS AS TO LOSS OR INACCESSIBILITY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Robert L. Hess, hereby declare that:

U.S. Patent No. 5,411,466 was assigned from me to United States Surgical by an assignment dated December 15, 1997;

The Original U.S. Letters Patent No. 5,411,466 was transferred to United States Surgical following the assignment;

I understand that United States Surgical cannot locate the above original letters patent:

I have not been able to locate the above original letters patent and believe that it is lost or inaccessible.

I further declare that all statements made herein of my own knowledge are true and that all statements made no 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 statement may jeopardize the validity of the application or any patent issuing thereon.

Dated: October 03, 2001

By: Robert L. Hess

#17

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of)
)
Robert L. HESS) Group Art Unit: 3736
)
Serial No.: 08/850,073) Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466))
)
Filed: May 2, 1997)
)
For: APPARATUS FOR RESTENOSIS)
TREATMENT)

SUPPLEMENTAL DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Robert L. Hess, the above-named inventor, hereby declare that:

I am a citizen of the United States, and my residence is 35 Tagus Court, Portola Valley, California, 94028.

I verily believe myself to be the original, first inventor of the invention described and claimed in U.S. Letters Patent No. 5,411,466 (the "'466 patent") and for which invention I have solicit a Reissue Patent.

I have reviewed and understand the contents of the specification and the claims of the Reissue Application. I have also reviewed and understand the contents of the original specification of Serial No. 08/219,179 (U.S. Pat. No. 5,411466) filed March 28, 1994 as a continuation of Serial No. 07/755,480 (U.S. Pat. No. 5,302,168) filed September 5, 1991. I have also reviewed and understand the amendments to the specification and claims filed herewith.

I do not know and do not believe that said invention was ever known or used in the United States of America before my invention thereof.

I acknowledge my duty to disclose all information known to me which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

PETITIONER further declares the following:

I verily believe the '466 patent may be at least partly inoperative or invalid for the reason that I claimed less than I had a right to claim in the '466 patent.

Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath or declaration submitted in this application, arose without deceptive intention on my part.

I further declare that all statements made herein of my own knowledge are true and that all statements made no 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 statement may jeopardize the validity of the application or any patent issuing thereon.

Dated: October 03, 2001 By: _____
Robert L. Hess

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.

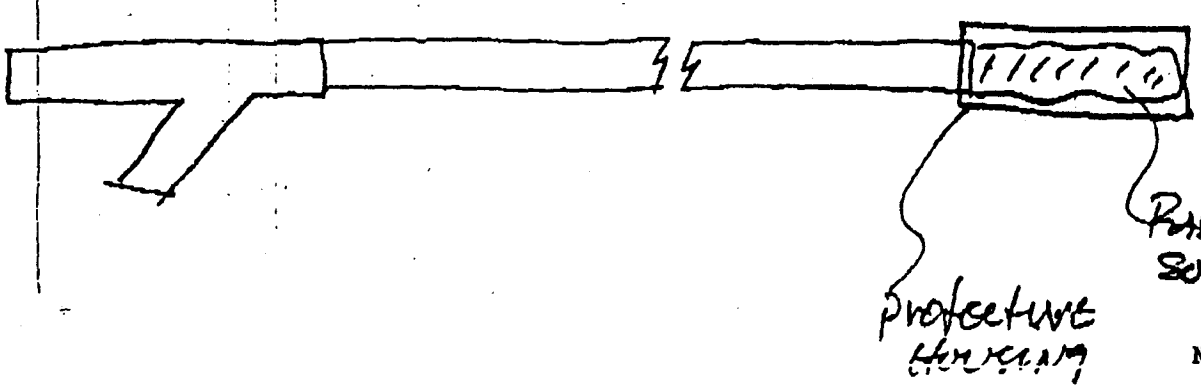
The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable 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.

6 Dec 1992
Date

Robert L. Hess

NC 000194

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 REGROW - THE RATE OF RESTENOSIS IS GENERALLY CONSIDERED TO BE ABOUT 33%. THERE FORE 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 RADIO ACTIVE SOURCE. THE SOURCE WOULD BE MANUVERED 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 Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
)
Robert L. HESS)
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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:

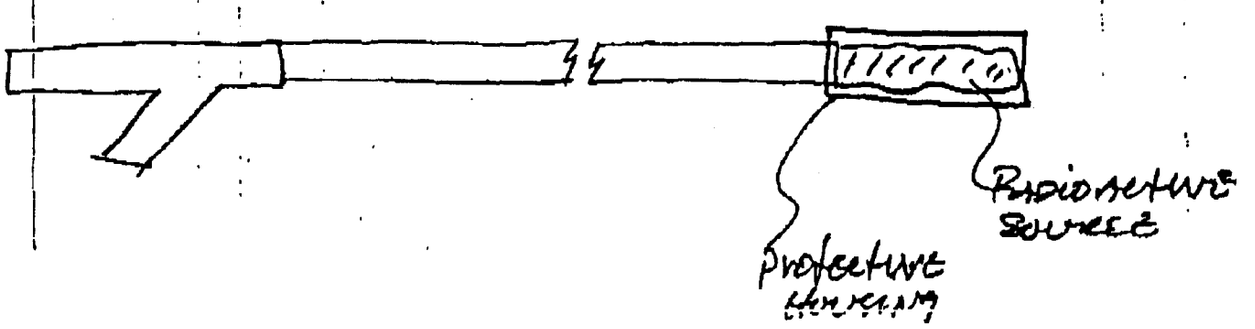
I, Robert L. Hess, declare that:

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

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 REGROW - 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 MANUVERED 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.



Express Mail Label No. EL 901833901 US

Date of Deposit: October 10, 2001

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

18

In re Patent Application of)
)
Robert L. HESS) Group Art Unit: 3736
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Application No.: 08/850,073) Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466))
)
Filed: May 2, 1997)
)
For: APPARATUS FOR RESTENOSIS)
TREATMENT)

PETITION FOR EXTENSION OF TIME

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The following extension of time is requested to respond to Office Action dated April 11, 2001:

three months to October 11, 2001 ; the extension fee is:

[X] $460.00 (217) [ ] $920.00 (117).

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

[X] An extension fee in the amount of $460.00 is enclosed.

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

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

10/16/2001 MHUI DER1 00000097 08850073
03 FC:217 460.00 OP

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: October 10, 2001

NC 000198

(10/01)

Express Mail Label No. EL 901833901 US

Date of Deposit: October 10, 2001

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#18 10/23

In re Reissue Application of	)	
	)	
Robert L. HESS	)	Group Art Unit: 3736
	)	
Serial No.: 08/850,073	)	Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466)	)	
	)	
Filed: May 2, 1997	)	
	)	
For: APPARATUS FOR RESTENOSIS TREATMENT	)	

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated April 11, 2001, please amend the application as follows:

In the Specification:

Please amend the specification as follows:

At column 4, replace the two paragraphs beginning on line 4 and ending on line 23 with the following new paragraphs:

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 proximate to the lesion site 56 of artery segment 58 in a deployed configuration and retractable within sheath 50 in a non-deployed configuration for insertion and removal within the artery segment 58.

In the Claims:

Please cancel Claim 18 without prejudice or disclaimer of the subject matter contained there.

Please amend Claims 6, 10, and 17 as follows:

6. Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

radioactive dose means for emitting radiation;

a device positioned in spaced relation to the dose means; and

positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein in the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery, said positioning means being operatively connected to said device and dose means for withdrawing said device and dose means from the artery

after said radioactive dose means is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

7. The apparatus of Claim 6, wherein the dose means is in solid form.

8. The apparatus of Claim 6, wherein the dose means is in liquid form.

9. The apparatus of Claim 6, wherein the dose means is in gaseous form.

10. Apparatus for post treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

a radiation source; and

a catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

11. The apparatus of Claim 10, wherein the radiation source is in solid form.

12. The apparatus of Claim 10, wherein the radiation source is in a liquid form.

13. The apparatus of Claim 10, wherein the radiation source is in gaseous form.

14. The apparatus of Claim 10, wherein the catheter includes a balloon, the catheter defining at least one hole distal to the balloon and at least one hole proximal to the balloon.

15. The apparatus of Claim 14, wherein the catheter includes a first lumen in fluid communication with the balloon.

16. The apparatus of Claim 15, wherein the catheter defines a plurality of perfusion holes and includes a second lumen in fluid communication with perfusion holes which allow perfusion of blood in the artery during inflation of the balloon.

17. The apparatus of Claim 10, wherein the radiation source provides a radiation dose to the stenosed region through a window in the catheter.

19. The apparatus of Claim 10, wherein the catheter includes a balloon capable of reducing the stenosed region and simultaneously performing the post-treatment by forcing a balloon into contact with a lesion, the balloon being inflated by a fluid having the radiation dose means incorporated therein.

20. The apparatus of Claim 6, wherein the radioactive dose means for emitting radiation is positioned within the device, the device defining a housing, wherein in the first position the dose means is shielded from treating the stenosed region and in the second position the housing is deployed to at least partially expose the dose means to the stenosed region of the artery.

21. The apparatus of Claim 20, wherein in the second deployed position a sheath is withdrawn relative to the dose means positioned in the stenosed region to expose the stenosed region to the dose means.

23. The apparatus of Claim 20, wherein the housing defines a window and a cover for the window such that in the second position the window is open and exposing the stenosed region to the dose means.

24. The apparatus of Claim 10, wherein the catheter includes a balloon with radioactive dose means for emitting radiation incorporated into and enclosed within the material of the balloon and the balloon is expanded in the second deployed configuration positioning the balloon at least partially in contact with the stenosed region of the artery.

25. The apparatus of Claim 24, wherein the portion of the device that is expanded includes a balloon with the dose means positioned on the surface of the balloon.

28. The apparatus for post-treatment of a stenosed region of Claim 17, wherein the dose means is a liquid.

29. The apparatus for post-treatment of a stenosed region of Claim 17, wherein the dose means is a gas.

30. The apparatus for post-treatment of a stenosed region of Claim 24, wherein the dose means incorporated into the balloon material is a solid.

31. The apparatus for post-treatment of a stenosed region of Claim 24, wherein the dose means incorporated into the balloon material is a liquid.

32. The apparatus for post-treatment of a stenosed region of Claim 24, wherein the dose means incorporated into the balloon material is a gas.

33. The apparatus for post-treatment of a stenosed region of Claim 23, wherein the apparatus controls the exposure of the dose means by controlling the radial direction and axial position of the window.

Please add Claims 34-40 as follows.

34. Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

radioactive dose means for emitting radiation;

a device movable with respect to the dose means; and

positioning means configured to advance said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also configured position the device and dose means between a first position and a second position, wherein in the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery, said positioning means configured to withdraw said device and dose means from the artery after said radioactive dose means is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

C3

35. The apparatus of Claim 34, wherein the dose means is in solid form.

36. The apparatus of Claim 34, wherein the dose means is in liquid form.

37. The apparatus of Claim 34, wherein the dose means is in gaseous form.

38. The apparatus of Claim 34, wherein the radioactive dose means for emitting radiation is positioned within the device, the device defining a housing, wherein in the first position the dose means is shielded from treating the stenosed region and in the second position the housing is deployed to at least partially expose the dose means to the stenosed region of the artery.

39. The apparatus of Claim 38, wherein in the second deployed position a sheath is withdrawn relative to the dose means positioned in the stenosed region to expose the stenosed region to the dose means.

40. The apparatus of Claim 38, wherein the housing defines a window and a cover for the window such that in the second position the window is open and exposing the stenosed region to the dose means.

Q3

REMARKS

Applicants would like to thank Examiner Lacyk for the courtesy extended in the telephone interview conducted on September 5, 2001. Claims 1-17, 19-21, 23-25, and 28-40 are currently pending.

As discussed in the telephone interview, enclosed herewith is a copy of a declaration of the inventor Robert Hess under 37 C.F.R. 1.131 executed on December 6, 1992 and previously filed in the parent application, serial number 07/755,480. Also enclosed is a Supplement Reissue Declaration as required in the Office Action.

In the Office Action, the Examiner has indicated that the Amendment filed December 8, 2000 is improper because the specification does not include underlining of the additions and the new claims lack the proper underlining. The foregoing amendments have been submitted in the proper format including underlining of the added subject matter in the specification and underlining of all the new claims. For ease of entry of the amendments, all the new pending claims 6-17, 19-21, 23-25, and 28-40 have been reproduced in this Amendment. Claims 1-5 of the original patent have been indicated to be allowed.

Rejection under 35 U.S.C. §102

In the Office Action, Claims 10 and 11 were rejected under 35 U.S.C. §102(b) as being anticipated by Weinstein et al. As discussed in the telephone interview with the Examiner, the Declaration under 37 C.F.R. 1.131 submitted in the parent application, a copy of which is enclosed herewith, establishes a date of invention for the claimed invention prior to the September 6, 1990 earliest filing date of Weinstein et al. Accordingly, the rejection under 35 U.S.C. §102 based on Weinstein et al. should be withdrawn.

In the foregoing amendments, the amendments made to Claims 6, 10, and 17 in the Preliminary Amendment filed on December 5, 2000, have been reversed. These amendments made in the December 5, 2000 Preliminary Amendment were unnecessary since Weinstein et al. is not prior art. The amendments to Claims 19-21, 23, and 24 made in the December 5, 2000 Preliminary Amendment have not been removed because these

amendments were made for purposes of clarification and not for purposes of distinguishing from Weinstein et al.

In addition, Claim 33 has been amended to depend from Claim 23 to provide antecedent basis and the term "cut out" has been amended to "window" for consistency.

Rejection under 35 U.S.C. §112

Claims 10 and 18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 18 has been canceled in order to expedite prosecution. In addition, the objectionable language "in close proximity" in Claim 10 has been removed by the foregoing Amendment.

New Claims 34-40 have been added in this amendment to further define the protection to which Applicant is entitled. Claims 34-40 are allowable over the prior art for at least the same reasons as Claims 6 and 10.

Finally, Applicants note that the original patent or an affidavit or declaration as to loss or inaccessibility of the original patent must be received before this reissue application can be allowed. The original patent is believed to have been lost. Two Declarations as to Loss or Inaccessibility are submitted herewith setting forth the facts resulting in the loss.

All outstanding matters in the Office Action are believed to be addressed by the foregoing amendments. In the event that there are any questions concerning this Amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

Date: October 10, 2001

10-12-01

GAU 3736

Express Mail Label No. EL 901833901 US

Date of Deposit: October 10, 2001

Patent
Attorney's Docket No. 011683-012

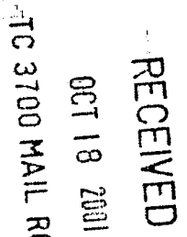
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
Robert L. HESS	)	Group Art Unit: 3736
	)	
Application No.: 08/850,073 (Reissue of U.S. Patent No. 5,411,466)	)	Examiner: J. Lacyk
	)	
Filed: May 2, 1997	)	
	)	
For: APPARATUS FOR RESTENOSIS TREATMENT	)	

AMENDMENT/REPLY TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:



Enclosed is a reply for the above-identified patent application.

[X] A Petition for Extension of Time is also enclosed.

[ ] A Terminal Disclaimer and a check for [ ] $55.00 (248) [ ] $110.00 (148) to cover the requisite Government fee are also enclosed.

[X] Also enclosed is Declaration of Kathleen Tracy as to Loss or Inaccessibility; Declaration of Robert L. Hess as to Loss or Inaccessibility; Supplemental Declaration (of Robert L. Hess); and Declaration under 37 CFR §1.131 dated December 6, 1992

[X] Small entity status is hereby claimed.

[ ] Applicant(s) request continued examination under 37 C.F.R. § 1.114 and enclose the[ ] $370.00 (279) [ ] $740.00 (179) fee due under 37 C.F.R. § 1.17(e).

[ ] Applicant(s) previously submitted ___, on ___, for which continued examination is requested.

[ ] A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (146/246) is also enclosed.

[ ] No additional claim fee is required.

[X] A additional claim fee is required, and is calculated as shown below:

AMENDED CLAIMS					
	NO. OF CLAIMS	HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADDT'L FEE
Total Claims	36	MINUS 30 =	6	× $18.00 (103) =	108.00
Independent Claims	6	MINUS 5 =	1	× $84.00 (102) =	84.00
If Amendment adds multiple dependent claims, add $280.00 (104)					
Total Amendment Fee					192.00
If small entity status is claimed, subtract 50% of Total Amendment Fee					96.00
TOTAL ADDITIONAL FEE DUE FOR THIS AMENDMENT					$96.00

[X] A claim fee in the amount of $ 96.00 is enclosed.

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

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: October 10, 2001

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,073	05/02/1997	ROBERT L. HESS	016565-049	4543

7590 01/30/2002

JAMES W. PETERSON, ESQ.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER
LACYK, JOHN P

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 01/30/2002

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

Office Action Summary	Application No.	Applicant(s)	
	08/850,073	HESS	
	Examiner	Art Unit	
	John P Lacyk	3736	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/10/2001* .

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

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

Disposition of Claims

4)☒ Claim(s) *1-17,19-21,23-25 and 28-40* is/are pending in the application.

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

5)☒ Claim(s) *1-5* is/are allowed.

6)☒ Claim(s) *6-17,19-21,23-25 and 28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

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

Application Papers

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

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

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

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

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

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

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

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-17, 19, 23-25, 28-33 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 19 the use of "capable of" is indefinite as stated in previous actions, in which the language had been removed and now is again placed in the claim. Also as stated previously claims 14 and 19 appear to add the balloon into the claims making it unclear how the current claims are not duplicates of the existing independent claims. Similarly with claims 17, 23-24 and 40.

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

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6-7, 10-11, 20-21, 34-35, 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson.

Lemelson discloses a radioactive dose means that has a positioning means for advancing and withdrawing the dose means The device has a retractable sheath that is removed to expose the dose means to the treatment area. The device is positioned from a "non-deployed configuration" when the radioactive source is enclosed to a "deployed configuration" when the radioactive source is exposed to the treatment area,

where the source and device are repositioned relative to one another the deploy the radioactive source.

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

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

6. Claims 8-9, 12-13, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson.

While Lemelson discloses the use of a radioactive source in the form of a solid, it is well known in the art to use radioactive material in different forms. Therefore a modification of Lemelson such that the radioactive source is a liquid or gas would have been obvious to one skilled in the art.

7. Applicant's arguments with respect to claims 6-17, 19-21, 23-25 have been considered but are moot in view of the new ground(s) of rejection.

8. Claims 1-5 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 703-308-2995. The fax phone numbers for the organization where this application or

proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

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

John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk
January 24, 2002

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the hea "Information on How to Effect Drawing Changes," on the of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein Identifying indicia, if provided, should include the title of the invention inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application If this informatio provided, it must be placed on the front of each sheet and centered within the t margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability Extensions of time may NOT be obtained under the provisions of 37 CFR 1 136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability The drawings should be filed as a separate paper with a transmittal letter addressed t the Official Draftsperson

2. Corrections other than Informalities Noted by Draftsperson on form PT 948.

All changes to the drawings, other than informalities noted by the Draftsperson MUST be made in the same manner as above except that, normally, a highlight (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication See 37 CFR 1.85(a)

Failure to take corrective action within the set period will result in ABANDONMENT of the application

Notice of References Cited	Application/Control No. 08/850,073	Applicant(s)/Patent Under Reexamination HESS	
	Examiner John P Lacyk	Art Unit 3736	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,588,395	05-1986	Lemelson	———
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

37369

#20
B. Webb 7/16/02

COPY OF PAPERS
ORIGINALLY FILED

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE WITH SUFFICIENT POSTAGE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C., 20231, ON:

Date: June 24, 2002

By: Joy A. Roeder
Joy A. Roeder

Patent

Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Robert L. HESS) Group Art Unit: 3736
)
Application No.: 08/850,073) Examiner: J. Lacyk
)
Filed: May 2, 1997) Confirmation No.:
)
For: APPARATUS FOR RESTENOSIS TREATMENT)

PETITION FOR EXTENSION OF TIME

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The following extension of time is requested to respond to the Office Action dated January 30, 2002 :

two months to June 30, 2002 ; the extension fee is:

[X] $200.00 (216) [ ] $400.00 (116).

[X] An extension fee in the amount of $ 200.00 is enclosed.

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

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

07/05/2002 MBERHE 00000052 08850073
03 FC:216 200.00 OP

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: June 21, 2002

(05/02)

COPY OF PAPERS
ORIGINALLY FILED

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE WITH SUFFICIENT POSTAGE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C., 20231, ON:

Date: June 24, 2002 By: Joy A. Roeder
Joy A. Roeder

21 D
B. Webb 7/16/02
(NE)

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)	
	)	
Robert L. HESS	)	Group Art Unit: 3736
	)	
Serial No.: 08/850,073	)	Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466)	)	
	)	
Filed: May 2, 1997	)	
	)	
For: APPARATUS FOR RESTENOSIS TREATMENT	)	

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated January 30, 2002, please amend the application as follows:

In the Claims:

Please cancel Claims 23 and 40 without prejudice or disclaimer of the subject matter contained therein.

Please amend Claim 19 as follows:

19. The apparatus of Claim 10, wherein the catheter includes a balloon inflated by a fluid having the radiation dose means incorporated therein.

Please add Claims 41 - 46 as follows.

41. The apparatus of Claim 6, wherein the radioactive dose means is incorporated into a liquid for delivery.

42. The apparatus of Claim 10, wherein the radioactive dose means is incorporated into a liquid for delivery.

43. The apparatus of Claim 34, wherein the radioactive dose means is incorporated into a liquid for delivery.

44. Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

a radioactive dose means for emitting radiation;

a sheath for delivering the radioactive dose means to and removing the radioactive dose means from the stenosed region of an artery that has been reduced by angioplasty or other procedure; and

means for moving the sheath and the radioactive dose means with respect to one another to move the radioactive dose means from a non-deployed and shielded position to a deployed and unshielded position for a period of time sufficient to reduce restenosis of the stenosed region.

45. The apparatus of Claim 44, wherein the radioactive dose means is incorporated into a liquid for delivery.

46. The apparatus of Claim 44, wherein the radiation source provides a radiation dose to the stenosed region through a window in the catheter.

REMARKS

Reconsideration and allowance of the above-identified reissue application are respectfully requested. Claims 1-17, 19-21, 23-25, and 28-40 are currently pending. Claims 1-5 of the original patent have been indicated to be allowed.

Enclosed is a Supplemental Reissue Declaration as required.

Rejection under 35 U.S.C. §112

Claims 14-17, 19, 23-25, and 28-33 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The term "capable of" in Claim 19 has been objected to and has been removed by the forgoing amendment.

The Office Action states that Claims 14, 17, 19, 23, 24, and 40 appear to be duplicates of the existing independent claims. These dependent claims differ from the original independent Claims 1, 3, and 5 as for at least the following reasons.

Claim 14 recites a catheter including a balloon. Claim 14 also recites at least one hole distal to the balloon and at least one hole proximal to the balloon. The original Claim 1 does not described the distal and proximal locations of the holes.

Claim 17 recites that the radiation source provides a radiation dose to the stenosed region through a window in the catheter. In contrast, original Claim 3 describes the window more specifically as a cut-out in a sidewall and includes a sheath covering the cut-out.

Claim 19 recites a balloon inflated by a fluid having the radiation dose means incorporated therein. In original Claim 1, the radiation dose means is not incorporated in a fluid in the balloon.

Claim 23 has been canceled.

Claim 24 recites a balloon with radioactive dose means incorporated into and enclosed within the material of the balloon. In contrast, Claim 1 does not describe the location of the dose means and Claim 2 recites that the dose means is distributed around the balloon.

Claim 40 has been canceled.

Rejections under 35 U.S.C. §102 and §103

In the Office Action, Claims 6, 7, 10, 11, 20, 21, 34, 35, 38, and 39 were rejected under 35 U.S.C. §102(b) as being anticipated by Lemelson. Claims 8, 9, 12, 13, 36, and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lemelson.

The rejected independent Claims 6, 10, and 34 each recite a treatment apparatus having a radioactive dose means and a positioning means. The positioning means is claimed as "configured to withdraw the... dose means from the artery" or "operatively connected to... the dose means for withdrawing the... dose means from the artery.

Lemelson describes a device for depositing a medication at a location in the body. The Lemelson device as is clearly described throughout the patent is an ejector or implanter for delivering a device or medication 37 into body tissue. (See column 1, lines 15-20 and 49-53, column 2, lines 32-36, 45, and 59-65). There is no teaching or suggestion in Lemelson to provide a device configured or connected to withdraw the dose means from the artery after use. Accordingly, the claims are allowable over Lemelson.

With respect to Claims 8, 9, 12, 13, 36, and 37 the Office Action states that a modification of Lemelson such that the radioactive source is a liquid or gas would have been obvious to one skilled in the art. Applicant respectfully disagrees. Lemelson specifically states that the material to be implanted with the device is a solid material. (See column 2, lines 32-33). There is no teaching or suggestion in Lemelson of using a liquid or gas medication. In addition, Lemelson is directed to placement of the medication at a predetermined position within the tissue. This predetermined positioning cannot be achieved with a liquid or gas medication which will move within the body duct once delivered.

New Claims 41-46 have been added to further define the protection to which applicant is entitled.

All outstanding matters in the Office Action are believed to be addressed by the foregoing amendments. In the event that there are any questions concerning this

Amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

Date: June 21, 2002

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE WITH SUFFICIENT POSTAGE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C., 20231, ON:

Date: June 24, 2002 By: Joy A. Roeder
Joy A. Roeder

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	**BOX FEE AMENDMENT**
Robert L. HESS	Group Art Unit: 3736
Application No.: 08/850,073 (Reissue of U.S. Patent No. 5,411,466)	Examiner: J. Lacyk
Filed: May 2, 1997	Confirmation No.:
For: APPARATUS FOR RESTENOSIS TREATMENT	

AMENDMENT/REPLY TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is a reply for the above-identified patent application.

[X] A Petition for Extension of Time is also enclosed.

[ ] A Terminal Disclaimer and a check for [ ] $55.00 (248) [ ] $110.00 (148) to cover the requisite Government fee are also enclosed.

[X] Also enclosed is Supplemental Declaration.

[X] Small entity status is hereby claimed.

[ ] Applicant(s) request continued examination under 37 C.F.R. § 1.114 and enclose the [ ] $370.00 (279) [ ] $740.00 (179) fee due under 37 C.F.R. § 1.17(e).

[ ] Applicant(s) previously submitted ___, on ___, for which continued examination is requested.

[ ] Applicant(s) request suspension of action by the Office until at least _, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

[ ] A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (146/246) is also enclosed.

[ ] No additional claim fee is required.

[X] An additional claim fee is required, and is calculated as shown below:

AMENDED CLAIMS					
	NO. OF CLAIMS	HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADDT'L FEE
Total Claims	41	MINUS 36 =	5	× $18.00 (103) =	90.00
Independent Claims	7	MINUS 6 =	1	× $84.00 (102) =	84.00
If Amendment adds multiple dependent claims, add $280.00 (104)					
Total Amendment Fee					174.00
If small entity status is claimed, subtract 50% of Total Amendment Fee					87.00
TOTAL ADDITIONAL FEE DUE FOR THIS AMENDMENT					$87.00

[X] A claim fee in the amount of $ 87.00 is enclosed.

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

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: June 21, 2002

#22 Webb 7/16/0.

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of)
)
Robert L. HESS) Group Art Unit: 3736
)
Serial No.: 08/850,073) Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466))
)
Filed: May 2, 1997)
)
For: APPARATUS FOR RESTENOSIS)
TREATMENT)

SUPPLEMENTAL DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Robert L. Hess, the above-named inventor, hereby declare that:

I am a citizen of the United States, and my residence is 35 Tagus Court, Portola Valley, California, 94028.

I verily believe myself to be the original, first inventor of the invention described and claimed in U.S. Letters Patent No. 5,411,466 (the "'466 patent") and for which invention I have solicit a Reissue Patent.

I have reviewed and understand the amendments to the claims filed herewith.

I do not know and do not believe that said invention was ever known or used in the United States of America before my invention thereof.

I acknowledge my duty to disclose all information known to me which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

PETITIONER further declares the following:

I verily believe the '466 patent may be at least partly inoperative or invalid for the reason that I claimed less than I had a right to claim in the '466 patent.

Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath or declaration submitted in this application, arose without deceptive intention on my part.

I further declare that all statements made herein of my own knowledge are true and that all statements made no 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 statement may jeopardize the validity of the application or any patent issuing thereon.

Dated: ~~May~~ June 20, 2002

By: _____
Robert L. Hess

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,073	05/02/1997	ROBERT L. HESS	016565-049	4543

7590 07/17/2002

JAMES W. PETERSON, ESQ.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
LACYK, JOHN P	
ART UNIT	PAPER NUMBER
3736	23

DATE MAILED: 07/17/2002

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

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	23

DATE MAILED:

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment filed on 7-1-02 is considered non-compliant because it has not been submitted in the format required under **37 CFR 1.121**, as amended on September 8, 2000 (see *65 Fed. Reg. 54603*, Sept. 8, 2000, and *1238 O.G. 77*, Sept. 19, 2000).

☐ 1. The amendment does not include a clean version of the **replacement paragraph(s)/section(s).** 37 CFR 1.121(b)(1)(ii).

☐ 2. The amendment does not include a marked-up version of the **replacement paragraph(s)/section(s).** 37 CFR 1.121(b)(1)(iii)

☑ 3. The amendment does not include a clean version of the **amended claim(s).** 37 CFR 1.121(c)(1)(i)

☐ 4. The amendment does not include a marked-up version of the **amended claim(s).** 37 CFR 1.121(c)(1)(ii)

☐ 5. Other_____.

☐ **PRELIMINARY AMENDMENT:** Unless applicant re-submits the preliminary amendment in compliance with revised 37 CFR 1.121 within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.

☑ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

For your convenience, attached to this correspondence is a copy of an informational flyer (MPEP Bookmark Bulletin on "Simplified Amendment Practice").

B. Webb
Legal Instruments Examiner

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of	)	
	)	
Robert L. HESS	)	Group Art Unit: 3736
	)	
Serial No.: 08/850,073	)	Examiner: J. Lacyk
(Reissue of U.S. Patent No. 5,411,466)	)	
	)	
Filed: May 2, 1997	)	
	)	
For: APPARATUS FOR RESTENOSIS TREATMENT	)	

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated January 30, 2002 and the Notice of Non-Compliant Amendment dated July 17, 2002, please amend the application as follows:

In the Claims:

Please cancel Claims 23 and 40 without prejudice or disclaimer of the subject matter contained therein.

Please amend Claim 19 as follows:

19. The apparatus of Claim 10, wherein the catheter includes a balloon inflated by a fluid having the radiation dose means incorporated therein.

Please add Claims 41 - 46 as follows.

41. The apparatus of Claim 6, wherein the radioactive dose means is incorporated into a liquid for delivery.

42. The apparatus of Claim 10, wherein the radioactive dose means is incorporated into a liquid for delivery.

43. The apparatus of Claim 34, wherein the radioactive dose means is incorporated into a liquid for delivery.

44. Apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other procedure comprising:

a radioactive dose means for emitting radiation;

a sheath for delivering the radioactive dose means to and removing the radioactive dose means from the stenosed region of an artery that has been reduced by angioplasty or other procedure; and

means for moving the sheath and the radioactive dose means with respect to one another to move the radioactive dose means from a non-deployed and shielded position to a deployed and unshielded position for a period of time sufficient to reduce restenosis of the stenosed region.

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Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

Date: August 9, 2002

CLAIMS AS AMENDED

19. The apparatus of Claim 10, wherein the catheter includes a balloon [capable of reducing the stenosed region and simultaneously performing the post treatment by forcing a balloon into contact with a lesion, the balloon being] inflated by a fluid having the radiation dose means incorporated therein.

9200/2899

Patent
Attorney's Docket No. 011683-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	**BOX FEE AMENDMENT**
Robert L. HESS	Group Art Unit: 3736
Application No.: 08/850,073 (Reissue of U.S. Patent No. ~~5,411,466~~)	Examiner: J. Lacyk
Filed: May 2, 1997	Confirmation No.:
For: APPARATUS FOR RESTENOSIS TREATMENT	

AMENDMENT/REPLY TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is a **reply in response to the Notice of Non-compliant Amendment dated July 17, 2002, for which the amendment fee was previously paid on June 24, 2002**, for the above-identified patent application.

[ ] A Petition for Extension of Time is also enclosed.

[ ] A Terminal Disclaimer and a check for [ ] $55.00 (248) [ ] $110.00 (148) to cover the requisite Government fee are also enclosed.

[ ] Also enclosed is _____.

[X] Small entity status is hereby claimed.

[ ] Applicant(s) request continued examination under 37 C.F.R. § 1.114 and enclose the [ ] $370.00 (279) [ ] $740.00 (179) fee due under 37 C.F.R. § 1.17(e).

[ ] Applicant(s) previously submitted ___, on ___, for which continued examination is requested.

[ ] Applicant(s) request suspension of action by the Office until at least _, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

[ ] A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (146/246) is also enclosed.

[ ] No additional claim fee is required.

[ ] An additional claim fee is required, and is calculated as shown below:

AMENDED CLAIMS					
	NO. OF CLAIMS	HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADDT'L FEE
Total Claims		MINUS =		× $18.00 (103) =	
Independent Claims		MINUS =		× $84.00 (102) =	
If Amendment adds multiple dependent claims, add $280.00 (104)					
Total Amendment Fee					
If small entity status is claimed, subtract 50% of Total Amendment Fee					
TOTAL ADDITIONAL FEE DUE FOR THIS AMENDMENT					

[ ] A claim fee in the amount of $_____ is enclosed.

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

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: August 9, 2002

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,073	05/02/1997	ROBERT L. HESS	~~016563-049~~ 011683-012	4543

7590 07/17/2002

JAMES W. PETERSON, ESQ.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
LACYK, JOHN P	
ART UNIT	**PAPER NUMBER**
3736	23

DATE MAILED: 07/17/2002

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

URGENT

Hess, Robert L

JWPICAL

PTO-90C (Rev. 07-01)

Response due 8/17/02

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	23

DATE MAILED:

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment filed on 7-1-02 is considered non-compliant because it has not been submitted in the format required under **37 CFR 1.121, as amended** on September 8, 2000 (see *65 Fed. Reg. 54603*, Sept. 8, 2000, and *1238 O.G. 77*, Sept. 19, 2000).

☐ 1. The amendment does not include a clean version of the **replacement paragraph(s)/section(s)**. 37 CFR 1.121(b)(1)(ii).

☐ 2. The amendment does not include a marked-up version of the **replacement paragraph(s)/section(s)**. 37 CFR 1.121(b)(1)(iii)

☑ 3. The amendment does not include a clean version of the **amended claim(s)**. 37 CFR 1.121(c)(1)(i)

☐ 4. The amendment does not include a marked-up version of the **amended claim(s)**. 37 CFR 1.121(c)(1)(ii)

☐ 5. Other_____.

☐ **PRELIMINARY AMENDMENT:** Unless applicant re-submits the preliminary amendment in compliance with revised 37 CFR 1.121 within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.

☑ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

For your convenience, attached to this correspondence is a copy of an informational flyer (MPEP Bookmark Bulletin on "Simplified Amendment Practice").

Brenda Webb
Legal Instruments Examiner

Notice of Allowability	Application No. 08/850,073	Applicant(s) HESS	
	Examiner John P Lacyk	Art Unit 3736	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed 8/13/2002*.
2. ☒ The allowed claim(s) is/are *1-17,19-21,23-25,28-46*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No.____ .
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6☐ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

John P Lacyk
Primary Examiner
Art Unit: 3736

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,073	05/02/1997	ROBERT L. HESS	016565-049	4543

7590 07/29/2003

JAMES W. PETERSON, ESQ.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
LACYK, JOHN P	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/29/2003

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

Office Action Summary	Application No.	Applicant(s)	
	08/850,073	HESS	
	Examiner	Art Unit	
	John P Lacyk	3736	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2002* .

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

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

Disposition of Claims

4)☒ Claim(s) *1-17,19-21,24,25,28-39 and 41-46* is/are pending in the application.

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

5)☒ Claim(s) *1-5,10-17,19,24-25, 28-32 and 42* is/are allowed.

6)☒ Claim(s) *6-9,20,21,33-39,41 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

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

Application Papers

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

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

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

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

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

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

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

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

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

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

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 depends on claim 23, which was cancelled in the amendment filed 8/13/2002.

Claims 6-9,20-21, 33-39, 41, 43-46 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

In the parent case 08/219,179 claim 15 was rejected on art while claim 16 was indicated as allowable. In the response filed November 15, 1994 the attorney

incorporated the language from claim 16 into claim 15 to overcome the rejection making claim 15 allowable. In particular the "positioning means" that allows the radioactive dose means to be exposed and covered by moving the positioning means from a first position to a second position, respectively, was amended to add "a cut-out" as part of the positioning means. In the reissue claims 6, 34 and 44 the "positioning means" is claimed to move the radioactive dose means from a (first) non-deployed state to a (second) deployed state, however the "cut- out" is no longer claimed.

Claims 1-5, 10-17, 19, 24-25, 28-32, 42 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 703-308-2995.

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

John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk
July 21, 2003

STAPLE AREA

☆ U.S. GOVERNMENT PRINTING OFFICE 1990-275-917

PATENT NUMBER

ORIGINAL CLASSIFICATION

CLASS	SUBCLASS
600	003

APPLICATION SERIAL NUMBER

08/850,073

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)			
606	007			

APPLICANT'S NAME (PLEASE PRINT)

HESS

IF REISSUE, ORIGINAL PATENT NUMBER

5,411,466

INTERNATIONAL CLASSIFICATION (INT. CL.)

A	61	N		5/00

GROUP ART UNIT: 3736

ASSISTANT EXAMINER (PLEASE STAMP OR PRINT FULL NAME)

PRIMARY EXAMINER (PLEASE STAMP OR PRINT FULL NAME): John P. Lacyk

PTO 270 (10-84)

ISSUE CLASSIFICATION SLIP

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Claim Final	Claim Original	Date 3/27/99	4/4/00	9/4/02	1/13/02	11/27/02
1	(1)	=	=	✓	=	=
2	2	|	|	|	|	|
3	(3)	|	|	|	|	|
4	4	|	|	|	|	|
5	(5)	=	=	|	=	=
6	(6)	✓	✓	|	✓	|
7	7	|	|	|	|	|
8	8	|	|	|	|	|
9	9	|	|	|	|	|
10	(10)	|	|	|	|	|
11	11	|	|	|	|	|
12	12	|	|	|	|	|
13	13	✓	|	|	|	|
14	14	O	|	|	|	|
15	15	|	|	|	|	|
16	16	O	|	|	|	|
17	17	✓	|	|	✓	=
18	~~18~~	✓	✓	|	|	|
19	19	✓	✓	|	✓	=
14	20	|	|	|	✓	|
20	21	|	|	|	✓	=
8	~~22~~	|	|	|	|	|
21	23	|	|	|	✓	=
22	24	|	|	|	✓	|
23	25	|	|	|	✓	=
	26	|	|	✓	|	|
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24	28	|	|	|	✓	=
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34	38	|	|	|	|	|
35	39	|	|	|	|	|
36	40	|	|	|	✓	|
37	41	|	|	|	|	|
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SYMBOLS

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

Claim Final	Claim Original	Date
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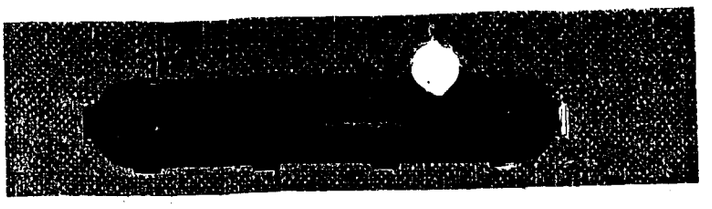

SEARCHED

Class	Sub.	Date	Exmr.
602	1-8		
606	7	9/4/02	sh
updated		7/9/03	sh
updated		11/23/04	sh
updated		11/28/05	sh

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
602	1-8		
607	7	11/28/05	sh

SEARCH NOTES

	Date	Exmr.

(RIGHT OUTSIDE)

65431 U.S. PTO
08/850073
05/02/97

PATENT APPLICATION

08850073

APPROVED FOR LICENSE ☐

INITIALS ____________

CONTENTS

Date Entered or Counted			Date Received or Mailed
	1.	Application ~~pts~~ papers.	
	2.	Title Report	9-18-97
	3.	Lost of Small Entity	2-19-98
	4.	Rev/PA	2-12-98
	5.	Notice of Acceptance	11-10-98
	6.	Rej (3 MOS.)	3-1-99
	7.	CHANGE OF ADDRESS	5.5.99
	8.	Restarted time Rej 3 (MOS)	4-7-00
	9.	Amdt B withdrawn	6/29/00
	10.	F. Rej. (3mos)	9-15-00
	11.	Req RCE	12-8-00
	12.	Amdt B	12-8-00
	13.		4/11/01
	14.	Rej (3)	3
	15.	Rev P/A	6-19-01
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	17.	Declaration	10/10/01
	18.	Amdt C / Ext. 3 mo.	10/10/01
[redacted] 1-28	19.	Rej (3)	1/30/02
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	21.	Amdt D (NE)	7-1-02
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7-29	26.	Rej (3)	07/29/03
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	31.		
	32.		

NC 000247

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