PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: John Kappos
O'MELVENY & MYERS LLP
610 Newport Center Drive, 17th Floor
Newport Beach, California 92660

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	24 APR 2008

Applicant's or agent's file reference	FOR FURTHER ACTION
639,219-011	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/023752	13 November 2007	13 November 2006

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/06 (2008.04)
USPC - 623/1.11

Applicant HLAVKA, Edwin J.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	27 March 2008	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/023752

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/023752

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	7-8, 36-37, 55-56, 81-82, 92-93	YES
	Claims	1-6, 9-35, 38-54, 57-80, 83-91, 94-96	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-96	NO
Industrial applicability (IA)	Claims	1-96	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-6, 9-35, 38-54, 57-80, 83-91 and 94-96 lack novelty under PCT Article 33(2) as being anticipated by LaDuca et al.

Referring to claim 1, LaDuca et al. disclose a method for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8H), comprising the steps of: providing a steerable catheter having a proximal end, a distal end, and an endoluminal implant carried in a distal region of the catheter, the catheter having a longitudinal axis at the distal end of the catheter, the endoluminal implant having a leading edge and a trailing edge (para. 0051; para. 0060-0061; figs. 5A-5C; para. 0077; para. 0079; para. 0042-0044); advancing the catheter into a curved region of a vessel having a centerline (para. 0077); steering the catheter to substantially align the longitudinal axis with the centerline of the vessel at the region where the implant lies within the vessel (fig. 8C; para. 0060-0061; para. 0077; para. 0079); and deploying the implant to achieve substantially uniform wall contact with the endoluminal surface of the vessel (para. 0020; para. 0082; para. 0084; fig. 8H; claims 36-37).

Referring to claim 16, LaDuca et al. disclose a medical device for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8C), comprising: an elongate member having a proximal end and a distal end (para. 0051); an endoluminal implant releasably carried near the distal end of the elongate member (para. 0012; claims 1-2; figs. 5A-5C; figs. 8B-8H; para. 0051-0054; para. 0079; para. 0020; para. 0042-0044); and a control member having a distal end attached at a point near the distal end of the elongate member and extending proximal from the point of attachment, wherein the control member causes a distal region of the catheter to bend when an axial displacement is applied to the control member (para. 0060; fig. 4).

Referring to claim 27, LaDuca et al. disclose a method for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8H), comprising the steps of: providing a catheter having a proximal end, a distal end, and an endoluminal implant carried in a distal region of the catheter, the catheter having a longitudinal axis at the distal end of the catheter, the endoluminal implant having a leading edge and a trailing edge (para. 0051; para. 0060-0061; figs. 5A-5C; para. 0077; para. 0079; para. 0042-0044) and further comprising a longitudinal adjustment member attached on the implant near the leading edge and extending proximally (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082); advancing the catheter into a curved region of a vessel having a centerline (para. 0077); deploying the implant (para. 0079); and moving the adjustment member to adjust the orientation of a plane defined by the leading edge of the endoluminal implant so that the endoluminal implant achieves uniform wall contact with the endoluminal surface of the vessel where the endoluminal implant engages the lesser curvature of the vessel (para. 0020; para. 0079; para. 0082; para. 0084-0086; fig. 8H; claims 36-37; fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0052-0054; para. 0076).

Referring to claim 45, LaDuca et al. disclose a method for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8H), comprising the steps of: providing a catheter having a proximal end, a distal end, and an endoluminal implant carried in a distal region of the catheter, the catheter having a longitudinal axis at the distal end of the catheter, the endoluminal implant having a leading edge and a trailing edge (para. 0051; para. 0060-0061; figs. 5A-5C; para. 0077; para. 0079; para. 0042-0044); advancing the catheter into a curved region of a vessel having a centerline (para. 0077); adjusting the orientation of a plane defined by the leading edge of the endoluminal implant (fig. 8C; para. 0060-0061; para. 0077; para. 0079; para. 0020; para. 0082; para. 0084-0086; fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0052-0054; para. 0076); and deploying the implant so that the endoluminal implant achieves uniform wall contact with the endoluminal surface of the vessel where the endoluminal implant engages the lesser curvature of the vessel (para. 0020; para. 0082; para. 0084; fig. 8H; claims 36-37).

Referring to claim 64, LaDuca et al. disclose a medical device for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8C) comprising: an elongate member having a proximal end and a distal end (para. 0051); an endoluminal implant releasably carried near the distal end of the elongate member, the endoluminal implant having a leading edge and a trailing edge (para. 0012; claims 1-2; figs. 5A-5C; figs. 8B-8H; para. 0051-0054; para. 0079; para. 0020; para. 0042-0044); and a longitudinal adjustment member comprising a distal segment attached on the implant near the leading edge and extending proximally, wherein the adjustment member causes the leading edge of the endoluminal implant to bend into uniform wall contact with the endoluminal surface of the curved vessel (para. 0060-0061; para. 0077; para. 0079; fig. 6C; 132; para. 0073; 182; figs. 8C-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claim 75, LaDuca et al. disclose a method for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8H), comprising the steps of: providing a steerable catheter having a proximal end, a distal end, and an endoluminal implant carried in a distal region of the catheter, the catheter having a longitudinal axis at the distal end of the catheter, the endoluminal implant having a leading edge and a trailing edge (para. 0051; para. 0060-0061; figs. 5A-5C; para. 0077; para. 0079; para. 0042-0044); advancing the catheter into a curved region of a vessel having a centerline (para. 0077); steering the catheter to substantially align the longitudinal axis parallel with a tangent to the centerline of the vessel at the region where the implant lies within the vessel (fig. 8C; para. 0060-0061; para. 0077; para. 0079); and deploying the implant to achieve substantially uniform wall contact with the endoluminal surface of the vessel (para. 0020; para. 0082; para. 0084; fig. 8H; claims 36-37).

(Continued in Supplemental Box)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/023752

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Box V

Referring to claim 86, LaDuca et al. disclose a method for deploying an implant in a curved vessel (para. 0001; para. 0014; figs. 8A-8H), comprising the steps of: providing a steerable catheter having a proximal end, a distal end, and an endoluminal implant carried in a distal region of the catheter, the catheter having a longitudinal axis at the distal end of the catheter, the endoluminal implant having a leading edge and a trailing edge (para. 0051; para. 0060-0061; figs. 5A-5C; para. 0077; para. 0079; para. 0042-0044); advancing the catheter into a curved region of a vessel having a centerline (para. 0077); steering the catheter to substantially align the longitudinal axis parallel with a tangent to the wall of the vessel at the region where the implant lies within the vessel (fig. 8C; para. 0060-0061; para. 0077; para. 0079); and deploying the implant to achieve substantially uniform wall contact with the endoluminal surface of the vessel (para. 0020; para. 0082; para. 0084; fig. 8H; claims 36-37).

Referring to claims 2, 31, 50, 76 and 87, LaDuca et al. disclose wherein the vessel is the aorta (claim 22; claim 31; para. 0002).

Referring to claims 3, 32, 51, 77 and 88, LaDuca et al. disclose wherein the step of advancing the catheter into a curved region of a vessel comprises advancing the catheter into the aorta arch (claim 22; claim 31; figs. 8A-8C; para. 0077; para. 0079).

Referring to claims 4, 33, 52, 78 and 89, LaDuca et al. discloses wherein the catheter is advanced into the ascending aorta upstream of the innominate artery (figs. 8C-8H; claim 32; para. 0042).

Referring to claims 5, 34, 53, 79 and 90, LaDuca et al. disclose wherein the catheter is advanced into the aortic arch downstream of the innominate artery (para. 0043-0044; para. 0046; para. 0077-0079).

Referring to claims 6, 35, 54, 80 and 91, LaDuca et al. disclose wherein the catheter is advanced into the aortic arch downstream of the left subclavian artery (para. 0043-0044; para. 0046; para. 0077-0079).

Referring to claims 9, 38, 57, 83 and 94, LaDuca et al. disclose wherein the catheter further comprises a control member attached to a point on the catheter near the distal end and extending proximally from the point of attachment, and wherein the step of steering the catheter further comprises the step of withdrawing the control member to cause the distal end to curve (para. 0060; fig. 4).

Referring to claim 10, LaDuca et al. disclose wherein the control member is attached to a point on the circumference of the catheter (para. 0060; para. 0064; para. 0067; para. 0051).

Referring to claim 11, LaDuca et al. disclose wherein the endoluminal implant further comprises a longitudinal adjustment member attached on the implant near the leading edge (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claim 12, LaDuca et al. disclose wherein the longitudinal adjustment member attached on the implant near the leading edge extends to a point of attachment near the trailing edge (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claims 46, 84 and 95, LaDuca et al. disclose wherein the endoluminal implant further comprises a longitudinal adjustment member attached on the implant near the leading edge and extending proximally (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claims 13, 43 and 62, LaDuca et al. disclose wherein the longitudinal adjustment member is releasably attached on the implant (192; fig. 8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claims 14, 44 and 63, LaDuca et al. disclose wherein the longitudinal adjustment member is fixedly attached on the implant (192; para. 0086).

Referring to claims 15, 39, 58, 85 and 96, LaDuca et al. disclose wherein the catheter further comprises an elongate sheath slideably covering the endoluminal implant, and wherein the step of deploying the implant further comprises the step of sliding the sheath proximally to release the endoluminal implant (fig. 5A; figs. 8C-8H; para. 0061; para. 0079; para. 0081).

Referring to claims 17 and 65, LaDuca et al. disclose wherein the endoluminal implant is a self-expanding stent (para. 0002).

Referring to claims 18 and 66, LaDuca et al. disclose wherein the endoluminal implant is a balloon-expanding stent (para. 0002).

Referring to claims 19 and 67, LaDuca et al. disclose wherein the elongate member is an elongate tubular catheter (para. 0012; para. 0051; claims 1-2; figs. 8B-8D).

Referring to claims 20 and 68, LaDuca et al. disclose wherein the elongate member further comprises an elongate sheath slideably covering the endoluminal implant (fig. 5A; figs. 8C-8H; para. 0061; para. 0079; para. 0081).

Referring to claims 21 and 69, LaDuca et al. discloses wherein the endoluminal implant is composed of nitinol (para. 0047).

Referring to claims 22 and 70, LaDuca et al. disclose wherein the endoluminal implant is a metal stent having a portion covered by textile (para. 0047-0049).

Referring to claim 71, LaDuca et al. disclose wherein the elongate member further comprises a control member attached to a point on the elongate member near the distal end and extending proximally from the point of attachment (para. 0060; fig. 4).

Referring to claims 23 and 72, LaDuca et al. disclose wherein the elongate member further comprises a proximal handle and wherein the control member is attached to a control mechanism in the proximal handle (para. 0051-0052; para. 0060; fig. 4; claims 3-5).

Referring to claim 24, LaDuca et al. disclose wherein the axial displacement is proximal displacement (fig. 4; para. 0060).

Referring to claim 25, LaDuca et al. disclose wherein the axial displacement is distal displacement (fig. 4; para. 0060).

Referring to claim 26, LaDuca et al. disclose the device further comprising a second control member having a distal end attached at a point near the distal end of the elongate member and extending proximal from the point of attachment (para. 0060; para. 0067).

Referring to claim 28, LaDuca et al. disclose wherein the adjustment member is attached near the leading edge of the endoluminal implant and extends proximally to a point of attachment near the trailing edge of the endoluminal implant (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claim 47, LaDuca et al. disclose wherein the adjustment member is attached near the leading edge of the endoluminal implant and extends proximally to a point of attachment near the trailing edge of the endoluminal implant (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claims 29 and 48, LaDuca et al. disclose wherein the adjustment member comprises a distal segment, a proximal segment, and an adjustable mechanism disposed between the distal and proximal segments (para. 0055-0056; fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Referring to claims 30 and 49, LaDuca et al. disclose the method further comprising the step of adjusting the adjustable mechanism to shorten or lengthen the adjustment member to adjust the radius of curvature of the endoluminal implant (para. 0055-0056; fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

(Continued in Next Supplemental Box)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/023752

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
(Previous Supplemental Box)

Referring to claims 40 and 59, LaDuca et al. disclose wherein the step of deploying the implant is performed while moving the adjustment member (para. 0079-0086).
Referring to claims 41 and 60, LaDuca et al. disclose wherein the step of deploying the implant is performed before moving the adjustment member (para. 0079-0086).
Referring to claims 42 and 61, LaDuca et al. disclose wherein the step of deploying the implant is performed after moving the adjustment member (para. 0079-0086).
Referring to claim 73, LaDuca et al. disclose wherein the adjustment member is attached on the circumference of the implant (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).
Referring to claim 74, LaDuca et al. disclose wherein the longitudinal adjustment member extends proximally to a proximal segment attached near the trailing edge (fig. 6C; 132; para. 0073; 192; figs. 8D-8G; para. 0086; para. 0052-0054; para. 0076; para. 0082).

Claims 7, 36, 55, 81 and 92 lack an inventive step under PCT Article 33(3) as being obvious over LaDuca et al. in view of Hartley et al.
Referring to claims 7, 36, 55, 81 and 92, LaDuca et al. disclose the method as shown in claims 3, 32, 51, 77 and 88 above. LaDuca et al. do not teach wherein the aortic arch has an aortic dissection and wherein the dissection has an entry point, wherein the leading edge of the implant substantially overlaps the entry point of the aortic dissection. However, Hartley et al. teach wherein the aortic arch has an aortic dissection and wherein the dissection has an entry point, wherein the leading edge of the implant substantially overlaps the entry point of the aortic dissection (claim 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of LaDuca et al. wherein the aortic arch has an aortic dissection and wherein the dissection has an entry point, wherein the leading edge of the implant substantially overlaps the entry point of the aortic dissection as taught by Hartley et al. The motivation for doing so would be to provide a better method for treating an aortic dissection.

Claims 8, 37, 56, 82 and 93 lack an inventive step under PCT Article 33(3) as being obvious over LaDuca et al. in view of Barbut et al.
Referring to claims 8, 37, 56, 82 and 93, LaDuca et al. disclose the method as shown in claims 3, 32, 51, 77 and 88 above. LaDuca et al. do not teach wherein the aortic arch has an aortic atheroma, and wherein the implant is deployed to retain the atheroma between the implant and the endoluminal surface of the aorta. However, Barbut et al. teach wherein the aortic arch has an aortic atheroma, and wherein the implant is deployed to retain the atheroma between the implant and the endoluminal surface of the aorta (claim 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of LaDuca et al. wherein the aortic arch has an aortic atheroma, and wherein the implant is deployed to retain the atheroma between the implant and the endoluminal surface of the aorta as taught by Barbut et al. The motivation for doing so would be to provide a better method for treating an aortic atheroma.

Claims 1-96 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.