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

In re Patent of: David T. Pollock & Peter Johansson

U.S. Patent No.: 7,147,662

Issue Date: December 12, 2006

Appl. No.: 10/326,719

Filing Date: December 19, 2002

Title: HOOK FOR ATTACHING TO A CORPOREAL LUMEN AND

METHOD OF MANUFACTURING

Submitted via Electronic Filing

**Mail Stop PATENT BOARD** 

Patent Trial and Appeal Board Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,147,662 UNDER 35 U.S.C. §§ 311-319

# TABLE OF CONTENTS

			Pag	<u> e</u>
I.	MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)1			. 1
II.	PAYMENT OF FEES UNDER 37 C.F.R. § 42.1032			
III.	GRO	GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)2		
IV.	SUM	IMAR	Y OF CHALLENGE AND RELIEF REQUESTED	.2
V.	SUMMARY OF THE '662 PATENT			
	A.	Mec	hanisms for Securing Endovascular Prostheses	.3
	B.	Sum	mary of the '662 Claims	.5
	C.	Perso	on of Ordinary Skill in the Art of the '662 Patent	.8
	D.	Clair	m Construction Under 37 C.F.R. § 42.104(b)(3)	.8
VI.	ANALYSIS OF GROUNDS FOR TRIAL9			
	A.	Intro	duction to the Unpatentability Arguments	.9
		and 1: Claims 1-6, 9-14 and 16 of the '662 Patent Are cipated Under 35 U.S.C. § 102(b) by Lefebvre1	0	
		1.	Summary of Lefebvre1	0
		2.	Lefebvre Discloses Each and Every Limitation of Claims 1-6, 9-14 and 16	2
	C. Ground 2: Claims 7, 8, and 15 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over Lefebvre in view of Lazaru		and 2: Claims 7, 8, and 15 of the '662 Patent Are Obvious er 35 U.S.C. § 103(a) Over Lefebvre in view of Lazarus1	8
		1.	Summary of Lazarus1	8
		2.	A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Lefebvre with Lazarus1	9

	D. Ground 3: Claims 1-6, 9-14 and 16 of the '662 Patent A Obvious Under 35 U.S.C. § 103(a) Over Marin in view Ostrovsky			22
		1.	Summary of Marin	23
		2.	Summary of Ostrovsky	25
		3.	A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Marin with Ostrovsky	27
	E.	Unde	nd 4: Claims 7 and 15 of the '662 Patent Are Obvious er 35 U.S.C. § 103(a) Over Marin & Ostrovsky in view of rus	34
	F.	Obvi	nd 5: Claims 1-6, 9-14, and 16 of the '662 Patent Are ous Under 35 U.S.C. § 103(a) Over Marin in view of ovre	36
		1.	Summary of Marin and Lefebvre	37
		2.	A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Marin with Lefebvre	37
	G.	Unde	nd 6: Claims 7, 8 and 15 of the '662 Patent Are Obvious er 35 U.S.C. § 103(a) Over Marin & Lefebvre in view of rus	43
	Н.	Ground 7: Claims 1-6, 8-14, and 16 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over White in view of Ostrovsky		
		1.	Summary of White	46
		2.	A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine White with Ostrovsky	49
	I.	Unde	nd 8: Claims 7 and 15 of the '662 Patent are Obvious er 35 U.S.C. § 103(a) Based on White in view of Ostrovsky zarus	56
VII.	CON	CLUS	ION	59

# **EXHIBIT LIST**

1001	U.S. Patent No. 7,147,662 to Pollock et al.
1002	Prosecution History of U.S. Patent No. 7,147,662
1003	U.S. Patent No. 5,108,418 to Lefebvre
1004	PCT Int'l Publication No. WO 00/18322 to White
1005	U.S. Patent No. 5,397,355 to Marin
1006	U.S. Patent No. 5,562,728 to Lazarus et al.
1007	U.S. Patent No. 6,447,530 to Ostrovsky et al.
1008	U.S. Patent No. 4,739,762 to Palmaz
1009	U.S. Patent No. 4,425,908 to Simon
1010	U.S. Patent No. 4,140,126 to Choudhury
1011	Charnsangavej et al., Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents, Radiology, Vol. 161:295-98 (1986)
1011 1012	Assessment of Treatment with Expandable Metallic Stents, Radiology,
	Assessment of Treatment with Expandable Metallic Stents, Radiology, Vol. 161:295-98 (1986)
1012	Assessment of Treatment with Expandable Metallic Stents, Radiology, Vol. 161:295-98 (1986)  U.S. Patent No. 4,688,553 to Metals
1012 1013	Assessment of Treatment with Expandable Metallic Stents, Radiology, Vol. 161:295-98 (1986)  U.S. Patent No. 4,688,553 to Metals  U.S. Patent No. 6,994,092 to van der Berg et al.
1012 1013 1014	Assessment of Treatment with Expandable Metallic Stents, Radiology, Vol. 161:295-98 (1986)  U.S. Patent No. 4,688,553 to Metals  U.S. Patent No. 6,994,092 to van der Berg et al.  U.S. Patent No. 6,620,183 to DiMatteo
1012 1013 1014 1015	Assessment of Treatment with Expandable Metallic Stents, Radiology, Vol. 161:295-98 (1986)  U.S. Patent No. 4,688,553 to Metals  U.S. Patent No. 6,994,092 to van der Berg et al.  U.S. Patent No. 6,620,183 to DiMatteo  U.S. Patent No. 5,836,969 to Kim

1019	Cragg et al., Nonsurgical Placement of Arterial Endoprosthesis: A New Technique Using Nitinol Wire, Radiology, Vol. 147:261-63 (1983)
1020	U.S. Patent No. 4,580,568 to Gianturco
1021	U.S. Patent No. 4,830,003 to Wolff et al.
1022	U.S. Patent No. 4,793,348 to Palmaz
1023	U.S. Patent No. 5,360,443 to Barone et al.
1024	Wallace et al., <i>Inferior Vena Caval Stent Filter</i> , AJR, Vol. 147:1247-1250 (December 1986)
1025	Prosecution History of U.S. Patent No. 7,736,387
1026	Declaration of Gary L. Loomis
1027	Curriculum Vitae of Gary L. Loomis

Medtronic, Inc. and Medtronic Vascular, Inc. (together, "Petitioners"), petition for *inter partes* review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-16 of U.S. Patent No. 7,147,662 (the "'662 patent") (Ex. 1001), and assert that there is a reasonable likelihood that they will prevail with respect to the claims challenged in this petition. A supporting Declaration of Gary L. Loomis, Ex. 1026, is submitted herewith.

#### I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

Petitioners are real parties-in-interest with respect to the instant petition.

The '662 patent is asserted in an action captioned *LifePort Sciences LLC v*. *Medtronic, Inc., et al.*, Case No. 1:12-cv-1793 (D. Del.), filed December 28, 2012.

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this petition. Service of any documents via hand-delivery may be made at the postal mailing address of the respective lead or back-up counsel designated below:

Lead Counsel	Back-Up Counsel
James J. Elacqua (Reg. # 28,412)	Edward L. Tulin (Reg. # 59,545)
SKADDEN, ARPS, SLATE, MEAGHER &	SKADDEN, ARPS, SLATE, MEAGHER &
FLOM LLP	FLOM LLP
525 University Avenue - Suite 1400	Four Times Square
Palo Alto, California 94301	New York, New York 10036-6522
Telephone: (650) 470-4510	Telephone: (212) 735-2815
Fax: (650) 798-6564	Fax: (917) 777-2815
James.Elacqua@skadden.com	Edward.Tulin@skadden.com

#### II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

Petitioners authorize the Patent and Trademark Office to charge Deposit Account No. 19-2385 for the fee set in 37 C.F.R. § 42.15(a) for this Petition and further authorizes payment of any additional fees to be charged to this Deposit Account.

### III. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioners certify that the '662 patent is available for IPR and that: (1) none of the Petitioners owns the '662 patent; (2) prior to the date this Petition was filed, neither Petitioners nor any real party-in-interest filed a civil action challenging the validity of a claim in the '662 patent; (3) this Petition has been filed less than one year after January 3, 2013, which was the date on which Petitioners were served with a complaint alleging infringement of the '662 patent; and (4) neither Petitioners, any real parties-in-interest, nor any privies of Petitioners, are estopped from challenging the claims on the grounds identified in this Petition.

#### IV. SUMMARY OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 1-16 of the '662 patent (collectively "the '662 Claims") in view of the following references:

Patent/Pub. Title	Priority Date	Date of Issuance or Publication	Exhibit
U.S. Patent No. 5,108,418 ("Lefebvre")	October 10, 1990	April 28, 1992	1003
U.S. Patent No. 5,562,728 ("Lazarus")	March 9, 1988	October 8, 1996	1006

PCT Publication No. WO 00/18322 ("White")	April 6, 2000	April 6, 2000	1004
U.S. Patent No. 5,397,355 ("Marin")	July 19, 1994	March 14, 1995	1005
U.S. Patent No. 6,447,530 ("Ostrovsky")	November 25, 1997	September 10, 2002	1007

Petitioners assert the following specific grounds of rejection under 35 U.S.C. §§ 102 and 103:

Ground	'662 Patent Claims	Grounds for Trial
1	1-6, 9-14 and 16	Anticipated by Lefebvre
2	7, 8 and 15	Obvious over Lefebvre in view of Lazarus
3	1-6, 8-14 and 16	Obvious over Marin in view of Ostrovsky
4	7 and 15	Obvious over Marin & Ostrovsky in view of Lazarus
5	1-6, 9-14 and 16	Obvious over Marin in view of Lefebvre
6	7, 8 and 15	Obvious over Marin & Lefebvre in view of Lazarus
7	1-6, 8-14 and 16	Obvious over White in view of Ostrovsky
8	7 and 15	Obvious over White & Ostrovsky in view of Lazarus

### V. SUMMARY OF THE '662 PATENT

# **A.** Mechanisms for Securing Endovascular Prostheses

Blood vessels, arteries, and other corporeal lumens can be affected by a number of potentially fatal deteriorative diseases and disorders, including aneurysms (localized enlargements that form due to weakened lumen walls),

stenosis (abnormal narrowing of blood vessels and arteries), and blood clots (clumps that form when blood hardens into a solid). Before 2000, a variety of endoluminal prosthetic devices had been developed to treat these various ailments, including stents, grafts, and filters. Ex. 1026 ¶ 8; *see also* Ex. 1001 ('662 patent) at 1:20-30; 3:61-48.

It was well-known before 2000 that each of these endovascular devices was potentially susceptible to unwanted drift or migration from the implantation site. *See, e.g.*, Ex. 1001, at col. 2: *see also, e.g.*, Ex. 1008, U.S. Patent No. 4,739,762 to Palmaz ("Palmaz"), at 1:61-2:1 (identifying the propensity of improperly secured grafts to "migrate away from the desired location within the body passageway"); Ex. 1009, U.S. Patent No. 4,425,908 to Simon ("Simon"), at 2:27-50, 3:11-16, and 7:3-7 (discussing the problem of implanted medical device migration and disclosing the use of hooks to prevent such migration). To counteract this problem, it was well-known to equip the endoluminal prosthesis with a mechanism for anchoring directly to the lumen wall, which typically was in the form of barbs or hooks. Ex. 1026 ¶¶ 12, 17,20, 22.

For instance, prior art such as U.S. Patent No. 4,140,126 to Choudhury ("Choudhury"), taught a device for intraluminal repair of an aneurysm that included "a plurality of radially spaced anchoring pins" for securing a graft to the blood vessel wall. *See* Ex. 1010 at 2:30-31; Fig. 3. Similarly, in Charnsangavej et

al., Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents ("Charnsangavej"), a self-expanding metallic stent "was modified by attaching barbs . . . which allowed the stent to become affixed to the wall of the vessel." Ex. 1011 at 295-96. Moreover, U.S. Patent No. 4,688,553 to Metals ("Metals") taught the importance of adding a "plurality of small hooks" that were flexible and curved to an implantable filter for trapping blood clots, so as to "facilitate the locking of the filter" into a fixed location in the lumen. Ex. 1012 at 3:54-64; Figs. 3-5, 10.

Thus, the use of "hooks to improve fixation of the prosthesis" was well-known in "[p]rior art grafts and stents," as well as in other types of intraluminal devices, including filters. Ex. 1001 at 1:31-32; *see also* Ex. 1026 ¶¶ 12, 17,20, 22.

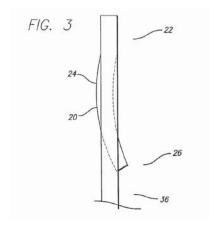
### B. Summary of the '662 Claims

The '662 Patent issued from U.S. Patent Application No. 10/326,719, filed on December 19, 2002, and claims priority to application No. 09/547,822, filed on Apr. 11, 2000. *See* Ex. 1001. The '662 patent has never previously been challenged in post-grant proceedings or in Court.

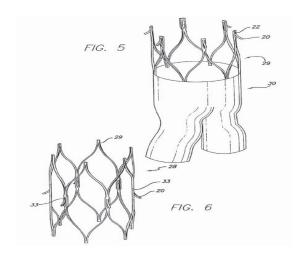
The '662 Claims relate to connecting mechanisms for attaching an intraluminal endoprosthesis to corporeal lumens. '662 patent, at Abstract. The independent claims of the '662 patent are generally directed to three elements relating to these connectors: (1) a frame that is **substantially tubular** and **lacking** 

a concentrically overlapping structure, *id.* at 6:24-26; 6:54-55; 7:8-9; (2) incisions, cuts, or slits are made in the frame to define an elongated member, hook or protrusion with a point or pointed end *id.* at 6:27-29; 6:56:59; 8:1-6; and (3) the elongated member, hook or protrusion has a permanent curve. *Id.* at 6:30-31; 6:60-61; 8:3-6. The dependent claims modify these elements by further specifying geometries, material resilience properties, and/or radii of curvature for the permanent curve. *Id.* at 6:31-7:4. Although the specification highlights that the claimed features are particularly appropriate for a graft used to treat abdominal aortic aneurysms, *id.* at 1:64-2:6, the '662 claims do not require that the claimed prosthesis be a graft, and the specification notes that the allegedly improved hooks would be useful on stents and "implantable blood clot filters such as those often put in the vena cava." *Id.* at 3:61-4:3.

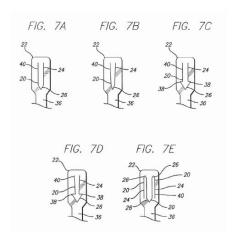
The claimed connecting mechanism is illustrated in several figures of the '662 patent, including Figure 3, which shows that the elongated member, hook, or protrusion (20), can be compressed until a portion of it fits within the circumference of the frame (22):

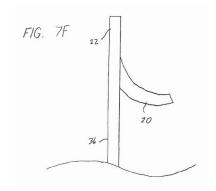


See also id. at 3:26-38. Figures 5 and 6 show that the hook (20) and frame (22) can be integral with an endoprosthesis and, in particular, a graft. *Id.* at 3:38-5:9.



Additionally, Figures 7A through 7F show that the engagement members, hooks, or protrusions (20) can be in a variety of geometric configurations:





See also id. at 5:10-55; 7:19-21; 7:29-32.

#### C. Person of Ordinary Skill in the Art of the '662 Patent

In 2000, a person of ordinary skill in the art of the '662 patent would have been highly skilled, and typically would possess the following education and experience: a degree in biomedical, mechanical, or chemical engineering, or material science, and would have knowledge of the vascular system of mammals and 3-5 years of experience in intravascular device design and methods of making intravascular devices. Ex. 1026 ¶ 44.

### D. Claim Construction Under 37 C.F.R. § 42.104(b)(3)

The claim terms of the '662 patent should be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). This standard of claim construction is broader than that generally employed by a federal district court when interpreting the scope of a claim. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). Although Petitioners reserve the right to

present different constructions in related litigation, Petitioners' proposed broadest reasonable constructions are set forth below.

The term "**permanent curve**" appears in all independent claims of the '662 patent, and should be construed to mean "a preset curve that maintains a permanent curve regardless of what configuration the device is in." Ex.  $1026 \, \P \, 60$ . All claims of the '662 patent were subject to final rejection before the claims were amended to require a permanent curve. Ex. 1002 at 105-11; 144-45. The proposed construction is consistent with the construction applied by the Examiner in his Reasons for Allowance. Ex.  $1026 \, \P \, 60$  (citing Ex. 1002 at 145).

For all other claim terms, the Board should apply their plain and ordinary meanings.<sup>1</sup>

#### VI. ANALYSIS OF GROUNDS FOR TRIAL

## A. Introduction to the Unpatentability Arguments

When the broadest reasonable interpretation is applied to the terms of the '662 claims, there is nothing to differentiate the claimed connecting mechanisms for affixing a prosthesis to a lumen wall from the identical prior art connecting mechanisms. As discussed in detail below, the '662 claims merely apply a well-known solution (the use of connectors to anchor an endoprosthesis) to

<sup>&</sup>lt;sup>1</sup> Even if the Board adopts a claim construction that differs from the one proposed, Petitioners believe that the prior art references invalidate the '662 claims under any possible construction.

a well-known problem (the propensity of such devices to migrate after implantation in a body lumen). In other words, the prior art references discussed below all teach connecting an endoprosthesis to a lumen wall using hooks, protrusions, or elongated members of varying shapes and sizes—and several references that were not before the examiner specifically teach the importance of providing those elongated members with a permanent curve, which was the basis upon which the examiner allowed the claims. The '662 claims simply recite these same well-recognized structures.

# B. Ground 1: Claims 1-6, 9-14 and 16 of the '662 Patent Are Anticipated Under 35 U.S.C. § 102(b) by Lefebvre

Each and every element of claims 1-6, 9-14 and 16 of the '662 patent is taught by Lefebvre, which was **not** before the examiner during prosecution of the '662 patent.<sup>2</sup> Lefebvre was filed on October 10, 1990, and issued on April 28, 1992. *See* Ex. 1003. Accordingly, it is prior art to the '662 patent under 35 U.S.C. § 102(b).

## 1. Summary of Lefebvre

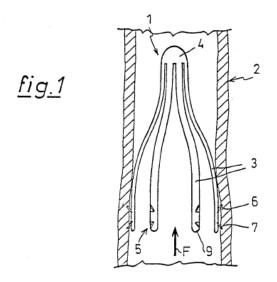
Lefebvre discloses intraluminal prostheses for implantation in a vessel, including the use of hooks to "ensure anchoring of the device in the wall of the

10

<sup>&</sup>lt;sup>2</sup> Though Lefebvre was not cited in the prosecution of the '662 patent, it was cited in the prosecution U.S. Patent No. 7,736,387, which is a continuation of the '662 application. Ex. 1025 at 170-71, 178.

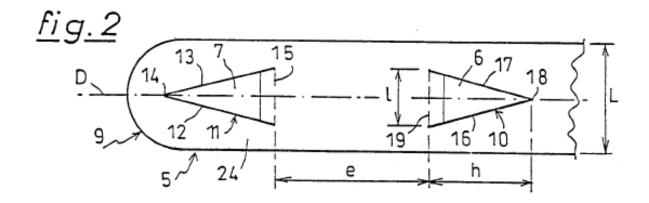
vessel." Lefebvre at 1:12-15. In particular, Lefebvre teaches that hooks should be placed on those intraluminal prostheses to "maintain the device at the place where it was implanted in the vessel, avoiding any displacement and any migration of the device." *Id.* at 1:26-30. And Lefebvre teaches that these hooks can be formed having a permanent curve. *Id.* at 4:15-20.

Lefebvre refers to the hooking means for connecting the intraluminal prosthesis to the vessel wall as a "tooth" or "rod projecting from the surface of the leg, of which one end is fast with the leg and the other end is pointed." *Id.* at 1:60-64. Figure 1 illustrates one such device (1) with teeth (6, 7):



As shown in Figure 2, Lefebvre teaches that these teeth are integrally formed from the frame (or "legs") of the prosthesis by making cuts or incisions (12 & 13, 16 & 17) in those legs. *Id.* at 3:4-9; *see also* Abstract ("The tooth is for example obtained by cutting out and pushing a median part of the leg, and possibly by

subsequent bending thereof."); 2:28-31 (same). One example of the cuts (11 and 12; 16 and 17, as illustrated below) shown in Lefebvre are straight and meet at a point (elements 14, 18, respectively), forming triangular connectors (6 & 7):



The material defined by the cuts (11 and 12, 16 and 17) is then pushed, bent or "curv[ed]" away from the surrounding leg material "along an arc of [a] circle" to form a permanently curved tooth. *Id.* at 3:10-15; 3:27-33; 4:15-20; Fig. 3.

# 2. Lefebvre Discloses Each and Every Limitation of Claims 1-6, 9-14 and 16

As discussed above in Section V(B), the claims of the '662 patent require three key elements, all of which are disclosed by Lefebvre. Ex. 1026 ¶¶ 72-74.

First, the '662 Claims require a "substantially tubular" frame element or body lacking concentrically overlapping structure. Ex. 1001 at 6:24-26; 6:54-55; 7:8-9. Lefebvre teaches a frame element or body (3, 5) that has a "substantially tubular" shape that is generally in the form of a cylinder, and that lacks a concentrically overlapping structure. Ex. 1026 ¶ 72; *see also* Ex. 1003 at 2:52-68; Fig. 1. Indeed, the shape of the Lefebvre endoprosthesis is much more tubular than

other shapes, such as those in U.S. Patent No. 6,447,530 to van der Berg (Ex. 1013, "van der Berg"), U.S. Patent No. 6,620,183 to DiMatteo (Ex. 1014, "DiMatteo"), and U.S. Patent No. 5,836,969 to Kim (Ex. 1015, "Kim"). All of the foregoing patents were recognized during prosecution of the '662 patent as depicting "substantially tubular" devices, and thus there is no question that Lefebvre is "substantially tubular" as well. Ex. 1026 ¶ 72 (citing Ex. 1002 at 82-83; 106-10).

Second, the '662 Claims require incisions, slits, or cuts to be made to define and "bound" an elongated member, hook or protrusion that has a "point" or "pointed end." Ex. 1001 at 6:24-29; 6:56-59; 8:1-6. Lefebvre teaches an elongated member, hook or protrusion (6, 7) with a point (14, 18) made by making incisions, slits, or cuts (12 and 13, 16 and 17) in the frame element or body (3, 5), such that the elongated member is bounded by Lefebvre's frame elements. Ex. 1003 at 3:4-33; Figs. 1-3.

Third, the '662 Claims require the "elongated member," "hook," or "protrusion" to have a "permanent curve." Ex. 1001 at 6:30-31; 6:60-61; 8:1-6. Lefebvre teaches that the elongated member, hook or protrusion (6, 7) is preset by curving the elongated member, hook or protrusion "along an arc of a circle." Ex. 1003 at 4:15-20; Fig. 3. The circular arc replaces the bend shown in Figure 3 and is a disclosed embodiment of Lefebvre. *Id.* In accordance with the disclosure, the

"tooth" of Lefebvre maintains a permanent curve regardless of what configuration the device is in. Ex.  $1026 \, \P \, 74$ .

For the foregoing reasons, and as shown in more detail in the claim chart below, each and every element of claims 1-6, 9-14 and 16 of the '662 Patent is taught by Lefebvre, and therefore those claims are unpatentable under Section 102(b).

'662 Patent: Claims 1-6, 9-14 & 16	Lefebvre (Ex. 1003)
1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:	Non-limiting preamble. But, Lefebvre discloses a mechanism for securing an endoprosthesis (1) within a corporeal lumen. 1:7-15; 1:52-2:5; Fig. 1.
a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;	Lefebvre discloses a frame element (3) with incisions (12 & 13, 16 & 17) formed therein, the frame element (3) having a substantially tubular shape and lacking concentrically overlapping structure. 2:60-68; 3:5-7; Figs. 1 & 2.
the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element;	Lefebvre discloses an elongated member (6, 7) formed by incisions (12 & 13, 16 & 17) having a pointed end (Figs 1 & 2), such that the elongated member (6, 7) being bounded by the frame element (3). 3:5-20; Figs. 1-3.
and the elongated member bent away from said frame element wherein the elongate member has a permanent curve.	Lefebvre discloses the elongated member (6, 7) bent away from the frame element (3) wherein the elongated member (6, 7) has a permanent curve. 4:15-20; Fig. 3.
2. The mechanism of claim 1, wherein the elongated member has parallel straight sides defining a constant width.	Lefebvre discloses elongated members in the form of teeth (6, 7) where each tooth is rod shaped with a point. 1:60-64; Fig. 2. When viewed perpendicular to its

'662 Patent: Claims 1-6, 9-14 & 16	Lefebvre (Ex. 1003)
	longitudinal axis, a rod has parallel straight sides that define a constant width.
3. The mechanism of claim 1, wherein the elongated member has non-parallel straight sides defining a narrowing width towards the pointed end.	Lefebvre discloses the elongated member (6, 7) having non-parallel straight sides defining a narrowing width towards the pointed end (14, 18). 3:5-20; Fig. 2.
4. The mechanism of claim 1, wherein the elongated member is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained.	Lefebvre discloses the elongated member (6, 7) being constructed of a material which has a "certain elasticity with the result that the legs may be brought against one another in a sheath for introduction." 2:59-68. The Loomis Declaration explains that a person of skill in the art would have recognized that the elongated member (6, 7) of Lefebvre is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained. Ex. 1026 ¶ 77.
5. The mechanism of claim 1, wherein the elongated member has a permanent constant radius curve.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "along an arc of circle, so that the outermost part of the tooth makes with the direction of the plane of the leg an angle α." 4:15-20; Fig. 3. Because a circle inherently has a constant radius, Lefebvre discloses the elongated member (6, 7) having a permanent constant radius curve. 4:15-20; Fig. 3.
<b>6.</b> The mechanism of claim 1, wherein the elongated member has a permanent curve of decreasing radius.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "so that the outermost part of the tooth makes with the direction of the plane of the leg an angle $\alpha$ ." 4:15-20. The Loomis Declaration explains that a person of ordinary skill in

'662 Patent: Claims 1-6, 9-14 & 16	Lefebvre (Ex. 1003)
	the art would have recognized that by increasing the angle $\alpha$ , so as to provide for a more secure connection with the lumen wall, the elongated member would have had a permanent curve of decreasing radius. Ex. $1026  \P  79$ .
<b>9.</b> The mechanism of claim 1, wherein the mechanism is integrally formed into an endoluminal prosthesis.	Lefebvre discloses the mechanism for securing an endoprosthesis being integrally formed into an endoluminal prosthesis (1). 1:7-15; 1:52-2:5; Fig. 1.
<b>10.</b> A connector for fastening a device to corporeal tissues, said connector comprising:	Non-limiting preamble. But, Lefebvre discloses a connector for fastening a device (1) to corporeal tissues. 1:7-15; 1:52-2:5; Fig. 1.
a substantially tubular body lacking concentrically overlapping structure;	Lefebvre discloses a substantially tubular body (3) lacking concentrically overlapping structure. 2:60-68; Fig. 1.
a hook having two sides and a point and being bounded by the tubular body;	Lefebvre discloses a hook (6, 7) having two sides and a point (14, 18) and being bounded by the tubular body (3). 3:5-45; Figs. 1-3.
said sides and said point defined by narrow slits in the connector; and	Lefebvre discloses the sides and the point (14, 18) defined by narrow slits (12 & 13, 16 & 17) in the connector. 3:5-45; Fig. 2
said hook having a permanent bend that forms a permanent curve.	Lefebvre discloses the hook having a permanent bend that forms a permanent curve. 4:15-20; Fig. 3.
11. The connector of claim 10, wherein the sides of the hook are parallel and straight and define a constant width.	Lefebvre discloses hooks in the form of teeth (6, 7) where each tooth is rod shaped with a point. 1:60-64; Fig. 2. When viewed perpendicular to its longitudinal axis, a rod has parallel straight sides that define a constant width.
<b>12.</b> The connector of claim 10, wherein the sides of the hook are	Lefebvre discloses sides of the hook (6, 7) that are non-parallel and straight and

'662 Patent: Claims 1-6, 9-14 & 16	Lefebvre (Ex. 1003)
non-parallel and straight and define a narrowing width towards the point.	define a narrowing width towards the point (14, 18). 3:5-20; Fig. 2.
13. The connector of claim 10, wherein the hook forms a permanent constant radius curve.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "along an arc of circle, so that the outermost part of the tooth makes with the direction of the plane of the leg an angle α." 4:15-20; Fig. 3. Because a circle inherently has a constant radius, Lefebvre discloses the hook (6, 7) forming a permanent constant radius curve. 4:15-20; Fig. 3.
14. The connector of claim 10, wherein the hook forms a permanent curve of decreasing radius.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "so that the outermost part of the tooth makes with the direction of the plane of the leg an angle $\alpha$ ." 4:15-20. The Loomis Declaration explains that a person of ordinary skill in the art would have recognized that by increasing the angle $\alpha$ , so as to provide for a more secure connection with the lumen wall, the elongated member would have had a permanent curve of decreasing radius. Ex. 1026 ¶ 79.
<b>16.</b> An endoluminal prosthesis, comprising:	Non-limiting preamble. But, Lefebvre discloses an endoluminal prosthesis (1). 1:7-15; 1:52-2:5; Fig. 1.
a substantially tubular frame element, the frame element lacking concentrically overlapping structure;	Lefebvre discloses a tubular frame element (3) that lacks concentrically overlapping structure. 2:60-68; 3:5-7; Figs. 1 & 2.
and at least one protrusion cut out of said frame element having a resiliently flexible bend formed therein,	Lefebvre discloses at least one protrusion (6, 7) cut out of said frame element (3). 3:5-20; Figs. 1-3. Lefebvre also inherently discloses that the protrusion has a resiliently flexible bend formed therein,

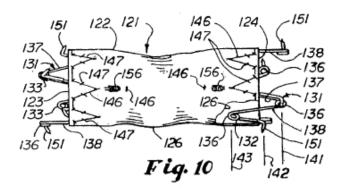
'662 Patent: Claims 1-6, 9-14 & 16	Lefebvre (Ex. 1003)
	because the frame element is made of a resilient material. 2:59-68.
wherein the at least one protrusion has a permanent curve the at least one protrusion being bounded by the frame element and the at least one protrusion having a pointed end.	Lefebvre discloses the at least one protrusion (6, 7) having a permanent curve. 4:15-20; Fig. 3. And Lefebvre discloses the at least one protrusion (6, 7) being bounded by the frame element (3) and the at least one protrusion having a pointed end (14, 18). Figs. 1-3.

# C. <u>Ground 2</u>: Claims 7, 8, and 15 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over Lefebvre in view of Lazarus

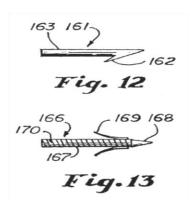
### 1. Summary of Lazarus

Lazarus was filed on April 12, 1995, and issued as a patent on October 8, 1996. *See* Ex. 1006. Accordingly, it is prior art under 35 U.S.C. § 102(b). Lazarus was **not** before the examiner during prosecution of the '662 patent.

Lazarus teaches an endovascular stent-graft that can be inserted percutaneously. *Id.* at 1:25-60; 2:48-64; Abstract. This endovascular graft is cylindrical, and is therefore substantially tubular. Ex.  $1026 \, \P \, 104$ . This cylindrical stent-graft from Lazarus is shown below in Fig. 10:



Further, Lazarus teaches that the stent-graft can use hooks or barbs to attach to the vessel wall "in order to ensure that the graft **121** will not become dislodged after it has been implanted." Ex. 1006 at 8:57-65; 10:23-54; Figs. 12-13. In discussing these hooks, Lazarus discloses several hook structures that can be used. *Id.* First, Lazarus notes that hooks can be "sharpened to provide conical tips." 8:57-65. Second, Lazarus teaches a "barb" (162) that extends outwardly from the main body (163) of the hook-like element (161). *Id.* at 10:23-35; Fig. 12. And third, Lazarus teaches arrowhead shaped projections (169) that inhibit removal of hooks after insertion. *Id.* at 10:35-54; Fig. 13. These embodiments are illustrated by Figures 12 and 13 of Lazarus:



### 2. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Lefebvre with Lazarus

The above discussions of Lefebvre are incorporated into this Ground. As discussed above, Lefebvre discloses each and every element of claims 1-6, 9-14, and 16 of the '662 patent. *See supra* at section VI(B)(2). The remaining three claims of the '662 patent (claims 7, 8 and 15) specifically describe the point or

pointed end of the attachment mechanism having various geometries. Ex. 1001 at 6:46-49; 7:5-6.

Claim 7 requires the pointed end of the connecting mechanism to include at least one "barb," claim 8 requires the pointed end of the connecting mechanism to be "sharpened," and claim 15 requires the point of the connector to be "formed in an arrowhead configuration." *Id.* at 6:46-49; 7:5-6. Lazarus specifically teaches connectors utilizing each of these geometries, including a barb, a sharpened point, and an arrowhead configuration." Ex. 1006 at 8:57-65; 10:23-54; Figs. 10-13; Ex. 1026 ¶¶ 116-18.

A person having ordinary skill in the art would have been motivated to combine Lefebvre with Lazarus, because both of these references discuss the use of hook-like elements to address the problem of unwanted intraluminal device migration, and because Lazarus expands on the teachings of Lefebvre by disclosing configurations for those hooks that provide for even better resistance to unwanted migration. Ex. 1026 ¶¶ 113-24.

Both Lefebvre and Lazarus are within the same field of art, and teach the importance of using engagement members, hooks or protrusions to prevent migration of devices in corporeal lumens. Ex. 1003 at 1:12-16; 1:26-30; Ex. 1006 at 10:23-26. Lazarus specifically teaches that by modifying hooks like those of Lefebvre to make them sharper, or to configure them as barbs or arrowheads, *more* 

secure anchoring of the device can be achieved. Ex. 1006 at 10:23-54 (noting that "in order to ensure that the graft . . . will not become dislodged after it has been implanted, it may be desirable to provide alternative hook-like elements," including a "barb" or an arrowhead configuration that "will become firmly imbedded in the tissue to inhibit . . . removal"); see also Ex. 1006 at Figs. 12 & 13. Thus, a person of skill in the art dealing with the problem of intraluminal device migration would have been motivated to combine the teaching of Lazarus with that of Lefebvre to achieve even stronger anchoring of the device to the lumen wall. Ex. 1026 ¶¶113-24.

For the foregoing reasons, and as shown in more detail in the claim chart below, Petitioners submit that claims 7, 8 and 15 of the '662 Patent are obvious under Section 103(a) based on Lefebvre in view of Lazarus.

'662 Patent: Claims 7, 8 and 15	Lefebvre (Ex. 1003) in view of Lazarus (Ex. 1006)
7. The mechanism of claim 1, wherein the pointed end includes at least one barb.	See discussion of claim 1 in Ground 1, supra.  Lazarus discloses at least one barb on the pointed end of the elongated member for securing an endoprosthesis. 10:23-35; Fig. 12. A person
	having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Lefebvre to achieve a more secure mechanism for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 121.
8. The mechanism of claim 1, wherein the	See discussion of claim 1 in Ground 1, supra.

'662 Patent: Claims 7, 8 and 15	Lefebvre (Ex. 1003) in view of Lazarus (Ex. 1006)
pointed end is sharpened.	Lazarus discloses sharpening the pointed end of the elongated member in a device for securing an endoprosthesis. 8:57-65. Figs. 10-13. A person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Lefebvre to achieve a more secure mechanism for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 122.
15. The connector of claim 10, wherein the point is formed in an arrowhead configuration.	See discussion of claim 10 in Ground 1, supra.  Lazarus discloses a hook (166) wherein the point of the hook is formed in an arrowhead configuration. 10:36-54; Fig. 13. A person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Lefebvre to achieve a more secure connector for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 123.

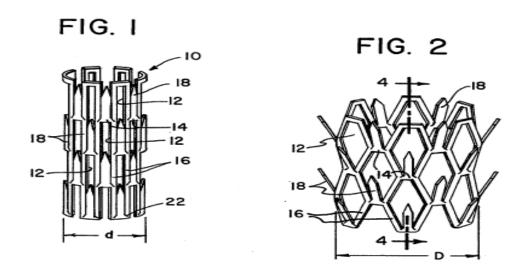
# D. Ground 3: Claims 1-6, 9-14 and 16 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over Marin in view of Ostrovsky

As noted above, the claims in the application that issued as the '662 patent were rejected over Marin during prosecution. Ex. 1002 at 105-11. In response, the '662 application's claims were amended to recite an elongated member with a "permanent curve." *Id.* at 144-45. But for Marin's failure to teach this limitation, the '662 claims would not have issued. *See id.* As discussed below, multiple references, including Ostrovsky, teach permanently curving the elongated members of endoprostheses.

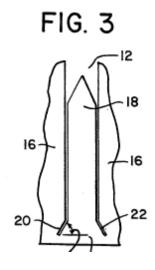
#### 1. Summary of Marin

Marin was filed on July 19, 1994, and issued on March 14, 1995. *See* Ex. 1005. Accordingly, it is prior art under 35 U.S.C. § 102(b).

Marin teaches an "intraluminal stent" with "barbs [that] are adapted to engage, for example, a graft and/or the inner layers of a blood vessel to mechanically attach the stent to the vessel." Ex. 1005 at Abstract; see also id. at 1:53-62. These barbs were added to a preexisting stent, known as the "Palmaz stent," which was disclosed in a patent that was incorporated by reference into Marin. See id. at 1:18-30 (incorporating U.S. Patent No. 5,397,355 by reference). This Palmaz stent had "a mesh-like tubular member which can be expanded from a first diameter to a second diameter." *Id.* at 1:31-33. The barbs of Marin were designed such that any preset, permanent curvature of those barbs would "remain within the surface of the [Palmaz] stent when the stent is in its unexpanded configuration, but . . . extend from the surface of the stent when the stent is expanded." *Id.* at 1:56-59; Ex. 1026 ¶¶ 90-92, 134. The disclosed connecting mechanism in the form of barbs is illustrated in Figures 1 and 2 of Marin:



The stent disclosed by Marin is made from a "metal in which elongated openings 12 are cut, for example by conventional laser cutting techniques." Ex. 1005 at 2:40-44. That same technique of cutting is also applied to produce the barbs taught by Marin, such that a pair of "oblique slots 20 and 22 . . . are provided, then the barb will "move radially outward from the surface of the stent as it expands," *id.* at 3:5-11, just as is contemplated by the curved connectors in the '662 patent. Those slots are illustrated in Figure 3 of Marin:



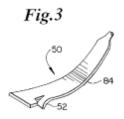
Marin thus discloses a connecting mechanism in form of a barb, which can be formed of a preset, resilient curve, and is formed from narrow slits that are made by incisions, where that barb has a pointed end. Ex. 1026 ¶¶ 90-92, 131.

The only limitation from the independent claims of the '662 patent that is not explicitly depicted in Marin is the use of a permanent curve in the connecting mechanism. However, as discussed below, Ostrovsky discloses a permanent curve, and the advantages of using such a configuration to anchor the device.

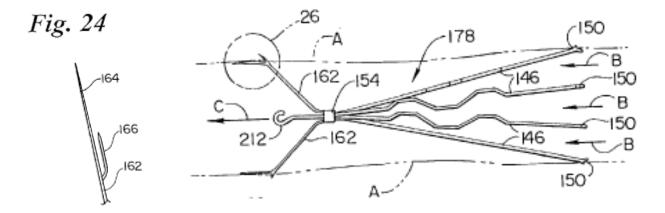
#### 2. Summary of Ostrovsky

Ostrovsky was filed on November 25, 1997, and issued on September 10, 2002. *See* Ex. 1007. It is therefore prior art to the '662 claims under 35 U.S.C. § 102(e). Ostrovsky was **not** before the examiner during prosecution of the '662 patent.

Ostrovsky teaches the use of permanently curved, pointed hooks on a recoverable thrombosis filter for intraluminal implantation. *Id.* at Abstract, Fig. 3, Fig. 24. This filter could be formed from any number of materials, including flexible metals such as "nitinol, stainless steel, or other biocompatible materials." The filter disclosed in Ostrovsky includes a number of leg members that are each equipped with "[a]n outward projection 52 . . . arranged for engaging the vein wall," as shown below:



*Id.* at 6:2-3. "A similar configuration is utilized for the anchoring elements," which are located at the opposite end of the Ostrovsky filter, and are also referred to as "anchoring struts." *Id.* at 6:3-4. These anchoring struts are in turn equipped with a "sharpened portion **166** [that is] sufficiently sharp to penetrate a vessel wall," as shown below in Figures 24 and 25:



*Id.* at 9:13-14. In an alternative configuration, these hook-like elements from Ostrovsky have been further modified to a shape resembling a saber-tooth (element **206**), so as to firmly anchor the device to the lumen wall. And the hook-like elements maintain a curve in both their compressed and expanded configurations. *See id.* at Figs. 33, 34.

Fig.33

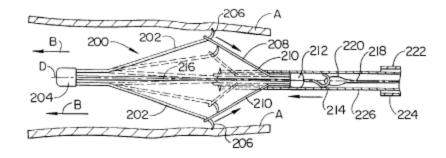
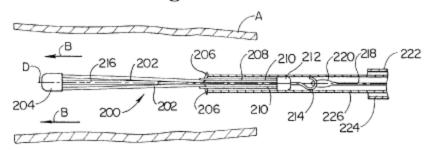


Fig. 34



Thus, Ostrovsky teaches the use of anchoring elements for affixing the filter to the lumen walls, where those elements have pointed, permanently curved hooks.

## 3. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Marin with Ostrovsky

The examiner only allowed the '662 claims to issue over Marin after the permanent curve limitation was added to the claims. Ex. 1002 at 145. And Ostrovsky, which was not before the examiner, teaches a permanent curve. Ex. 1007 at Fig. 3. Because there was motivation to combine Marin and Ostrovsky, the claims of the '662 patent are invalid.

As discussed above, both Marin and Ostrovsky teach the importance of using connectors on a substantially tubular intraluminal device to prevent migration of devices in corporeal lumens. Indeed, Marin specifically highlights that it improves on preexisting stents by cutting "a means for mechanically anchoring the stents to the blood vessel." Ex. 1005 at 1:54-55. Ostrovsky similarly teaches the importance of securing intraluminal devices to the lumen wall for use in "permanent implant device[s]. Ex. 1007 at 1:1-3; see Figs. 3, 11-33. Ostrovsky further teaches the importance of providing a permanent curve, such that even if the configuration of the legs of the filter changes (as part of deployment or removal of the device), the hook-like elements remain in their permanently curved configuration, so as to be in a position to anchor the device. Ex. 1007 at Figs. 33 & 34; 9:58-67; Ex. 1026 ¶¶ 111-12. Thus, a person of ordinary skill in the art would have been motivated to utilize the combined teachings of Marin with Ostrovsky to ensure a permanent curve in the connecting frame elements of the Marin endoprosthesis. Ex. 1026 ¶¶ 125-40. In this way, each and every element of claims 1-6, 8-14 and 16 of the '662 patent is disclosed by the combination of Marin and Ostrovsky.

For the foregoing reasons, and as shown in more detail in the claim chart below, claims 1-6, 8-14 and 16 of the '662 patent are obvious under Section 103(a) based on Marin in view of Ostrovsky.

'662 Patent: Claims 1-6, 8-14 and 16	Marin (Ex. 1005) in view of Ostrovsky (Ex. 1007)
1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:	Non-limiting preamble. But, Marin discloses a mechanism for securing an endoprosthesis within a corporeal lumen. 1:6-8; 1:53-68; Abstract.
	Ostrovsky discloses a mechanism for securing an endoprosthesis within a corporeal lumen. 1:14-1:18; 3:17-20; Abstract.
a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;	Marin discloses a frame element (10) with incisions formed therein. 2:39-51; Figs. 1-2. The frame element (10) has a substantially tubular shape and lacks concentrically overlapping structure. 2:39-51; Figs. 1-2.
	Ostrovsky discloses a frame element (50) with incisions formed therein. 5:29-32; 5:64-6:4; Fig. 3.
the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element;	Marin discloses the incisions forming an elongated member (18) with a pointed end, the elongated member (18) being bound by the frame element (10). 2:39-51; Figs. 1-3.
	Ostrovsky discloses the incisions having a pointed end (166). 5:64-6:4; 9:11-9:29; Fig. 24.
and the elongated member bent away from said frame element wherein the elongate member has a	Marin discloses the elongated member (18) bent away from the frame element (10). 2:54-59; 3:3-15; Figs. 2 and 4.
permanent curve.	Ostrovsky discloses the elongated member (52) bent away from the frame element (50) wherein the elongated member (52) has a permanent curve. Fig. 3. The Loomis Declaration explains that a person of ordinary skill in the art would have been motivated to apply the teachings of Ostrovsky to make the elongated member of Marin with a permanent curve. Ex. 1026 ¶ 131.

'662 Patent: Marin (Ex. 1005)	
Claims 1-6, 8-14 and 16	Marin (Ex. 1005) in view of Ostrovsky (Ex. 1007)
2. The mechanism of claim 1, wherein the elongated member has parallel straight sides defining a constant width.	Marin discloses the elongated member (18) having parallel straight sides defining constant width. Figs. 1-3.  Ostrovsky discloses the elongated member (52) having parallel straight sides defining a constant
3. The mechanism of claim 1, wherein the elongated member has non-parallel straight sides defining a narrowing width towards the pointed end.	width. Fig. 3.  Ostrovsky discloses an element (164) with non-parallel straight sides defining a narrowing width towards the pointed end. 9:11-29; Figs. 24-28.  And, Ostrovsky discloses the elongated member (166) made of the same material. The Loomis Declaration explains that not only would a person of skill in the art have recognized that the elongated member (166) could be constructed with non-parallel straight sides, but also that such person would have been motivated to so construct the elongated members to ensure that they more securely anchor the device against the vessel wall. Ex. 1026 ¶ 133.
4. The mechanism of claim 1, wherein the elongated member is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained.	Marin discloses that the elongated member (18) will "remain within the surface of the stent when the stent is in its unexpanded condition, but [will] [] extend from the surface of the stent when the stent is expanded." 1:55-59.  Ostrovsky discloses an elongated member (166) as being made of a "flexible" and "resilient" material. 9:11-29; 10:57-11:3. The Loomis Declaration explains that the disclosure inherently provides an elongated member (166) that is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained. Ex. 1026 ¶ 134.

'662 Patent: Claims 1-6, 8-14 and 16	Marin (Ex. 1005) in view of Ostrovsky (Ex. 1007)
5. The mechanism of claim 1, wherein the elongated member has a permanent constant radius curve.	As discussed above in the context of claim 1, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See</i> , <i>e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of constant radius. Ex. 1026 ¶ 135.
6. The mechanism of claim 1, wherein the elongated member has a permanent curve of decreasing radius.	As discussed above in the context of claim 1, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See</i> , <i>e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of decreasing radius. Ex. 1026 ¶ 136.
8. The mechanism of claim 1, wherein the pointed end is sharpened.	Ostrovsky discloses an elongated member (166) wherein the pointed end is sharpened. 9:11-29; Fig. 24.
9. The mechanism of claim 1, wherein the mechanism is integrally formed into an endoluminal prosthesis.	Marin discloses the mechanism being integrally formed into an endoluminal prosthesis. 2:39-51; Figs. 1-5.
	Ostrovsky discloses the mechanism being integrally formed into an endoluminal prosthesis. 3:17-20.
<b>10.</b> A connector for fastening a device to corporeal tissues, said connector comprising:	Non-limiting preamble. But, Marin discloses a connector for fastening a device to corporeal tissues. 1:6-8; 1:53-68; Abstract.
a substantially tubular body lacking concentrically overlapping structure;	Marin discloses a substantially tubular body (10) lacking concentrically overlapping structure. 2:39-51; Figs. 1-2.
	Ostrovsky discloses a substantially tubular body

'662 Patent: Claims 1-6, 8-14 and 16	Marin (Ex. 1005) in view of Ostrovsky (Ex. 1007)
	(46) lacking concentrically overlapping structure. 5:29-32; 7:8-7:19; Fig. 14.
a hook having two sides and a point and being bounded by the tubular body;	Marin discloses a hook (18) having two sides and a point and being bounded by the tubular body. 2:39-51; Figs. 1-3.
said sides and said point defined by narrow slits in the connector; and	Marin discloses the sides and point being defined by narrow slits in the connector. 2:39-51; Figs. 1-3.
said hook having a permanent bend that forms a permanent curve.	Ostrovsky discloses the hook (52, 166) having a permanent bend that forms a permanent curve. 5:64-6:4; 9:11-9:29; Fig. 3; Fig. 24. The Loomis Declaration explains that a person of ordinary skill in the art would have been motivated to apply the teachings of Ostrovsky to make the hook (18) of Marin with a permanent curve. Ex. 1026 ¶ 131.
11. The connector of claim 10, wherein the sides of the hook are parallel and straight and define a constant width.	Marin discloses a hook (18) having sides that are parallel and straight and define a constant width. Figs. 1-3.  Ostrovsky discloses the sides of the hook (52) being parallel and straight and defining a constant
12. The connector of claim 10, wherein the sides of the hook are non-parallel and straight and define a narrowing width towards the point.	width. Fig. 3.  Ostrovsky discloses an element (164) with non-parallel straight sides defining a narrowing width towards a pointed end. 9:11-29; Figs. 24-28. And, Ostrovsky also discloses an elongated member (166) made of the same material. The Loomis Declaration explains that not only would a person of skill in the art have recognized that the elongated member (166) could be constructed with non-parallel straight sides, but also that such person would have been motivated to so construct the elongated members to ensure that they more securely anchor the device against the vessel wall.

'662 Patent: Claims 1-6, 8-14 and 16	Marin (Ex. 1005) in view of Ostrovsky (Ex. 1007)
	Ex. 1026 ¶ 133.
13. The connector of claim 10, wherein the hook forms a permanent constant radius curve.	As discussed above in the context of claim 10, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See, e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of constant radius. Ex. 1026 ¶ 135.
14. The connector of claim 10, wherein the hook forms a permanent curve of decreasing radius.	As discussed above in the context of claim 10, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See, e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of decreasing radius. Ex. 1026 ¶ 136.
<b>16.</b> An endoluminal prosthesis, comprising:	Non-limiting preamble. But, Marin discloses an endoluminal prosthesis. 1:6-8; 1:53-68; Abstract.  Ostrovsky discloses an endoluminal prosthesis. 1:14-1:18; 3:17-20; Abstract.
a substantially tubular frame element, the frame element lacking concentrically overlapping structure;	Marin discloses a substantially tubular frame element (10), the frame element (10) lacking concentrically overlapping structure. 2:39-51; Figs. 1-2.
and at least one protrusion cut out of said frame element having a resiliently flexible bend formed therein,	Marin discloses at least one protrusion (18) cut out of said frame element (10). 2:39-51; Figs. 1-3.  Ostrovsky discloses a frame element (166) made of "flexible" and "resilient" material. 9:11-29; 10:57-11:3.

### E. <u>Ground 4</u>: Claims 7 and 15 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over Marin & Ostrovsky in view of Lazarus

The above discussions of Marin, Ostrovsky and Lazarus are incorporated into this Ground. As discussed above, the combination of Marin and Ostrovsky discloses each and every element of claims 1-6, 8-14, and 16 of the '662 patent. *See supra* at section VI(D)(3). The remaining two claims of the '662 patent (claims 7 and 15) require specific geometric configurations for the "point" or "pointed end" of the "attachment mechanism." 'Ex. 1001 at 6:46-49; 7:5-6.

Claim 7 requires the pointed end of the connecting mechanism to include at least one "barb," and claim 15 requires the point of the connector to be "formed in an arrowhead configuration." *Id.* at 6:46-49; 7:5-6. Lazarus specifically teaches connectors utilizing each of these geometries, including a barb, a sharpened point, and an "arrowhead configuration." Ex. 1006 at 8:57-65; 10:23-54; Figs. 10-13; Ex. 1026 ¶ 106, 141-47.

As discussed above, Marin, Ostrovsky and Lazarus all teach the importance of using engagement members, hooks or protrusions with pointed ends to prevent migration of devices in corporeal lumens. Marin teaches that mechanical connecting means are superior to relying solely upon "friction" to hold a prosthesis in place and resist migration. Ex. 1005 at Abstract; 1:62-68. Likewise, Ostrovsky teaches that such engagement members, hooks, or protrusions can "permanently" secure a filtration device. Ex. 1007 at 1:1-3. And Lazarus teaches that

alternatively shaped engagement members, hooks, or protrusions can help better "ensure that the graft will remain in place after it has been implanted." Ex. 1006 at 10:23-26.

In particular, Lazarus teaches that by modifying the pointed hooks of the combination of Marin and Ostrovsky to configure them as barbs or arrowheads, more secure anchoring of the device can be achieved. *Id.* at 10:23-54 (noting that "in order to ensure that the graft . . . will not become dislodged after it has been implanted, it may be desirable to provide alternative hook-like elements," including a "barb" or an arrowhead configuration that "will become firmly imbedded in the tissue to inhibit . . . removal"); *see also id.* at Figs. 12 & 13. Thus, a person of skill in the art dealing with the problem of intraluminal device migration would have been motivated to combine the teaching of Lazarus with that of Marin and Ostrovsky to achieve even stronger anchoring of the device to the lumen wall. Ex. 1026 ¶¶ 141-47.

For the foregoing reasons, and as shown in more detail in the claim chart below, Petitioners submit that claims 7 and 15 of the '662 Patent are obvious under 102(a) based on Marin and Ostrovsky in view of Lazarus.

'662 Patent:	Marin (Ex. 1005) & Ostrovsky (Ex. 1007)
Claims 7 and 15	in view of Lazarus (Ex. 1006)
7. The mechanism of claim 1, wherein the pointed end includes at least one barb.	See discussion of claim 1 in Ground 3, supra.

'662 Patent: Claims 7 and 15	Marin (Ex. 1005) & Ostrovsky (Ex. 1007) in view of Lazarus (Ex. 1006)
	Lazarus discloses an at least one barb on the pointed end of the elongated member for securing an endoprosthesis. 10:23-35; Fig. 12. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Marin and Ostrovsky to achieve a more secure mechanism for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 145.
<b>15.</b> The connector of claim 10, wherein the point is	See discussion of claim 10 in Ground 3, supra.
formed in an arrowhead configuration.	Lazarus discloses a hook (166) wherein the point of the hook is formed in an arrowhead configuration. 10:36-54; Fig. 13. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Marin and Ostrovsky to achieve a more secure connector for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 146.

### F. Ground 5: Claims 1-6, 9-14, and 16 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over Marin in view of Lefebvre

As discussed above in Grounds 3 and 4, all claims of the '662 patent are rendered obvious by either the combination of Marin in view of Ostrovsky, or the combination of Marin & Ostrovsky in view of Lazarus. To the extent that the patent holder is able to swear behind Ostrovsky, Lefebvre can be substituted for Ostrovsky, for the reasons set forth below.

#### 1. Summary of Marin and Lefebvre

The above discussions of Marin and Lefebvre are incorporated into this Ground. Marin teaches a substantially tubular "intraluminal stent" with "barbs [that] are adapted to engage, for example, a graft and/or the inner layers of a blood vessel to mechanically attach the stent to the vessel." Ex. 1005 at Abstract; *see also id.* at 1:53-62. These barbs are created through laser incisions, which leave behind narrow slots on either side of the barb. *Id.* at Fig. 3; *see also id.* at 3:5-11. The barb is shown in Marin as having two parallel sides and a pointed end. *Id.* at Fig. 3. Thus, the only element from the independent claims of the '662 patent that Marin fails to explicitly depict is a "permanent curve" in the barb. *See* Ex. 1026 ¶ 149, 154.

Lefebvre describes just such a permanent curve. Lefebvre, like Marin, is directed to a substantially tubular endoprosthesis, in which pointed hooks for anchoring the device to the corporeal lumen have been cut. *Id.* ¶¶ 148-51; *see also* Ex. 1003 at 2:52-68; Figs. 1-2. Lefebvre teaches that the configuration of this hook is preset by curving it "along an arc of a circle." Ex. 1003 at 4:15-20; Fig. 3. The connecting elements taught by Lefebvre thus maintain a permanent curve regardless of what configuration the device is in. *See* Ex. 1026 ¶ 154.

#### 2. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Marin with Lefebvre

As discussed above, both Marin and Lefebvre teach the importance of using connectors on a substantially tubular intraluminal device to prevent migration of devices in corporeal lumens. Indeed, Marin specifically highlights that it improves on preexisting stents by cutting "a means for mechanically anchoring the stents to the blood vessel." Ex. 1005 at 1:54-55. Lefebvre further teaches the importance of providing a permanent curve, such that even if the configuration of the legs of the filter changes (as is often required or desired with respect to intraluminal devices, cite Loomis), the hook-like elements remain in their permanently curved configuration, so as to be in a position to anchor the device. Ex. 1003 at 4:15-20; Fig. 3; Ex. 1026 ¶¶ 148-54.

A person of ordinary skill would have recognized that is it advantageous to preset the curvature of a device that needs to undergo reconfiguration at the deployment site, so as to avoid potential difficulties with trying to make intraluminal adjustments to the curvature. Ex. 1026 ¶ 148-51. Thus, a person of ordinary skill in the art would have been motivated to utilize the combined teachings of Marin with Lefebvre to ensure a permanent curve in the connecting frame elements of the Marin endoprosthesis. In this way, each and every element of claims 1-6, 9-14 and 16 of the '662 patent is disclosed by the combination of Marin and Lefebvre.

For the foregoing reasons, and as shown in more detail in the claim chart below, claims 1-6, 9-14 and 16 of the '662 patent are obvious under Section 103(a) based on Marin in view of Lefebvre.

'662 Patent: Claims 1-6, 9-14 and 16	Marin (Ex. 1005) in view of Lefebvre (Ex. 1003)
1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:	Non-limiting preamble. But, Marin discloses a mechanism for securing an endoprosthesis within a corporeal lumen. 1:6-8; 1:53-68; Abstract.
a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;	Marin discloses a frame element (10) with incisions formed therein. 2:39-51; Figs. 1-2. The frame element (10) has a substantially tubular shape and lacks concentrically overlapping structure. 2:39-51; Figs. 1-2.
the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element;	Marin discloses the incisions forming an elongated member (18) with a pointed end, the elongated member (18) being bound by the frame element (10). 2:39-51; Figs. 1-3.
and the elongated member bent away from said frame element wherein the elongate member has a	Marin discloses the elongated member (18) bent away from the frame element (10). 2:54-59; 3:3-15; Figs. 2 and 4.
permanent curve.	Lefebvre discloses the elongated member (6, 7) bent away from the frame element (3) wherein the elongated member (6, 7) has a permanent curve. 4:15-20; Fig. 3. The Loomis Declaration explains that a person of ordinary skill in the art would have been motivated to combine this teaching of a permanent curve from Lefebvre with the elongated member from Marin. Ex. 1026 ¶ 154.
2. The mechanism of claim 1, wherein the elongated member has parallel	Marin discloses the elongated member (18) having parallel straight sides defining constant width. Figs. 1-3.

'662 Patent: Claims 1-6, 9-14 and 16	Marin (Ex. 1005) in view of Lefebvre (Ex. 1003)
straight sides defining a constant width.	
3. The mechanism of claim 1, wherein the elongated member has non-parallel straight sides defining a narrowing width towards the pointed end.	Lefebvre discloses the elongated member (6, 7) having non-parallel straight sides defining a narrowing width towards the pointed end (14, 18). 3:5-20; Fig. 2.
4. The mechanism of claim 1, wherein the elongated member is resilient so as to be compressed into a position within the circumference of the frame	Marin discloses that the elongated member (18) will "remain within the surface of the stent when the stent is in its unexpanded condition, but [will] [] extend from the surface of the stent when the stent is expanded." 1:55-59.
element when constrained and to extend outside the circumference of the frame element when unconstrained.	Lefebvre discloses the elongated member (6, 7) being constructed of a material which has a "certain elasticity, with the result that the legs may be brought against one another in a sheath for introduction." 2:59-68 The Loomis Declaration explains that an inherent property of the elongated member (6, 7) disclosed by Lefebvre is that it is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained. Ex. 1026 ¶ 157.
5. The mechanism of claim 1, wherein the elongated member has a permanent constant radius curve.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "along an arc of circle so that the outermost part of the tooth makes with the direction of the plane of the leg an angle $\alpha$ ." 4:15-20; Fig. 3. Because a circle inherently has a constant radius, Lefebvre discloses the elongated member (6, 7) having a permanent constant radius curve. 4:15-20; Fig. 3.

'662 Patent: Claims 1-6, 9-14 and 16	Marin (Ex. 1005) in view of Lefebvre (Ex. 1003)
6. The mechanism of claim 1, wherein the elongated member has a permanent curve of decreasing radius.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "so that the outermost part of the tooth makes with the direction of the plane of the leg an angle $\alpha$ ." 4:15-20; Fig. 3. The Loomis Declaration explains that a person of ordinary skill in the art would have recognized that by increasing the angle $\alpha$ , so as to provide for a more secure connection with the lumen wall, the elongated member would have had a permanent curve of decreasing radius. Ex. 1026 ¶ 159.
9. The mechanism of claim 1, wherein the mechanism is integrally formed into an endoluminal prosthesis.	Marin discloses the mechanism being integrally formed into an endoluminal prosthesis. 2:39-51; Figs. 1-5.
<b>10.</b> A connector for fastening a device to corporeal tissues, said connector comprising:	Non-limiting preamble. But, Marin discloses a connector for fastening a device to corporeal tissues. 1:6-8; 1:53-68; Abstract.
a substantially tubular body lacking concentrically overlapping structure;	Marin discloses a substantially tubular body (10) lacking concentrically overlapping structure. 2:39-51; Figs. 1-2.
a hook having two sides and a point and being bounded by the tubular body;	Marin discloses a hook (18) having two sides and a point and being bounded by the tubular body. 2:39-51; Figs. 1-3.
said sides and said point defined by narrow slits in the connector; and	Marin discloses the sides and point being defined by narrow slits in the connector. 2:39-51; Figs. 1-3.
said hook having a permanent bend that forms a permanent curve.	Lefebvre discloses the hook having a permanent bend that forms a permanent curve. 4:15-20; Fig. 3. The Loomis Declaration explains that a person of ordinary skill in the art would have been motivated to combine this teaching of a permanent curve from Lefebvre with the hook (18) from Marin. Ex. 1026 ¶ 154.

'662 Patent: Claims 1-6, 9-14 and 16	Marin (Ex. 1005) in view of Lefebvre (Ex. 1003)
11. The connector of claim 10, wherein the sides of the hook are parallel and straight and define a constant width.	Marin discloses a hook (18) having sides that are parallel and straight and define a constant width. Figs. 1-3.
12. The connector of claim 10, wherein the sides of the hook are non-parallel and straight and define a narrowing width towards the point.	Lefebvre discloses sides of the hook (6, 7) that are non-parallel and straight and define a narrowing width towards the point (14, 18). 3:5-20; Fig. 2.
13. The connector of claim 10, wherein the hook forms a permanent constant radius curve.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "along an arc of circle so that the outermost part of the tooth makes with the direction of the plane of the leg an angle α." 4:15-20; Fig. 3. Because a circle inherently has a constant radius, Lefebvre discloses the hook (6, 7) forming a permanent constant radius curve. 4:15-20; Fig. 3.
14. The connector of claim 10, wherein the hook forms a permanent curve of decreasing radius.	Lefebvre teaches the bend (20) of a tooth (6, 7) formed by curving it "so that the outermost part of the tooth makes with the direction of the plane of the leg an angle $\alpha$ ." 4:15-20; Fig. 3. The Loomis Declaration explains that a person of ordinary skill in the art would have recognized that by increasing the angle $\alpha$ , so as to provide for a more secure connection with the lumen wall, the elongated member would have had a permanent curve of decreasing radius. Ex. 1026 ¶ 159.
<b>16.</b> An endoluminal prosthesis, comprising:	Non-limiting preamble. But, Marin discloses an endoluminal prosthesis. 1:6-8; 1:53-68; Abstract.
a substantially tubular frame element, the frame element lacking concentrically overlapping structure;	Marin discloses a substantially tubular frame element (10), the frame element (10) lacking concentrically overlapping structure. 2:39-51; Figs. 1-2.

'662 Patent: Claims 1-6, 9-14 and 16	Marin (Ex. 1005) in view of Lefebvre (Ex. 1003)
and at least one protrusion cut out of said frame element having a resiliently flexible bend formed therein,	Marin discloses at least one protrusion (18) cut out of said frame element (10). 2:39-51; Figs. 1-3.  Lefebvre also a frame element made of a resilient, flexible material with a bend. 2:60-68.
wherein the at least one protrusion has a permanent curve the at least one protrusion being bounded by the frame element and the at least one protrusion having a pointed end.	Marin discloses at least one protrusion (18) being bounded by the frame element. 2:39-51; Figs. 1-5.  Lefebvre discloses the at least one protrusion (6, 7) having a permanent curve. 4:15-20; Fig. 3.

### G. Ground 6: Claims 7, 8 and 15 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over Marin & Lefebvre in view of Lazarus

The above discussions of Marin, Lefebvre and Lazarus are incorporated into this Ground. As discussed above, the combination of Marin and Lefebvre discloses each and every element of claims 1-6, 9-14, and 16 of the '662 patent. *See supra* at section VI(F)(2). The remaining three claims of the '662 patent (claims 7, 8 and 15) require specific geometric configurations for the "point" or "pointed end" of the "attachment mechanism." Ex. 1001 at 6:46-49; 7:5-6.

Claim 7 requires the pointed end of the connecting mechanism to include at least one "barb," claim 8 requires the pointed end of the connecting mechanism to be "sharpened," and claim 15 requires the point of the connector to be "formed in an arrowhead configuration." *Id.* at 6:46-49; 7:5-6. Lazarus specifically teaches

connectors utilizing each of these geometries, including a barb, a sharpened point, and an "arrowhead configuration." Ex. 1006 at 8:57-65; 10:23-54; Figs. 10-13; Ex. 1026 ¶¶ 106, 165.

Marin, Lefebvre and Lazarus all teach the importance of using engagement members, hooks or protrusions with pointed ends to prevent migration of devices in corporeal lumens. Marin teaches that these pointed engagement members, hooks or protrusions can "mechanically attach the stent to the vessel." Ex. 1005 at 1:60-62. Likewise, Lefebvre teaches that such pointed engagement members, hooks, or protrusions can prevent migration. Ex. 1003 at 1:12-16; 1:26-30. And Lazarus teaches that alternatively shaped engagement members, hooks, or protrusions can help to better "ensure that the graft will remain in place after it has been implanted." Ex. 1006 at 10:23-26.

In particular, Lazarus teaches that by modifying the pointed hooks of the combination of Marin and Lefebvre to sharpen them, or to configure them as barbs or arrowheads, more secure anchoring of the device can be achieved. Ex. 1006 at 10:23-54 (noting that "in order to ensure that the graft . . . will not become dislodged after it has been implanted, it may be desirable to provide alternative hook-like elements," including a "barb" or an arrowhead configuration that "will become firmly imbedded in the tissue to inhibit . . . removal"); *see also* Ex. 1006 at Figs. 12 & 13. Thus, a person of skill in the art dealing with the problem of

intraluminal device migration would have been motivated to combine the teaching of Lazarus with that of Marin and Lefebvre to achieve even stronger anchoring of the device to the lumen wall. Ex. 1026 ¶¶ 163-70.

For the foregoing reasons, and as shown in more detail in the claim chart below, Petitioners submit that claims 7, 8 and 15 of the '662 Patent are obvious based on the combination of Marin and Lefebvre in view of Lazarus.

'662 Patent: Claims 7, 8 and 15	Marin (Ex. 1005) & Lefebvre (Ex. 1003) in view of Lazarus (Ex. 1006)
7. The mechanism of claim 1, wherein the	See discussion of claim 1 in Ground 5, supra.
pointed end includes at least one barb.	Lazarus discloses at least one barb on the pointed end of the elongated member for securing an endoprosthesis. 10:23-35; Fig. 12. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Marin and Lefebvre to achieve a more secure mechanism for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 167.
<b>8.</b> The mechanism of claim 1, wherein the	See discussion of claim 1 in Ground 5, supra.
pointed end is sharpened.	Lazarus discloses sharpening the pointed end of the elongated member in a device for securing an endoprosthesis. 8:57-65. Figs. 10-13. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Marin and Lefebvre to achieve a more secure connector for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 168.
<b>15.</b> The connector of claim 10, wherein the point	See discussion of claim 10 in Ground 5, supra.

'662 Patent: Claims 7, 8 and 15	Marin (Ex. 1005) & Lefebvre (Ex. 1003) in view of Lazarus (Ex. 1006)
is formed in an arrowhead	
configuration.	Lazarus discloses a hook (166) wherein the point of the hook is formed in an arrowhead configuration. 10:36-54; Fig. 13. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with Marin and Lefebvre to achieve a more secure connector for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 169.

# H. Ground 7: Claims 1-6, 8-14, and 16 of the '662 Patent Are Obvious Under 35 U.S.C. § 103(a) Over White in view of Ostrovsky

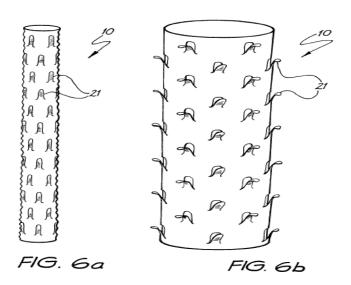
#### 1. Summary of White

White was filed on September 29, 1999, and published on April 6, 2000. *See* Ex. 1004. Accordingly, it is prior art under 35 U.S.C. § 102(a). White was **not** before the examiner during prosecution of the '662 patent.

White teaches an intraluminal endoprosthesis used to treat aneurysms and other vascular diseases. *Id.* at 1:8-2:33; 3:11-22; Abstract. White further teaches that this prosthesis has "a tubular body with two ends" that can expand "from a radially compressed state to a radially expanded state." *Id.* at 2:8-12; 2:21-25. Further, White recognizes that there are "a number of problems associated with such known intraluminal devices," including "the problem of maintaining the

device against longitudinal movement along the lumen in which it is placed." *Id.* at 1:28-30.

To prevent such undesired migration, White teaches the use of connectors for fastening the prosthesis to the lumen wall. Ex. 1026 ¶ 172. White identifies these mechanisms for securing the prosthesis as "engagement members" that are either "integral with a wall of the body," or integral with the device body. Ex. 1004 at 2:13-15; 2:26-27; 8:20-23; 16:35-17:3. As with the '662 patent, the engagement members were formed by making "a small incision in the wall of the device." *Id.* These "engagement members . . . act as an attachment, hook or anchor to prevent the device from moving longitudinally within the vessel," *id.* at 7:34-8:2, and are shown in Figures 6a and 6b (illustrating the compressed and expanded states of the intraluminal device):



White also notes that spring-aided change can be used to cause "the engagement members to change from a first angular relationship to a second angular relationship" after they are deformed. *Id.* at 12:5-31. In particular, White teaches that "the respective first angular relationships of the engagement members "may be either flat, . . . or alternatively, the engagement members *may project inwardly*, within the lumen of the device body." *Id.* at 9:29-33 (emphasis added). Thus, White discloses that, even if the "engagement means" are temporarily deformed prior to deployment at the desired site (as in a catheter for delivery), the "engagement members" will maintain their preset or "memori[z]ed" curvature by "project[ing] inwardly, within the lumen of the device body" and then "spring" into a position outside the device circumference to engage with the lumen walls at the desired site. *See id.*; Ex. 1026 ¶¶ 99-101.

In short, White teaches the key elements of the '662 patent claims, including a substantially tubular frame element, in which incisions have been made to form a flexible, elongated member with a permanent curve. The only element of the independent claims of the '662 patent not explicitly taught by White is that White's engagement members are not expressly shown with a pointed end. As discussed below, Ostrovsky teaches precisely that configuration for its engagement members.

#### 2. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine White with Ostrovsky

The above discussion of Ostrovsky is incorporated by reference into this Ground. Both White and Ostrovsky teach the importance of using connectors with a preset, permanent curve, on a substantially tubular intraluminal device to prevent migration of devices in corporeal lumens. Ex. 1026 ¶¶ 171-86. White teaches that engagement members, hooks or protrusions can help "prevent the device from moving longitudinally within the vessel following deployment of the invention." Ex. 1004 at 7:33-8:5. Ostrovsky likewise teaches the importance of using such connecting mechanisms with pointed ends that must be "sufficiently sharp to penetrate a vessel wall," such that a firm anchoring is achieved. Ex. 1007 at 9:13-14; Ex. 1026 ¶171-86. Thus, a person of ordinary skill dealing with the propensity of an intraluminal device to migrate from the desired location would have been motivated to utilize the combined teachings of White and Ostrovsky to create a pointed end on White's engagement members, and in so doing create a firmer and more secure anchoring of the device. Ex. 1026 ¶¶171-86. In this way, each and every element of claims 1-6, 8-14, and 16 of the '662 patent are disclosed by the combination of White with Ostrovsky.

For the foregoing reasons, and as shown in more detail in the claim chart below, claims 1-6, 8-14 and 16 of the '662 Patent are obvious under Section 103(a) based on White in view of Ostrovsky.

'662 Patent:	White (Ex. 1004)
Claims 1-6, 8-14 and 16	in view of Ostrovsky (Ex. 1007)
1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:	Non-limiting preamble. But, White discloses a mechanism for securing an endoprosthesis within a corporeal lumen. 1:3-2:33; 3:11-3:22; Abstract.
	Ostrovsky discloses a mechanism for securing an endoprosthesis within a corporeal lumen. 1:14-1:18; 3:17-20; Abstract.
a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;	White discloses a frame element (10) with incisions formed therein. 16:34-17:3; Figs 6a & 6b. The frame element (10) has a substantially tubular shape and lacks concentrically overlapping structure. 2:8-12; 2:21-25; Figs. 6a & 6b.
	Ostrovsky discloses a frame element (50) with incisions formed therein. 5:29-32; 5:64-6:4; Fig. 3.
the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element;	White discloses the incisions forming an elongated member (21), the elongated member (21) being bound by the frame element (10). 7:33-8:36; 16:34-17:15; Figs. 6a & 6b.
	Ostrovsky discloses the incisions having a pointed end (166). 5:64-6:4; 9:11-9:29; Fig. 24.
and the elongated member bent away from said frame element wherein the elongate member has a permanent curve.	White discloses the elongated member (21) bent away from the frame element (10) wherein the elongated member has a curve that "project[s] inwardly, within the lumen of the device body" during a first angular position, and then maintains that curvature when moved into a second angular position, such that the curve is permanent. 9:29-33; see also Figs. 6a & 6b.
	Ostrovsky discloses the elongated member (52) bent away from the frame element (50) wherein the elongated member (52) has a permanent curve. Fig. 3.

WILL (E. 1004)
White (Ex. 1004) in view of Ostrovely (Ex. 1007)
in view of Ostrovsky (Ex. 1007)  White discloses the elongated member (21) having parallel straight sides defining constant width. Figs. 4a, 6a and 7.  Ostrovsky discloses the elongated member (52) having parallel straight sides defining a constant width. Fig. 3
Ostrovsky discloses an element (164) with non-parallel straight sides defining a narrowing width towards the pointed end. 9:11-29; Figs. 24-28. And, Ostrovsky discloses the elongated member (166) made of the same material. The Loomis Declaration explains that not only would a person of skill in the art have recognized that the elongated member (166) could be constructed with non-parallel straight sides, but also that such person would have been motivated to so construct the elongated members to ensure that they more securely anchor the device against the vessel wall. Ex. 1026 ¶ 179.
White discloses the elongated member (21) being made of nitinol and having a first angular relationship when compressed to a second angular relationship when deployed. 15:32-16:12; 16:35-17:11; Figs. 3a & 3b, 6a & 6b. Because nitinol is a resilient metal, the elongated member (21) disclosed by White is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained. 9:27-36; 12:5-12:31; 20:15-19.  Ostrovsky discloses an elongated member (166) as being made of a "flexible" and "resilient" material. 9:11-29; 10:57-11:3. The Loomis Declaration

'662 Patent: Claims 1-6, 8-14 and 16	White (Ex. 1004) in view of Ostrovsky (Ex. 1007)
	explains that the disclosure inherently provides an elongated member (166) that is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained. Ex. 1026 ¶ 180.
5. The mechanism of claim 1, wherein the elongated member has a permanent constant radius curve.	As discussed above in the context of claim 1, White discloses a permanent curve. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of White would have been a constant radius curve. Ex. 1026 ¶ 181.  As discussed above in the context of claim 1, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See, e.g.</i> , Figs. 3, 26-29.
	The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a constant radius curve. Ex. 1026 ¶ 181.
6. The mechanism of claim 1, wherein the elongated member has a permanent curve of decreasing radius.	As discussed above in the context of claim 1, White discloses a permanent curve. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of White would have been a curve of decreasing radius. Ex. 1026 ¶ 182. As discussed above in the context of claim 1, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See</i> , <i>e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of decreasing radius. Ex. 1026 ¶ 182.

'662 Patent: Claims 1-6, 8-14 and 16	White (Ex. 1004) in view of Ostrovsky (Ex. 1007)
8. The mechanism of claim 1, wherein the pointed end is sharpened.	Ostrovsky discloses an elongated member (166) wherein the pointed end is sharpened. 9:11-29; Fig. 24.
9. The mechanism of claim 1, wherein the mechanism is integrally formed into an endoluminal prosthesis.	White discloses the mechanism being integrally formed into an endoluminal prosthesis. 8:20-9:11; Fig. 6.
	Ostrovsky discloses the mechanism being integrally formed into an endoluminal prosthesis. 3:17-20.
<b>10.</b> A connector for fastening a device to corporeal tissues, said connector comprising:	Non-limiting preamble. But, White discloses a connector for fastening a device to corporeal tissues. 1:8-2:33; 3:11-3:22; Abstract.
	Ostrovsky discloses a connector for fastening a device to corporeal tissues. 1:14-1:18; 3:17-20; Abstract.
a substantially tubular body lacking concentrically overlapping structure;	White discloses a substantially tubular body (10) lacking concentrically overlapping structure. 1:8-12; Figs. 1-7.
a hook having two sides and a point and being bounded by the tubular body;	White discloses a hook (21) having two sides being bounded by the tubular body. 7:34-8:5; Figs. 6a & 6b.
	Ostrovsky discloses a hook (166) having two sides and a point. 5:64-6:4; 9:11-9:29; Fig. 24.
	The Loomis Declaration explains that a person of ordinary skill in the art would have been motivated to combine the teaching of Ostrovsky with that of White to achieve a hook having two sides and a point. Ex. 1026 ¶ 176.
said sides and said point defined by narrow slits in the connector; and	White discloses a hook being defined by narrow slits in the connector. 7:34-8:5; Figs. 6a & 6b.

'662 Patent: Claims 1-6, 8-14 and 16	White (Ex. 1004) in view of Ostrovsky (Ex. 1007)
	Ostrovsky discloses the hook having two sides and a point. 9:11-15; Fig. 24.
	The Loomis Declaration explains that a person of ordinary skill in the art would have been motivated to combine the teaching of Ostrovsky with that of White to achieve a connector with a point defined by narrow slits. Ex. 1026 ¶ 177.
said hook having a permanent bend that forms a permanent curve.	White discloses the elongated member (21) bent away from the frame element (10) wherein the elongated member has a curve that "project[s] inwardly, within the lumen of the device body" during a first angular position, and then maintains that curvature when moved into a second angular position, such that the curve is permanent. 9:29-33; see also Figs. 6a & 6b.  Ostrovsky discloses the hook (52, 166) having a permanent bend that forms a permanent curve. 5:64-6:4; 9:11-9:29; Fig. 3; Fig. 24.
11. The connector of claim 10, wherein the sides of the hook are parallel and straight and define a constant width.	White discloses a hook (21) having sides that are parallel and straight and define a constant width. 7:34-8:5; Figs. 4a, 6a & 7.
Constant width.	Ostrovsky discloses the sides of the hook (52) being parallel and straight and defining a constant width. Fig. 3.
12. The connector of claim 10, wherein the sides of the hook are non-parallel and straight and define a narrowing width towards the point.	Ostrovsky discloses an element (164) with non-parallel straight sides defining a narrowing width towards a pointed end. 9:11-29; Figs. 24-28. And, Ostrovsky also discloses an elongated member (166) made of the same material. The Loomis Declaration explains that not only would a person of skill in the art have recognized that the elongated member (166) could be constructed with non-parallel straight sides, but also that such person would have been motivated to so construct the

'662 Patent: Claims 1-6, 8-14 and 16	White (Ex. 1004) in view of Ostrovsky (Ex. 1007)
	elongated members to ensure that they more securely anchor the device against the vessel wall. Ex. 1026 ¶ 179.
13. The connector of claim 10, wherein the hook forms a permanent constant radius curve.	As discussed above in the context of claim 10, White discloses a permanent curve. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of White would have been a curve of constant radius. Ex. 1026 ¶ 181.
	As discussed above in the context of claim 1, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See, e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of constant radius. Ex. 1026 ¶ 181.
14. The connector of claim 10, wherein the hook forms a permanent curve of decreasing radius.	As discussed above in the context of claim 1, White discloses a permanent curve. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of White would have been a curve of decreasing radius. Ex. 1026 ¶ 182.
	As discussed above in the context of claim 1, Ostrovsky discloses a permanent curve, including those of varying radii. <i>See, e.g.</i> , Figs. 3, 26-29. The Loomis Declaration explains that a person of skill in the art would have recognized that one configuration consistent with the disclosure of Ostrovsky would have been a curve of decreasing radius. Ex. 1026 ¶ 182.
<b>16.</b> An endoluminal prosthesis, comprising:	Non-limiting preamble. But, White discloses an endoluminal prosthesis. E.g. 1:8-2:33; 3:11-3:22; Abstract.

'662 Patent: Claims 1-6, 8-14 and 16	White (Ex. 1004) in view of Ostrovsky (Ex. 1007)
	Ostrovsky discloses an endoluminal prosthesis. 1:14-1:18; 3:17-20; Abstract.
a substantially tubular frame element, the frame element lacking concentrically overlapping structure;	White discloses a substantially tubular frame element (10), the frame element (10) lacking concentrically overlapping structure. 1:8-12; Figs. 1-7.
and at least one protrusion cut out of said frame element having a resiliently flexible bend formed therein,	White discloses at least one protrusion (21) cut out of said frame element (10) having a resiliently flexible bend formed therein. 7:33-8:36; 9:27-33; 12:5-12:31; 16:34-17:15; 20:15-19; Figs. 6a & 6b. Ostrovsky discloses a frame element (166) made of "flexible" and "resilient" material. 9:11-29; 10:57-11:3.
wherein the at least one protrusion has a permanent curve the at least one protrusion being bounded by the frame element and the at least one protrusion having a pointed end.	White discloses at least one protrusion (21) having a permanent curve and the at least one protrusion being bounded by the frame element. Fig. 6b; <i>see also</i> discussion in claim 1, above.  Ostrovsky discloses at least one protrusion (52, 166) having a permanent curve. Fig. 3. Ostrovsky also discloses the at least one protrusion (52, 166) having a pointed end. 5:64-6:4; 9:11-9:29; Fig. 3; Fig. 24.

## I. Ground 8: Claims 7 and 15 of the '662 Patent are Obvious Under 35 U.S.C. § 103(a) Based on White in view of Ostrovsky & Lazarus

The above discussions of White, Ostrovsky, and Lazarus are incorporated into this Ground. As discussed above, the combination of White in view of Ostrovsky discloses each and every element of claims 1-6, 8-14, and 16 of the '662 patent. *See supra* at section VI(H)(2). The remaining two claims of the '662

patent (claims 7 and 15) require specific geometric configurations for the "point" or "pointed end" of the "attachment mechanism." Ex. 1001 at 6:46-49; 7:5-6.

Claim 7 requires the pointed end of the connecting mechanism to include at least one "barb," and claim 15 requires the point of the connector to be "formed in an arrowhead configuration." *Id.* at 6:46-49; 7:5-6. Lazarus specifically teaches connectors utilizing each of these geometries, including a barb, a sharpened point, and an arrowhead configuration." Ex. 1006 at 8:57-65; 10:23-54; Figs. 10-13; Ex. 1026 ¶¶ 106, 189.

As discussed above, White, Ostrovsky and Lazarus all teach the importance of using engagement members, hooks or protrusions to prevent migration of devices in corporeal lumens. White teaches that engagement members, hooks or protrusions can help "prevent the device from moving longitudinally within the vessel following deployment of the invention. Ex. 1004 at 7:33-8:5. Ostrovsky teaches that such engagement members, hooks, or protrusions can "permanently" secure a filtration device. Ex. 1007 at 1:1-3. And Lazarus teaches that alternatively shaped engagement members, hooks, or protrusions can help to better "ensure that the graft will remain in place after it has been implanted." Ex. 1006 at 10:23-26.

In particular, Lazarus teaches that by modifying hooks like those of White and Ostrovsky to make them sharper, or to configure them as barbs or arrowheads,

more secure anchoring of the device can be achieved. Ex. 1006 at 10:23-54 (noting that "in order to ensure that the graft . . . will not become dislodged after it has been implanted, it may be desirable to provide alternative hook-like elements," including a "barb" or an arrowhead configuration that "will become firmly imbedded in the tissue to inhibit . . . removal"); *see also* Ex. 1006 at Figs. 12 & 13. Thus, a person of skill in the art dealing with the problem of intraluminal device migration would have been motivated to combine the teaching of Lazarus with that of White and Ostrovsky to achieve even stronger anchoring of the device to the lumen wall. Ex. 1026 ¶¶ 187-93.

For the foregoing reasons, and as shown in more detail in the claim chart below, Petitioners submit that claims 7 and 15 of the '662 Patent are obvious under Section 103(a) based on White and Ostrovsky in view of Lazarus.

'662 Patent: Claims 7 and 15	White (Ex. 1004) and Ostrovsky (Ex. 1007) in view of Lazarus (Ex. 1006)
7. The mechanism of claim 1, wherein the pointed end includes at least one barb.	Lazarus discloses at least one barb on the pointed end of the elongated member for securing an endoprosthesis. 10:23-35; Fig. 12. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with White and Ostrovsky to achieve a more secure mechanism for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 191.
<b>15.</b> The connector of claim	See discussion of claim 10 in Ground 7, supra.

'662 Patent: Claims 7 and 15	White (Ex. 1004) and Ostrovsky (Ex. 1007) in view of Lazarus (Ex. 1006)
10, wherein the point is formed in an arrowhead configuration.	Lazarus discloses a hook (166) wherein the point of the hook is formed in an arrowhead configuration. 10:36-54; Fig. 13. The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to combine this teaching of Lazarus with White and Ostrovsky to achieve a more secure connector for securing an endoprosthesis to the lumen wall. Ex. 1026 ¶ 192.

#### VII. CONCLUSION

For the foregoing reasons, Inter Partes Review of claims 1-16 of the '662

Patent is respectfully requested.

Respectfully Submitted,

Date: December 20, 2013 By: /s/ James J. Elacqua

James J. Elacqua

USPTO Reg. No. 28,412

SKADDEN, ARPS, SLATE, MEAGHER &

FLOM LLP

525 University Avenue

**Suite 1400** 

Palo Alto, California 94301

Tel: (650) 470-4510 Fax: (650) 798-6564

Email: James.Elacqua@skadden.com

#### § 42.6(e) - CERTIFICATION OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105 on the Patent Owner of a copy of this Petition for *Inter Partes* Review and supporting materials at the corresponding address of record for the '662 patent:

Edward J. Brooks & Kevin Waddick Brooks, Cameron & Huebsch, PLLC 1221 Nicollet Avenue, Suite 500 Minneapolis, MN 55403 Email: brooks@bipl.net Email: waddick@bipl.net

The undersigned further certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105 to the Patent Owner of a copy of this Petition for *Inter Partes* Review and supporting materials at the address of counsel in Case No. 1:12-cv-1793, filed December 28, 2012, in the United States District Court for the District of Delaware:

Martin J. Black & Kevin M. Flannery
Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
Email: martin.black@dechert.com
Email: kevin.flannery@dechert.com

Dated: December 20, 2013 /s/ James J. Elacqua

James J. Elacqua (Reg. # 28,412)

ATTORNEY FOR REAL PARTIES IN INTEREST MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.