IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

W.L. GORE & ASSOCIATES, INC.
Petitioner

v.

LIFEPORT SCIENCES LLC
Patent Owner

Patent No. 6,117,167
Filing Date: February 9, 1998
Issue Date: September 12, 2000
Title: ENDOLUMINAL PROSTHESIS AND SYSTEM FOR JOINING

Inter Partes Review No. Unassigned

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.*

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[1] Citations in this Petition to Exhibits 1006, 1007, and 1018 are to the consecutive pagination added by Petitioner in the lower right footer of each Exhibit.

Exhibit 1012:	Office Action in Appl. No. 13/601,902 (March 25, 2013)
Exhibit 1013:	Office Action in Appl. No. 13/603,937 (May 7, 2013)
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Exhibit 1019:	Declaration of Enrique Criado, M.D.
Exhibit 1020:	Curriculum Vitae of Enrique Criado, M.D.
Exhibit 1021:	Schaer, John, et al. "Treatment of malignant esophageal obstruction with silicone-coated metallic self-expanding stents," *Gastrointest Endosc* 1992; 38:7-11 ("Schaer")
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Exhibit 1023:	U.S. Patent No. 4,580,568 ("Gianturco")
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Exhibit 1025:	U.S. Patent No. 5,064,435 ("Porter")
Exhibit 1026:	U.S. Patent No. 5,366,504 ("Andersen")
Exhibit 1027:	*"Transfemoral endovascular aortic graft placement,"* Journal of Vascular Surgery; 1993; 18:185-197 (Chuter et al.)

Exhibit 1028:	U.S. Patent No. 5,236,446 ("Dumon")
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Exhibit 1031:	U.S. Patent No. 5,735,892 ("Myers I")
Exhibit 1032:	U.S. Patent No. 5,700,285("Myers II")
Exhibit 1033:	U.S. Patent No. 5,405,377 ("Cragg")
Exhibit 1034:	French Patent No. 2678508 ("Chevillon") (English translation)

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*, W.L. Gore & Associates, Inc. ("Petitioner") respectfully requests *inter partes* review of all claims 1-82 of U.S. Patent No. 6,117,167 (the "'167 Patent") (Ex. 1001).

I. MANDATORY NOTICES AND REQUIREMENTS

A. Real Party In Interest

W.L. Gore & Associates, Inc. is the real party-in-interest for this petition ("Petition").

B. Related Matters

The '167 Patent is the subject of a patent infringement lawsuit brought by LifePort Sciences LLC ("LifePort" or "Patent Owner")[2] against Petitioner in the United States District Court for the District of Delaware, Case No. 1:12-cv-01792-GMS.

C. Lead and Back-Up Counsel and Request for *Pro Hac Vice* Motion

Lead Counsel	Back-Up Counsel	Back-Up Counsel
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[2] LifePort has represented in the litigation that it is the lawful assignee of all right, title and interest in and to the '167 Patent. Petitioner reserves the right to challenge LifePort's ownership of and interest in the '167 Patent.

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A power of attorney designating counsel is being filed with this Petition. Petitioners request authorization to file a motion under 37 C.F.R. § 42.10(c) for Back-Up Counsel, who are lead attorneys in the pending case referred to in Section I.B., to appear *pro hac vice*. Petitioners will file such a motion upon the granting of this request.

D. Service Information

Please address all correspondence to the lead counsel at the address shown above. Petitioner also consents to electronic service to the email address above.

E. Grounds for Standing

Petitioner hereby certifies that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the ‘167 Patent claims on the grounds identified in this Petition.

F. Power of Attorney

A power of attorney designating counsel is being filed with this Petition.

G. Fees

The Commissioner is authorized to charge the $9,000 request fee, $14,000

post-institution fee, $12,400 excess claim fee, $26,800 post-institution excess claims fee (total of $62,200), and any additional fees to our Deposit Account No. 06-0029, and to notify us of the same.

II. OVERVIEW OF THE '167 PATENT

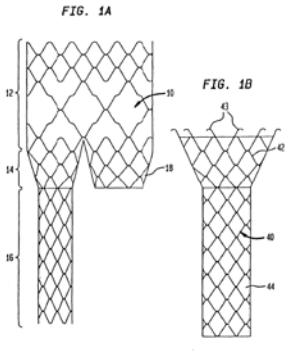
A. The Disclosed Alleged Invention of the '167 Patent

The '167 Patent is entitled "Endoluminal Prosthesis and System for Joining," and names George Goicoechea, John Hudson, Claude Mialhe, Andrew H. Cragg and Michael D. Dake as inventors. Ex. 1001. The patent issued on September 12, 2000 from U.S. Application 09/020,749, filed on February 9, 1998.[3] The patent claims priority to U.S. Application No. 08/312,881, filed on September 27, 1994. The face of the patent also lists two EP applications, but as explained further in Section II.C below, the '167 Patent cannot claim priority to those applications pursuant to a related interference proceeding and subsequent Federal Circuit decision.

In simple terms, the '167 Patent relates to assembling two stents together by inserting one stent into the other stent. In some of the claims, one of the stents

[3] The '167 Patent is a continuation of Application No. 08/461,513, U.S. Patent No. 5,716,365 ("'365 Patent"). Petitioner is filing separate petitions for *inter partes* review of the '365 Patent.

comprises two openings at one end of the stent and the other stent is inserted into one of the two openings. *Id.* at 1:18-27; 2:27-33. The stent may have a bifurcation so that the lumen splits from one opening to two openings, for use in blood vessels that split into two vessels at a vessel "bifurcation." *Id.* at 3:7-11. Figures 1A and 1B of the '167 Patent below, show a split, or "bifurcated" stent (FIG. 1A) and another, additional stent that is meant to be inserted into the split stent (FIG. 1B) in the body, or *in vivo*. Ex. 1001 at 8:50-54; 11:15-23. As shown, one of the openings of the bifurcated stent may be located above the other opening. In order to extend the length of the original stent, the additional stent (FIG. 1B) is inserted into the opening. *Id.*at 8:50-54; 11:15-23.



In more technical terms, the '167 Patent describes that the first stent includes "means for joining" the first stent to the second stent, including a radially compressible "male engaging portion" on the first stent that is capable of being entered into a "female cooperating portion" on the second stent, and thereafter caused or allowed to expand to inter-engage the female portion in order to resist

longitudinal separation of the two stents. *Id.* at 1:18-27; 2:27-40. The second stent includes "two transversely spaced distal female cooperating portions" and "may therefore constitute a bifurcated stent for use in juxtaposition with a bifurcation in a blood vessel." *Id.* at 3:7-11. Each of the female cooperating portions may be adapted for connection to the first male stent "which, in use, extends across the bifurcation into a respective one of the branched blood vessels." *Id.* at 3:12-15.

The patent discloses that the stent may be made from "shape memory nitinol (nickel-titanium) wire," which may recover its original shape and expand at a body temperature. *Id.* at 3:46-4:4. The patent further discloses that each of the first and second stents may carry a tubular graft layer, which may be disposed externally or internally of the stent. *Id.* at 5:1-15. A graft layer on the external surface of the female portion may be folded over its distal extremity to form an inner sleeve, which may but against an external graft of the male engaging portion to form a substantially blood-tight seal. *Id.* at 5:16-25.

The '167 Patent contains 82 claims. Independent claims 1-4, 13, 31-33, 51, 52, and 71 generally recite a stent joining means or endoluminal prothesis system for joining two stents or prosthesis segments, with different claims reciting different configurations of the male engaging portion, female portion, and graft layers. Independent claims 5 and 72 generally recite stent joining means in which the one of the stents has two transversely spaced female portions (*i.e.*, bifurcated

structure). The dependent claims add similar limitations to the various independent claims, as generally summarized below:

Claims	**General description of limitation**
1-5	stents consists of "a shape memory alloy"
1, 33	male engaging portion "flared radially outwardly"
2, 51	female portion is "tapered radially inwardly"
3	"the male engaging portion comprises a frustoconical wall flaring outwardly"
4	"female portion comprises a frustoconical wall tapering radially"
15, 72	"two transversely spaced female portions"
13, 52, 72	graft layer "configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly"
31, 71	graft layer of male engaging portion "configured to be in face-to-face contact with said graft layer [portion] of said female portion to form a substantially fluid-tight seal upon assembly"
6, 24, 44, 64	"at least one of said [stents/prosthesis segments] having a taper to resist longitudinal separation"
7, 25, 45, 65	"at least one of said [stents/prosthesis segments] having a flare to

	engage the body lumen"
8, 26, 46, 66	"said male engaging portion providing a substantially blood tight seal with said graft layer"
9, 27, 47, 67	"said male engaging portion being flared when uncompressed"
10, 29, 49, 69	"wherein said second endoluminal stent is adapted to extend across a bifurcation in a blood vessel such that in use a proximal end of said second endoluminal stent is disposed proximally of the bifurcation, one of said female portions of said second endoluminal stent is disposed in a branched blood vessel, and said first endoluminal stent is adapted to extend from the other one of said female portions into another branched blood vessel" (10) "wherein [said/a] proximal prosthesis segment defines two distal lumens, one of which is adapted to extend across a bifurcation in a blood vessel such that in use a proximal end of said proximal prosthesis segment is disposed proximally of the bifurcation, and a distal end of said proximal prosthesis segment is disposed in one of the branched blood vessels, the other of said distal lumens comprising said female portion and being disposed intermediate said proximal and distal ends of said proximal prosthesis

	segment, and said male engaging portion is disposed on [a/said] distal prosthesis segment and is adapted to mate with said female portion and to extend into the other of said branched blood vessels" (Claims 29, 49, 69)
12	"said male engaging portion of said first endoluminal stent and said one spaced distal female portion and said first and second endoluminal stents, in combination, extend across a bifurcation in a blood vessel into two respective branched blood vessels"
11, 30, 50, 55, 70	hoops defining/comprising "a zig zag pattern"
14, 34, 53, 73	graft layer attached to stent "by a filament"
15, 35, 54, 74	hoops with/having "a common axis . . . positioned along [that/said] axis"
16, 36, 37, 56, 75	"plurality of apices" alternately pointing "in opposite axial directions, oppositely pointed apices [in/of] adjoining hoops abutting one another," "abutting apices being joined by a connecting member" (Claims 16, 36, 56, 75) "a plurality of apices disposed about the circumference of said

	hoop and alternatingly pointing in opposite axial directions; and a member which extends, as a single continuous member, from an apex pointed in a first axial direction to the apex of an adjacent hoop pointed in the opposite axial direction" (Claim 37)
17, 57, 76	"each of said hoops comprising wire disposed in a sinuous or zig zag configuration around the circumference of said hoop, the wire of at least one of said hoops being continuous with the wire of an adjacent hoop" (Claims 17, 57, 76)
18, 38, 58, 77	end portion of stent "extends beyond" graft layer
19, 39, 59, 78	"at least one of said [prosthesis segments/stents] comprising barbs or hooks adapted to engage a surrounding body lumen and to resist longitudinal movement or slippage of [prosthesis segment/stent] in service"
20, 40, 60, 79	"at least one of said [prosthesis segments/stents] comprising barbs or hooks to resist longitudinal separation of said [prosthesis segments/stents] in service"
21, 41, 61, 80	"at least one of said [prosthesis segments/stents] comprising [a/at least one] [radiopaque] marker . . . being adapted to facilitate

	proper alignment or positioning of said [prosthesis segment/stent]"
22, 42, 62, 82	"marker [being/is] adapted to facilitate alignment of said [prosthesis segment/stent] with the other" prosthesis segment/stent
23, 32, 43, 63, 81	"said [radiopaque] marker differs depending on the rotational orientation . . . so that said rotational orientation can be determined" (Claims 23, 43, 63, 81) "said radiographic image of said portion differing depending on the rotational orientation of said at least one of said proximal and distal segments so that said rotational orientation in the body lumen can be determined, and said portion having said different radiopacity being configured in a 'V' shape" (Claim 32)
28, 48, 68	"said male engaging portion being compressible and capable of self re-expansion to engage said female portion"

B. Summary of Prosecution History of the '167 Patent

On May 10, 1999, the Examiner issued a Non-Final Rejection of various claims based on WO 92/00043, without providing analysis. Ex. 1006 at 178. The Examiner objected to other claims "as being depended upon a rejected base claim,

but would be allowable if rewritten in independent form." *Id.* In response, applicants cancelled the rejected claims and amended the remaining claims according to the Examiner's instructions. On March 13, 2000, the Examiner issued a Notice of Allowability, and the '167 Patent issued on September 12, 2000.

C. The '167 Patent Cannot Claim Prioirty to EP 94400284 or EP 94401306 Based on A Related Interference, which Precludes Patent Owner from Patentably Indistinct Claims and from Litigating the Issue of Prioirty

The '167 Patent is a division of U.S. Application No. 08/317,763, now U.S. Patent No. 5,609,627 ("'763 Application"). Another division of the '763 Application, U.S. Application No. 08/461,402 (the "'402 Application," or "Goicoechea"), was the subject of an interference before the BPAI, No. 104,192. Based on this interference and subsequent district court and Federal Circuit litigation, it is conclusive that the '167 Patent cannot claim priority to EP 94400284 ("EP '284") or EP 94401306 ("EP '306").

The '192 Interference was declared on April 23, 1998, among Goicoechea and (1) U.S. Application No. 08/463,836 ("Ryan"), and (2) U.S. Patent No. 5,575,817 ("Martin"). Ex. 1007.[4] On July 28, 1998, the BPAI re-declared the

[4] Petitioner notes that because of corrections of inventorship, Goicoechea is often referred to in the '192 interference proceedings as "Cragg," and Ryan is

interference to substitute a new count (Count 2). Ex. 1008 at 1.

The BPAI initially accorded Goicoechea the benefit of the EP '284 and EP '306 application filing dates, and thus determined Goicoechea to be the senior party. Ex. 1007 at 28-30. However, the BPAI ultimately determined that because two of the inventors on the Goicoechea '402 Application, Michael Dake and Andrew Cragg, did not assign their rights to the EP applicant until after the filing of the EP applications, the EP applications were not filed on Dake's or Cragg's behalf as required by 35 U.S.C. § 119, and thus Goicoechea could not claim priority to the EP applications. Ex. 1009 at 7-23.[5] This determination was affirmed by the United States District Court for the District of Columbia and the Federal Circuit. Exs. 1010, 1011.

Accordingly, it is conclusive that all patents in the Goicoechea patent family that list Dake or Cragg as an inventor cannot claim priority to the EP applications. *See, e.g.*, Ex. 1012 at 2 ¶ 1; Ex. 1013 at 2, ¶ 1.

In addition, as discussed further with respect to Ground 6 in Section IV.F

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referred to as "Fogarty." The Ryan '836 application ultimately issued as U.S. Patent No. 8,206,437, which Petitioner asserts herein in Grounds 1, 3, and 5.

[5] The '402 Application was also subject to a separate interference (No. 104,083) with Martin, in which Martin elected not to participate. Ex. 1017 at 1-2.

below, Patent Owner is not entitled to claims that are patentably indistinct from the claims involved in the interference. *See, e.g.*, *In re Deckler*, 977 F.2d 1449 (Fed. Cir. 1992); *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. Int. 1985); MPEP 2308.03. The claims involved in the interference recite the basic limitations of all claims of the '167 Patent, including a male engaging portion on one stent that can be positioned within and joined to a female portion on another stent to prevent relative movement of two stents. And the remaining limitations of the '167 Patent are not independently patentable, as described in the Grounds below.

Further, Patent Owner is precluded from litigating the issue of priority with respect to Ryan and Martin in this proceeding. *See, e.g.*, MPEP 2308.03 ("If a party loses on an issue, it may not re-litigate the issue before the examiner or in a subsequent Board of Patent Appeals and Interferences (Board) proceeding. The time for the party to make all pertinent arguments is during the interference, unless the Board expressly prevented the party from litigating the issue during the interference."); *Deckler*, 977 F.2d at 1452 ("[A] judgment in an action precludes relitigation of claims or issues that were or could have been raised in that proceeding."); *Tytgat*, 225 USPQ at 912 ("[W]e believe that as a matter of sound judicial policy, a patent applicant should not have 'repeated bites at the apple' in interference cases. . . . Nothing in the PTO rules would have precluded Tytgat from establishing—if he could—priority of invention in the Tytgat/Koyanagi

interference of the presently claimed subject matter vis-a-vis the subject matter which Koyanagi won in that interference.").

III. STATEMENT OF THE PRECISE RELIEF REQUESTED

A. Claims and statutory grounds (37 C.F.R. § 104(b)(1)-(2))

Petitioner respectfully requests that all claims 1-82 of the '167 Patent be canceled based on the following grounds. A full statement of the reasons for this request is presented in later sections of this Petition.

Ground 1: Claims 2, 4-6, 8, 10-18, 24, 26, 28-31, 51-58, 64, 66, and 68-77 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 8,206,427 ("Ryan") (Ex. 1002).

Ground 2: Claims 13, 18-22, 24-29, 31, 33, 38-42, 44-49, 51, 52, 58-62, 64-69, 71, 72, 77-80, and 82 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,575,817 ("Martin") (Ex. 1003).

Ground 3: Claims 1-3, 5-10, 12, 34-37 and 50 are obvious under 35 U.S.C. § 103 over Martin in view of Ryan.

Ground 4: Claims 23, 32, 43, 63, and 81 are obvious under 35 U.S.C. § 103 over Martin in view of U.S. Patent No. 4,830,003 ("Wolff") (Ex. 1004).

Ground 5: Claim 3 is obvious over Martin in view of Ryan and U.S. 5,226,913 ("Pinchuk") (Ex. 1005).

Ground 6: Patent Owner Is Not Entitled to Claims that are Patentably

Indistinct from the Claims Involved in the '192 Interference.

B. Construction of Challenged Claim Terms (37 C.F.R. § 104(b)(3))

Normally, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." *See*, 37 C.F.R § 42.100(b). However, the '167 Patent expires on September 27, 2014. 35 U.S.C. § 154(a). Accordingly, if the Board institutes trial, the '167 Patent will expire before trial is instiuted. 35 U.S.C. § 314(b); 37 C.F.R. § 42.107(b). Where a challenged patent is expired, the standard set forth in *Phillips v. AWH Corp*., 415 F.3d 103 (Fed. Cir. 2005) (en banc), applies. *See* IPR2013-00065, Paper 11 at 10; MPEP 2258(I)(G). Thus, it is unclear whether the broadest reasonable construction or the *Phillips* standard applies to this proceeding. Petitioner, however, asserts that all claims of the '167 Patent are unpatentable under either standard.

Petitioner notes that the preamble of claims 1-12 and 72-82 each recite "stent joining means for joining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents, said stent joining means comprising.. . ." However, "a statement of function appearing only in the claim preamble is generally insufficient to invoke . . . pre-AIA 35 U.S.C. 112, sixth paragraph." MPEP 2181(I)(B). The use of the "means" phrase in the preamble of the claims appears directed to stating the intended use of the claimed invention as recited in the subsequent limitations, not to reciting a

means-plus-function limitation, and thus it does not appear that these claims fall within pre-AIA Section 112, paragraph six. MPEP 2181(I)(A). Petitioner notes the additional following terms and proposed constructions:[6]

Term	**Proposed construction and support**
"proximal" (Claims 1-5)	"nearest to the heart" Ex. 1001 at 2:23-24.
"distal" (Claims 2, 12, 13, 29, 31, 32, 49, 52, 53, 69, 71,)	"furthest from the heart" *Id.* at 2:24-25.
"shape memory alloy" (Claims 1-5)	"alloy that recovers original shape on being raised to a higher temperature" *Id.* at 3:43-4:4.
"endoluminal prosthesis " (Claims 13, 31-33, 51, 52, 71)	"a stent with a graft layer" *Id.* at 1:29-35; 5:1-5.

IV. STATEMENT OF REASONS FOR RELIEF REQUESTED

A petition for *inter partes* review must demonstrate "a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). This Petition meets this threshold. All elements of claims 1-82 of the '167 Patent are taught in the prior art references as explained below pursuant to 37 C.F.R. § 104(b)(4), and reasons to combine the

[6] Petitioner reserves the right to argue or respond to different constructions in other proceedings.

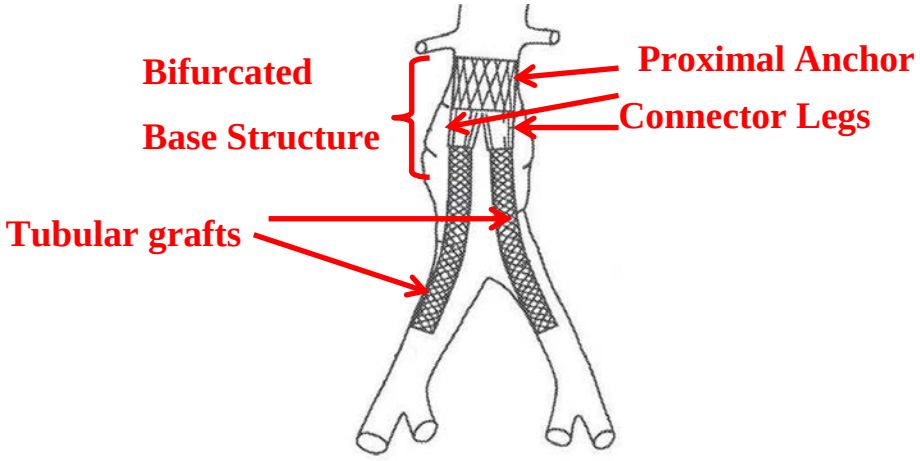
features of these prior art references are established for each ground under 35 U.S.C. § 103(a).

A. Ground 1: Claims 2, 4-6, 8, 10-18, 24, 26, 28-31, 51-58, 64, 66, and 68-77 are anticipated by Ryan.

1. Overview of Ryan

Ryan, titled "Apparatus and Methods for Endoluminal Graft Placement," was filed June 5, 1995, issued on June 26, 2012, and claims priority to App. No. 08/255,681, filed June 8, 1994. Ex. 1002. Ryan is thus 102(e) prior art to the '167 Patent. Ryan was not before the Examiner during prosecution of the '167 Patent.

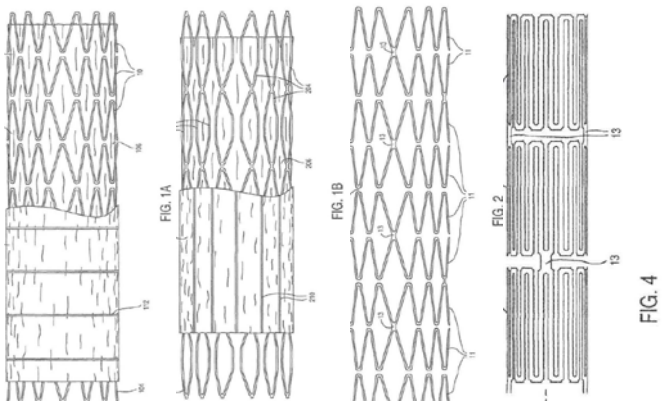
Ryan describes an endovascular bifurcated stent graft system having a trunk and modular legs. Ryan discloses that "[t]he system comprised a **bifurcated base structure** including a proximal anchor, typically a self-expanding frame, which defines a common flow lumen and a pair of connector legs that establish divergent flow lumens from the common flow lumen. The system also includes a **first tubular graft which can be anchored within first of the connector legs** to form a continuous extension of the first divergent flow lumen and **a second tubular graft which can be anchored within a second of the connector legs to form a continuous extension of the second divergent flow lumen**." *Id.* at 3:41-49 (emphasis added). This endovascular bifurcated stent graft system is shown in annotated Figure 12 below:



Ryan discloses that the bifurcated base structure and tubular grafts comprise a tubular frame/stent. *Id.* at 2:31-57; 3:16-21; 3:62-66. Ryan describes that the stents "will be composed of a resilient material, usually metal, often times a heat and/or **shape memory alloy**, such as nickel titanium alloys which are commercially available under the trade name **Nitinol**®." *Id.* at 6:47-51 (emphasis added).) The stents "can be compressed from a relaxed, large diameter configuration to a small diameter configuration to facilitate introduction." *Id.* at 5:24-30; 7:49-52. Ryan further states that the stents should have "a relaxed (i.e., non-compressed) diameter which is greater than the diameter of the blood vessel to be treated." *Id.* at 3:16-19.

In addition, Ryan discloses that the stent configuration "can take a variety of forms" including "independent or interconnected structural elements, such as rings, bands, helical elements, serpentine elements, axial struts, parallel bars" and "zig-zag or Z-shaped element which forms a continuous circular ring." *Id.* at 5:24-30;

7:49-52. Several of these configurations are shown in the patent's figures:



Ryan discloses that the bifurcated stent graft system incorporates an inner graft and may incorporate an outer graft. The patent describes that "[p]referably, the bifurcated base structure, first tubular graft, and second tubular graft, will be formed from radially compressible perforate tubular frames having interior and/or exterior liners." *Id.* at 3:62-65. "By covering the lumen of the tubular frame, thrombogenicity of the graft resulting from exposed frame elements is greatly reduced or eliminated." *Id.* at 2:62-64. In addition, "a second liner may be provided over at least a portion of the exterior of the frame to cover both sides of the frame," which "provides a circumferential seal against the inner wall of the blood vessel lumen in order to inhibit leakage of blood flow between the graft and the luminal wall into the aneurysm or stenosis which is being treated." *Id.* at 2:41-47. The band members of the stent can be" stitched, welded, or otherwise joined to the liners to hold them in place." *Id.* at 9:1-3.

In addition, Ryan discloses the "placement of a bifurcated aortic graft using

the bifurcated graft placement system." *Id.* at 4:59-61. Referring to Figures 7-12 below, Ryan describes that the bifurcated base structure 20 is delivered in a radially compressed configuration via delivery catheter 30 and subsequently allowed to self-expand. *Id.* at 10:23-31. Then vascular graft 10 is delivered in a radially compressed configuration via delivery catheter 30 and inserted within the right fabric liner leg 28 of the bifurcated base structure and subsequently allowed to self-expand within the right leg 28 and the right iliac artery. *Id.* at 10:33-36. A person of ordinary skill would understand that the overlapping of the bifurcated base structure right leg 28 and second vascular graft 10 would cause the vascular graft 10 to become anchored within the right leg 28 through frictional inter-engagement which would prevent separation and relative movement. Ex. 1019, ¶¶ 57-59, 75. A second vascular graft 10 is delivered in a radially compressed configuration via delivery catheter 30 and inserted within the left fabric liner leg 26 of the bifurcated base structure and subsequently allowed to self-expand within the left leg 26 and the left iliac artery. *Id.* at 10:42-47. A person of ordinary skill would understand that the overlapping of the bifurcated base structure left leg 26 and second vascular graft 10 would cause the vascular graft 10 to become anchored within the left leg 26 through frictional inter-engagement which would prevent separation and relative movement. *Id.* at ¶¶ 75, 76.

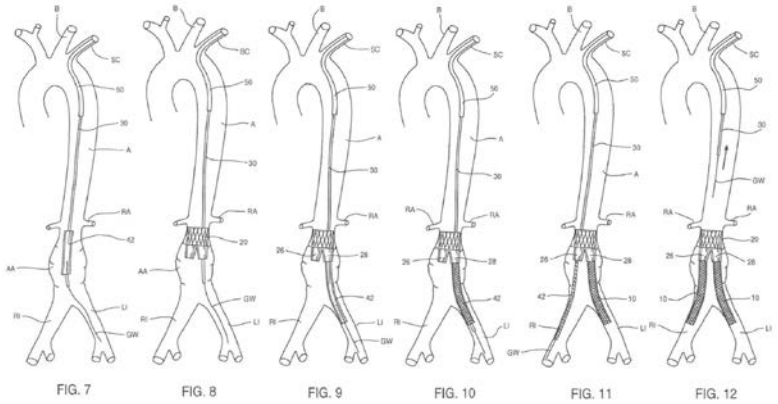


FIG. 7 FIG. 8 FIG. 9 FIG. 10 FIG. 11 FIG. 12

Moreover, the bifurcated base structure and first vascular graft may be delivered to the site of treatment such that the anchor section of the base structure is disposed within the primary artery and the first vascular graft is at least partially disposed in a first branch artery. *Id.* at 11:17-27; 12:10-14. Then the second vascular graft may be delivered and secured to a connector leg of the bifurcated base structure so that it is disposed in a second branch artery. *Id.* at 11:28-32; 12:16-20. To assist with the delivery and placement process, the patent describes that an ultrasonic imaging catheter or guidewire may be used. *Id.* at 10:54-11:7.

2. Ryan discloses each element of Claims 2, 4-6, 8, 10-18, 24, 26, 28-31, 51-58, 64, 66, and 68-77.

Ryan teaches joining two endoluminal stents or prosthesis segments in the same manner as claimed in the ‘167 Patent. With respect to independent claims 2, 4, 13, 31, 51, 52, and 71, Ryan discloses inserting a portion of a radially compressible tubular graft into a portion of another tubular graft so that, when expanded, the inserted tubular graft will be anchored within the other tubular graft

through contact between the outer surface of a portion of the inserted tubular graft and inner surface of the other tubular graft, and thus will prevent separation of the grafts. *Id.* at 3:37-66; 10:23-50; 11:14-32; 12:7-20; FIGS. 8-12; Ex. 1019, ¶ 104. Ryan further discloses that such anchoring can be performed in a bifurcated blood vessel using a bifurcated base structure having two connector legs, such that the proximal end of the bifurcated base structure will be disposed proximally of the bifurcation and a first tubular graft will be disposed in one branched vessel via one connector leg, and a second tubular graft can then be introduced into into the bifurcated base structure through the other connector leg and extend into the second blood vessel, as recited in claims 5, 10, 29, 49, 69 and 72. Ex. 1002 at 3:37-66; 10:23-50; FIGS. 5, 11-12; Ex. 1019 ¶ 104.

Ryan further discloses all of the other features of the identified claims of the '167 Patent. For example, a person of ordinary skill in the art would understand that the anchoring of the tubular grafts together as disclosed by Ryan would result in an inter-engagement of the outer surface of the male engaging portion and inner surface of the female portion to resist longitudinal movement to prevent separation of stents or prosthesis segments in service, as disclosed in claims 2, 4, 5, 13, 31, 32, 33, 51, and 72 of the '167 Patent. *E.g.*, Ex. 1002 at 3:37-66; 10:23-50; 11:14-32; 12:7-20; Ex. 1019, ¶ 105. A person of ordinary skill in the art would further understand that Ryan discloses that a graft layer of at least one of the tubular grafts

is "configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly," recited in claims 13, 52, and 72, and that such a seal may be formed by face-to-face contact between a graft layer of the male engaging portion and a graft layer of a female portion, as recited in claims 31 and 71. *E.g.*, Ex. 1002 at 2:43-47; 3:39-58; 11:14-32; 12:7-20; Ex. 1019, ¶ 105.

Ryan further discloses that the connector leg of the bifurcated base structure may be tapered radially inwardly, including comprising a frustoconical wall, as recited in claims 2, 4, and 51, and that such taper resists longitudinal separation of the bifurcated base structure and tubular graft, as recited in claims 6, 24, 44, and 64, *e.g.* Ex. 1002, FIGS. 8-12; Ex. 1019, ¶ 106. A person of ordinary skill in the art would further understand that Ryan discloses that the male engaging portion of the tubular graft may provide a substantially blood tight seal with the graft layer associated with the female portion, as recited in claims 8, 26, 46, 66. *E.g.*, Ex. 1002 at 2:43-47; 3:39-58; 5:19-23; 6:3-11; 9:35-44; 11:14-32; 12:7-20; FIGS. 5, 8-12; Ex. 1019, ¶ 106.

Ryan further discloses that the tubular frames comprise hoops defining "a zig zag pattern," having "a common axis . . . positioned along" the axis, and comprising oppositely pointing and abutting apices, as recited in claims 11, 15-17, 30, 35-37, 50, 54-57, 70, and 74- 76. *E.g.* Ex. 1002 at 3:16-25; 3:62-66; 7:49-61;

9:27-33; FIGS 1-4; Ex. 1019 ¶ 106. Ryan further discloses that a graft layer can be attached to the tubular frame by a filament, as disclosed in claims 14, 34, 53, and 73. *E.g.* Ex. 1002 at 2:36-47; 3:26-34; 5:50-53; 6:3-16; Ex. 1019, ¶ 106. Ryan further discloses that the male engaging portion of the tubular graft is "compressible and capable of self re-expansion to engage said female portion," as recited in claims 28, 48, and 68. *E.g.*, Ex. 1002 at 2:33-36; 3:3-7; 3:62-66; 6:47-59; Ex. 1019, ¶ 106.

For at least such reasons and as evidenced by the claim chart that follows, Ryan anticipates claims 2, 4-6, 8, 10-18, 24, 26, 28-31, 51-58, 64, 66, and 68-77.

In various instances, multiple claims identified in the instant Ground recite similar limitations (*e.g.*, as outlined in the table in Section II.A). For example: Claims 24, 26, 29, 30 recite similar limitations as claims 6, 8, 10, and 11; Claims 53, 54, 55, 56, 57, 58, 64, 66, 68, 69, 70 recite similar limitations as claims 14, 15, 11, 16, 17, 18, 24, 26, 28, 29, 30; Claim 71 generally recites the limitations of claim 31 ("face-to-face contact with said graft layer of said female portion to form a substantially fluid-tight seal upon assembly") and 52 ("define a substantially continuous lumen upon assembly of said proximal and distal prosthesis segments"); and Claims 73, 74, 75, 76, and 77 recite similar limitations as claims 14, 15, 16, 17, and 18.

These claims thus are treated cumulatively in the following chart, which further identifies where the elements of the challenged claims can be found in Ryan (citations are to Ex. 1002):

USPN 6,117,167	**USPN 8,206,427 (Ryan)**
Claim 2. A stent joining means for joining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents, said stent joining means comprising:	Ryan discloses anchoring a tubular graft within another tubular graft "to form a continuous extension" of a "divergent flow lumen." 3:44-49; *see also* 11:14-32; 12:7-20 (anchoring tubular graft to bifurcated structure to form a continuous flow path). The tubular grafts comprise a tubular frame/stent. *E.g.*, 2:31-39; 2:48-57; 3:16-21; 3:62-66; 10:54-11:4.
[2b] a male engaging portion on said first endoluminal stent which has an outer surface and can be compressed radially inwardly; and	Ryan discloses a "second tubular graft" (first endoluminal stent) that has an outer surface and "is radially compressed while being introduced." 5:19-49 (radially compressible frame with outer liner over exterior); 10:28-47 (vascular graft expands from radially compressed state); 11:61-62. Tubular graft (10) has a portion that engages female portion of other endoluminal stent. *E.g.*, Fig. 12; 10:42-47.
[2c] a female portion on said second endoluminal stent cooperating with said male engaging portion, said female portion having an inner surface, wherein the female portion is tapered radially inwardly towards a distal end;	Ryan discloses a connector leg (female portion) on a bifurcated base structure (second endoluminal stent), into which a portion of a tubular graft (male engaging portion) is inserted, thus cooperating with the male engaging portion. *E.g.*, 3:44-58. The connector leg (26) is tapered radially inwardly. FIGS. 8-12.
[2d] wherein said first endoluminal stent and said second endoluminal stent consist of a shape memory alloy and the male engaging portion can be	Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. 6:47-59. Ryan discloses that a portion of the second tubular graft (male

entered into the female portion in a radially compressed state and thereafter expanded in the female portion and wherein said outer surface of the male engaging portion and said inner surface of the female portion are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service.	engaging portion) is entered into the connector leg of the bifurcated base structure (female portion) in a radially compressed state, and thereafter expanded such that the outer surface of the second tubular graft portion and inner surface of the connector leg are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service. *E.g.*, 3:44-48; 10:42-47; 11:14-32; 12:7-20; FIGS. 10-12.
Claim 4 contains the same limitations as Claim 2, but recites that the female portion "comprises a frustoconical wall tapering radially inwardly towards a longitudinal extremity."	Ryan discloses that the connector leg (26) comprises a frustoconical wall tapering radially inwardly towards a longitudinal extremity. FIGS. 8-12.
Claim 5 contains the same limitations as Claim 2, but recites "two transversely spaced female portions on said second endoluminal stent"	Ryan discloses two transversely spaced connector legs (female portions) on the bifurcated stent structure. *E.g.*, 3:37-49; 10:23-50; FIGS. 5, 8-12. The bifurcated base structure and first tubular graft in combination also have two transversely spaced female portions. *E.g.*, FIG. 10.
Claim 6. A stent joining means as claimed in claim 5, at least one of said stents having a taper to resist longitudinal separation of said stents in service.	Ryan discloses that the connector leg (26) of the bifurcated base structure is tapered to resist longitudinal separation from the second tubular graft. FIGS. 8-12.
Claim 8. A stent joining means as claimed in claim 5, further comprising a graft layer associated with said female portion, said male engaging portion providing a substantially blood tight seal with said graft	Ryan discloses that the bifurcated base structure, including the connector leg, comprises an inner and/or outer liner or graft, *e.g.*, 5:19-23 (inner and outer liner); 6:3-11 (liner composed of "conventional biological graft materials"); 9:35-44 (liner defines pair of flow lumens in connector legs); FIGS. 5, 8-12;

layer.	and that the second tubular graft provides a substantially blood tight seal with the graft layer, *e.g.,* 3:39-58 (form a continuous extension of the divergent flow lumen); 11:14-32; 12:7-20 (continuous flow path); 2:43-47 (exterior coverage provides seal).
Claim 10. A stent joining means as claimed in claim 5, wherein said second endoluminal stent is adapted to extend across a bifurcation in a blood vessel such that in use a proximal end of said second endoluminal stent is disposed proximally of the bifurcation, one of said female portions of said second endoluminal stent is disposed in a branched blood vessel, and said first endoluminal stent is adapted to extend from the other one of said female portions into another branched blood vessel.	Ryan discloses that the bifurcated base structure and first tubular graft (second endoluminal stent) extends across a bifurcation such that the anchor section (proximal end of second endoluminal stent) is disposed proximally of the bifurcation, and the first tubular graft (one of female portions of second endoluminal stent) is disposed within the first branch artery; and the second tubular graft (first endoluminal stent) is adapted to extend from the connector leg of the anchor section (other female portion) into the second branch artery. *E.g.,* 3:37-58; 10:23-50; 11:14-32; 12:7-20.
Claim 11. A stent joining means as claimed in claim 5, at least one of said stents comprising a plurality of co-axial hoops, each of said hoops comprising a zig zag pattern around the circumference thereof.	Ryan discloses that the tubular frame/stent comprises from 1 to 30 radially compressible band members, each of which comprises "a zig-zag or Z-shaped element" which forms a continuous circular ring. 7:49-59; *see also, e.g.,* FIGS. 1-4; 9:27-33 (similar or identical structure in bifurcated base structure).
Claim 12. A stent joining means as claimed in claim 5 wherein one of said two transversely spaced distal female portions is adapted for connection to said male engaging portion of said first endoluminal stent and said one spaced distal female portion and said first and second endoluminal stents, in	Ryan discloses that at least connector leg (26) is adapted to connect to a portion of the second tubular graft, and that in combination, the bifurcated base structure and first and second tubular grafts extend across a bifurcation into two respective branched blood vessels. *E.g.,* 3:39-62; 10:23-50; 11:14-32; 12:7-20.

combination, extend across a bifurcation in a blood vessel into two respective branched blood vessels.	
Claim 13 recites similar limitations to claim 2, but is directed to "an endoluminal prosthesis system," and requires "at least one of said proximal and distal prosthesis segments comprising a graft layer attached to said stent, said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly."	Ryan is directed to an endoluminal prosthesis system. *E.g.*, 1:10-12; 5:19-49. Ryan discloses that at least one of the prosthesis segments comprises a graft layer attached to a stent, *e.g.*, 5:19-23 (inner and outer liner); 6:3-11 (liner composed of "conventional biological graft materials"); 9:35-44 (liner defines pair of flow lumens in connector legs); and the graft layer can be interposed to form a substantially fluid-tight seal upon assembly, *e.g.*, 3:39-58 (form a continuous extension of the divergent flow lumen); 11:14-32; 12:7-20 (continuous flow path); 2:43-47 (exterior coverage provides seal).
Claim 14. A system as claimed in claim 13, said graft layer being attached to said stent of at least one of said prosthesis segments by a filament.	Ryan discloses that the liner (graft layer) will be attached to the tubular frame by various means, and discloses that the liner may be woven at 27 filaments. *E.g.*, 2:36-47; 3:26-34; 5:50-53; 6:3-16.
Claim 15. A system as claimed in claim 13, said stent of at least one of said prosthesis segments having hoops with a common axis positioned along that axis.	Ryan discloses that radially compressible band members of the tubular frame have hoops with a common axis and are positioned along that axis. *E.g.*, 3:16-21; 3:62-66; 7:49-59 (zig-zag or Z-shaped element which forms a continuous circular ring); FIGS. 1-2, 4.
Claim 16. A system as claimed in claim 15, each of said hoops comprising a plurality of apices alternately pointing in opposite axial directions, oppositely pointed apices in adjoining hoops abutting one another, at least one pair of said abutting apices being joined by a connecting member.	Ryan discloses that the band members comprise alternately pointing apices that abut one another, and may be joined at two diametrically opposed points, including by bridge elements. *E.g.*, 3:16-24; 3:62-66; 7:49-59; FIGS. 1, 1B, 2.

Claim 17. A system as claimed in claim 15, each of said hoops comprising wire disposed in a sinuous or zig zag configuration around the circumference of said hoop, the wire of at least one of said hoops being continuous with the wire of an adjacent hoop.	Ryan discloses that the band members each comprise a zig-zag or Z-shaped element which forms a continuous circular ring, and there may be only one band member or it may be joined (continuous). *E.g.*, 3:16-24; 3:62-66; 7:49-59; FIGS. 1, 1B, 2.
Claim 18. A system as claimed in claim 13, wherein an end portion of said stent of at least one of said prosthesis segments extends beyond said graft layer.	Ryan discloses that the tubular frame may be "left open at each end, *e.g.*, at least a portion of the last band member 11 will remain uncovered by the liner 12." 7:62-64; *see also, e.g.*, 6:34-38; 9:23-26.
Claims 24 and 26.	*See* cites for claims 6 and 8, respectively.
Claim 28. A system as claimed in claim 13, said male engaging portion being compressible and capable of self re-expansion to engage said female portion.	Ryan discloses that the tubular frames of the intraluminal grafts, including the second tubular graft and engaging portion thereof, are compressible and capable of self-re-expansion to engage a female portion. *E.g.*, 2:33-36; 3:3-7; 3:62-66; 6:47-59.
Claims 29 and 30.	*See* cites for claims 10 and 11, respectively.
Claim 31 recites similar limitations to claim 13, but requires "a graft layer being provided adjacent said outer surface of said male engaging portion and adjacent said inner surface of said female portion, said graft layer of said male engaging portion being configured to be in face-to-face contact with said graft layer of said female portion to form a substantially fluid-tight seal upon assembly."	Ryan discloses a graft layer adjacent to the outer surface of a tubular graft and an inner surface of another tubular graft, the outer graft layer being configured to be in face-to-face contact with the inner graft layer of the other tubular graft to form a substantially fluid-tight seal. *E.g.*, 2:31-59; 5:19-23 (inner and outer liner); FIGS. 1, 1A and 1B; 6:3-11 (liner composed of "conventional biological graft materials"); 8:35-39 (liner folded over to external surface); 9:35-44 (liner defines pair of flow lumens in connector legs); 3:39-58 (form a continuous extension of the divergent flow lumen); 2:43-47 (exterior coverage provides seal); 11:14-32; 12:7-20 (continuous flow path).

Claim 51 recites similar limitations to claim 2, but is directed to a "system for joining endoluminal prosthesis segments in a vessel."	Ryan is directed to a system for joining endoluminal prosthesis segments in a vessel. *E.g.*, 1:10-12; 2:31-39; 2:48-57; 3:16-21; 3:44-49; 3:62-66; 5:19-49; 10:54-11:4.
Claim 52 recites similar limitations to claim 13, but requires that the proximal and distal prosthesis segments each comprise a graft layer and together define a continuous lumen upon assembly.	Ryan discloses tubular grafts that each comprise a graft layer, and that define a continuous lumen upon assembly. *E.g.*, 5:19-23 (inner and outer liner); FIGS. 1, 1A and 1B; 6:3-11 (liner composed of "conventional biological graft materials"); 8:35-39 (liner folded over to external surface); 9:35-44 (liner defines pair of flow lumens in connector legs); 3:39-58 (form a continuous extension of the divergent flow lumen); 11:14-32; 12:7-20 (continuous flow path).
Claims 53, 54, 55, 56, 57, 58, 64, 66, 68, 69, and 70.	*See* cites for claims 14, 15, 11, 16, 17, 18, 24, 26, 28, 29, 30, respectively.
Claim 71.	*See* cites for claims 31 and 52.
Claim 72 recites similar limitations as claim 5, but requires "a graft layer attached to at least one of said first and second endoluminal stents, said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly."	Ryan discloses a graft layer attached to the bifurcated base structure and second tubular graft, *e.g.*, 2:31-59; 5:19-23 (inner and outer liner); 6:3-11 (liner composed of "conventional biological graft materials"); 9:35-44 (liner defines pair of flow lumens in connector legs); and that the graft layer can be interposed to form a substantially fluid-tight seal upon assembly, *e.g.*, 3:39-58 (form a continuous extension of the divergent flow lumen); 11:14-32; 12:7-20 (continuous flow path); 2:43-47 (exterior coverage provides seal).
Claims 73, 74, 75, 76, and 77.	*See* cites for claims 14, 15, 16, 17, and 18, respectively.

B. Ground 2: Claims 13, 18-22, 24-29, 31, 33, 38-42, 44-49, 51, 52, 58-62, 64-69, 72, 77-80, and 82 Are Anticipated by Martin

1. Overview of Martin

Martin, titled "Apparatus and Methods for Endoluminal Graft Placement," was filed on August 19, 1994 and issued on June 26, 2012. Ex. 1003. Martin is thus 102(e) prior art to the '167 Patent.

Martin describes an endovascular bifurcated stent graft system having two sections—a bifurcated upper section and distal limb, which form an inverted Y graft when joined together inside a blood vessel. *Id.* at 1:66-2:45. "The first section of the inverted Y graft is comprised of the upper limb, the first lower limb, and a partial length of the second lower limb of the inverted Y. The second section of the inverted Y graft is comprised of the remainder of the second lower limb of the inverted Y." *Id.* at 1:46-51.

Martin discloses "bonding the graft to the inside of a **self-expanding**, mesh support tailored to the same measurements. The support may be a **stent** or a similar structure." *Id.* at 2:35-41 (emphasis added). The patent further describes the self-expansion of the stent, stating that "[b]y partially withdrawing the retractable membrane, the upper limb of the inverted Y is released." *Id.* at 2:10-13. Moreover, Martin discloses that the stent is a "**compressible** expanding mesh support 7." *Id.* at 3:11-13; 4:57 (emphasis added).

Martin further discloses that the bifurcated stent graft system incorporates an inner graft along its length. Martin states that "[t]he first section 1 comprises a hollow bifurcation graft 3 made of a suitable material" including "Dacron or thin

walled polytetrafluoroethaline [sic] (PTFE)." *Id.* at 3:2-3. "The whole of this first section is bonded and attached to the inside of a compressible expanding mesh support 7." *Id.* at 3:11-13. Martin describes that "[t]he second section 2 comprises a hollow tube graft which may be of the same material as the first section" and "is bonded to the inside of an expanding mesh support of the same dimensions." *Id.* at 3:23-26. Martin further discloses that in order to prevent the formation of thrombi, the mesh support may be covered with a suitable non-metallic material. *Id.* at 2:44-48.

The system of Martin also describes that the second lower section is joined to the first upper section through a friction fit and/or hooks, barbs or other means of attachment, to prevent separation and relative longitudinal movement of the lower section and the upper section. The patent discloses that "[t]he upper end 13 of the second section 2 is slightly larger in diameter than the corresponding diameter 14 of the partial length of the second lower limb 5 of the first section 1. This allows for a **friction fit** of the two sections when the **second section 2 expands within the first section 1**." *Id.* at 3:29-34 (emphasis added). In addition, the patent describes that "[a]lternatively or in conjunction with this friction fit, the upper end 13 **may include a fastener means such as barbs, outward-facing hooks, or some other means of attachment**." *Id.* at 3:34-37 (emphasis added). A person of ordinary skill would understand that the friction fit and/or hooks and

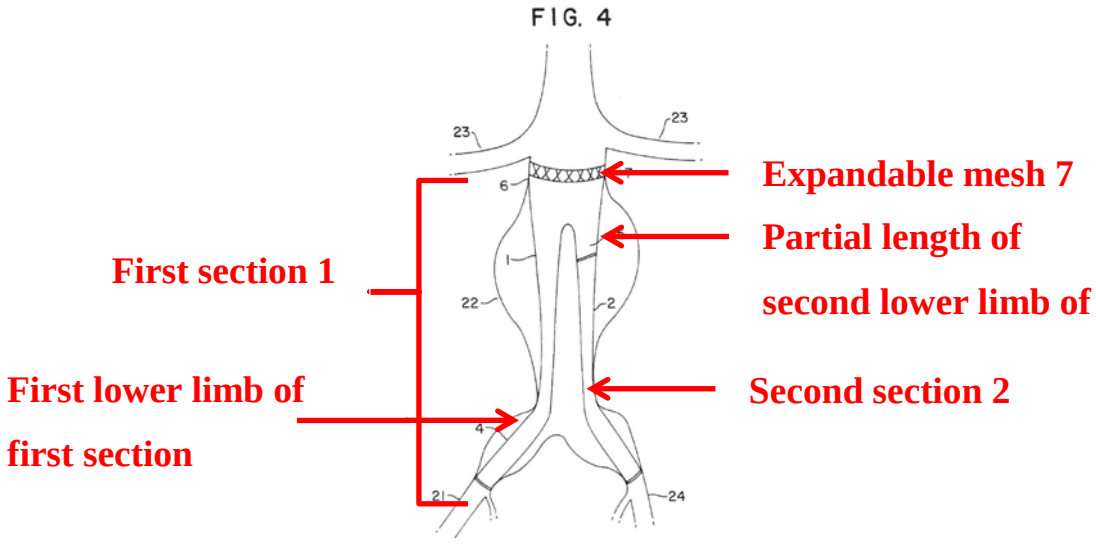
barbs would prevent separation and relative longitudinal movement of the first and second sections. Ex. 1019, ¶ 85.

The system further incorporates a fastener means to anchor the first upper limb to the vessel wall to prevent migration. Martin states that the stent "extends approximately 1 cm beyond the material of the upper limb 6," which "accommodates some fastener means such as barbs 10 or outward facing hooks 11 to fasten it to the inside of the lumen." *Id.* at 3:17-22.

In addition, Martin teaches a method of placement that "comprises inserting the two sections into the bifurcating blood vessel by encasing the sections in retractable membranes mounted on two catheters, inserting the catheters into the blood vessel, deploying and attaching the first section to the vessel, deploying the second section and joining it to the first section." *Id.* at Abstract. Under fluoroscopic and angiographic control, the "catheter on which the first section is mounted is introduced into the aorta 22 and positioned immediately below the renal arteries 23." *Id.* at 4:6-8.

Then the upper limb of the first section is partially deployed by partially withdrawing the retaining member. *Id.* at 4:8-10. "As it deploys, the upper limb expands and fastens to the wall of the aorta under the force of the expandable mesh 7. The fastening means may be barbs, hooks, or some other means." *Id.* at 4:10-13. The upper limb of the first section is then fully deployed by fully withdrawing

the retaining member. *Id.* at 4:13-14. "The catheter is removed through the iliac artery 21. The first lower limb 4 of the inverted Y is thus positioned in the iliac artery." *Id.* at 4:15-17. Also, under fluoroscopic and angiographic control, the second section 2 is introduced via catheter through the contralateral iliac artery 24, and "is positioned so that its upper end 13 is inside the partial length of the second lower limb 5 of the first section 1." *Id.* at 4:17-22. Then the second section is partially deployed by partially withdrawing the retaining member. *Id.* at 4:22-24. The "second section 2 expands within the first section 1." *Id.* at 3:29-34. "As it deploys, **the second section expands under the force of the expandable mesh and fastens to the inside of the first section**. The fastening means may be barbs, hooks, or some other means." *Id.* at 4:24-27 (emphasis added). The second section is then fully deployed by fully withdrawing the retaining member. *Id.* at 4:28-30.



To assist in the placement of the sections, on the first section, "[t]he line of attachment of the section to the support may be marked with fine platinum wire 12 for heightened fluoroscopic visibility." *Id.* at 3:19-22. Also, "[t]he upper and lower ends of the second section 2 may be traced with platinum wire 12 in order to enhance their fluoroscopic visibility." *Id.* at 3:37-39.

2. Martin discloses each element of Claims 13, 18-22, 24-29, 31, 33, 38-42, 44-49, 51, 52, 58-62, 64-69, 71, 72, 77-80, and 82.

Martin teaches joining two endoluminal stents or prosthesis segments in the same manner as claimed in the '167 Patent. With respect to claims 13, 31, 33, and 51, Martin discloses inserting the upper end of the radially compressible second section into the partial length of the second lower limb of the first section, and exanding the second section to provide a inter-engagement between the outer surface of the upper end of the second section and inner surface of the partial length of the second lower limb, to resist longitudinal movement to prevent separation. *E.g.*, *id.*, 2:66-3; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract; Ex. 1019, ¶ 107. These joined sections define a continuous lumen as recited in claims 52, 71, and 72. Ex. 1003, Abstract; 1:38-67; 2:66-3:26; FIGS. 1, 4; Ex. 1019, ¶ 107.

Martin further discloses joinng two sections of an endoluminal bifurcated "inverted Y graft" prosthesis in a bifurcated blood vessel such that upon insertion and union of the two sections the bifurcated prosthesis is disposed proximally of

the bifurcation at the upper or proximal end and into two branched vessels at the lower or distal end. *E.g.*, Abstract; 1:8-10; 1:38-44; 2:65-3:2; Ex. 1019, ¶ 108. Martin descirbes two steps for joining the sections of the bifurcated prosthesis: (1) inserting a radially compressible first section of an endoluminal bifurcated "inverted Y graft" prosthesis in a bifurcated blood vessel, such that the upper limb of the first section is disposed proximally of the bifurcation, the first lower limb of the first section is disposed in one of the brached arteries, and the partial length of the second lower limb of the first section is disposed intermediate the proximal and distal ends of the first section, *e.g.*, 2:45-63; 2:1-16; 3:2-22; 4:5-17; 4:34-46; and (2) inserting the upper end of a radially compressible second section into the partial length of the second lower limb of the first section, then expanding the second section to form a friction fit with the partial length of the second lower limb of the first section, such that the second lower limb of the bifurcated prosthesis is placed in the other branched artery, *e.g.*, 2:63-67; 3:17-35; 3:23-40; 4:17-32; 4:47-53; FIGS 1, 4. Martin thus discloses all of the limitations of at least claims 29, 49, 69 and 72. Ex. 1019, ¶ 108.

Martin further discloses all of the other features of the identified claims of the '167 Patent. For example, a person of ordinary skill in the art would understand that the joining of the two sections as disclosed by Ryan would result in an inter-engagement of the outer surface of the male engaging portion and inner

surface of the female portion to resist longitudinal movement to prevent separation of stents or prosthesis segments in service, as disclosed in claims 13, 31, 33, 51, and 72 of the '167 Patent. *E.g.*, Ex. 1003 at 3:37-66; 10:23-50; 11:14-32; 12:7-20; Ex. 1019, ¶ 109. A person of ordinary skill in the art would further understand that Martin discloses that a graft layer of at least one of the sections is "configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly," recited in claims 13, 52, and 72, and that such a seal may be formed by face-to-face contact between a graft layer of the male engaging portion and a graft layer of a female portion, as recited in claims 31 and 71. *E.g.*, 2:44-48; 2:66-3:13; 3:23-45; 4:17-32; FIGS. 1, 4; Abstract; Ex. 1019, ¶ 109.

Martin further discloses that the male engaging portion of the second section may be flared radially outwardly, as recited in claims 27, 33, 47, and 67. *E.g.* Ex. 1003, FIGS. 1, 4; 3:29-37; Ex. 1019, ¶ 110. Martin further discloses that the partial length of the lower limb of the first section may be tapered radially inwardly, as recited in claims 2 and 51, and that such taper resists longitudinal separation of the two sections, as recited in claims 6, 24, 44, and 64, *E.g.* Ex. 1003, FIG. 4; 3:32-34; Ex. 1019, ¶ 110. A person of ordinary skill in the art would further understand that Martin discloses that the male engaging portion of second section may provide a substantially blood tight seal with the graft layer associated

with the female portion, as recited in claims 8, 26, 46, and 66. *E.g.*, Ex. 1003 at 2:66-3:13; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract; Ex. 1019, ¶ 110.

Martin further discloses that the upper limb of the first section has a flare to engage the body lumen, as disclosed in claims 25, 45, and 65, as well as barbs or hooks adapted to engage a surrounding body lumen and to resist longitudinal movement or slippage, as recited in claims 19, 39, 59, and 78. *E.g.*, Ex, 1003 at 2:11-13; 3:14-19; 4:11-13; 5:3-7; FIGS. 1, 4; Ex. 1019, ¶ 111. Martin also discloses that the second section may comprise barbs or hooks to resist longitudinal separation of the first and second section, as recited in claims 20, 40, 60, and 79. *E.g.*, Ex. 1003 at 3:29-37; 4:24-27; 5:10-6:2; Ex. 1019, ¶ 111.

Martin further discloses that both the first and section sections may be marked with a platinum wire to enhance fluoroscopic visibility, which facilitates proper alignment or positioning of the section or sections, as disclosed in claims 21, 22, 41, 42, 61, 62, 80, 82. *E.g.*, Ex. 1003 at 3:14-22; 3:37-39; 4:5-22; 4:65-67; Ex. 1019, ¶ 111.

For at least such reasons and as evidenced by the claim chart that follows, Martin anticipates claims 13, 18-22, 24-29, 31, 33, 38-42, 44-49, 51, 52, 58-62, 64-69, 71, 72, 77-80, and 82 of the ‘167 Patent.

In various instances, multiple claims identified in the instant Ground recite similar limitations (*e.g.*, as outlined in the table in Section II.A and in IV.A).

These claims thus are treated cumulatively in the chart that follows, which further identifies where the elements of the challenged claims are found in Martin (citations are to Ex. 1003):

USPN 6,117,167	**USPN 5,575,817 ("Martin")**
Claim 13. An endoluminal prosthesis system adapted to be assembled within a body lumen, said endoluminal prosthesis system comprising	Martin discloses an endoluminal prosthesis system adapted to be assembled within a body lumen, *e.g.*, 1:7-10, 1:38-67,
[13.b] proximal and distal prosthesis segments, a male engaging portion on a selected one of said proximal and distal prosthesis segments, and a female portion on another one of said proximal and distal prosthesis segments, said male engaging portion being configured to be positioned at least partially within said female portion for inter-engagement between the outer surface of said male engaging portion and the inner surface of said female portion to resist longitudinal movement to prevent separation of said proximal and distal prosthesis segments in service,	Martin discloses an "upper end" on a second section of an inverted Y graft, *e.g.*, 3:29-37, a partial length of the second lower limb of the first section, *e.g.*, 3:29-44, and that the upper end of the second section is configured to be positioned at least partially into the partial length of the second lower limb for inter-engagement of the outer surface of the upper end and the inner surface of partial length of the second lower limb, to resist longitudinal movement to prevent separation of said proximal and distal prosthesis segments in service. *E.g.*, 2:66-3:2; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract.
[13.c] each of said male engaging portion and said female portion comprising a stent and at least one of said proximal and distal prosthesis segments comprising a graft layer attached to said stent, said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon	Martin discloses that each of the upper end of the second lower limb and partial length of the second lower limb both comprise a stent, e.*g.*, 1:38-67; 2:66-3:26, and that the first section comprises a graft layer, which can be bonded and attached to the inside of the expanding mesh support, and thus is interposed between the upper end of the second section and partial length of the second lower limb of the first section

assembly.	to form a substantially fluid-tight seal upon assembly. *E.g.*, 2:66-3:13; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract.
Claim 18. A system as claimed in claim 13, wherein an end portion of said stent of at least one of said prosthesis segments extends beyond said graft layer.	Martin discloses that the mesh support may extend beyond the graft layer of the upper limb and partial length of the second lower limb of the first section. *E.g.*, 3:13-17; 3:40-45; 5:1-2.
Claim 19. A system as claimed in claim 13, at least one of said prosthesis segments comprising barbs or hooks adapted to engage a surrounding body lumen and to resist longitudinal movement or slippage of the segment in service.	Martin discloses that the upper limb of the first section may comprise "barbs 10 or outward-facing hooks 11 to fasten it to the inside of the lumen" to resist longitudinal movement or slippage of the first section. 3:14-19; *see also* 2:11-13; 4:11-13; 5:3-7.
Claim 20. A system as claimed in claim 13, at least one of said prosthesis segments comprising barbs or hooks to resist longitudinal separation of said prosthesis segments in service.	Martin discloses that the second section may fasten to the inside of the first section by barbs or hooks to resist longitudinal separation of the first and section sections. *E.g.*, 3:29-37; 4:24-27; 5:10-6:2.
Claim 21. A system as claimed in claim 14, at least one of said prosthesis segments comprising a marker, capable of being imaged from outside of a body in which said prosthesis segment is located, said marker being adapted to facilitate proper alignment or positioning of said prosthesis segment.	Martin discloses that both the first and section sections may be marked with a platinum wire to enhance fluoroscopic visibility, which facilitates proper alignment or positioning of the sections. *E.g.*, 3:14-22; 3:37-39; 4:5-22; 4:65-67.
Claim 22. A system as claimed in claim 21, said marker being adapted to facilitate alignment of said prosthesis segment with the other one of the prosthesis segments.	Martin discloses that both the platinum wire on the first and section sections enhances fluoroscopic visibility to facilitate alignment of the sections. *E.g.*, 3:37-39; 4:5-22; 4:65-67.
Claim 24. A system as claimed in claim 13, at least one of said prosthesis segments having a taper to resist longitudinal separation of said	FIG. 4 of Martin shows the partial length of the second lower limb of the first section has a taper to resist longitudinal separation of the first and second sections.

prosthesis segments in service.	*See also* 3:32-34.
Claim 25. A system as claimed in claim 13, at least one of said prosthesis segments having a flare to engage the body lumen.	FIGS. 1 and 4 of Martin show that the upper limb of the first section is flared to engage the body lumen. Martin further discloses that the upper limb of the first section fastens to the wall of the aorta by barbs, hooks, or "some other means." 4:11-13.
Claim 26. A system as claimed in claim 13, wherein said graft layer is associated with said female portion, said male engaging portion providing a substantially blood tight seal with said graft layer.	Martin discloses that the first section comprises a graft layer, which can be bonded and attached to the inside of the expanding mesh support. 3:2-13. The upper end of the second section provides a substantially blood tight seal with the graft layer by expanding and forming a friction fit with the lower limb of the first section. *E.g.*, 2:66-3:2; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract.
Claim 27. A system as claimed in claim 13, said male engaging portion being flared when uncompressed.	Martin discloses that the upper end of the second section is flared when uncompressed. FIGS. 1, 4; 3:29-37; 4:24-27.
Claim 28. A system as claimed in claim 13, said male engaging portion being compressible and capable of self re-expansion to engage said female portion.	Martin discloses that the upper end of second section (male engaging portion) is compressible and capable of self re-expansion to engage the partial length of the second lower limb of the first section. *E.g.*, 2:24-41; 3:12-14, 23-34; 4:24-27; 4:56-57.
Claim 29. A system as claimed in claim 13, wherein said proximal prosthesis segment defines two distal lumens, one of which is adapted to extend across a bifurcation in a blood vessel such that in use a proximal end of said proximal prosthesis segment is disposed proximally of the bifurcation, and a distal end of said	Martin discloses that the first section (second endoluminal stent) defines two distal lumens, the first lower limb of which is adapted to extend across a bifurcation such that in use the upper limb of the first section is disposed proximally of the bifurcation and the distal end of the first lower limb is disposed in one of the branched blood vessels, and the partial

proximal prosthesis segment is disposed in one of the branched blood vessels, the other of said distal lumens comprising said female portion and being disposed intermediate said proximal and distal ends of said proximal prosthesis segment, and said male engaging portion is disposed on said distal prosthesis segment and is adapted to mate with said female portion and to extend into the other of said branched blood vessels.	length of the second lower limb (other of said distal lumens) is disposed intermediate the proximal and distal ends of the first section, and the upper end of the second section (male engaging portion disposed on distal prosthesis segment) is adapted to mate with the partial length of the second lower limb and to extend into the other branched blood vessel. *E.g.*, 1:45-51, 2:66-3:10; 3:23-37; 3:60-61; 4:13-32; 4:34-51; FIGS. 1, 4.
Claim 31 recites similar limitations to claim 13, but requires "a graft layer being provided adjacent said outer surface of said male engaging portion and adjacent said inner surface of said female portion, said graft layer of said male engaging portion being configured to be in face-to-face contact with said graft layer of said female portion to form a substantially fluid-tight seal upon assembly."	Martin discloses a graft layer adjacent the outer surface of the second section and inner surface of the partial length of the second lower limb of the first section, the first graft layer being configured to be in face-to-face contact with the second graft layer to form a fluid-tight seal upon assembly. *E.g.*, 2:44-48; 2:66-3:16; 3:23-37; 3:40-45; 4:17-32; FIG. 1 (showing graft layer on outer surface of upper end of second section and inner surface of partial length of the second lower limb of first section); FIG. 4.
Claim 33. A system for joining endoluminal prosthesis segments in a vessel, said system comprising	Martin discloses a system for joining endoluminal prosthesis segments in a vessel. *E.g.*, 1:7-10; 1:38-2:35; Abstract.
[33b] a male engaging portion on a selected one of said endoluminal prosthesis segments and a female portion on another one of said endoluminal prosthesis segments cooperating with said male engaging portion, each of said male engaging portion and said female portion comprising a stent,	Martin discloses that the upper end of the second section (male engaging portion) and second lower limb of the first section (female portion) cooperating with the male engaging portion each comprise a stent, *e.g.*, 1:38-67; 2:66-3:44; FIGS. 1, 4.
[33c] said male engaging portion being flared radially outwardly	Martin discloses that the upper end of the second section may be flared radially

towards an end thereof,	outwardly towards an end. FIGS. 1, 4; 3:29-37; 4:24-27.
[33d] said male engaging portion can be entered at least partially into said female portion, and inter-engagement between the outer surface of said male engaging portion and the inner surface of said female portion resists longitudinal movement to prevent separation of said endoluminal prosthesis segments in service.	Martin discloses that the upper end of the second section enters at least partially into the partial length of the second lower limb of the first section, wherein inter-engagement between the outer surface of the upper section and inner surface of the lower limb are resists longitudinal movement to prevent separation of the first and second endoluminal stents in service. *E.g.*, 2:66-3:2; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract.
Claims 38, 39, 40, 41, and 42.	*See* cites for claims 18, 19, 20, 21, and 22, respectively.
Claims 44, 45, 46, 47, and 49.	*See* cites for claims 24, 25, 26, 27, and 29, respectively.
Claim 48.	*See* cites for claim 28.
Claim 51. recites similar limitations to claim 33, but recites the "female portion being tapered radially inwardly towards an end thereof," and does not recite "said male engaging portion being flared radially outwardly towards an end thereof."	FIG. 4 of Martin shows the partial length of the second lower limb of the first section is tapered radially inwardly towards a distal end. *See also* 3:32-34.
Claim 52 recites similar limitations to claim 13, but requires that the proximal and distal prosthesis segments each comprise a graft layer and together define a continuous lumen upon assembly.	Martin discloses that the first and second sections each comprise a graft layer and together define a continuous lumen upon assembly. *E.g.*, 2:66-3:16; 3:23-37; 3:40-45; 4:17-32; FIGS. 1, 4; Abstract.
Claims 58, 59, 60, 61, and 62.	*See* cites for claims 18, 19, 20, 21, and 22, respectively.
Claims 64, 65, 66, 67, and 69.	*See* cites for claims 24, 25, 26, 27, and 29, respectively.
Claim 68.	*See* cites for claim 28.
Claim 71.	*See* cites for claims 31 and 52.

Claim 72. A stent joining means for joining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents, said stent joining means comprising:	Martin discloses "joining" a first section of a bifurcated graft prosthesis to a second section, each of which comprise stents, to define a continuous lumen. *E.g.*, Abstract; 1:38-67; 2:66-3:26; FIGS. 1, 4.
two transversely spaced female portions on said first endoluminal stent, each of said female portions having an inner surface;	Martin discloses that the first section has a first lower limb and partial length of second lower limb (transversely spaced female portions). *E.g.*, 1:46-49; 3:2-9; FIGS. 1, 4.
a male engaging portion on said second endoluminal stent which has an outer surface and can be compressed radially inwardly, the male engaging portion being configured to be entered into one of the female portions in a radially compressed state and thereafter expanded in the female portion such that the outer surface of the male engaging portion and the inner surface of the female portion are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service; and	Martin discloses that the upper end of the second section has an outer surface and can be compressed radially inwardly, and is configured to be entered into the partial length of the second lower limb of the first section, such that the outer surface of the upper section and inner surface of the lower limb are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service. E.g., 2:66-3:2, 3:23-37; 3; 4:17-32; FIGS. 1, 4; Abstract.
a graft layer attached to at least one of said first and second endoluminal stents, said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly.	Martin discloses that a graft layer may be attached to at least one of the first or second sections, and that the graft layer may be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly. *E.g.*, 2:66-3:13; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract.
Claims 77, 78, 79, 80, and 82.	*See* cites for claims 18, 19, 20, 21, and 22, respectively.

C. Ground 3: Claims 1-3, 5-10, 12, 34-37 and 50 are obvious

over Martin in view of Ryan

The combined teachings of Martin and Ryan are § 103(a) art to the '167 Patent. Ryan discloses the features of claims 1-2 and 6-10 that are also recited in claims 33, 51, 24-27, and 29, respectively, as described above. Martin further discloses that the first section has a first lower limb and partial length of second lower limb (two transversely spaced female portions), as recited in claim 5, and that the partial length of the second lower limb of the first section is adapted for connection to the upper end of the second section such that the first and second sections extend across a bifurcation into two respective branched blood vessels, as recited in claim 12. *E.g.*, Ex. 1003 at 1:45-51, 2:66-3:10; 3:23-37; 3:60-61; 4:13-32; FIGS. 1, 4; Ex. 1019, ¶ 113. Martin further discloses that the upper end of the second section may comprise a frustoconical shape flared radially outwardly. *E.g.*, Ex. 1003, FIG. 1; Ex. 1019, ¶ 113.

Martin thus discloses every claim limitation of claims 1-3, 5-10, 12, 34-37 and 50, with the possible exception of explicitly disclosing (1) a shape memory alloy that is thermally induced to expand or a stent that expands by thermal transformation, as required by claims 1-3, 5-10, and 12;[7] (2) a graft layer attached

[7] During prosecution of the parent '365 Patent, the Examiner rejected issued claims 1, 13, and 14 of the '365 Patent, determining that "Martin shows everything

to the stent by a filament, as recited in claim 34; (3) that the stent defines hoops having a common axis, as required by claim 35; and (4) that the hoops have a plurality of apices alternatingly pointing in opposite axial directions, and a connecting or extending member, as required by claims 36 and 37. Ex. 1019, ¶ 113.

With respect to claims 1-3, 5-10, and 12, it would have been obvious to apply Ryan's explicit teaching of a memory shape alloy (such as Nitinol) (Ex. 1002 at 6:47-59), to the "medical grade, super alloy, stainless steel" mesh support disclosed in Martin (Ex. 1003 at 3:11-16). Ex. 1019, ¶¶ 114-15. With respect to claims 34, 35, 36, 37, and 50, these claims depend off of clam 33, which requires

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as claimed except the stent made from shape memory alloy." Ex. 1018 at 270. The applicants overcame this rejection merely by arguing that their priority claim to the EP '284 and EP '306 applications antedated Martin. *Id.* at 332. However, this priority claim is no longer valid in light of the related interference and Federal Circuit decision, as explained in Part II.C. Office actions in related applications have recognized Martin as prior art to the Goicoechea family under 102(e), 102(f), and 102(g). *See, e.g.*, Ex. 1013 at 18-20; Ex. 1014 at 14-19; Ex. 1015 at 3-6. In addition, Patent Owner should be precluded from re-litigating priority of the Ryan and Martin references, for the reasons set forth in Part II.C.

that the male engaging portion is flared radially outwardly towards an end thereof. Martin discloses that the male engaging portion may be flared radially outwardly, and Ryan discloses that each of the features recited by claims 34, 35, 36, 37, and 50 may be applied to prostheses having other configurations, such as a tapered female portion. The features of these claims, including stents comprising hoops defining a zig-zag pattern and having alternately pointing apices, were well known in the art, as recognized by the '167 Patent. *E.g.* Ex. 1001 at 1:28-65. It would have been obvious to apply the known stent configurations of Ryan to the flared embodiment of Martin. Ex. 1019, ¶¶ 116-118.

A claim chart further specifying how each of these claims is obvious over Martin in view of Ryan is provided below:

USPN 6,117,167	**Martin in view of Ryan**
Claim 1. A stent joining means for joining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents, said stent joining means comprising:	Martin discloses "joining" a first section of a bifurcated graft prosthesis to a second section, each of which comprise stents, to define a continuous lumen. *E.g.*, Ex. 1003, Abstract; 1:38-67; 2:66-3:26; FIGS. 1, 4.
[1b] a male engaging portion on said first endoluminal stent which has an outer surface and can be compressed radially inwardly, wherein said male engaging portion is flared radially outwardly towards a proximal end; and	Martin discloses an "upper end" of a second section of an inverted Y graft, which can be compressed radially inwardly and is flared radially outwardly towards a proximal end. *E.g.*, Ex. 1003 at 3:29-37; 3:12-14, 23-26 (first and second sections comprise compressible expanding mesh support); 4:24-27; FIGS. 1, 4.

[1c] a female portion on said second endoluminal stent cooperating with said male engaging portion, said female portion having an inner surface;	Martin discloses a partial length of the second lower limb of the first section that cooperates with the male engaging portion. *E.g.*, Ex. 1003 at 3:29-44.
[1d] wherein said first endoluminal stent and said second endoluminal stent consist of a shape memory alloy and the male engaging portion can be entered into the female portion in a radially compressed state and thereafter expanded in the female portion and wherein said outer surface of the male engaging portion and said inner surface of the female portion are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service.	Martin discloses that the stents may consist of "a medical grade, super alloy, stainless steel," 3:11-16, and that the upper end of the second section enters into the partial length of the second lower limb of the first section, wherein the outer surface of the upper section and inner surface of the lower limb are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service. *E.g.*, Ex. 1003 at 2:66-3:2; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 2 contains the same limitations as Claim 1, but requires that "the female portion is tapered radially inwardly towards a distal end" and does not require the male engaging portion be flared radially outwardly towards a proximal end.	FIG. 4 of Martin shows the partial length of the second lower limb of the first section is tapered radially inwardly towards a distal end. *See also* Ex. 1003 at 3:32-34. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 3 contains the same limitations as Claim 1, but requires that "the male engaging portion comprises a frustoconical wall flaring outwardly towards a longitudinal extremity."	FIGS. 1 and 4 of Martin show that the upper end of the second section may comprise a frustoconical wall flaring outwardly towards a longitudinal extremity. *See also* Ex. 1003 at 3:29-37 (upper end may have "other means of attachment"). Ryan discloses that the second tubular graft

	(first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 5 contains the same limitations as Claim 2, but recites "two transversely spaced female portions on said second endoluminal stent."	Martin discloses that the first section has a first lower limb and partial length of second lower limb (transversely spaced female portions). *E.g.*, Ex. 1003 at 1:46-49; 3:2-9; FIGS. 1, 4. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 6. A stent joining means as claimed in claim 5, at least one of said stents having a taper to resist longitudinal separation of said stents in service.	FIG. 4 of Martin shows the partial length of the second lower limb of the first section has a taper to resist longitudinal separation of the first and second sections. *See also* 3:32-34. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1003 at 6:47-59.
Claim 7. A stent joining means as claimed in claim 5, at least one of said stents having a flare to engage the body lumen.	FIGS. 1 and 4 of Martin show that the upper limb of the first section is flared to engage the body lumen. Martin further discloses that the upper limb of the first section fastens to the wall of the aorta by barbs, hooks, or "some other means." Ex. 1003 at 4:11-13. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 8. A stent joining means as claimed in claim 5, further comprising a graft layer associated with said female portion, said male engaging portion providing a substantially blood tight seal with said graft layer.	Martin discloses that the first section comprises a graft layer, which can be bonded and attached to the inside of the expanding mesh support. 3:2-13. The upper end of the second section provides a substantially blood tight seal with the graft layer by expanding and forming a friction fit with the lower limb of the first section. *E.g.*, Ex. 1003 at 2:66-3:2; 3:23-37; 4:17-32; FIGS. 1, 4; Abstract. Ryan discloses that the second tubular graft

	(first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 9. A stent joining means as claimed in claim 5, said male engaging portion being flared when uncompressed.	Martin discloses that the upper end of the second section is flared when uncompressed. Ex. 1003, FIGS. 1, 4; 3:29-37; 3:12-14, 23-26; 4:24-27. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 10. A stent joining means as claimed in claim 5, wherein said second endoluminal stent is adapted to extend across a bifurcation in a blood vessel such that in use a proximal end of said second endoluminal stent is disposed proximally of the bifurcation, one of said female portions of said second endoluminal stent is disposed in a branched blood vessel, and said first endoluminal stent is adapted to extend from the other one of said female portions into another branched blood vessel.	Martin discloses that the first section (second endoluminal stent) is adapted to extend across a bifurcation such that the upper limb is disposed proximally of the bifurcation and the first lower limb (one female portion) is disposed in a branched blood vessel, and the second section (first endoluminal stent) is adapted to extend from the partial length of the second lower limb of the first section (other female portion) into another branched blood vessel. *E.g.*, Ex. 1003 at 1:45-51, 2:66-3:10; 3:23-37; 3:60-61; 4:13-32; 4:34-51; FIGS. 1, 4. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.
Claim 12. A stent joining means as claimed in claim 5 wherein one of said two transversely spaced distal female portions is adapted for connection to said male engaging portion of said first endoluminal stent and said one spaced distal female portion and said first and second endoluminal stents, in combination, extend across a bifurcation in a blood vessel	Martin discloses that the partial length of the second lower limb of the first section is adapted for connection to the upper end of the second section such that the first and second sections extend across a bifurcation into two respective branched blood vessels. *E.g.*, Ex. 1003 at 1:45-51, 2:66-3:10; 3:23-37; 3:60-61; 4:13-32; FIGS. 1, 4. Ryan discloses that the second tubular graft (first endoluminal stent) and a bifurcated base structure (second endoluminal stent) consist of memory shape alloy. Ex. 1002 at 6:47-59.

into two respective branched blood vessels.	
Claim 34. A system as claimed in claim 33, at least one of said prosthesis segments comprising a graft layer attached to said stent by a filament.	Martin discloses the features of claim 33, as described above for Grounds 2. Ryan discloses that the liner (graft layer) will be attached to the tubular frame by various means, and discloses that the liner may be woven at 27 filaments. *E.g.*, Ex. 1002 at 2:36-47; 3:26-34; 5:50-53; 6:3-16.)
Claim 35. A system as claimed in claim 33, said stent of at least one of said male engaging portion and said female portion defining hoops having a common axis and positioned along that axis.	Martin discloses the features of claim 33, as described above for Grounds 2. Ryan discloses that radially compressible band members of the tubular frame have hoops with a common axis and are positioned along that axis. *E.g.*, Ex. 1002 at 3:16-21; 3:62-66; 7:49-59 (zig-zag or Z-shaped element which forms a continuous circular ring); FIGS. 1-2, 4.
Claim 36. A system as claimed in claim 35, said hoops having a plurality of apices alternatingly pointing in opposite axial directions, oppositely pointed apices of adjoining hoops abutting one another, said abutting apices being joined by a connecting member.	Martin discloses the features of claim 33, as described above for Grounds 2. Ryan discloses that the band members comprise alternately pointing apices that abut one another, and may be joined at two diametrically opposed points, including by bridge elements. *E.g.*, Ex. 1002 at 3:16-24; 3:62-66; 7:49-59; FIGS. 1, 1B, 2.
Claim 37. A system as claimed in claim 35, the configuration of each of said hoops including: a plurality of apices disposed about the circumference of said hoop and alternatingly pointing in opposite axial directions; and a member which extends, as a single continuous member, from an apex pointed in a first axial direction to the apex of an adjacent hoop pointed in the opposite axial direction.	Martin discloses the features of claim 33, as described above for Grounds 2. Ryan discloses that the band members comprise a plurality of alternately pointing apices disposed around the circumference of the band member, and a bridge element that extends as a continuous member, from an apex pointed in one direction to an apex pointed in an opposite direction. *E.g.*, Ex. 1002 at 3:16-24; 3:62-66; 7:49-59; FIGS. 1, 2, 3B.

Claim 50. A system as claimed in claim 33, said stent of at least one of said male engaging portion and said female portion comprising a plurality of hoops, each defining a zig zag pattern about the circumference thereof.	Martin discloses the features of claim 33, as described above for Grounds 2. Ryan discloses that the tubular frame/stent comprises from 1 to 30 radially compressible band members, each of which comprises "a zig-zag or Z-shaped element" which forms a continuous circular ring. Ex. 1002 at 7:49-59; *see also, e.g., id.*, FIGS. 1-4.

D. Ground 4: Claims 23, 32, 43, 63, and 81 are obvious over Martin in view of Wolff

U.S. 4,830,003 ("Wolff"), titled "Compressive Stent and Delivery System," was filed June 17, 1988 and issued on May 16, 1989. Wolff is thus 102(b) prior art to the '167 Patent. The combined teachings of Martin and Wolff are thus § 103(a) art to the '167 Patent. Wolff discloses an intravascular stent having bends that form a "V" at each weld, and that the stent may be made of radiopaque material to facilitate precise location of the stent. Ex. 1004 at 1:31-34; 3:31-39; 4:18-23; 5:55-57; 6:2-4; 7:41-44. The radiographic image of a V-shaped radiopaque stent section as disclosed by Wolff would differ depending on the rotational orientation of the prostheses such that rotational orientation in the body lumen could be determined. *E.g.*, Ex. 1019, ¶ 95. Such radiopaque markers applied to stents or stent grafts were well known in the art before September 1994. *Id.* at ¶ 95.

Dependent claims 23, 43, 63, 81 of the '167 Patent each recite that one of the claimed prosthesis segments or stents comprises a marker capable of being imaged from outside the body, wherein the image of the marker differs depending

on the rotational orientation of the prosthesis segment so that rotational orientation can be determined. Independent claim 32 further recites a "V" shaped portion of one of the prosthesis segments having a different radiopacity from the prosthesis segment, so that rotational orientation can be determined.

As discussed above, Martin discloses all of the base features of the claims 23, 32, 43, 63, and 81, and further discloses that both the first and section bifurcated graft sections may be marked with a platinum wire to enhance fluoroscopic visibility to facilitate proper alignment or positioning of the sections. *E.g.*, Ex. 1004 at 3:14-22; 3:37-39; 4:5-22; 4:65-67. It would have been obvious to apply a V-shaped radiopaque section from Wolff's stent to the platinum wire of Martin to more specifically determine the rotational orientation of the first and second prosthesis segments to further facilitate alignment and positioning. Ex. 1019, ¶ 119. The fluoroscopic image of Wolff's radiopaque, V-shaped section would differ depending on the rotational orientation of the stent, thus allowing rotational orientation to be determined during delivery. *Id* at ¶ 119. Accordingly, claims 23, 32, 43, 63, and 81 of the '167 Patent are obvious over Martin in view of Wolff.

E. Ground 5: Claim 3 is obvious over Martin in view of Ryan and Pinchuk

Pinchuk, titled "Method of Making a Radially Expandable Prosthesis," was

filed on March 2, 1992 and issued on July 13, 1993. Ex. 1005. Pinchuk is thus 102(b) prior art to the '167 Patent. The combined teachings of Martin, Ryan and Pinchuk are thus § 103(a) art to the '167 Patent.

Pinchuk discloses "a radially expandable axially extending endoprosthesis or stent." *Id.* at 4:51-54. The stent includes a plurality of generally circumferential sections 32 that "are formed from the same continuous, helically wrapped length, such as the undulating length 33 shown in FIG. 2." *E.g.*, *id.*at 4:55-58. Pinchuk discloses the stent can be made from Nitinol (as disclosed by Ryan), or stainless steel (as disclosed by Martin), for example. *E.g.*, *id.* at 7:10-16. Pinchuk teaches that stents of these types need not be uniformly shaped or shaped in the form of a right cylinder, but can be "tapered, truncated cone-shaped stents." *E.g. id.* at 6:51-57. This would include a frustoconical shape. Ex. 1019, ¶ 91. Thus, Pinchuk teaches tapered, truncated cone-shaped stent designs in association with stainless steel or self-expanding, memory alloy stents for endovascular deployment. *E.g.*, *id.* at 6:51-57; 7:16; FIGS.1-12.

To the extent that Ryan and Martin do not disclose that "the male engaging portion comprises a frustoconical wall flaring outwardly towards a longitudinal extremity," as recited in claim 3 of the '167 Patent, it would have been obvious to apply the cone-shaped or frustoconical stent design of Pinchuk to the stents of Ryan and Martin to realize this design. Ex. 1019, ¶ 120.

For example, Martin discloses that the upper end (13) the second section (2) may comprise a frustoconical shape flared radially outwardly. *E.g.*, Ex. 1003, FIG. 1; Ex. 1019, ¶ 113. Martin also discloses that the upper end may have "other means of attachment" than hooks or barbs. *Id.* at 3:29-37. It would have been obvious to a person of ordinary skill in the art to use Pinchuk's frustoconical design as other means of attaching the second section to the first section of Martin, while employing stent comprising a memory shape alloy, as disclosed by Ryan. Ex. 1019, ¶ 120. Claim 3 of the '167 Patent is thus obvious over Martin in view of Ryan and Pinchuk.

F. Ground 6: Patent Owner Is Not Entitled to Claims that are Patentably Indistinct from the Claims Involved in the '192 Interference

When a party loses an interference, that party is not entitled to claims that are patentably indistinct from the claims involved in the interference. *See, e.g.*, *Deckler*, 977 F.2d 1449; *Tytgat*, 225 USPQ 907; MPEP 2308.03. Here, as discussed above in Part II.C., the Board has already determined that Ryan is the senior party to Goicoechea in the '192 Interference, the Count of which corresponds directly to Claim 2 of Martin:

> An apparatus for reinforcing a bifurcated lumen comprising:
> a first section, configured to be positioned within the lumen, comprising:
> an upper limb, configured to fit within the lumen upstream of the

bifurcation;

a first lower limb, configured to extend into a first leg of said bifurcation when said first section is positioned in the lumen, and

a second lower limb, shorter than said first lower limb, and configured so that when said first section is positioned in the lumen, said second lower limb does not extend into a second leg of said bifurcation,

and further comprising a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation.

See Ex. 1008 at 1; Ex. 1009 at 69.

The claims that Goicoechea lost in the interference included claims 55, 59, 63, and 88 of the '402 Application, set forth as amended in prosecution below:

55. A method of treating an angeological disease at a bifurcation site where a blood vessel branches into a first branched vessel and a second branched vessel using a bifurcation prosthesis having a bifurcation, a proximal portion, a first distal portion, and an extension portion extending distally relative to said bifurcation, and using a second prosthesis, said method comprising the steps of:

(a) disposing said proximal portion of said bifurcated prosthesis in said blood vessel such that said first distal portion of said bifurcated prosthesis extends into said first branched vessel;

(b) directing blood flow from said blood vessel into said first branched vessel through said first distal portion of said

bifurcated prosthesis;

(c) attaching said second prosthesis to said extension portion of said bifurcated prosthesis such that said second prosthesis extends into said second branched vessel; and

(d) directing blood flow from said blood vessel into said second branched vessel through said second prosthesis.

59. A bifurcated prosthesis for use with an angeological bifurcation of a blood vessel into two branched vessels comprising a bifurcated proximal portion adapted to be disposed within said blood vessel, a distal portion adapted to extend across the bifurcation into one of the branched vessels, and a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel.

63. A method as claimed in claim 55 further comprising the step of:

(d) covering at least a portion of said proximal portion, said first distal portion, and said second prosthesis with a graft layer.

88. The bifurcated prosthesis of claim 59 wherein said proximal portion, distal portion, and distal segment each comprise a stent and graft combination.

Ex. 1016 at 1-3. Thus, Patent Owner is not entitled to claims that are patently indistinct from these claims. These claims recite many of the same limitations as the claims of the '167 Patent, including a male engaging portion on one stent that can be positioned within and joined to a female portion on another stent to prevent

relative movement of two stents, as illustrated below with respect to claim 72:[8]

USPN 6,117,167	**'192 Interference claims**
Claim 72. A stent joining means for joining a first endoluminal stent to a second endoluminal stent to define a continuous lumen through the first and second endoluminal stents, said stent joining means comprising:	Martin claim 2 ("further comprising a second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation") '402 claim 55 ("attaching said second prosthesis to said extension portion of said bifurcated prosthesis such that said second prosthesis extends into said second branched vessel") '402 claim 59 ("a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel")
two transversely spaced female portions on said first endoluminal stent, each of said female portions having an inner surface;	Martin claim 2 ("a first section . . . comprising. . . a first lower limb, configured to extend into a first leg of said bifurcation when said first section is positioned in the lumen, and a second lower limb") '402 claim 55 ("a bifurcation prosthesis having a bifurcation, a proximal portion, a first distal portion, and an extension portion extending distally relative to said bifurcation") '402 claim 59 ("a bifurcated proximal portion adapted to be disposed within said blood vessel")
a male engaging portion on said second endoluminal stent which has an outer surface and can be compressed radially inwardly, the male engaging	Martin claim 2 ("second section configured to be positioned separately within the lumen and joined to said second lower limb of the first section, effectively extending said second lower limb into said second leg of said bifurcation")

[8] The '167 Patent issued before the '192 Interference was decided, and thus the Examiner did not consider the interference during prosecution.

portion being configured to be entered into one of the female portions in a radially compressed state and thereafter expanded in the female portion such that the outer surface of the male engaging portion and the inner surface of the female portion are inter-engaged to resist longitudinal movement to prevent separation of the first and second endoluminal stents in service; and	'402 claim 55 (steps (c)-(d)) '402 claim 59 ("a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel")
a graft layer attached to at least one of said first and second endoluminal stents, said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly.	'402 claim 55(steps (c)-(d)); claim 63 ("covering at least a portion of said proximal portion, said first distal portion, and said second prosthesis with a graft layer") '402 claim 59 ("a separate distal segment joined to said proximal portion and adapted to allow blood to flow from the proximal portion into the other branched vessel"); claim 88 ("each comprise a stent and graft combination")

As is evident from the arguments presented in Grounds 1 through 5 above, the additional limitations recited in the '167 Patent claims are not independently patentable. Accordingly, the claims of the '167 Patent are unpatentable for these reasons as well.

G. The Primary Grounds Asserted in this Petition Are Not Redundant with the Grounds Presented in a Separately Filed Petition Seeking *Inter Partes* Review of the '167 Patent

The grounds asserted in this petition are the primary grounds of invalidity that Petitioner is asserting, as they most directly anticipate or render obvious

claims 1-82 of the '167 Patent. Petitioner is filing a separate petition for *inter partes* review of claims 1-82 of the '167 based on different prior art and different statutory grounds. Specifically, most of the prior art references presented in the separate petition qualify as prior art under 35 U.S.C. § 102(b), as opposed to § 102(e). Although Petitioner believes that Patent Owner cannot antedate the Ryan and Martin references asserted in this petition both procedurally and factually, should Patent Owner succeed in such an argument, Petitioner relies on the separate grounds presented in the other petition. In addition, the prior art references asserted in the separate petition present different arguments of unpatentability than the Ryan and Martin references asserted in this petition. Accordingly, although the primary grounds are presented here, the grounds for unpatentability asserted in the two petitions are not redundant.

V. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests the grant of this Petition and cancellation of all claims 1-82 of the '167 Patent.

Dated: August 18, 2014

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that on August 18, 2014, I caused a true and correct copy of the Petition for *Inter Partes* Review in connection with U.S. Patent No. 6,117,167 and supporting evidence to be served via Fed Ex Priority Overnight delivery on the following:

Ratner & Prestia
One Westlake Berwyn, Suite 301
Valley Forge, PA 19482-0980

I further certify that on August 18, 2014, I caused a true and correct copy of the same Petition for *Inter Partes* Review and supporting evidence to be served via Fed Ex Priority Overnight delivery to the following additional address:

Ratner & Prestia
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FAEGRE BAKER DANIELS LLP

Dated: August 18, 2014

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