IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Inter Partes Review of: Trial Number: To Be Assigned

U.S. Patent No. 5,593,417

Filed: November 27, 1995

Issued: January 14, 1997 Attorney Docket No.: 058888-0000022

Inventor: Rhodes, Valentine J.

Assignee: Rhodes, Valentine J.

Title: INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS Panel: To Be Assigned

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SECOND PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO 5,593,417

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***Inter Partes* Review of U.S. Patent No. 5,593,417**

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Inter partes review is respectfully requested for claims 1, 2, 9, 10, and 13 of U.S. Patent No. 5,593,417 ("the '417 patent") (Exh. 1001). Filed concurrently with this Petition is a motion for joinder with the instituted inter partes review, *Medtronic, Inc., et al. v. Endotach LLC,* Case No. IPR2014-00100, setting forth fully the reasons supporting the institution of this Petition and the reasons for joinder.

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

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '417 patent is presently the subject of litigation brought by the exclusive licensee (hereinafter, "Patent Owner") against Petitioner in the U.S. District Court for the Northern District of California, San Jose Division, in a case titled *Endotach LLC v. Medtronic, Inc., et al.*, No. 5:13-cv-03292-BLF, and the subject of the instituted inter partes review, *Medtronic, Inc.*, *et al. v. Endotach LLC*, Case No. IPR2014-00100 ("IPR2014-00100"). *See* Exh. 1009 (IPR 2014-00100 Decision).

The '417 patent is also the subject of other litigation brought by Patent Owner against other parties—namely, *Endotach LLC v. Cook Medical Inc.*, No. 1:13-cv-1135 (S.D. Ind.) (hereinafter, "Cook Case"), and *Endotach LLC v. W.L.*

Gore & Associates, Inc., No. 3:12-cv-00308 (N.D. Fla.) (hereinafter, "W.L. Gore District Court Case"). *See* Exh. 1009, pg. 2.

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service of any documents via hand-delivery may be made at the postal mailing address of the respective lead or back-up counsel designated above with courtesy email copies to the email addresses and docket_ip@pillsburylaw.com.

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

The undersigned authorizes the Office to charge Deposit Account No. 033975 for the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for inter partes review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF THE '417 PATENT

A. Description of the Alleged Invention of the '417 Patent

The alleged invention of the '417 patent relates generally to intraluminal medical devices (e.g., grafts or stents) having anchoring means for securing the devices in vessels, ducts, or lumens of living beings. Exh. 1001, 1:5-10. The '417 patent states that numerous grafts and stents were known in the prior art. *Id.* at 2:15-63. These stents and grafts were inserted into blood vessels and expanded in revascularization procedures to preclude restenosis. *Id.* at 1:64 to 2:17. The '417 patent also explains that another useful area of stent application was percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenosis. *Id.* at 2:17-21.

The alleged invention of the '417 patent addresses in particular a perceived shortcoming in prior art grafts. Specifically, the '417 patent allegedly addresses the manner in which grafts were anchored within the body duct, vessel or lumen. The

'417 patent specification points to the patentee's own prior U.S. Patent No. 5,122,154 ("the '154 patent"), which was of the same construction of the '417 patent, except for the particular anchoring means for securing the graft in place. In particular, the '417 patent specification states that:

> The graft of my aforementioned patent makes use of some anchoring means, e.g., small dome shaped projections, for aiding in the securement of the graft in place within the vessel, duct, or lumen. While such anchoring means are believed effective for their intended purpose, they never the less appear to be amenable to improvement insofar as graft retention is concerned.

Id. at 3:21-27.

Aside from the specific anchoring means employed by the '417 patent, the patentee acknowledged that the alleged invention was otherwise the same as the prior art U.S. Patent No. 5,122,154[1]:

> The graft device [] is constructed in accordance with the teachings of my aforementioned patent, except for the means

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[1] U.S. Patent No. 5,122,154 was granted on June 16, 1992, more than one year prior to the earliest priority date of the '417 patent and is thus prior art under 35 USC § 102(b) against the '417 patent.

> for fixedly holding it in place within the vessel, duct, or lumen. In this regard the subject invention makes use of anchoring means, to be described later, which offer an improvement in retention over the "protuberances" disclosed in my aforementioned patent.

Id. at 5:10-17.

In alleged contrast to the above-mentioned dome shaped projections, the '417 patent states that the unique or patentable feature of the alleged invention is the specific angle or orientation of the projections. In particular, the '417 patent explains that the essence of the alleged invention is to provide projections that are oriented at an acute angle to the direction of blood flow. It was believed that this orientation would help prevent migration of the graft:

> It should be pointed out that anchoring projections constructed in accordance with this invention can take numerous other shapes and sizes than those shown herein. In this regard, the projections need not include sharp edges and/or planar surfaces or points, and can be rounded, domed, or any other suitable shape, so long as they are preferentially oriented to project or extend at some acute [] angle to the direction of fluid flow, whereupon the force applied to them by the fluid flowing through the vessel, duct, or lumen, in which the device to be secured by them flows produces on each of them a force component extending in the direction of the fluid flow and a force component extending perpendicularly to that direction. As

> discussed above this action causes the projections to tightly engage (and not necessarily penetrate) the interior of the wall of the vessel, duct, or lumen to fixedly secure the device in place against migration.

Id. at 9:1-17.

B. Summary of the Prosecution History of the '417 Patent

Referring to the prosecution history of the '417 patent (Exh. 1002), the '417 patent was filed as U.S. App. Serial No. 08/562,727 on Nov. 27, 1995. *See* Exh. 1002, Application as Filed (paper 1). The '417 patent does not claim priority to any earlier filed applications.

Application claims 1 and 9-15 were originally rejected under 35 U.S.C. § 102(b) as being anticipated by the patentee's own '154 patent. *See id.* at First Office Action (paper 2), pg. 2. In response to the First Office Action, patentee filed an amendment on May 17, 1996 that, among other things, added limitations concerning the projections of the claimed anchoring means. *Id.* at Amendment (paper 3). For example, claim 1 was amended to additionally recite that each of the projections has a trailing portion located in the downstream direction thereof, where the trailing portion includes at least one surface preferentially oriented to extend at an acute angle to a first direction in which the body fluid flows. *Id.* at paper 3, pg. 2.

In addition, the patentee admitted that the patentee's own '154 patent "discloses a similar device with anchoring means to secure it to the wall of the vessel, duct, or lumen in which [the device] is located." *Id.* at paper 3, pg. 4. The patentee further explained that while the '154 patent taught projections or protuberances that project outward from the outer surface of a graft to secure the graft in place within an artery, the '154 patent did not disclose the essence of the alleged invention – i.e., projections that have a trailing portion with at least one surface preferentially oriented to extend at an acute angle to the direction of the fluid flow. Specifically, the patentee states that:

> [T]he anchoring means of applicant's earlier patent are protuberances which are disclosed . . . as projecting slightly out of the outer surface of the graft to act as small pressure points that help impact the graft into the artery wall to hold it in place. There isn't any disclosure . . . that the projections include a trailing portion having at least one surface (e.g., a trailing surface) which is preferentially oriented to extend at an acute angle to the direction of the fluid flow.

Id. at paper 3, pgs. 4-5.

The Examiner subsequently issued a Notice of Allowability on July 29, 1996 that included a few Examiner amendments to the claim language. *Id.* at Notice of Allowability (paper 6).

IV. REQUIREMENTS FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. §§ 42.104

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for inter partes review of the '417 patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner hereby certifies that the '417 patent is available for inter partes review and that Petitioner is not barred or estopped from requesting inter partes review challenging the claims of the '417 patent on the grounds identified herein. Although Petitioner was served more than one year ago with a complaint asserting infringement of the '417 patent, the normal statutory one-year bar under 35 U.S.C. § 315(b) does not apply here because (1) the Board has already instituted an inter partes review trial on the '417 patent on a timely first petition filed by Petitioner (Case No. IPR2014-00100), and (2) Petitioner accompanies this second petition with a motion for joinder under 35 U.S.C. § 315(c).

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

The precise relief requested by Petitioner is that claims 1, 2, 9, 10, and 13 ("the challenged claims") of the '417 patent be found unpatentable.

C. Claims for Which *Inter Partes* Review Is Requested Under 37 C.F.R § 42.104(b)(1)

Inter partes review of the challenged claims of the '417 patent is requested.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

Inter partes review of the challenged claims is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103: (1) the challenged claims are anticipated by U.S. Patent No. 5,104,399 to Lazarus ("Lazarus"); (2) the challenged claims are obvious over U.S. Patent No. 5,122,154 to Rhodes ("Rhodes '154") in view of Lazarus; (3) the challenged claims are anticipated by U.S. Patent No. 5,562,725 to Schmitt ("Schmitt"); (4) the challenged claims are obvious over Rhodes '154 in view of Schmitt; and (5) the challenged claims are obvious over Rhodes '154 in view of U.S. Patent No. 5,370,657 to Irie ("Irie").

Each reference and grounds listed above establishes a reasonable likelihood that Petitioner will prevail on at least one claim and thus this petition for inter partes review should be granted.

E. How the Challenged Claims Are to Be Construed Under 37 C.F.R. § 42.104(b)(3)

In the related instituted inter partes review, IPR2014-00100, the Board indicated that the terms "projection," "leading portion," "trailing portion," and "stent," carried "their ordinary and customary meaning and do not need further construction at this stage of the proceeding." Exh. 1009 (IPR2014-00100 Decision), pg. 6. As suggested, Petitioner offers no further claim construction of

those terms in this Second Petition. Likewise, the term "tightly engage" (which was not construed in IPR2014-00100) should also be given its plain and ordinary meaning for purposes of the Board's review.

F. How the Construed Claim(s) Are Unpatentable Under 37 C.F.R. § 42.104(b)(4)

An explanation of how construed claims 1, 2, 9, 10, and 13 of the '417 patent are unpatentable under the statutory grounds identified above, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section V and in Claim Charts (or Appendices) A1-A5.

G. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below in Section V and in Claim Charts (or Appendices) A1-A5.

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b) (4)

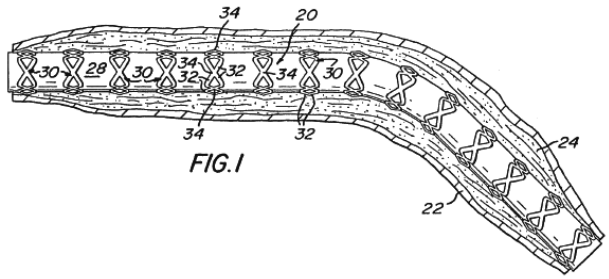
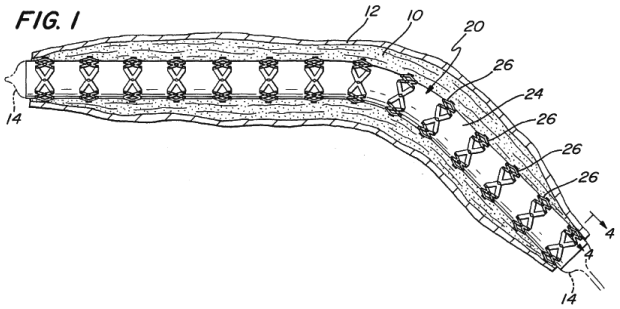
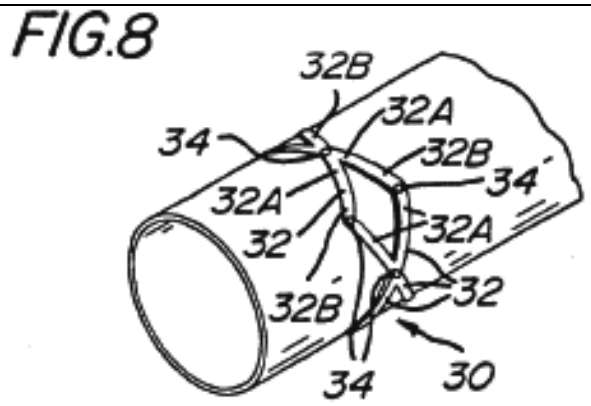
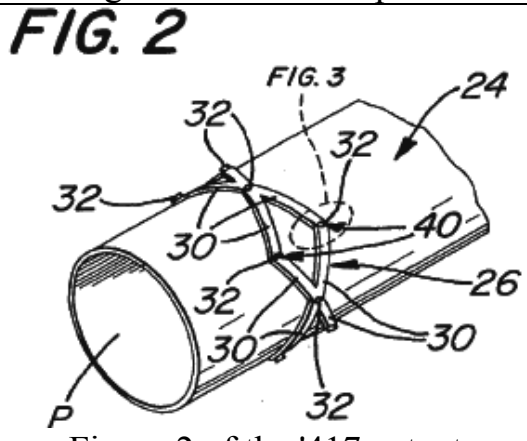
Claims 1, 2, 9, 10, and 13 of the '417 patent ("the challenged claims") are unpatentable because of one or more of the following grounds: (i) the challenged claims are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,104,399 to Lazarus ("Lazarus"); (ii) the challenged claims are obvious under 35 U.S.C.

§ 103(a) over U.S. Patent No. 5,122,154 to Rhodes ("Rhodes '154") in view of Lazarus; (iii) the challenged claims are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,562,725 to Schmitt ("Schmitt"); (iv) the challenged claims are obvious under 35 U.S.C. § 103(a) over Rhodes '154 in view of Schmitt; and (v) the challenged claims are obvious under 35 U.S.C. § 103(a) over Rhodes '154 in view of Irie.

With respect to the obviousness challenge under 35 U.S.C. § 103(a), as clarified by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), Petitioner notes that purported inventions arising from ordinary innovation, ordinary skill, or common sense should not be patentable. *Id.* at 400, 403-04, 418-22, 427-428. That is, "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416.

Of special relevance to the obviousness challenges is Rhodes '154 (or the '154 patent). In particular, as detailed in Section III above, the patentee made numerous statements in the '417 patent specification and during prosecution admitting that the alleged inventive intraluminal medical device of the '417 patent was otherwise the same as the intraluminal medical device of the '154 patent except for the specific means of the device for fixedly holding the device in place within a vessel, duct, or lumen. Exh. 1001, 5:10-17; *see also id.* at 3:21-27, 9:1-17,

and Exh. 1002, paper 3, pg. 4. In other words, the alleged novelty (which is itself questionable) of the '417 patent over the prior art '154 patent is the specific orientation of the device's projections – that the projections be oriented to extend at an acute angle to the direction of fluid flow. *Id.*; *see also* Comparison Chart below.

Comparison of the '154 Patent and	**the '417 Patent**
 Figure 1 of the '154 patent	 Figure 1 of the '417 patent
 Figure 8 of the '154 patent	 Figure 2 of the '417 patent

Nevertheless, as described herein, projections of intraluminal medical devices (e.g., graft or stent devices) that are preferentially oriented to extend at an acute angle to the direction of fluid flow were well known in the prior art for the purpose of securing the devices in place within a vessel, duct, or lumen of a living being.

As shown below, the alleged invention of the '417 patent is clearly anticipated by several prior art references that were not considered by the U.S. Patent and Trademark Office when deciding to grant the '417 patent. Moreover, as also shown below, the '417 patent is obvious over the patentee's own prior '154 patent mentioned above, particularly when viewed in light of several prior art references not considered by the U.S. Patent and Trademark Office when deciding to grant the '417 patent.

A. Claims 1, 2, 9, 10, and 13 are Anticipated Under 35 U.S.C. § 102(b) by Lazarus (Exh. 1005)

Lazarus, which discloses an intraluminal medical device for securement within a vessel, duct, or lumen of a living being, was filed on March 9, 1988, and issued on April 14, 1992, and thus qualifies as prior art under § 102(b). Exh. 1005, 1:19-22. While Lazarus was not cited during prosecution of the '417 patent, related U.S. Patent No. 5,397,345 to Lazarus ("Lazarus II") was considered but not applied by the Examiner during prosecution. The claim chart attached as Appendix A1 details how each element recited in claims 1, 2, 9, 10, and 13 is anticipated by Lazarus.

For example, annotated Figures 2, 3, 6, and 7 of Lazarus below illustrate an intraluminal balloon-expanded medical device, a tubular member and anchoring means of the intraluminal balloon-expanded medical device, and cross-sectional views of the intraluminal balloon-expanded medical device being placed within a

vessel, duct, or lumen of a living being, respectively.

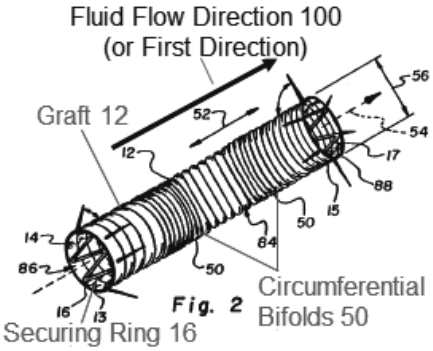


Fig. 2

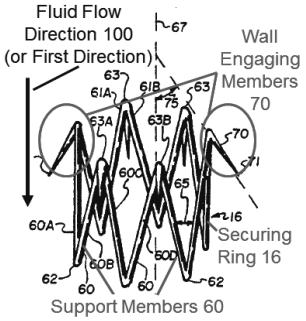


Fig. 3

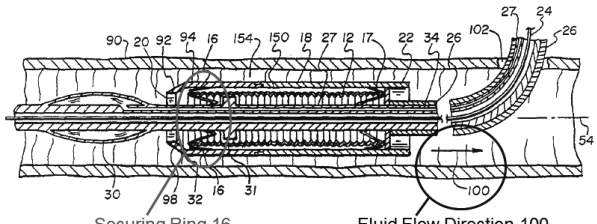


Fig. 6

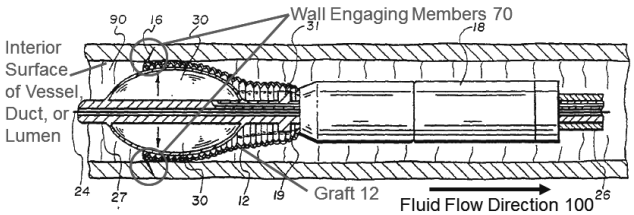


Fig. 7

In particular, among other features shown by annotated Figures 2, 3, 6, 7 above, Lazarus discloses an intraluminal balloon-expanded medical device ("graft 12") comprising a tubular member ("securing ring 16" (which is also referred to as staple 16)) and anchoring means ("wall engaging members 70"). *See also id.* at 5:4-39. The anchoring means ("wall engaging members 70") are located adjacent the outer periphery of the tubular member ("securing ring 16"), and comprise plural projections (e.g., the wall engaging members 70 are projections having pointed ends 71) arranged for engagement with the interior surface of a vessel, duct, or lumen of a living being. *See* annotated Fig. 3 of Lazarus above; *see also* Exh. 1005, 5:61-63.

As further shown by annotated Figures 3 and 6 of Lazarus below, each of the

projections ("wall engaging members 70") has a leading portion in the form of the upstream portion of each wall engaging member 70 that is located in the upstream direction of the fluid flow and a trailing portion in the form of the downstream portion of each wall engaging member 70 that is located in the downstream direction thereof. *See also* Exh. 1005, 5:47-51.

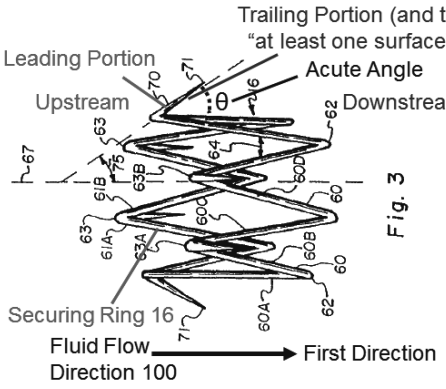


Fig. 3

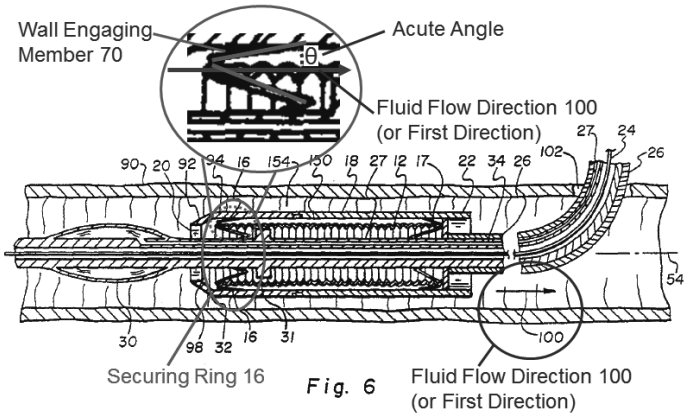


Fig. 6

In addition, the trailing portion of each projection ("wall engaging member 70") comprises at least one surface that is preferentially oriented to extend at an acute angle to a first direction ("fluid flow direction 100"). *See* annotated Figs. 3 and 6 of Lazarus above; *see also* Exh. 1005, 5:47-51 ("Preferably the wall engaging members 70 angulate away from the axis 67 in a downstream direction 100 . . . [at an angle that is] preferably less than 90° and desirably in the range from 30° to about 60°.").

Lazarus further discloses other (distal) projections ("wall engaging members 72) that are similar to the projections 70 where the trailing portion of each distal projection 72 are preferentially oriented to extend at an acute angle to the fluid

flow direction. Specifically, Figure 4 of Lazarus illustrates members or projections 72 extending at 90°, while the specification states that the angle of each "wall engaging members 72 . . . may vary between about 45 degrees and 115 degrees." Exh. 1005, 6:61-65. Thus, clearly projections 72 are also disclosed as extending at an acute angle (less than 90°).

Furthermore, force applied to the balloon-expanded tubular member ("securing ring 16") of Lazarus by fluid flowing through the interior passageway thereof produces on each of the projections ("wall engaging members 70") a force component that causes at least one surface of the trailing portion to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. Exh. 1005, 10:1-14 ("After emplacement, it can be seen that the pressure of the lumen fluid, for example, blood forces the graft 12 against the lumen interior surface 154, helping to hold the graft 12 in its place. . . . That is, the internal pressure of the fluid within the lumen 90 holds the graft 12 in place and assists the [securing rings] 16 and 17 in preventing leakage at both ends of the graft 12.").

To the extent that Patent Owner argues for the interpretation of the terms "engagement with," "engage," and "tightly" in accordance with its Infringement Contentions and the claim construction ruling in *Endotach LLC v. Cook Medical Inc.,* 1:12-cv-1630-LJM-DKL, Southern District of Indiana (Dkt. No. 102)("the

Cook case"), annotated Figure 7 of Lazarus above shows that the at least one surface of each projection ("wall engaging member 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. Lazarus also discloses "that wall engaging members 70 are used to penetrate and hook into the interior surface of the lumen to hold the graft 12 in place." Exh. 1005, 5:61-63. Lazarus additionally discloses that the proximal securing ring 16 that comprises the wall engaging members 70 and the distal securing ring 17 that comprises the wall engaging members 72 "prevent[] leakage at both ends of the graft 12." *Id.* at 10:11-14. Lazarus further discloses that the distal projections or members 72 "are sufficiently short so as not to perforate the vessel wall." *Id.* at 6:61-65.

With respect to dependent claims 2, 9, 10, and 13 of the '417 patent, annotated Figures 3 and 6 of Lazarus above show that the at least one surface of the trailing portion is inclined upward in the first direction ("fluid flow direction 100") when the device ("graft 12") is placed in a vessel, duct, or lumen (claim 2). Annotated Figures 3 and 6 of Lazarus above further show that the tubular member ("securing ring 16") of Lazarus is a stent having support members 60 (claim 9), *see also* Exh. 1005, 5:4-23, and that the stent ("securing ring 16") is expandable from a contracted state (Fig. 6) to an expanded state (Fig. 7), where the anchoring means

("wall engaging members 70") engage the interior surface of the vessel, duct, or lumen when the stent ("securing ring 16") is in the expanded state to secure the device ("graft 12") in place (claim 10). *See also id.* at 9:38.42. In addition, Lazarus discloses that the device ("graft 12") is an endovascular graft that further comprises a graft sleeve ("circumferential bifolds 50"), where the graft sleeve ("circumferential bifolds 50") is coupled to the stent ("securing ring 16"), and has an outer surface and inner passageway through which the body fluid (e.g., blood) flows in the first direction ("fluid flow direction 100") to apply the force (e.g., from the fluid flowing through the tubular member) to the projections ("wall engaging members 70") (claim 13). *See id.* at 4:50-58; *see also* annotated Fig. 2 of Lazarus above.

B. Claims 1, 2, 9, 10, and 13 are Obvious Under 35 U.S.C. § 103(a) Over Rhodes '154 (Exh. 1006) In View of Lazarus

Rhodes '154, which describes an intraluminal medical device for securement within a vessel, duct, or lumen of a living being, was filed on August 15, 1990, and issued on June 16, 1992, and thus qualifies as prior art under § 103(a). Exh. 1006, Abstract, 7:18-30. The claim chart attached as Appendix A2 details how each element recited in claims 1, 2, 9, 10, and 13 is obvious over Rhodes '154 in view of Lazarus.

Regardless of whether Patent Owner argues for the interpretation of the terms "engagement with," "engage," and "tightly" in accordance with its

Infringement Contentions and the claim construction ruling in the Cook Case, Rhodes '154 admittedly teaches that the at least one surface of each projection ("protuberances 50") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See also* Exh. 1006, 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein").

Rhodes '154 teaches an intraluminal balloon-expanded medical device ("graft 20") comprising projections ("protuberances 50") that project "slightly outward from the outer surface of the graft," Exh. 1006, 7:18-24. As noted above, the '417 patent admits that the only alleged novelty over Rhodes '154 (or the '154 patent) is the specific orientation of the intraluminal medical device's projections – that the projections be oriented to extend at an acute angle to the direction of fluid flow. *See also* Exh. 1001, 5:10-17, 9:1-17; *see also id.* at 3:21-27, and Exh. 1002, paper 3, pg. 4. This distinction is thin at best, since both the '417 patent and Rhodes '154 disclose that the projections can be dome shaped (compare '417 patent col. 3, lines 21-27 to '417 patent col. 9, lines 1-17). The admitted dome shaped projections of Rhodes '154 have trailing surfaces that must extend acutely,

obliquely or orthogonally. Given only these three choices, the fact that Rhodes '154 is silent on directionality hardly makes anything patentable in the '417 patent merely because the acute directionality is expressly stated. Thus, it is submitted that Rhodes '154 alone anticipates and/or renders obvious all of the claims of the '417 patent. Nevertheless, Petitioner further relies on Lazarus to extinguish any doubt on the issue.

Lazarus teaches this expressly. Specifically, Lazarus discloses an intraluminal balloon-expanded medical device comprising projections ("wall engaging members 70") where the trailing portion ("downstream portions") of each projection ("wall engaging member 70") has at least one surface that is preferentially oriented to extend at an acute angle to the fluid flow direction 100. Exh. 1005, 5:47-51, Figs. 3 and 6. As discussed, and shown by annotated Figure 7 of Lazarus above, Lazarus also teaches that the at least one surface of each projection ("wall engaging member 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See also* Exh. 1005, 5:61-63, 10:12-14, 6:61-65. Both Rhodes '154 and Lazarus utilize their respective projections on intraluminal medical devices for securing the devices in place within a vessel, duct, or lumen of a living being. *See* Exh. 1006; 7:18-24, and Exh.

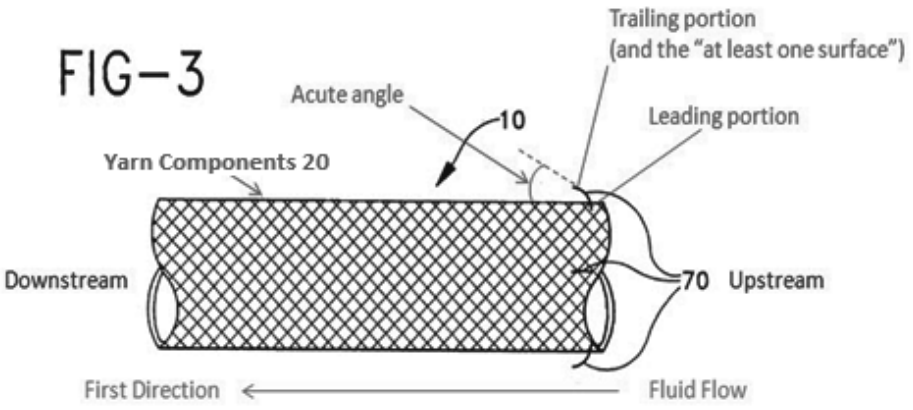
1005, 5:61-63, 10:1-14.

A person of ordinary skill in the art would have known to combine the teachings of the projections of Rhodes '154 ("protuberances 50") with the teachings of the projections of Lazarus ("wall engaging members 70") that have at least one surface preferentially oriented to extend at an acute angle to the fluid flow direction ("first direction") to provide an intraluminal medical device with improved anchoring capabilities for securing the device in place within a vessel, duct, or lumen of a living being. In particular, a person of ordinary skill in the art would have known that Rhodes '154 would provide its protuberances or projections with an acutely oriented trailing surface to secure the stent against migration. This was well known in the art and expressly disclosed by Lazarus. Alternatively, one of ordinary skill in the art would know to utilize the Lazarus-shaped projections 70 in lieu of the Rhodes '154 projections (e.g., smaller protuberances 50) and orient the Lazarus-shaped projections 70 at an acute angle downstream to prevent migration of the intraluminal medical device. *See* Exh. 1004, pg. 9, ¶ 24. Thus, and as further detailed in Appendix A2, a person of ordinary skill in the art would understand Rhodes '154 in view of Lazarus to teach an intraluminal medical device as claimed by the challenged claims. In addition, it should be noted that the motivation to combine the teachings of Rhodes '154 with the teachings of Lazarus as applied to independent claim 1 similarly applies to the

dependent claims.

C. Claims 1, 2, 9, 10, and 13 are Anticipated Under 35 U.S.C. § 102(e) by Schmitt (Exh. 1011)

Schmitt was filed on September 14, 1992, and issued on October 8, 1996, and thus qualifies as prior art under § 102(e). Schmitt was not cited during prosecution of the '417 patent even though Schmitt describes an intraluminal medical device for securement within a vessel, duct, or lumen of a living being. Exh. 1011, Abstract. The claim chart attached as Appendix A3 details how each element recited in claims 1, 2, 9, 10, and 13 is anticipated by Schmitt. For example, annotated Figure 3 of Schmitt below illustrates an intraluminal medical device comprising a tubular member and anchoring means.



In particular, among other features shown by annotated Figure 3 above, Schmitt discloses an intraluminal medical device ("graft 10") comprising a tubular member ("tubular braid or graft 10") and anchoring means ("hooks 70"). *See also see also id.* at 2:58-64, 4:34-43. The anchoring means ("hooks 70") are located

adjacent the outer periphery of the tubular member ("tubular braid or graft 10"), and comprise plural projections (e.g., hooks 70) arranged for engagement with the interior surface of a vessel, duct, or lumen of a living being. *Id.*

As further shown by annotated Figure 3 of Schmitt above, each of the projections ("hooks 70") has a leading portion in the form of the upstream portion of each hook 70 that is located in the upstream direction of the fluid flow and a trailing portion in the form of the downstream portion of each hook 70 that is located in the downstream direction thereof. The trailing portion of each projection ("hook 70") comprises at least one surface that is preferentially oriented to extend at an acute angle to a first direction ("fluid flow direction"). *See* annotated Fig. 3 of Schmitt above.

Furthermore, force applied to the tubular member ("tubular braid or graft 10") of Schmitt by fluid flowing through the interior passageway thereof inherently produces on each of the projections ("hook 70") a force component that causes at least one surface of the trailing portion to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 10") in place. Exh. 1011, 9:23-33 ("[T]he intraluminal device may include a means for anchoring the device within the lumen in which it is inserted. An example of this embodiment is illustrated in FIG. 3. The tubular braid 10 has hooks 70 integrally formed in at least one end of the braid. Upon radial expansion, the hooks slightly

impinge the inner surface of the lumen or blood vessel to anchor the intraluminal device in position. In a blood vessel, the hooks 70 might only be necessary at one end of the device since the flow of blood will further serve to keep the graft in the expanded state, thereby providing sufficient contact with the lumen wall to stabilize against unwanted movement.").

To the extent that Patent Owner argues for the interpretation of the terms "engagement with," "engage," and "tightly" in accordance with its Infringement Contentions and the claim construction ruling in the Cook Case, Schmitt discloses that the at least one surface of each projection ("hook 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 10") in place. *Id.* ("[T]he intraluminal device may include a means for anchoring the device within the lumen in which it is inserted. An example of this embodiment is illustrated in FIG. 3. . . . Upon radial expansion, the hooks slightly impinge the inner surface of the lumen or blood vessel to anchor the intraluminal device in position.").

With respect to dependent claims 2, 9, 10, and 13 of the '417 patent, annotated Figure 3 of Schmitt above show that the at least one surface of the trailing portion is inclined upward in the first direction ("fluid flow direction") when the device ("graft 10") is placed in a vessel, duct, or lumen (claim 2).

Schmitt also discloses that the tubular member ("tubular braid or graft 10") is a stent. *Id.* at 6:59-63 ("The intraluminal device of the present invention is most likely to be used to support a weakened body passageway or maintain an opening in an occluded body passageway."), 8:5-7 ("The intraluminal braided device of the present invention is radially self-expanding and has the stent feature inherently incorporated into the device.").

Schmit additionally discloses that the stent ("tubular braid or graft 10") is expandable from a contracted state to an expanded state, where the anchoring means ("hooks 70") engage the interior surface of the vessel, duct, or lumen when the stent is in the expanded state to secure the device in place (claim 9). *Id.* at 3:38-42 ("The expanding radial force is preferably designed so that the intraluminal device will open up to be in intimate contact with the interior surface of the body passageway in which it is inserted and anchor itself thereto.").

Schmitt further discloses that the device ("graft 10") is an endovascular graft where the endovascular graft additionally comprises a graft sleeve ("yarn components 20"), and the graft sleeve ("yarn components 20") is coupled to the stent ("tubular braid or graft 10") and has an outer surface and inner passageway through which the body fluid (e.g., blood) flows in the first direction ("fluid flow direction") to apply the force to the projections ("hooks 70"). *See* annotated Fig. 3 of Schmitt above; *see also* Exh. 1011, 9:29-33 ("In a blood vessel, the hooks 70

might only be necessary at one end of the device since the flow of blood will further serve to keep the graft in the expanded state, thereby providing sufficient contact with the lumen wall to stabilize against unwanted movement.").

D. Claims 1, 2, 9, 10, and 13 are Obvious Under 35 U.S.C. § 103(a) Over Rhodes '154 In View of Schmitt

The claim chart attached as Appendix A4 details how each element recited in claims 1, 2, 9, 10, and 13 is obvious over Rhodes '154 in view of Schmitt.

As noted above, the '417 patent admits that the only alleged novelty over Rhodes '154 (or the '154 patent) is the specific orientation of the intraluminal medical device's projections – that the projections be oriented to extend at an acute angle to the direction of fluid flow. *See also* Exh. 1001, 5:10-17, 9:1-17; *see also id.* at 3:21-27, and Exh. 1002, paper 3, pg. 4.

As such, regardless of whether Patent Owner argues for the interpretation of the terms "engagement with," "engage," and "tightly" in accordance with its Infringement Contentions and the claim construction ruling in the Cook Case, Rhodes '154 admittedly teaches that the at least one surface of each projection ("protuberances 50") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See also* Exh. 1006, 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and]

. . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein").

Rhodes '154 teaches an intraluminal balloon-expanded medical device ("graft 20") comprising projections ("protuberances 50") that project "slightly outward from the outer surface of the graft," Exh. 1006, 7:18-24, and Schmitt teaches an intraluminal medical device comprising projections ("hooks 70") where the trailing portion ("downstream portions") of each projection ("hook 70") has at least one surface that is preferentially oriented to extend at an acute angle to the fluid flow direction 100. *See* annotated Fig. 3 of Schmitt above. As discussed, Schmitt also teaches that the at least one surface of each projection ("hook 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 10") in place. 9:23-33 ("[T]he intraluminal device may include a means for anchoring the device within the lumen in which it is inserted. An example of this embodiment is illustrated in FIG. 3. . . . Upon radial expansion, the hooks slightly impinge the inner surface of the lumen or blood vessel to anchor the intraluminal device in position."). Both Rhodes '154 and Schmitt utilize their respective projections on intraluminal medical devices for securing the devices in place within a vessel, duct, or lumen of a living being. *See* Exh. 1006; 7:18-24, and Exh.

1011, 4:34-43, 9:23-33.

A person of ordinary skill in the art would have known to combine the teachings of the projections of Rhodes '154 (“protuberances 50”) with the teachings of the projections of Schmitt (“hooks 70”) that have at least one surface preferentially oriented to extend at an acute angle to the fluid flow direction (“first direction”) to provide an intraluminal medical device with improved anchoring capabilities for securing the device in place within a vessel, duct, or lumen of a living being. In particular, a person of ordinary skill in the art would have known that the protuberances in Rhodes ‘154 should be provided with an acute trailing surface as taught by Schmitt. Alternatively, one of ordinary skill in the art would also know to utilize the Schmitt-shaped projections 70 in lieu of the Rhodes '154 projections (e.g., protuberances 50) and orient the Schmitt-shaped projections 70 at an acute angle downstream to prevent migration of the intraluminal medical device. Thus, and as further detailed in Appendix A4, a person of ordinary skill in the art would understand Rhodes '154 in view of Schmitt to teach an intraluminal medical device as claimed by the challenged claims. In addition, it should be noted that the motivation to combine the teachings of Rhodes '154 with the teachings of Schmitt as applied to independent claim 1 similarly applies to the dependent claims.

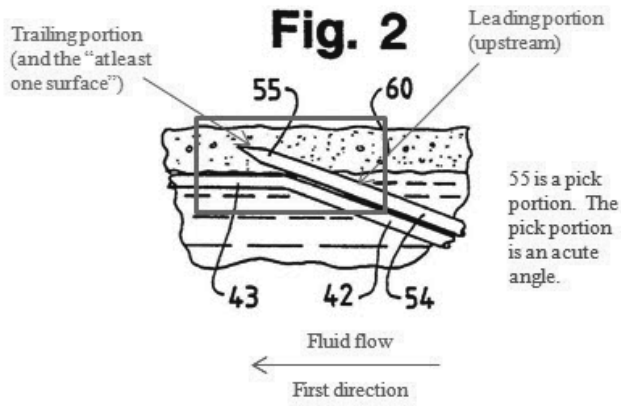
E. Claims 1, 2, 9, 10, and 13 are Obvious Under 35 U.S.C. § 103(a) Over Rhodes '154 In View of Irie (Exh. 1012)

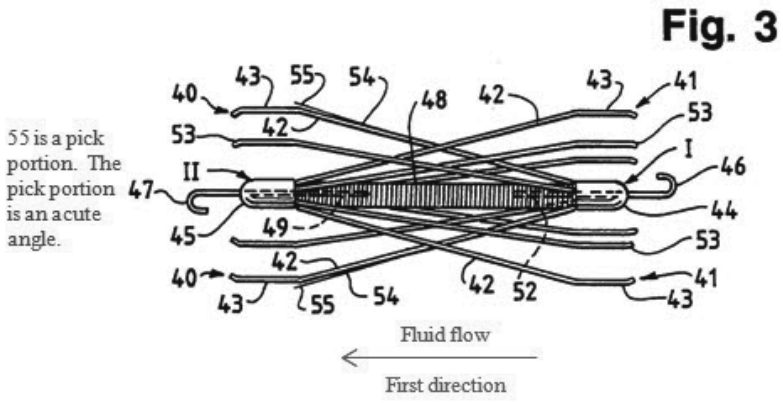
Rhodes '154 was filed on August 15, 1990 and issued on June 16, 1992, and Irie was filed March 26, 1993 and issued on December 6, 1994. Thus, Rhodes '154 and Irie qualify as prior art under § 103(a). The claim chart attached as Appendix A5 details how each element recited in claims 1, 2, 9, 10, and 13 is obvious over Rhodes '154 in view of Irie.

As noted above, the '417 patent admits that the only alleged novelty over Rhodes '154 (or the '154 patent) is the specific orientation of the intraluminal medical device's projections – that the projections be oriented to extend at an acute angle to the direction of fluid flow. *See also* Exh. 1001, 5:10-17, 9:1-17; *see also id.* at 3:21-27, and Exh. 1002, paper 3, pg. 4. As such, regardless of whether Patent Owner argues for the interpretation of the terms "engagement with," "engage," and "tightly" " in accordance with its Infringement Contentions and the claim construction ruling in the Cook Case, Rhodes '154 admittedly teaches that the at least one surface of each projection ("protuberances 50") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See also* Exh. 1006, 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help

impact the graft into the arterial wall to maintain a fixed position therein").

Rhodes '154 teaches an intraluminal balloon-expanded medical device ("graft 20") comprising projections ("protuberances 50") that project "slightly outward from the outer surface of the graft," Exh. 1006, 7:18-24, and Irie teaches an intraluminal medical device comprising projections ("pick portions 55") where the trailing portion ("downstream portions") of each projection ("pick portion 55") has at least one surface that is preferentially oriented to extend at an acute angle to the fluid flow direction 100. *See* annotated Figs. 2 and 3 of Irie below.





In addition, Irie also teaches that that the at least one surface of each projection ("pick portions 50") is tightly engaged with the interior surface of the

vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See* Exh. 1012, Abstract ("The preferred embodiment includes picks that impale the vein wall to a limited depth."); *see also id.* at 4:37-51, 4:59-66, 5:66-6:4, 6:8-14, 9:56-66. Both Rhodes '154 and Irie utilize their respective projections on intraluminal medical devices for securing the devices in place within a vessel, duct, or lumen of a living being. *See* Exh. 1006; 7:18-24, and Exh. 1012, 4:59-66, 6:8-14.

A person of ordinary skill in the art would have known to combine the teachings of the projections of Rhodes '154 ("protuberances 50") with the teachings of the projections of Irie ("pick portions 55") that have at least one surface preferentially oriented to extend at an acute angle to the fluid flow direction ("first direction") to provide an intraluminal medical device with improved anchoring capabilities for securing the device in place within a vessel, duct, or lumen of a living being. In particular, a person of ordinary skill in the art would have known to provide the protuberances in Rhodes '154 with an actuely oriented trailing surface as taught by Irie. Alternatively, one of ordinary skill in the art would know to utilize the Irie-shaped projections 55 in lieu of the Rhodes '154 projections (e.g., smaller protuberances 50) and orient the Irie-shaped projections 55 at an acute angle downstream to prevent migration of the intraluminal medical

device. Thus, and as further detailed in Appendix A5, a person of ordinary skill in the art would understand Rhodes '154 in view of Irie to teach an intraluminal medical device as claimed by the challenged claims. In addition, it should be noted that the motivation to combine the teachings of Rhodes '154 with the teachings of Irie as applied to independent claim 1 similarly applies to the dependent claims.

VI. CONCLUSION

Based on the foregoing, it is clear that claims 1, 2, 9, 10, and 13 of the '417 patent define subject matter that is anticipated and/or obvious. At least some of the art cited above was never considered by the original Examiner, and, if they had been, claims 1, 2, 9, 10, and 13 of the '417 patent would not have issued. The art cited above establishes a reasonable likelihood that Petitioner will prevail on at least one claim. Thus, Petitioner requests institution of an inter partes review to cancel those claims.

Respectfully submitted,

Date: April 25, 2014 PILLSBURY WINTHROP SHAW PITTMAN LLP

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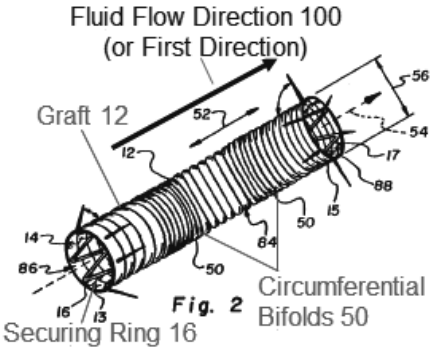
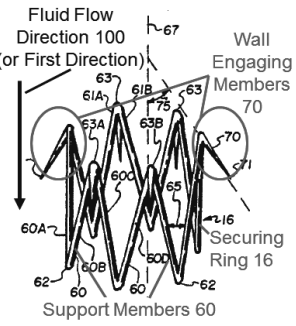
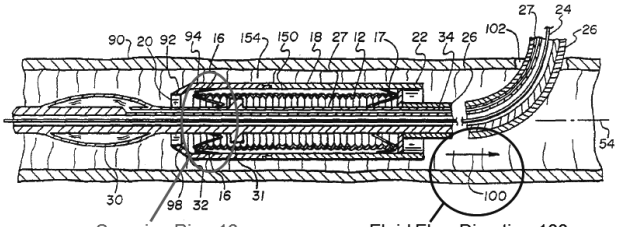
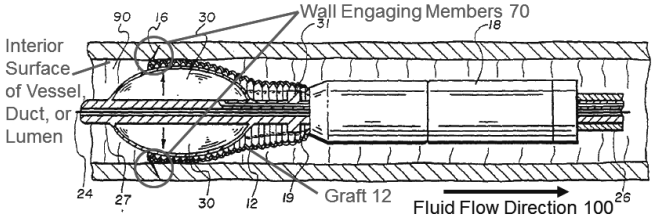
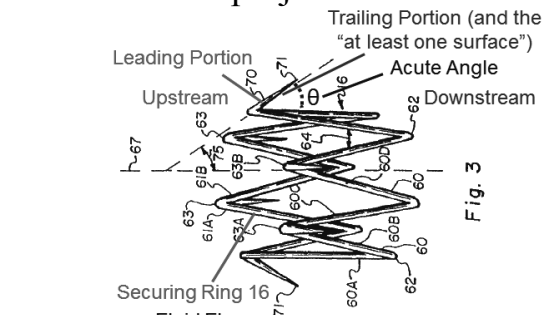
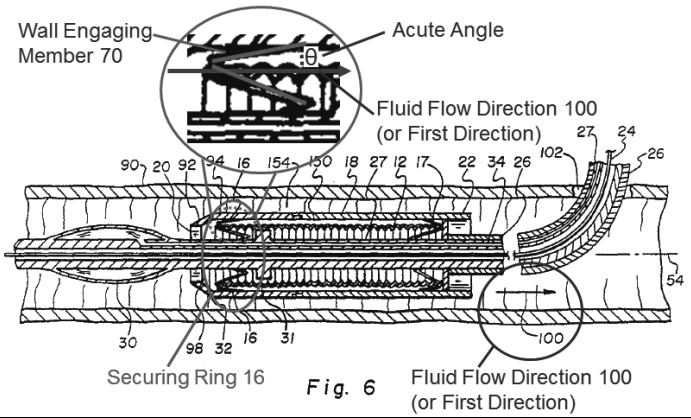
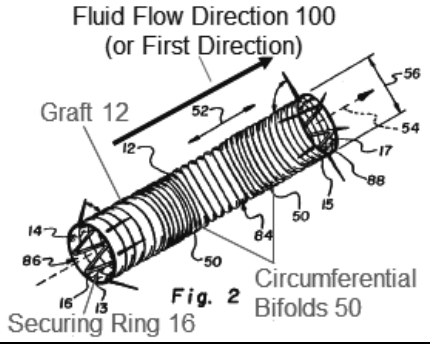
Attachments: Appendices A1-A5 (Claim Charts) & Exhibits 1001-1014

The '417 Patent	Appendix A1: US 5,104,399 to Lazarus (Exh. 1005)
1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface,	To the extent that the preamble is a limitation, Lazarus discloses an intraluminal medical device ("graft 12") for securement within a vessel, duct, or lumen of a living being, where the vessel, duct, or lumen has an interior surface. Abstract, 1:19-22; *see also* annotated Figs. 6 and 7 below.
said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,	Lazarus discloses that the device ("graft 12") comprises a tubular member in the form of a securing ring 16 (which is also referred to as a staple 16), and anchoring means in the form of wall engaging members 70. *See* annotated Figs. 2, 3, 6, and 7 below; *see also* 5:4-39 ("[T]wo staples or 'securing rings' 16 and 17 are positioned about the circumference of the substantially cylindrically shaped graft 12. . . . The proximal [securing ring] 16 has a plurality of V-shaped support members 60 . . . each [of which] are connected one to another in a generally circular arrangement around the longitudinal axis 67 . . . . A wall engaging member 70 is attached to each support member 60."). The tubular member ("securing ring 16") has a passageway extending therethrough and an outer periphery. S*ee* annotated Figs. 2, 3, 6, and 7 below. The tubular member ("securing ring 16") is arranged to have a body fluid (e.g., blood) flow through the passageway in a first direction (*see* annotated Figs. 2, 3, 6, and 7 below) when the device ("graft 12") is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member ("securing ring 16") as a result of fluid pressure (e.g., blood) passing through the passageway. 10:1-14. Annotated figures 2, 3, 6, and 7 illustrate a perspective view of the intraluminal medical device ("graft 12"), a perspective view of a tubular member ("securing ring 16"), and cross-sectional views of the intraluminal medical device ("graft 12") being emplaced into a vessel, duct, or lumen of a living being.

The '417 Patent	Appendix A1: US 5,104,399 to Lazarus (Exh. 1005)
	 Fig. 2  Fig. 3  Fig. 6  Fig. 7
said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen,	As shown by annotated Fig. 2 above, the anchoring means ("wall engaging members 70" and "wall engaging members 72") are located adjacent the outer periphery of the tubular member ("securing ring 16") and comprising plural projections ("plural wall engaging members 70" and "plural wall engaging members 72") that are arranged for engagement with the interior surface of the vessel, duct, or lumen. *See also* annotated Fig. 7 above (illustrating engagement of the wall engaging members 70 with the interior surface of a vessel, duct, or lumen), 5:61-63 ("It should be noted that wall engaging members 70 are used to penetrate and hook into the interior surface of the lumen to hold the graft 12 in place."), 10:12-14 ("the [securing rings] 16 and 17 . . . prevent[] leakage at both ends of the graft 12."), 6:61-65 ("The angle 76 between the wall engaging members 72 and the longitudinal axis 77 may vary between about 45 degrees and about

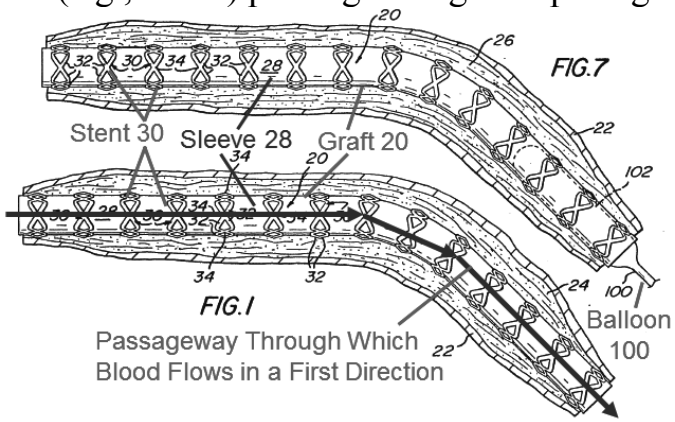
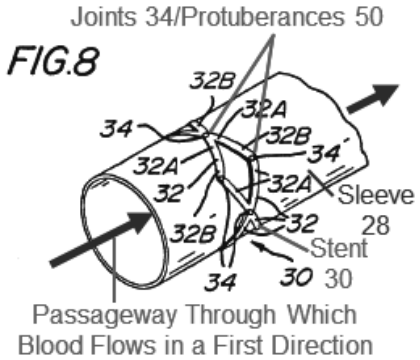
The '417 Patent	Appendix A1: US 5,104,399 to Lazarus (Exh. 1005)
	115 degrees. Preferably, the wall engaging members 72 of the distal staples are sufficiently short so as not to perforate the vessel wall.”).
each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof,	As shown by annotated Figs. 3 and 6 below, each of the projections (“wall engaging members 70”) has: (i) a leading portion in the form of the upstream portion of each wall engaging member 70 (e.g., a surface that faces the upstream direction) that is located in the upstream direction of the fluid flow 100; and (ii) a trailing portion in the form of the downstream portion of each wall engaging member 70 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow 100. *See also* Exh. 1005, Fig. 4 (illustrating projections or members 72 that are similar to projections or members 70).  Fig. 3  Fig. 6
said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,	As shown by annotated Figs. 3 and 6 above, the trailing portion includes at least one surface (a surface of the downstream portion of each wall engaging member 70) that is preferentially oriented to extend at an acute angle to the first direction (“fluid flow direction 100”). The acute angle (*see* acute angle illustrated by

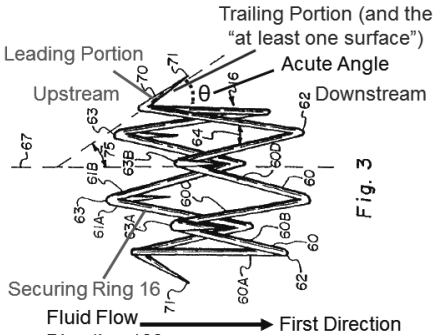
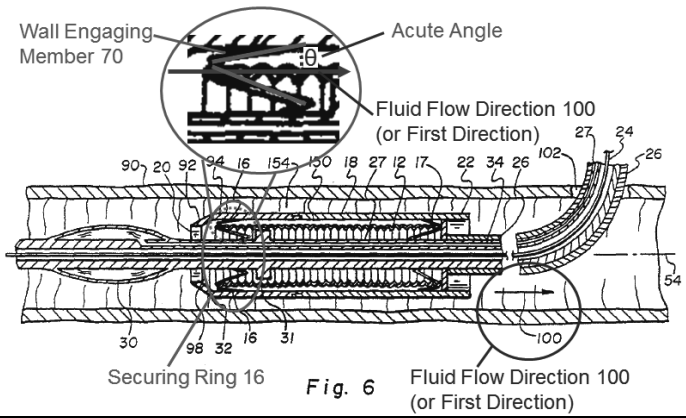
The '417 Patent	Appendix A1: US 5,104,399 to Lazarus (Exh. 1005)
	reference numeral 75 in annotated Fig. 3 above) is described by Lazarus as being "preferably less than 90° and desirably in the range from 30° to about 60°." 5:47-51; *see also* 6:61-65 ("The angle 76 between the wall engaging members 72 and the longitudinal axis 77 may vary between about 45 degrees and about 115 degrees. Preferably, the wall engaging members 72 of the distal staples are sufficiently short so as not to perforate the vessel wall.").
whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.	Lazarus discloses that the force (e.g., blood pressure) applied to the tubular member ("securing ring 16") by the fluid flowing through the passageway of the tubular member ("securing ring 16") produces on each of the projections ("wall engaging members 70") a force component to cause the at least one surface (a surface of the downstream portion of each wall engaging member 70) to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. 10:1-14 ("After emplacement, it can be seen that the pressure of the lumen fluid, for example, blood forces the graft 12 against the lumen interior surface 154, helping to hold the graft 12 in its place. . . . That is, the internal pressure of the fluid within the lumen 90 holds the graft 12 in place and assists the [securing rings] 16 and 17 in preventing leakage at both ends of the graft 12."). Moreover, as shown by annotated Fig. 7 above, Lazarus discloses that the at least one surface of each projection ("wall engaging member 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See also* 5:61-63 ("It should also be noted that wall engaging members 70 are used to penetrate and hook into the interior surface of the lumen to hold the graft 12 in place"), 10:12-14 ("the [securing rings] 16 and 17 . . .

The '417 Patent	Appendix A1: US 5,104,399 to Lazarus (Exh. 1005)
	prevent[] leakage at both ends of the graft 12."), 6:61-65 ("The angle 76 between the wall engaging members 72 and the longitudinal axis 77 may vary between about 45 degrees and about 115 degrees. Preferably, the wall engaging members 72 of the distal staples are sufficiently short so as not to perforate the vessel wall.").
2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.	As shown by annotated Figs. 3 and 6 above, at least one surface of the trailing portion of each projection ("wall engaging member 70") is inclined upward in the first direction ("fluid flow direction 100") when the device ("graft 12") is placed in a vessel, duct, or lumen.
9. The device of claim 1 wherein said tubular member is a stent.	As shown by annotated Figs. 2 and 3 below, the tubular member ("securing ring 16") is a stent having support members 60. *See also* 5:4-23 ("[T]wo staples or 'securing rings' 16 and 17 are positioned about the circumference of the substantially cylindrically shaped graft 12. . . . The [securing rings] 16 and 17 are sized to urge the graft 12 outwardly against the inside surface of the lumen into which the graft 12 is placed."). 
10. The device of claim 9 wherein said stent is expandable from a contracted state to an expanded state, said anchoring means engaging the interior surface of the vessel, duct, or lumen when said stent is in said expanded	As shown by annotated Figs. 6 and 7 above, the stent ("securing ring 16") is expandable from a contracted state (Fig. 6) to an expanded state (Fig. 7), where the anchoring means ("wall engaging members 70") engage the interior surface of the vessel, duct, or lumen when the stent ("securing ring 16") is in the expanded state to secure the device ("graft 12") in place. *See also* 9:38-42 ("[T]he inflatable membrane ('balloon') 30 is then inflated . . . to urge the wall engaging members 70 into the wall surface of the lumen 90 to firmly lodge

The '417 Patent	Appendix A1: US 5,104,399 to Lazarus (Exh. 1005)
state to secure said device in place.	the proximal [securing ring] 16 and graft 12 in place.").
13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.	Lazarus discloses that the device ("graft 12") is an endovascular graft where the endovascular graft additionally comprises a graft sleeve ("circumferential bifolds 50"). 4:50-58 ("The artificial graft 12 . . . is preferably made of a deformable material having a high tissue ingrowth rate. . . . The graft 12 is preferably formed to have a plurality of substantially evenly spaced circumferential bifolds 50."). As shown by annotated Fig. 2 above, the graft sleeve ("circumferential bifolds 50") is coupled to the stent ("securing ring 16") and has an outer surface and inner passageway through which the body fluid (e.g., blood) flows in the first direction ("fluid flow direction 100") to apply the force (via blood pressure) to the projections ("wall engaging members 70").

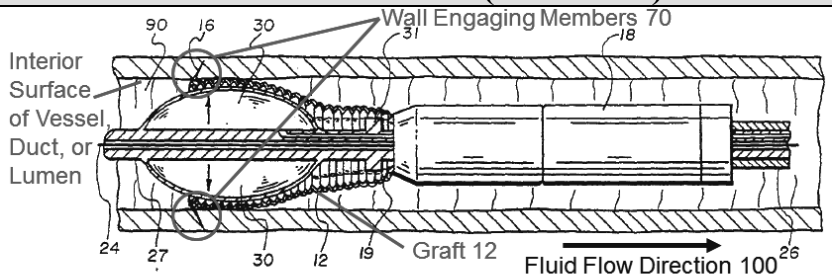
The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface,	To the extent that the preamble is a limitation, Rhodes teaches an intraluminal medical device ("graft 20") for securement within a vessel, duct, or lumen of a living being, where the vessel, duct, or lumen has an interior surface. Abstract, 7:18-30.
said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said	Rhodes teaches that the device ("graft 20") comprises a tubular member in the form of a stent 30 (which is also referred to as stent members 30), and anchoring means in the form of protuberances 50 that project slightly outward from the outer surface of the graft 20. 5:61-66, 7:18-24. The tubular member ("stent 30") has a passageway extending therethrough and an outer periphery. S*ee* annotated Figs. 1, 7, and 8 below (illustrating that the graft sleeve 28 fits and extends through the passageway of the stent 30). The tubular member ("stent 30") is arranged to have a body fluid (e.g., blood) flow through the passageway in a first

The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,	direction (*see* annotated Figs. 1, 7, and 8 below) when the device ("graft 12") is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member ("stent 30") as a result of fluid pressure (e.g., blood) passing through the passageway.  
said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen,	As shown by annotated Fig. 8 above, the anchoring means ("protuberances 50") are located adjacent the outer periphery of the tubular member ("stent 30") and comprising plural projections ("plural protuberances 50") that are arranged for engagement with the interior surface of the vessel, duct, or lumen. *See also* 7:18-30 ("In order to help hold or secure the graft in position in the artery (or lumen or duct) once the graft has been expanded, the stents may include a plurality of protuberances 50 projecting slightly outward from the outer surface of the graft. These protuberances 50 act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein. . . . [T]he protuberances are preferably located at the

The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
	joints 34 of the various stents.")
each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof,	Rhodes discloses projections or protuberances 50, which inherently must have a leading and trailing portion relative to the direction of fluid flow. In addition, Lazarus teaches, as shown by annotated Figs. 3 and 6 of Lazarus below, that each of the projections ("wall engaging members 70") has: (i) a leading portion in the form of the upstream portion of each wall engaging member 70 (e.g., a surface that faces the upstream direction) that is located in the upstream direction of the fluid flow 100; and (ii) a trailing portion in the form of the downstream portion of each wall engaging member 70 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow 100. *See also* 5:47-51.  Fig. 3  Fig. 6
said trailing portion including at least one surface preferentially oriented to extend at an	Lazarus teaches, as shown by annotated Figs. 3 and 6 of Lazarus above, that the trailing portion includes at least one surface (a surface of the downstream portion of each wall engaging member 70) that is preferentially

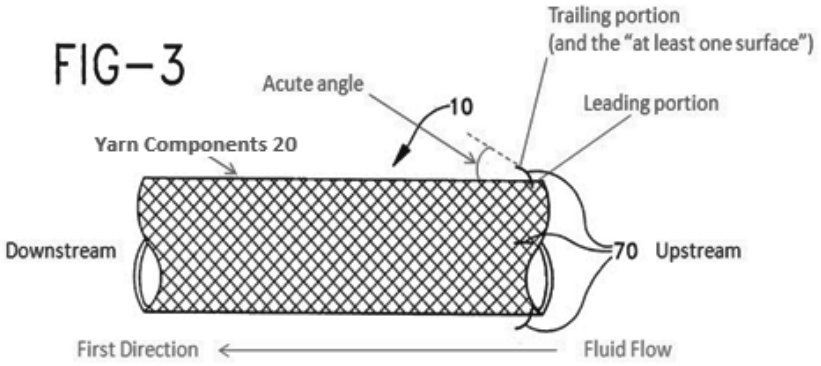
The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
acute angle to the first direction,	oriented to extend at an acute angle to the first direction ("fluid flow direction 100"). The acute angle (*see* acute angle illustrated by reference numeral 75 in annotated Fig. 3 above) is described by Lazarus as being "preferably less than 90° and desirably in the range from 30° to about 60°." 5:47-51.
whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.	Rhodes teaches that the force (e.g., blood pressure) applied to the tubular member ("stent 30") by the fluid flowing through the passageway of the tubular member ("stent 30") produces on each of the projections ("protuberances 50") a force component to cause the at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 20") in place. *See* 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein"). Rhodes further discloses that the at least one surface of each projection ("protuberances 50") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 20") in place. 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein"). As explained by Expert Rowe, the force applied to the stent 30 by fluid flowing through the passageway of the stent 30 would necessarily and inherently produce a force component on the surfaces of the protuberances 50 to cause the surfaces to tightly engage the interior surface of the blood vessel to fixedly secure the graft

The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
	20 in place. Exh. 1003, pgs. 7-8, ¶¶ 17-19. Moreover, the patentee of the '417 patent admits that the alleged distinguishing feature of his alleged invention over Rhodes (the '154 patent) is only the specific orientation of his projections. Any pressure forces in the '417 patent necessarily and inherently exist in the prior art '154 patent to Rhodes. These forces would be applied to the disclosed projections in Rhodes (the '154 patent) and would likewise be applied to the Lazarus projections when used with Rhodes (the '154 patent). *See* Exh. 1001, 3:21-27, 5:10-17, 9:1-17. In addition, as shown by annotated Fig. 7 of Lazarus below, Lazarus discloses that the at least one surface of each projection ("wall engaging member 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 12") in place. *See also* 5:61-63 ("It should also be noted that wall engaging members 70 are used to penetrate and hook into the interior surface of the lumen to hold the graft 12 in place"), 10:12-14 ("the [securing rings] 16 and 17 . . . prevent[] leakage at both ends of the graft 12."), 6:61-65 ("The angle 76 between the wall engaging members 72 and the longitudinal axis 77 may vary between about 45 degrees and about 115 degrees. Preferably, the wall engaging members 72 of the distal staples are sufficiently short so as not to perforate the vessel wall.").

The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
	 Fig. 7 Rhodes utilizes the projections ("protuberances 50") to secure the device ("graft 20") in place within a vessel, duct, or lumen. Exh. 1006, 7:18-24. Lazarus also utilizes the projections ("wall engaging members 70") to secure the device ("graft 12") in place within a vessel, duct, or lumen. Exh. 1005, 5:61-63, 10:1-14. The Gupta Expert Declaration explains that "[a] POSA [(person of ordinary skill in the art)] . . . would have been motivated[] to combine the teachings of the projections of [Rhodes] ('protuberances 50') with the teachings of the projections of [Lazarus] ('wall engaging members 70') that have at least one surface preferentially oriented to extend an acute angle to the fluid flow direction to provide an intraluminal medical device with improved anchoring capabilities for securing the device in place within a vessel, duct, or lumen of a living being." Exh. 1004, pg. 9, ¶ 24.
2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.	Lazarus teaches, as shown by annotated Figs. 3 and 6 of Lazarus above, at least one surface of the trailing portion of each projection ("wall engaging member 70") is inclined upward in the first direction ("fluid flow direction 100") when the device ("graft 12") is placed in a vessel, duct, or lumen.
9. The device of claim 1 wherein said tubular member is a stent.	Rhodes and Lazarus both disclose that the respective tubular members are structured to hold open the vessel in which they are placed and, thus, the respective tubular members are stents. Exh. 1006, 5:61-66, and Exh. 1005, 5:4-23.
10. The device of claim 9 wherein said stent is	Rhodes teaches that the stent 30 is expandable from a contracted state to an expanded state, where the

The '417 Patent	Appendix A2: US 5,122,154 to Rhodes (Exh. 1006) in View of Lazarus (Exh. 1005)
expandable from a contracted state to an expanded state, said anchoring means engaging the interior surface of the vessel, duct, or lumen when said stent is in said expanded state to secure said device in place.	anchoring means ("protuberances 50") engages the interior surface of the vessel, duct, or lumen when the stent 30 is in said expanded state to secure the device ("graft 20") in place. 7:18-24 (explaining that when the graft 20 and stent 30 are expanded, the protuberances 50 engage the interior surface of the vessel, duct, or lumen to secure the graft 20 in place). Lazarus similarly teaches that the stent 16 is expandable from a contracted state to an expanded state, where the anchoring means 70 engage the interior surface of the vessel, duct, or lumen when the stent 16 is in the expanded state to secure the device 12 in place. *See* Exh. 1005, 9:38-42.
13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.	Rhodes teaches that the device ("graft 20") is an endovascular graft ("endovascular graft 20"). 5:43-44. Rhodes further teaches the endovascular graft ("graft 20") comprise a graft sleeve ("sleeve 28") coupled to the stent 30 and having a passageway extending therethrough and an outer periphery such that body fluid can flow through the passageway. 5:50-53; *see also* annotated Figs. 1 and 8 of Rhodes above. Moreover, the patentee of the '417 patent admits that the alleged distinguishing feature of his alleged invention over Rhodes (the '154 patent) is the specific orientation of his projections. Any pressure forces in the '417 patent necessarily and inherently exist in the prior art '154 patent to Rhodes. These forces would be applied to the disclosed projections in Rhodes (the '154 patent) and would likewise be applied to the Lazarus projections when used with Rhodes (the '154 patent). *See* Exh. 1001, 3:21-27, 5:10-17, 9:1-17.

The '417 Patent	Appendix A3: US 5,562,725 to Schmitt (Exh. 1011)
1. An intraluminal medical device for securement within a vessel, duct, or lumen of	To the extent that the preamble is a limitation, Schmitt discloses an intraluminal medical device ("graft 10") for securement within a vessel, duct, or lumen of a living being, where the vessel, duct, or lumen has an

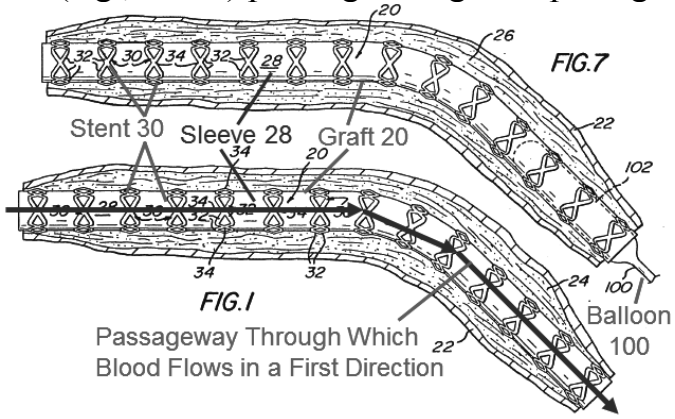
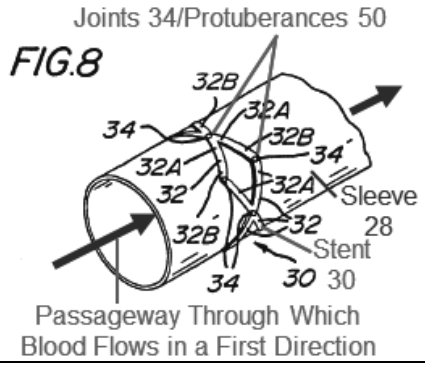
The '417 Patent	Appendix A3: US 5,562,725 to Schmitt (Exh. 1011)
a living being, the vessel, duct, or lumen having an interior surface,	interior surface. Abstract; *see also* annotated Fig. 3 below.
said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,	Schmitt discloses that the device ("graft 10") comprises a tubular member ("tubular braid or graft 10") and anchoring means ("hooks 70"). *See* annotated Fig. 3 below; *see also* 2:58-64 ("[T]he present invention is formed from a hollow tubular braid which may be implanted intraluminally and thereafter radially self-expands to come in intimate contact with the inner surface of the lumen in which it is inserted."); 4:34-43 ("[T]he intraluminal device may also include a means for attaching the device to the inner surface of the lumen to provide additional anchoring of the device. Such attaching means may include small hooks which are integrally formed on the outside or extraluminal surface of the device during the braiding process. Preferably, the hooks are integrally formed in at least one end of the device, although depending upon the procedure being performed, both ends may include hooks.").  As shown by annotated Fig. 3 above, the tubular member ("tubular braid or graft 10") has a passageway extending therethrough and an outer periphery, and the tubular member is arranged to have a body fluid (e.g., blood) flow through the passageway in a first direction when the device is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member as a result of fluid (e.g., blood) passing through the passageway.

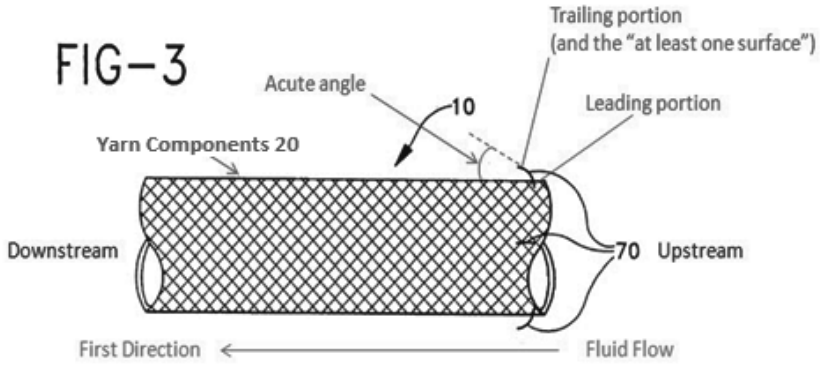
The '417 Patent	Appendix A3: US 5,562,725 to Schmitt (Exh. 1011)
said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen,	As shown by annotated Fig. 3 above, the anchoring means ("hooks 70") are located adjacent the outer periphery of the tubular member ("tubular braid or graft 10") and comprising plural projections ("plural hooks 70") that are arranged for engagement with the interior surface of the vessel, duct, or lumen. *See also* 4:34-43 ("[T]he intraluminal device may also include a means for attaching the device to the inner surface of the lumen to provide additional anchoring of the device. Such attaching means may include small hooks which are integrally formed on the outside or extraluminal surface of the device during the braiding process. Preferably, the hooks are integrally formed in at least one end of the device, although depending upon the procedure being performed, both ends may include hooks.").
each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof,	As shown by annotated Fig. 3 above, each of the projections ("hooks 70") has: (i) a leading portion in the form of the upstream portion of each hook 70 (e.g., a surface that faces the upstream direction) that is located in the upstream direction of the fluid flow; and (ii) a trailing portion in the form of the downstream portion of each hook 70 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow.
said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,	As shown by annotated Fig. 3 above, the trailing portion includes at least one surface (a surface of the downstream portion of each hook 70) that is preferentially oriented to extend at an acute angle to the first direction ("fluid flow direction").
whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one	Schmitt discloses that the force applied to the tubular member ("tubular braid or graft 10") by the fluid flowing through the passageway of the tubular member produces on each of the projections ("hooks 70") a force component to cause the at least one surface (a surface of the downstream portion of each hook 70) to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 10") in

The '417 Patent	Appendix A3: US 5,562,725 to Schmitt (Exh. 1011)
surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.	place. 9:23-33 ("[T]he intraluminal device may include a means for anchoring the device within the lumen in which it is inserted. An example of this embodiment is illustrated in FIG. 3. The tubular braid 10 has hooks 70 integrally formed in at least one end of the braid. Upon radial expansion, the hooks slightly impinge the inner surface of the lumen or blood vessel to anchor the intraluminal device in position. In a blood vessel, the hooks 70 might only be necessary at one end of the device since the flow of blood will further serve to keep the graft in the expanded state, thereby providing sufficient contact with the lumen wall to stabilize against unwanted movement.").
2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.	As shown by annotated Fig. 3 above, at least one surface of the trailing portion of each projection ("hook 70") is inclined upward in the first direction ("fluid flow direction") when the device ("graft 10") is placed in a vessel, duct, or lumen.
9. The device of claim 1 wherein said tubular member is a stent.	Schmitt discloses that the tubular member ("tubular braid or graft 10") is a stent. 6:59-63 ("The intraluminal device of the present invention is most likely to be used to support a weakened body passageway or maintain an opening in an occluded body passageway."); 8:5-7 ("The intraluminal braided device of the present invention is radially self-expanding and has the stent feature inherently incorporated into the device.")
10. The device of claim 9 wherein said stent is expandable from a contracted state to an expanded state, said anchoring means engaging the interior surface of the vessel, duct, or lumen when said stent is in said expanded state to secure said device in place.	Schmitt discloses that the stent ("tubular braid or graft 10") is expandable from a contracted state to an expanded state, where the anchoring means ("hooks 70") engage the interior surface of the vessel, duct, or lumen when the stent is in the expanded state to secure the device ("graft 10") in place. *See also* 3:38-42 ("The expanding radial force is preferably designed so that the intraluminal device will open up to be in intimate contact with the interior surface of the body passageway in which it is inserted and anchor itself thereto.").

The '417 Patent	Appendix A3: US 5,562,725 to Schmitt (Exh. 1011)
13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.	As shown by annotated FIG. 3 above, the device ("graft 10") is an endovascular graft where the endovascular graft additionally comprises a graft sleeve ("yarn components 20"), and the graft sleeve ("yarn components 20") is coupled to the stent ("tubular braid or graft 10") and has an outer surface and inner passageway through which the body fluid (e.g., blood) flows in the first direction ("fluid flow direction") to apply the force to the projections ("hooks 70"). *See also* 9:30-33 ("In a blood vessel, the hooks 70 might only be necessary at one end of the device since the flow of blood will further serve to keep the graft in the expanded state, thereby providing sufficient contact with the lumen wall to stabilize against unwanted movement.").

The '417 Patent	Appendix A4: Rhodes (Exh. 1006) in view of Schmitt (Exh. 1011)
1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface,	To the extent that the preamble is a limitation, Rhodes teaches an intraluminal medical device ("graft 20") for securement within a vessel, duct, or lumen of a living being, where the vessel, duct, or lumen has an interior surface. Abstract, 7:18-30.
said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or	Rhodes teaches that the device ("graft 20") comprises a tubular member in the form of a stent 30 (which is also referred to as stent members 30), and anchoring means in the form of protuberances 50 that project slightly outward from the outer surface of the graft 20. 5:61-66, 7:18-24. The tubular member ("stent 30") has a passageway extending therethrough and an outer periphery. S*ee* annotated Figs. 1, 7, and 8 below (illustrating that the graft sleeve 28 fits and extends through the passageway of the stent 30). The tubular member ("stent 30") is arranged to have a body fluid (e.g., blood) flow through the passageway in a first direction (*see* annotated Figs. 1, 7, and 8 below) when the device ("graft 12") is located within the vessel,

The '417 Patent	Appendix A4: Rhodes (Exh. 1006) in view of Schmitt (Exh. 1011)
lumen, whereupon a force is applied to said tubular-member,	duct, or lumen, whereupon a force is applied to the tubular member ("stent 30") as a result of fluid pressure (e.g., blood) passing through the passageway.  
said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen,	As shown by annotated Fig. 8 above, the anchoring means ("protuberances 50") are located adjacent the outer periphery of the tubular member ("stent 30") and comprising plural projections ("plural protuberances 50") that are arranged for engagement with the interior surface of the vessel, duct, or lumen. *See also* 7:18-30 ("In order to help hold or secure the graft in position in the artery (or lumen or duct) once the graft has been expanded, the stents may include a plurality of protuberances 50 projecting slightly outward from the outer surface of the graft. These protuberances 50 act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein. . . . [T]he protuberances are preferably located at the joints 34 of the various stents.")
each of said projections	Rhodes discloses projections or protuberances 50,

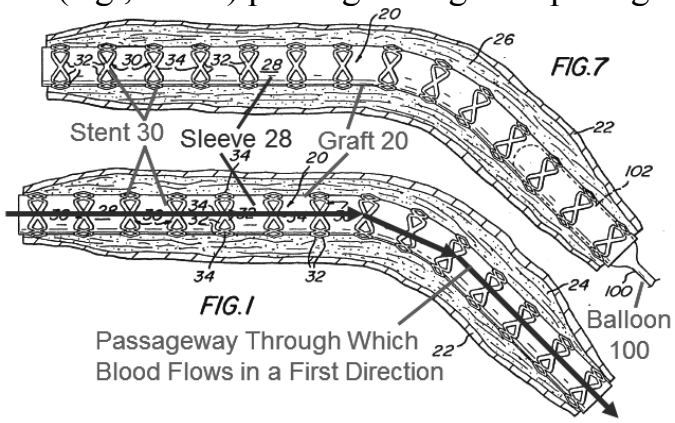
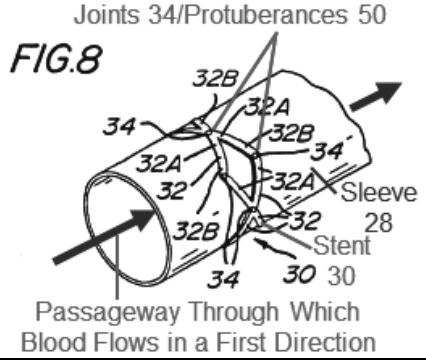
The '417 Patent	Appendix A4: Rhodes (Exh. 1006) in view of Schmitt (Exh. 1011)
having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof,	which inherently must have a leading and trailing portion relative to the direction of fluid flow. In addition, as shown by annotated Fig. 3 of Schmitt below, each of the projections ("hooks 70") has: (i) a leading portion in the form of the upstream portion of each hook 70 (e.g., a surface that faces the upstream direction) that is located in the upstream direction of the fluid flow; and (ii) a trailing portion in the form of the downstream portion of each hook 70 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow. 
said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,	As shown by annotated Fig. 3 of Schmitt above, the trailing portion includes at least one surface (a surface of the downstream portion of each hook 70) that is preferentially oriented to extend at an acute angle to the first direction ("fluid flow direction").
whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said	Rhodes teaches that the force (e.g., blood pressure) applied to the tubular member ("stent 30") by the fluid flowing through the passageway of the tubular member ("stent 30") produces on each of the projections ("protuberances 50") a force component to cause the at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 20") in place. *See* 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the

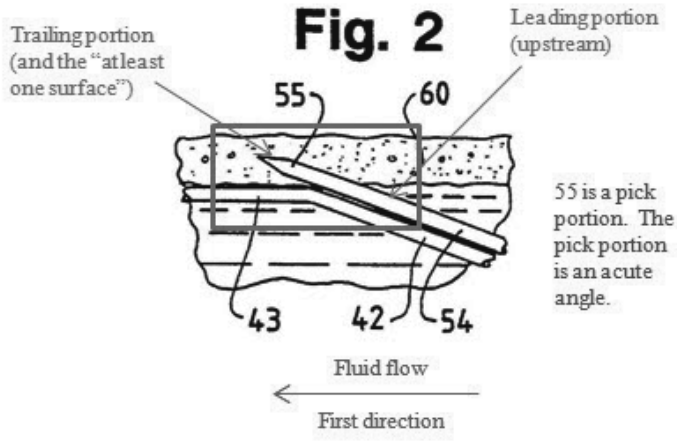
The '417 Patent	Appendix A4: Rhodes (Exh. 1006) in view of Schmitt (Exh. 1011)
device in place.	arterial wall to maintain a fixed position therein").
	Rhodes further discloses that the at least one surface of each projection ("protuberances 50") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 20") in place. 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein").
	As explained by Expert Rowe, the force applied to the stent 30 by fluid flowing through the passageway of the stent 30 would necessarily and inherently produce a force component on the surfaces of the protuberances 50 to cause the surfaces to tightly engage the interior surface of the blood vessel to fixedly secure the graft 20 in place. Exh. 1003, pgs. 7-8, ¶¶ 17-19.
	Moreover, the patentee of the '417 patent admits that the alleged distinguishing feature of his alleged invention over Rhodes (the '154 patent) is the specific orientation of his projections. Any pressure forces in the '417 patent necessarily and inherently exist in the prior art '154 patent to Rhodes. These forces would be applied to the disclosed projections in Rhodes (the '154 patent) and would likewise be applied to the Lazarus projections when used with Rhodes (the '154 patent). *See* Exh. 1001, 3:21-27, 5:10-17, 9:1-17.
	In addition, Schmitt discloses that the at least one surface of each projection ("hook 70") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly

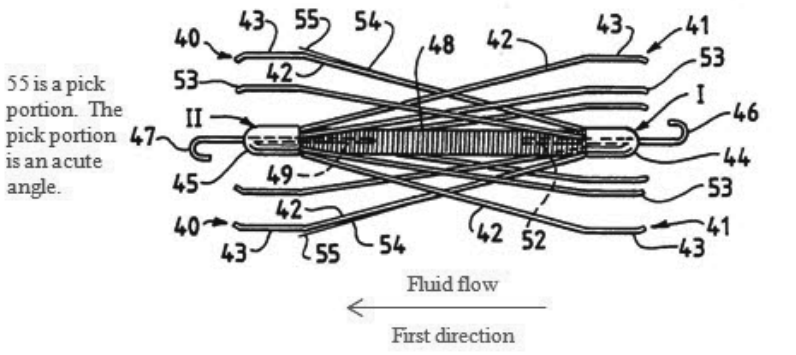
The '417 Patent	Appendix A4: Rhodes (Exh. 1006) in view of Schmitt (Exh. 1011)
	embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 10") in place. 9:23-33 ("[T]he intraluminal device may include a means for anchoring the device within the lumen in which it is inserted. An example of this embodiment is illustrated in FIG. 3. The tubular braid 10 has hooks 70 integrally formed in at least one end of the braid. Upon radial expansion, the hooks slightly impinge the inner surface of the lumen or blood vessel to anchor the intraluminal device in position. In a blood vessel, the hooks 70 might only be necessary at one end of the device since the flow of blood will further serve to keep the graft in the expanded state, thereby providing sufficient contact with the lumen wall to stabilize against unwanted movement."). Rhodes utilizes the projections ("protuberances 50") to secure the device ("graft 20") in place within a vessel, duct, or lumen. Exh. 1006, 7:18-24. Schmitt also utilizes the projections ("hooks 70") to secure the device ("graft 10") in place within a vessel, duct, or lumen. Exh. 1011, Abstract, 4:34-43, 9:23-33.
2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.	As shown by annotated Fig. 3 of Schmitt above, at least one surface of the trailing portion of each projection ("hook 70") is inclined upward in the first direction ("fluid flow direction") when the device ("graft 10") is placed in a vessel, duct, or lumen.
9. The device of claim 1 wherein said tubular member is a stent.	Rhodes discloses that the tubular member is structured to hold open the vessel in which it is placed and, thus, the tubular member is a stent. Exh. 1006, 5:61-66.
10. The device of claim 9 wherein said stent is expandable from a contracted state to an expanded state, said anchoring means engaging the interior	Rhodes teaches that the stent 30 is expandable from a contracted state to an expanded state, where the anchoring means ("protuberances 50") engages the interior surface of the vessel, duct, or lumen when the stent 30 is in said expanded state to secure the device ("graft 20") in place. 7:18-24 (explaining that when the graft 20 and stent 30 are expanded, the protuberances

The '417 Patent	Appendix A4: Rhodes (Exh. 1006) in view of Schmitt (Exh. 1011)
surface of the vessel, duct, or lumen when said stent is in said expanded state to secure said device in place.	50 engage the interior surface of the vessel, duct, or lumen to secure the graft 20 in place).
13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.	Rhodes teaches that the device ("graft 20") is an endovascular graft ("endovascular graft 20"). 5:43-44. Rhodes further teaches the endovascular graft ("graft 20") comprise a graft sleeve ("sleeve 28") coupled to the stent 30 and having a passageway extending therethrough and an outer periphery such that body fluid can flow through the passageway. 5:50-53; *see also* annotated Figs. 1 and 8 of Rhodes above. Moreover, the patentee of the '417 patent admits that the alleged distinguishing feature of his alleged invention over Rhodes (the '154 patent) is the specific orientation of his projections. Any pressure forces in the '417 patent necessarily and inherently exist in the prior art '154 patent to Rhodes. These forces would be applied to the disclosed projections in Rhodes (the '154 patent) and would likewise be applied to the Lazarus projections when used with Rhodes (the '154 patent). *See* Exh. 1001, 3:21-27, 5:10-17, 9:1-17.

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface,	To the extent that the preamble is a limitation, Rhodes teaches an intraluminal medical device ("graft 20") for securement within a vessel, duct, or lumen of a living being, where the vessel, duct, or lumen has an interior surface. Abstract, 7:18-30.
said device comprising a tubular member and anchoring means, said tubular member having a	Rhodes teaches that the device ("graft 20") comprises a tubular member in the form of a stent 30 (which is also referred to as stent members 30), and anchoring means in the form of protuberances 50 that project slightly

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,	outward from the outer surface of the graft 20. 5:61-66, 7:18-24. The tubular member ("stent 30") has a passageway extending therethrough and an outer periphery. S*ee* annotated Figs. 1, 7, and 8 below (illustrating that the graft sleeve 28 fits and extends through the passageway of the stent 30). The tubular member ("stent 30") is arranged to have a body fluid (e.g., blood) flow through the passageway in a first direction (*see* annotated Figs. 1, 7, and 8 below) when the device ("graft 12") is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member ("stent 30") as a result of fluid pressure (e.g., blood) passing through the passageway.  
said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for	As shown by annotated Fig. 8 above, the anchoring means ("protuberances 50") are located adjacent the outer periphery of the tubular member ("stent 30") and comprising plural projections ("plural protuberances 50") that are arranged for engagement with the interior surface of the vessel, duct, or lumen. *See also* 7:18-30

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
engagement with the interior surface of the vessel, duct, or lumen,	("In order to help hold or secure the graft in position in the artery (or lumen or duct) once the graft has been expanded, the stents may include a plurality of protuberances 50 projecting slightly outward from the outer surface of the graft. These protuberances 50 act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein. . . . [T]he protuberances are preferably located at the joints 34 of the various stents.")
each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof,	Rhodes discloses projections or protuberances 50, which inherently must have a leading and trailing portion relative to the direction of fluid flow. In addition, Irie teaches, as shown by annotated Figs. 2 and 3 of Irie below, that each of the projections ("pick portion 55") has: (i) a leading portion in the form of the upstream portion of each pick portion (e.g., a surface that faces the upstream direction) that is located in the upstream direction of the fluid flow; and (ii) a trailing portion in the form of the downstream portion of each pick portion 55 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow. 

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
	Fig. 3 
said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,	Irie teaches, as shown by annotated Figs. 2 and 3 of Irie above, that the trailing portion includes at least one surface (a surface of the downstream portion of each pick portion 55) that is preferentially oriented to extend at an acute angle to the first direction ("fluid flow direction"). The acute angle is described by Irie: "said anchor legs extend past the intersection of the initial and vein wall junction portion of the second unit struts and terminate in picks that can pierce the vein wall at an acute angle thereto." Claim 8.
whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.	Rhodes teaches that the force (e.g., blood pressure) applied to the tubular member ("stent 30") by the fluid flowing through the passageway of the tubular member ("stent 30") produces on each of the projections ("protuberances 50") a force component to cause the at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 20") in place. *See* 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein"). Rhodes further discloses that the at least one surface of each projection ("protuberances 50") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
	interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 20") in place. 7:18-30 (explaining that the protuberances 50 project "slightly outward from the outer surface of the graft [and] . . . act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein"). As explained by Expert Rowe, the force applied to the stent 30 by fluid flowing through the passageway of the stent 30 would necessarily and inherently produce a force component on the surfaces of the protuberances 50 to cause the surfaces to tightly engage the interior surface of the blood vessel to fixedly secure the graft 20 in place. Exh. 1003, pgs. 7-8, ¶¶ 17-19. Moreover, the patentee of the '417 patent admits that the alleged distinguishing feature of his alleged invention over Rhodes (the '154 patent) is the specific orientation of his projections. Any pressure forces in the '417 patent necessarily and inherently exist in the prior art '154 patent to Rhodes. These forces would be applied to the disclosed projections in Rhodes (the '154 patent) and would likewise be applied to the Lazarus projections when used with Rhodes (the '154 patent). *See* Exh. 1001, 3:21-27, 5:10-17, 9:1-17. In addition, as shown by annotated Fig. 2 above, Irie discloses that the at least one surface of each projection ("pick portion 55") is tightly engaged with the interior surface of the vessel, duct, or lumen such that the projections are partly and firmly embedded, interlocked, or enmeshed in/with the interior surface of the vessel, duct, or lumen to fixedly secure the device ("filter") in place. *See also*: • Abstract ("The preferred embodiment includes picks that impale the vein wall to a limited depth."),

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
	• 4:37-51 ("In this embodiment the free end sections are contoured to avoid penetration of the vessel wall to thereby positively anchor the filter in a desired location. The depth to which the picks can be implanted is limited and thus the trauma and disadvantages associated with uncontrolled penetration of the vessel wall has been eliminated. The picks enter the vein wall at an angle to the filter's longitudinal axis and in the direction such that the fluid flow exerts a constant pressure to force the picks deeper into the vein wall. Thus blood flow through the vein exerts a force on the filter maintaining the limited penetration of the picks in the vein wall."), • 4:59-66 ("Since the picks are inserted into the vein wall at an angle, provided their length is equal to the thickness of the vein wall, they will not extend completely through the wall. However, the picks effectively serve their purpose of providing the filter with means for positively securing the filter in a preferred location. They serve this purpose while doing minimum damage to the vein wall."); • 5:66-6:4 ("The ends of the pick portions 55 can be sharpened to a point. The length of the pick portion is in the range of 0.50 to 1.00 millimeters, which does not exceed the usual thickness of the vein wall. Since the picks extend into the vein wall at an angle, picks having a length equal to or less than the usual vein wall will not extend through the vein wall."); • 6:8-14 ("…causing picks 55 to pierce the vein wall at an angle. The vein wall junction portion 43 of the strut 40 will however limit the penetration of the pick 55. Thus the cooperation

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
	between the vein wall junction portions 43 and the picks 55 will positively anchor the filter at the selected location in the vein wall as well as limit the penetration depth of the picks 55."); • 9:56-66 ("During the implanting process an insertion tube, containing the filter, is percutaneously inserted into the patient's inferior vena cava through the femoral vein. The filtering and holding device is expelled from the distal end of the insertion tube, by a pusher rod and is implanted at a selected location in the inferior vena cava. When the filter is expelled from the insertion tube it is propelled, by blood flow, in the direction that will cause the picks 55 to impale the wall of the vein and thus insure that the filter will remain at the selected location."). Rhodes utilizes the projections ("protuberances 50") to secure the device ("graft 20") in place within a vessel, duct, or lumen. Exh. 1006, 7:18-24. Irie also utilizes the projections ("pick portions 55") to secure the device ("filter") in place within a vessel, duct, or lumen. Exh. 1012, 4:59-66, 6:8-14.
2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.	Irie teaches, as shown by annotated Figs. 2 and 3 of Irie above, at least one surface of the trailing portion of each projection ("pick portions 55") is inclined upward in the first direction when the device is placed in a vessel, duct, or lumen.
9. The device of claim 1 wherein said tubular member is a stent.	Rhodes discloses that the tubular member is structured to hold open the vessel in which it is placed and, thus, the tubular member is a stent. Exh. 1006, 5:61-66.
10. The device of claim 9 wherein said stent is expandable from a contracted state to an expanded state, said anchoring means	Rhodes teaches that the stent 30 is expandable from a contracted state to an expanded state, where the anchoring means ("protuberances 50") engages the interior surface of the vessel, duct, or lumen when the stent 30 is in said expanded state to secure the device ("graft 20") in place. 7:18-24 (explaining that when the

The '417 Patent	Appendix A5: Rhodes (Exh. 1006) in View of U.S. 5,370,657 to Irie (Exh. 1012)
engaging the interior surface of the vessel, duct, or lumen when said stent is in said expanded state to secure said device in place.	graft 20 and stent 30 are expanded, the protuberances 50 engage the interior surface of the vessel, duct, or lumen to secure the graft 20 in place).
13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.	Rhodes teaches that the device ("graft 20") is an endovascular graft ("endovascular graft 20"). 5:43-44. Rhodes further teaches the endovascular graft ("graft 20") comprise a graft sleeve ("sleeve 28") coupled to the stent 30 and having a passageway extending therethrough and an outer periphery such that body fluid can flow through the passageway. 5:50-53; *see also* annotated Figs. 1 and 8 of Rhodes above. Moreover, the patentee of the '417 patent admits that the alleged distinguishing feature of his alleged invention over Rhodes (the '154 patent) is the specific orientation of his projections. Any pressure forces in the '417 patent necessarily and inherently exist in the prior art '154 patent to Rhodes. These forces would be applied to the disclosed projections in Rhodes (the '154 patent) and would likewise be applied to the Lazarus projections when used with Rhodes (the '154 patent). *See* Exh. 1001, 3:21-27, 5:10-17, 9:1-17.

CERTIFICATE OF SERVICE (37 C.F.R. § 42.205)

I hereby certify that a true copy of the SECOND PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO 5,593,417 with Appendices A1-A5 was served by EXPRESS MAIL (or by means at least as fast and reliable) this 25th day of April, 2014 on the attorney of record of the '417 patent shown in PAIR:

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