

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

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Inventor: Rhodes, Valentine J.

Assignee: Rhodes, Valentine J.

Title: INTRAVASCULAR STENT WITH
SECURE MOUNTING MEANS

Panel: To Be Assigned

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PETITION FOR INTER PARTES REVIEW UNDER 37 C.F.R. § 42.100

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Appendix of Exhibits (Exhibit List) for
Inter Partes Review of U.S. Patent No. 5,593,417

Exhibit Description	Exhibit No.
U.S. Patent No. 5,593,417 to Rhodes	1001
File History for U.S. Patent No. 5,593,417	1002
Declaration of Travis Rowe	1003
Declaration of Atul Gupta	1004
U.S. Patent No. 5,104,399 to Lazarus	1005
U.S. Patent No. 4,562,596 to Kornberg	1006
U.S. Patent No. 5,397,355 to Marin	1007
U.S. Patent No. 5,122,154 to Rhodes	1008

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).

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 against Petitioner in the U.S. District Court for the District of California San Jose Division in a case titled *Endotach LLC v. Medtronic, Inc., et al.*, No. 5:13-cv-03292-EJD.

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

Petitioner provides the following designation of counsel:

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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. 5,122,154¹:

The graft device [] is constructed in accordance with the teachings of my aforementioned patent, except for the means 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 contrast to the above-mentioned dome shaped projections, the '417 patent alleges 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:

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.

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 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 the Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '417 patent on the grounds identified herein. More particularly, Petitioner certifies that: (1) Petitioner is not the owner of the '417 patent; (2) Petitioner has not filed a civil action challenging the validity of a claim of the '417 patent; (3) this Petition is filed less than one year after the date on which the Petitioner, the Petitioner's real party-in-interest, or a privy of the Petitioner was served with a complaint alleging infringement of the '417 patent; (4) the estoppel provisions of 35 U.S.C. § 315(e)(1) do not prohibit this *inter partes*

review; and (5) this Petition is filed after the later of (a) the date that is nine months after the date of the grant of the '417 patent or (b) the date of termination of any post-grant review of the '417 patent.

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 anticipated by U.S. Patent No. 4,562,596 to Kornberg (“Kornberg”); (3) the challenged claims are anticipated by U.S. Patent No. 5,397,355 to Marin (“Marin”); (4) the challenged claims are obvious over U.S. Patent No. 5,122,154 to Rhodes (“Rhodes '154”) in view of Lazarus; (5) the challenged claims are obvious over Rhodes '154 in view of Kornberg; and (6) the challenged claims are obvious over Rhodes '154 in view of Marin.

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)

Petitioner notes that a claim is given the “broadest reasonable construction in light of the specification” in *inter partes* review. *See 37 C.F.R. § 42.100(b).*² Petitioner’s claim construction herein should not be taken to mean that Petitioner agrees or admits that any claim element of the challenged claims should receive the benefits of the doctrine of equivalents, that Petitioner is precluded from propounding alternative claim constructions, or that Petitioner agrees or believes that the claims at issue are amendable to a meaningful construction or satisfy the requirements of 35 U.S.C. § 112. All claim terms not specifically addressed in this

² Other forums, such as U.S. District Courts, require different standards of proof and utilize different claim interpretation rules that are not applied by, or applicable to, the Patent Office for *inter partes* reviews. Therefore, any interpretation or construction of the challenged claims in this Petition is made solely pursuant to the broadest reasonable construction rule applicable to this Petition, and shall not be viewed as constituting, in whole or in part, Petitioner’s interpretation or construction under any other forum’s rules or standards.

section have been accorded their broadest reasonable interpretation in light of the patent specification.

1. “projection”

Claims 1, 3-6, 8, and 13 include the term “projection.” The written description of the '417 patent describes that a projection constructed in accordance with the alleged invention “can take numerous other shapes and sizes than those shown herein. . . . [T]he projection 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.” Exh. 1001, 9:1-8. In light of the written description, the broadest reasonable interpretation of the term “projection” is any structure that is arranged to extend out from a surface at an acute angle to the the direction of fluid flow.

2. “leading portion”

Claim 1 includes the term “leading portion.” The written description of the '417 patent describes an edge of each projection 40 that is located in the upstream direction of the fluid flow (relative to the trailing edges 48, 50, and 52 of the respective projection 40) as the leading edge 42. *Id.* at 7:63 to 8:4. The written description further describes a surface of each projection 70 that is located in the upstream direction of the fluid flow (relative to the trailing surface 76 of the

respective projection 70) as the leading surface 72. *Id.* at 8:54-64. In light of the written description, the term “leading portion” is a portion of the projection that is located in the upstream direction of the fluid flow.

3. “trailing portion”

Claim 1 includes the term “trailing portion.” The written description of the '417 patent describes edges of each projection 40 that is located in the downstream direction of the fluid flow (relative to the leading edge 42 of the respective projection 40) as the trailing edges 48, 50, and 52. *Id.* at 7:63 to 8:4. The written description further describes a surface of each projection 70 that is located in the downstream direction of the fluid flow (relative to the leading surface 72 of the respective projection 70) as the trailing surface 76. *Id.* at 8:54-64. In light of the written description, the broadest reasonable interpretation of the term “trailing portion” is a portion of the projection that is located in the downstream direction of the fluid flow relative to the leading portion.

4. “stent”

Claims 9, 10, and 13 include the term “stent.” The written description of the '417 patent uses the term “stent members 26” and “stents 26” interchangeably with one another. *See id.* at 6:21-26, 6:55-64, 7:2-7. As well known in the art, and as supported by the '417 patent specification, a stent is a structure that provides structural support (e.g., the stent is “the means for holding or retaining the sleeve

24 in any desired expanded state”). *Id.* at 6:21-22. In light of the written description, the broadest reasonable interpretation of the term “stent” is any structure that can provide structural support (e.g., for a graft sleeve, a blood vessel, etc.).

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-A6.

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-A6.

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)

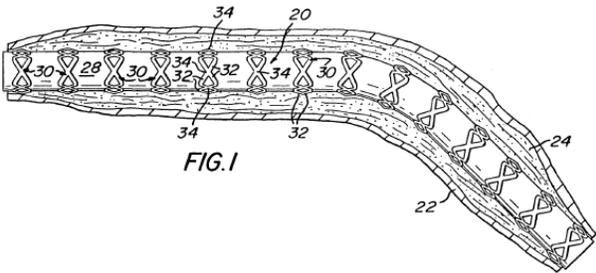
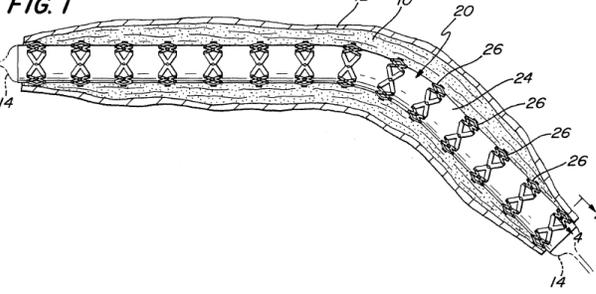
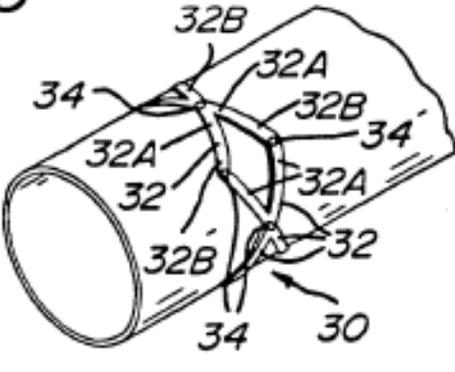
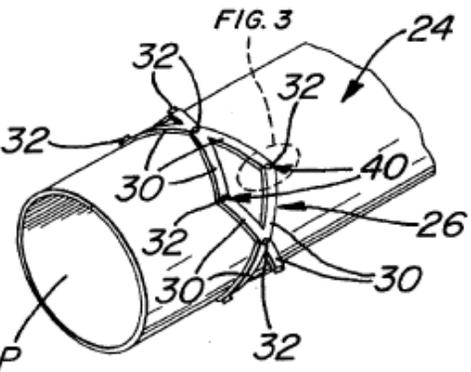
Claims 1, 2, 9, 10, and 13 of the '417 patent (“the challenged claims”) are unpatentable because of one or more of the following grounds: (i) the challenged claims are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,104,399 to

Lazarus (“Lazarus”); (ii) the challenged claims are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,562,596 to Kornberg (“Kornberg”); (iii) the challenged claims are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,397,355 to Marin (“Marin”); (iv) 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; (v) the challenged claims are obvious under 35 U.S.C. § 103(a) over Rhodes '154 in view of Kornberg; and (vi) the challenged claims are obvious under 35 U.S.C. § 103(a) over Rhodes '154 in view of Marin.

With respect to the obviousness challenges 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 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
 <p data-bbox="293 1052 691 1094">Figure 1 of the '154 patent</p>	 <p data-bbox="933 1060 1331 1102">Figure 1 of the '417 patent</p>
 <p data-bbox="293 1564 691 1606">Figure 8 of the '154 patent</p>	 <p data-bbox="933 1564 1331 1606">Figure 2 of the '417 patent</p>

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.

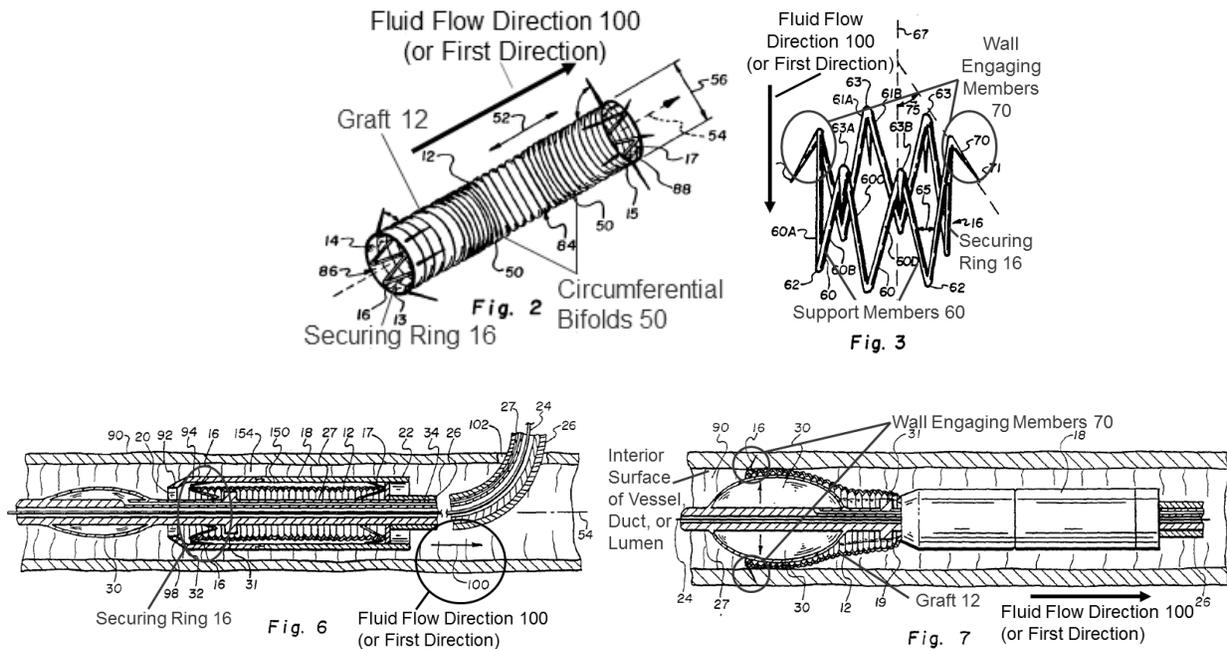
As shown below, the alleged invention of the '417 patent is clearly anticipated by several prior art references that were not considered by the U.S. Patent and Trademark Office when deciding to grant the '417 patent. Moreover, as also shown below, the '417 patent is obvious over the patentee's own prior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

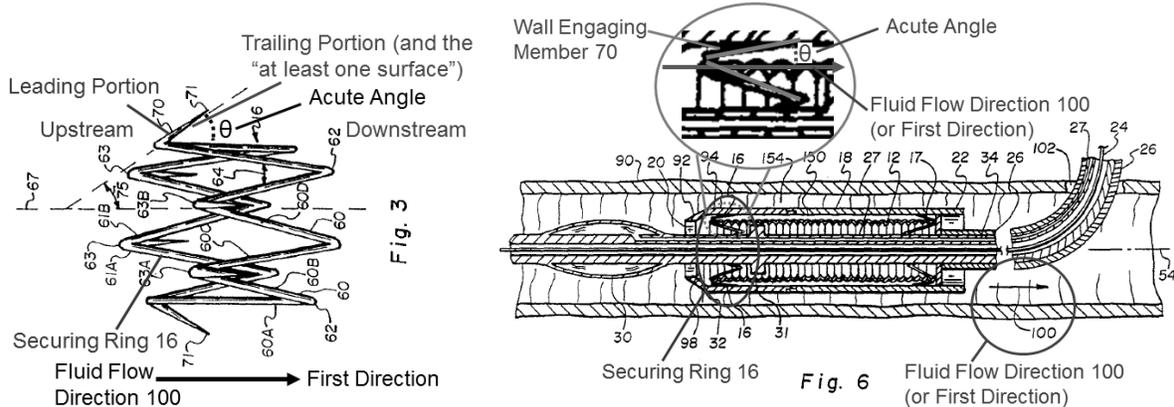
means of the intraluminal balloon-expanded medical device, and cross-sectional views of the intraluminal balloon-expanded medical device being placed within a vessel, duct, or lumen of a living being, respectively.



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 (i.e., 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.



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.

Furthermore, force applied to the balloon-expanded tubular member (“securing ring 16”) of Lazarus by fluid flowing through the interior passageway thereof inherently 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.”).

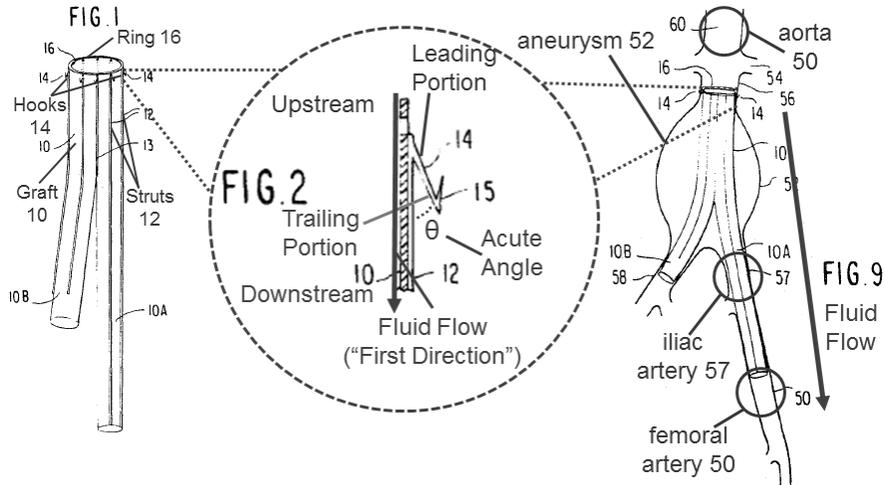
With respect to dependent claims 2, 9, 10, and 13 of the '417 patent, annotated Figures 3 and 6 of Lazarus above show that the at least one surface of the trailing portion is inclined upward in the first direction (“fluid flow direction 100”) when the device (“graft 12”) is placed in a vessel, duct, 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 Anticipated Under 35 U.S.C. § 102(b) by U.S. Patent No. 4,562,596 to Kornberg (Exh. 1006)

Kornberg was filed on April 25, 1984, and issued on January 7, 1986, and thus qualifies as prior art under § 102(b). Kornberg was not cited during prosecution of the '417 patent even though Kornberg describes an intraluminal medical device for securement within a vessel, duct, or lumen of a living being. Exh. 1006, Abstract. The claim chart attached as Appendix A2 details how each element recited in claims 1, 2, 9, 10, and 13 is anticipated by Kornberg.

For example, annotated Figures 1, 2, and 9 of Kornberg below illustrate an intraluminal manually-anchored medical device, anchoring means of the intraluminal manually-anchored medical device, and a view of the intraluminal medical device manually anchored in place within a vessel, duct, or lumen of a living being, respectively.

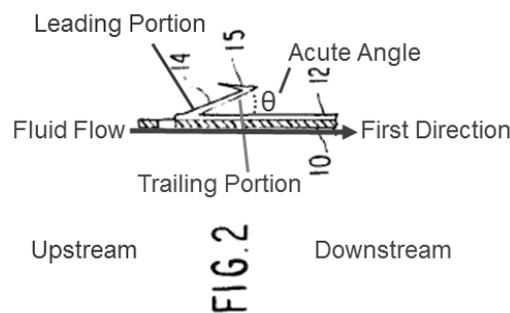


Specifically, among other features shown by annotated Figures 1, 2, and 9 above, Kornberg discloses an intraluminal manually-anchored medical device (“graft 10”) comprising a tubular member (“struts 12 and ring 16”) and anchoring means (“hooks 14”). *See also id.* at Abstract, 2:62-65, 3:60-65. The anchoring means (“hooks 14”) are located adjacent the outer periphery of the tubular member (“struts 12 and ring 16”), and comprise plural projections (“plural hooks 14”) arranged for engagement with the interior surface of a vessel, duct, or lumen of a living being. *See* annotated Figs. 1, 2, and 9 of Kornberg above; *see also* Exh. 1006, Abstract, 3:60-65, 4:6-9, 4:28-36. Each of the projections (“hooks 14”) has a leading portion in the form of the upstream portion of each hook 14 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 14 that is located in the downstream direction thereof. *See* annotated Figs. 1, 2, and 9 of Kornberg above. The trailing portion of each projection (“hook 14”) comprises at least one surface that is preferentially

oriented to extend at an acute angle to a first direction (“fluid flow direction”). See annotated Figs. 1, 2, and 9 of Kornberg above; see Exh. 1006, 3:62-67.

Furthermore, force applied to the manually-anchored tubular member (“struts 12 and ring 16”) of Kornberg by fluid flowing through the interior passageway thereof inherently produces on each of the projections (“hooks 14”) 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. See Exh. 1003, pgs. 10-12, ¶¶ 22-26.

With respect to dependent claims 2, 9, 10, and 13 of the '417 patent, annotated Figure 2 of Kornberg below 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).



As shown by annotated Figures 1, 2, and 9 of Kornberg above, the tubular member (“struts 12 and ring 16”) is a stent comprising longitudinal supporting and reinforcing members called struts 12 and the ring 16 that functions to keep the device (“graft 10”) expanded (e.g., claim 9), see also Exh. 1006, 2:62-65, 6:35-37,

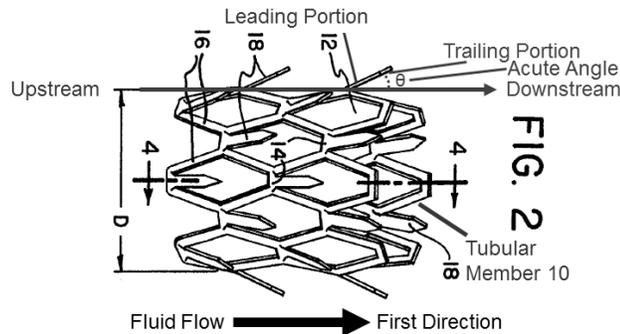
and that the stent (“struts 12 and ring 16”) is expandable from a contracted state to an expanded state, where the anchoring means (“hooks 14”) engage the interior surface of the vessel, duct, or lumen when the stent (“struts 12 and ring 16”) is in the expanded state to secure the device (“graft 10”) in place (claim 10). *See id.* at 4:6-12. In addition, Kornberg discloses that the device (“graft 10”) is an endovascular graft that further comprises a graft sleeve (“cylindrical, hollow, bifurcated sleeve”), *see id.* at 2:62-65, where the graft sleeve (“cylindrical, hollow, bifurcated sleeve”) is coupled to the stent (“struts 12 and 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”) to apply the force (e.g., from the fluid flowing through the tubular member) to the projections (“hooks 14”) (claim 13). *See* annotated Fig. 9 of Kornberg above.

C. Claims 1, 2, 9, 10, and 13 are Anticipated Under 35 U.S.C. § 102(e) by U.S. Patent No. US 5,397,355 to Marin (Exh. 1007)

U.S. Patent No. 5,397,355 to Marin (“Marin”) was filed on July 19, 1994, and issued on March 14, 1995, and thus qualifies as prior art under § 102(e). Marin was not cited during prosecution of the '417 patent even though Marin describes an intraluminal medical device for securement within a vessel, duct, or lumen of a living being. Exh. 1007, Abstract. The claim chart attached as Appendix A3 details how each element recited in claims 1, 2, 9, 10, and 13 is anticipated by Marin.

For example, annotated Figure 2 of Marin below illustrates an intraluminal

medical device comprising a balloon-expanded tubular member and anchoring means.



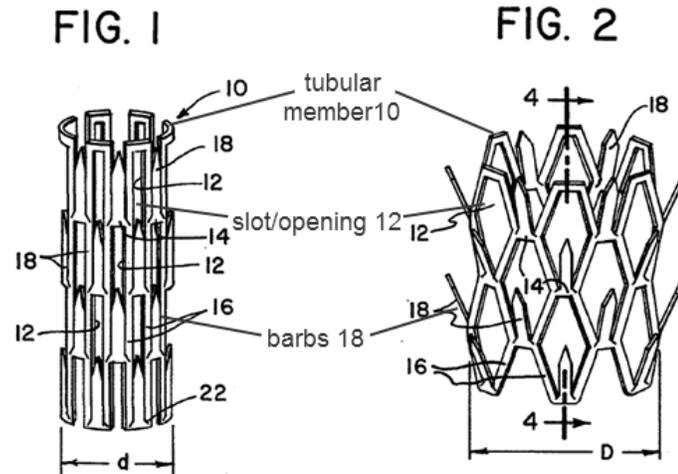
In particular, among other features shown by annotated Figure 2 above, Marin discloses an intraluminal medical device (“stented graft”) comprising a balloon-expanded tubular member (“tubular member 10”) and anchoring means (“barbs 18”). See also *id.* at 1:60-62, 2:39-40. The anchoring means (“barbs 18”) are located adjacent the outer periphery of the tubular member (“tubular member 10”), and comprise plural projections (“plural barbs 18”) arranged for engagement with the interior surface of a vessel, duct, or lumen of a living being. *Id.* at Abstract, 1:60:62, 3:11-15. Each of the projections (“barbs 18”) has a leading portion in the form of the upstream portion of each barb 18 that is located in the upstream direction of the fluid flow and a trailing portion in the form of the downstream portion of each barbs 18 that is located in the downstream direction thereof. See annotated Fig. 2 of Marin above. The trailing portion of each projection (“barb 18”) comprises at least one surface that is preferentially oriented to extend at an acute angle to a first direction (“fluid flow direction”). *Id.*

In addition, Marin further discloses that, in one embodiment, each slot/opening 12 of the tubular member 10 can have opposing barbs 18 that extend toward each other in each slot/opening 12 such that two barbs 18 would extend in opposite directions from each circumferential rib 14. Exh. 1007, 3:26-31. Thus, irrespective of which direction the tubular member 10 is oriented in a body lumen, it would necessarily have at least one of the two barbs 18 in each slot/opening 12 with a trailing portion that has at least one surface preferentially oriented to extend at an acute angle to the first direction (“fluid flow direction”).

Furthermore, force applied to the balloon-expanded tubular member (“tubular member 10”) of Marin by fluid flowing through the interior passageway thereof inherently produces on each of the projections (“barbs 18”) 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 (“stented graft”) in place. *See* Exh. 1003, pgs. 10-13, ¶¶ 22, 23, 27.

With respect to dependent claims 2, 9, 10, and 13 of the '417 patent, annotated Figure 2 of Marin above show that the at least one surface of the trailing portion is inclined upward in the first direction (“fluid flow direction”) (claim 2). As shown by annotated Figures 1 and 2 of Marin below, the tubular member 10 is a stent (claim 9), *see also id.* at 2:39-40, 2:54-59, and that the stent (“tubular member 10”) is expandable from a contracted state (Fig. 1) to an expanded state

(Fig. 2), where the anchoring means (“barbs 18”) engage the interior surface of the vessel, duct, or lumen when the stent (“tubular member 10”) is in the expanded state to secure the device (“stented graft”) in place (claim 10). *See id.* at 3:8-15.



In addition, Marin discloses that the device (“stented graft”) is an endovascular graft that further comprises a graft sleeve, *see id.* at 1:14-17, 2:20-25, where the graft sleeve is coupled to the stent (claim 13). *See* 1:60-62. As explained by Expert Rowe, the graft sleeve of the stented graft would inherently and necessarily have an outer surface and inner passageway through which the body fluid (e.g., blood) flows in a first direction (“fluid flow direction”) to apply the force (e.g., from the fluid flowing through the tubular member) to the projections. Exh. 1003, pg. 13, ¶ 27.

D. Claims 1, 2, 9, 10, and 13 are Obvious Under 35 U.S.C. § 103(a) Over Rhodes '154 (Exh. 1008) 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. 1008, Abstract, 7:18-30. 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 Lazarus.

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.

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. 1008, 7:18-24, and Lazarus teaches 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. 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. 1008; 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 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, pgs. 10-11, ¶¶ 26-29. Thus, and as further detailed in Appendix A4, 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.

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

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 Kornberg.

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.

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. 1008, 7:18-24, and Kornberg teaches an intraluminal manually-anchored medical device comprising projections (“hooks 14”) where the trailing portion (“downstream portions”) of each projection (“hooks 14”) has at least one surface that is preferentially oriented to extend at an acute angle to the fluid flow direction. Exh. 1006, 3:60-65, Figs. 1, 2, and 9. Both Rhodes '154 and Kornberg 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. 1008; 7:18-24, and Exh. 1006, Abstract, 3:60-65.

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 Kornberg (“hooks 14”) 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 utilize the Kornberg-shaped projections 14 in lieu of the Rhodes '154 projections (e.g., smaller protuberances 50) and orient the Kornberg-shaped projections 14 at an acute angle downstream to prevent migration of the intraluminal medical device. *See* Exh. 1004, pgs. 11-13, ¶¶ 30-33. Thus, and as further detailed in Appendix A5, a person of ordinary skill in the art would understand Rhodes '154 in view of Kornberg 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 Kornberg as applied to independent claim 1 similarly applies to the dependent claims.

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

The claim chart attached as Appendix A6 details how each element recited in claims 1, 2, 9, 10, and 13 is obvious over Rhodes '154 in view of Marin.

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.

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. 1008, 7:18-24, and Marin teaches an intraluminal balloon-expanded medical device comprising projections (“barbs 18”) where the trailing portion (“downstream portions”) of each projection (“barbs 18”) has at least one surface that is preferentially oriented to extend at an acute angle to the fluid flow direction. Exh. 1007, 3:26-31, Fig. 2. Both Rhodes '154 and Marin 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. 1008; 7:18-24, and Exh. 1007, Abstract, 3:11-15, 3:29-31.

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 Marin (“barbs 18”) 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 utilize the Marin-shaped projections 18 in lieu of the Rhodes '154 projections (e.g., smaller protuberances 50) and orient the Marin-shaped projections 18 at an acute angle downstream to prevent migration of the intraluminal medical device. *See* Exh. 1004, pgs. 13-14, ¶¶ 34-37. Thus, and as further detailed in Appendix A6, a person of ordinary skill in the art would understand Rhodes '154 in view of Marin

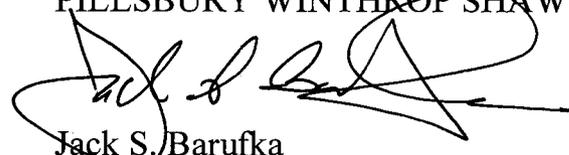
to teach an intraluminal medical device as claimed by the challenged claims. In addition, it should be noted that the motivation to combine the teachings of Rhodes '154 with the teachings of Marin as applied to independent claim 1 similarly applies to the dependent claim.

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, the Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP



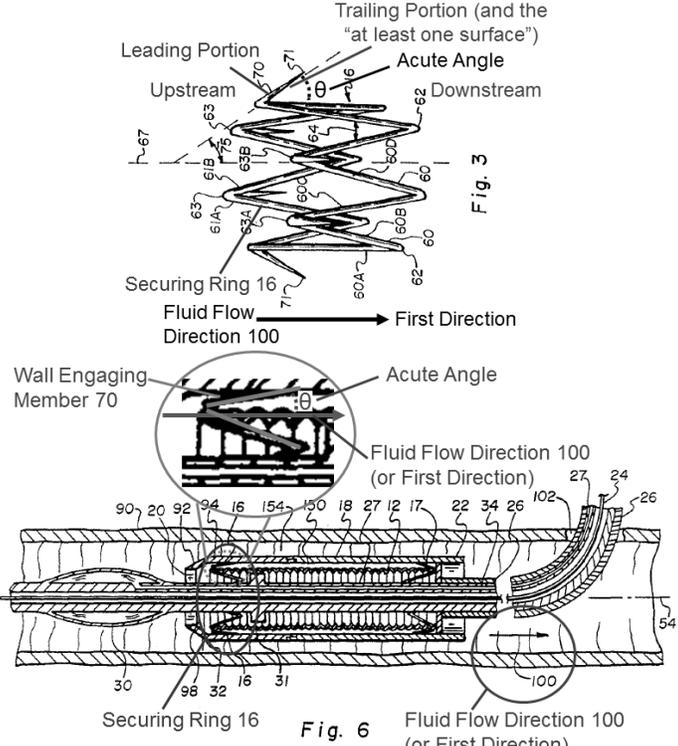
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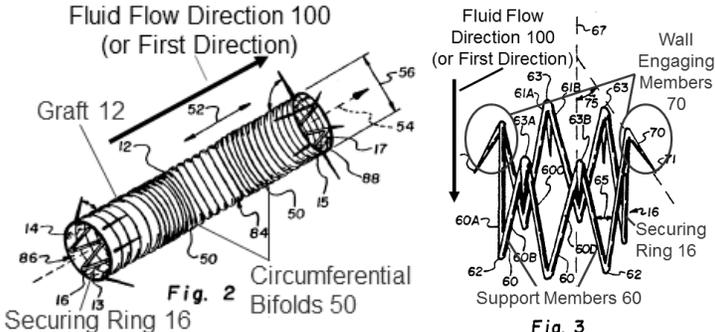
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Attachments: Appendices A1-A6 (Claim Charts)

Exhibits 1001-1008

The '417 Patent	Appendix A1: Anticipation by US 5,104,399 to Lazarus (Exh. 1005)
<p>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,</p>	<p>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; <i>see also</i> annotated Figs. 6 and 7 below.</p>
<p>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,</p>	<p>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. <i>See</i> annotated Figs. 2, 3, 6, and 7 below; <i>see also</i> 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. <i>See</i> 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 (<i>see</i> 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.</p> <p>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.</p>

The '417 Patent	Appendix A1: Anticipation by US 5,104,399 to Lazarus (Exh. 1005)
<p>flow and a trailing portion located in the downstream direction thereof,</p>	<p>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. <i>See also</i> 5:47-51.</p> 
<p>said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,</p>	<p>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 (<i>see</i> 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.</p>
<p>whereupon the force applied to said tubular member by the fluid</p>	<p>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</p>

The '417 Patent	Appendix A1: Anticipation by US 5,104,399 to Lazarus (Exh. 1005)
<p>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.</p>	<p>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.”).</p>
<p>2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.</p>	<p>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.</p>
<p>9. The device of claim 1 wherein said tubular member is a stent.</p>	<p>As shown by annotated Figs. 2 and 3 below, the tubular member (“securing ring 16”) is a stent having support members 60. <i>See also</i> 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.”).</p>  <p>The diagrams illustrate the device components. Fig. 2 shows a perspective view of a cylindrical graft 12 with a stent 16 (securing ring) around it. The stent has support members 60 and bifolds 50. Labels include Fluid Flow Direction 100 (or First Direction), Graft 12, Securing Ring 16, Circumferential Bifolds 50, and various reference numerals (12, 13, 14, 15, 16, 17, 50, 52, 54, 56, 64, 86, 88). Fig. 3 shows a cross-sectional view of the stent 16 with support members 60 and wall engaging members 70. Labels include Fluid Flow Direction 100 (or First Direction), Wall Engaging Members 70, Securing Ring 16, Support Members 60, and various reference numerals (60A, 60B, 60C, 60D, 60E, 60F, 60G, 60H, 60I, 60J, 60K, 60L, 60M, 60N, 60O, 60P, 60Q, 60R, 60S, 60T, 60U, 60V, 60W, 60X, 60Y, 60Z, 61A, 61B, 62, 63, 64, 65, 66, 67, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90).</p>
<p>10. The device of claim 9 wherein said stent is</p>	<p>As shown by annotated Figs. 6 and 7 above, the stent (“securing ring 16”) is expandable from a contracted</p>

The '417 Patent	Appendix A1: Anticipation by US 5,104,399 to 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.	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. <i>See also</i> 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 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”).

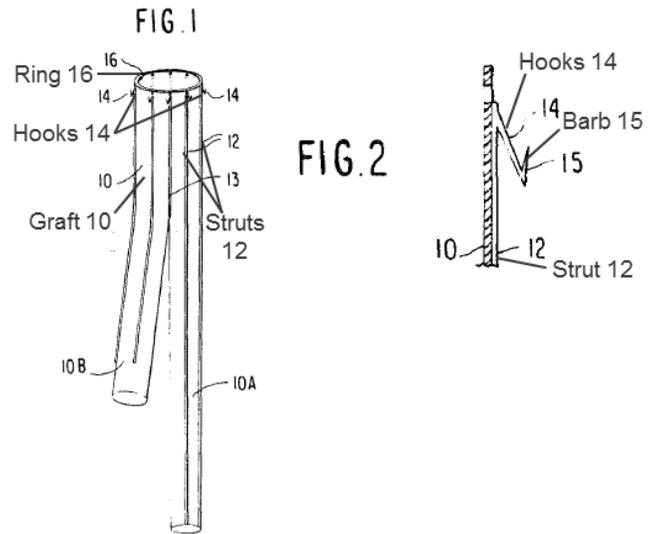
The '417 Patent	Appendix A2: Anticipation by US 4,562,596 to Kornberg (Exh. 1006)
1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface,	To the extent that the preamble is a limitation, Kornberg discloses 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 interior surface. Abstract.
said device comprising a tubular member and anchoring means, said	As shown by annotated Figs. 1 and 2 below, the device (“graft 10”) comprises a tubular member in the form of longitudinal supporting and reinforcing members

The '417 Patent

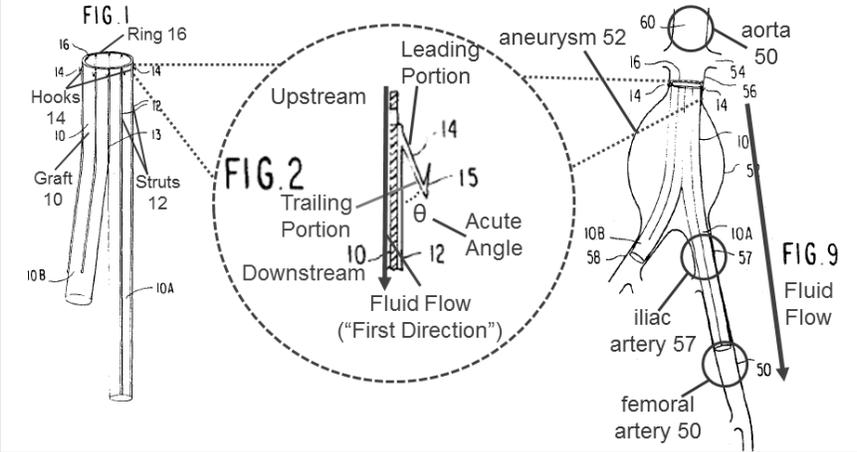
tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,

Appendix A2: Anticipation by US 4,562,596 to Kornberg (Exh. 1006)

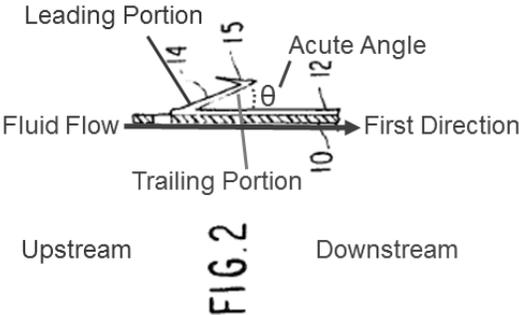
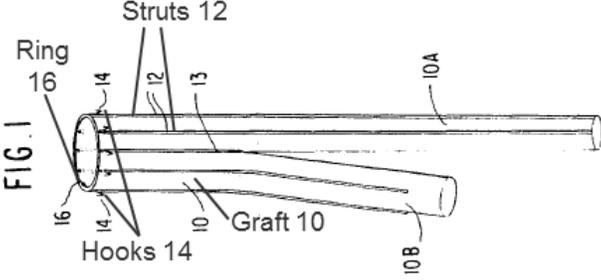
(“struts 12”) attached to the ring 16, and anchoring means in the form of hooks 14. *See also* Abstract, 2:62-65, 3:60-65.

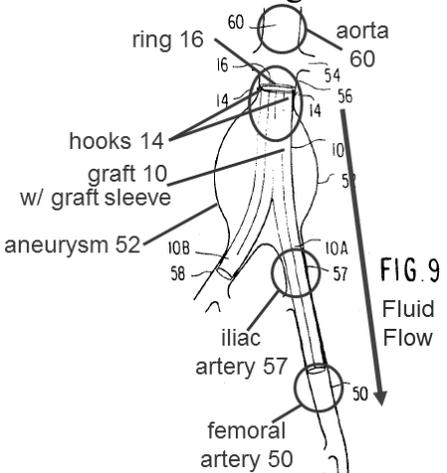


As shown by annotated Fig. 1 above, the tubular member (“struts 12 and ring 16”) has a passageway extending therethrough and an outer periphery. As shown by annotated Figs. 1, 2, and 9 below, the tubular member (“struts 12 and ring 16”) is arranged to have a body fluid (e.g., blood) flow through the passageway in a first direction when the device (“graft 10”) is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member (“struts 12 and ring 16”) as a result of fluid pressure (e.g., blood) passing through the passageway.

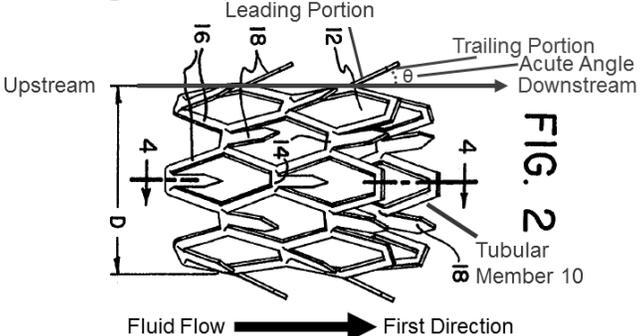


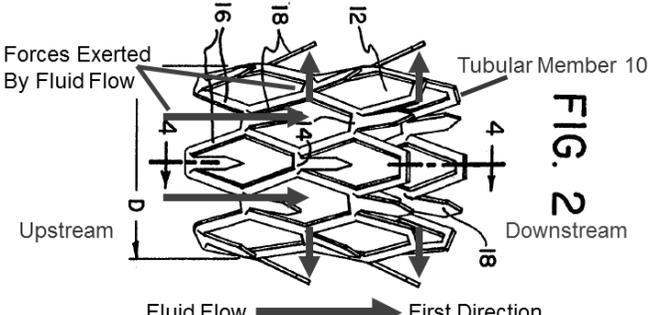
The '417 Patent	Appendix A2: Anticipation by US 4,562,596 to Kornberg (Exh. 1006)
said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen,	As shown by annotated Figs. 1 and 2 above, the anchoring means (“hooks 14”) are located adjacent the outer periphery of the tubular member (“struts 12 and ring 16”) and comprising plural projections (“plural hooks 14”) that are arranged for engagement with the interior surface of the vessel, duct, or lumen. <i>See also</i> Abstract, 3:60-65, 4:6-9, 4:28-36.
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. 1, 2, and 9 above, each of the projections (“hooks 14”) has: (i) a leading portion in the form of the upstream portion of each hook 14 (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 a downstream portion of each hook 14 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow. <i>See also</i> Exh. 1003, pg. 7, ¶ 16 (noting that blood flows from the aorta 60 to femoral artery 50).
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. 1, 2, and 9 above, the trailing portion includes at least one surface (a surface of the downstream portion of each hook 14) that is preferentially oriented to extend at an acute angle to the first direction (<i>see</i> direction of fluid flow in annotated Figs. 2 and 9 above). Each hook 14 may, for example, be “oriented downward at an angle of about 10° to 45° [] with respect to the vertical.” 3:62-67; <i>see also</i> Exh. 1003, pg. 7, ¶ 16 (noting that blood flows from the aorta 60 to femoral artery 50).
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	In Kornberg, the force (e.g., blood pressure) applied to the tubular member (“struts 12 and ring 16”) by the fluid flowing through the passageway of the tubular member (“struts 12 and ring 16”) would produce on each of the projections (“hooks 14”) a force component. In addition, the at least one surface (a surface of the downstream portion of each hook 14) is tightly engaged with the interior surface of the vessel,

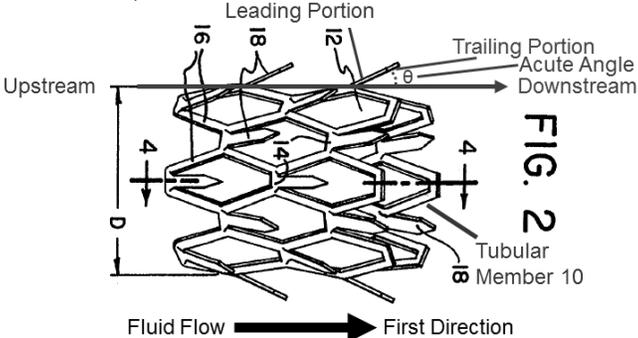
The '417 Patent	Appendix A2: Anticipation by US 4,562,596 to Kornberg (Exh. 1006)
<p>surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.</p>	<p>duct, or lumen, and the device (“graft 10”) is fixedly secured in place. <i>See</i> Abstract (stating that the angled hooks at the upper end of the struts allow the graft to be securely attached to the inside of the aorta), 3:60-61 (explaining that the “attachment of the graft 10 to the inside wall of the aorta is accomplished by the hooks 14 which are located at the upper end of each strut 12”); <i>see also</i> Exh. 1003, pgs. 10-12, ¶¶ 22-26.</p>
<p>2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.</p>	<p>As shown by annotated Fig. 2 below, at least one surface of the trailing portion of each projection (“hook 14”) is inclined upward in the first direction (“fluid flow direction”) when the device (“graft 10”) is placed in a vessel, duct, or lumen.</p>  <p style="text-align: center;">FIG. 2</p>
<p>9. The device of claim 1 wherein said tubular member is a stent.</p>	<p>As shown by annotated Fig. 1 below, the tubular member (“struts 12 and ring 16”) is a stent comprising longitudinal supporting and reinforcing members called struts 12 and the ring 16 that functions to keep the device (“graft 10”) expanded. <i>See also</i> 2:62-65, 6:35-37.</p>  <p style="text-align: center;">FIG. 1</p>
<p>10. The device of claim 9 wherein said stent is expandable from a contracted state to an</p>	<p>Kornberg discloses that the stent (“struts 12 and ring 16”) is expandable from a contracted state to an expanded state, where the anchoring means (“hooks 14”) engage the interior surface of the vessel, duct, or</p>

The '417 Patent	Appendix A2: Anticipation by US 4,562,596 to Kornberg (Exh. 1006)
<p>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.</p>	<p>lumen when the stent (“struts 12 and ring 16”) is in the expanded state to secure the device (“graft 10”) in place. 4:6-12 (stating that the ring 16 may be in “a compressed, or partially open state prior to positioning [of the graft 10] in the damaged [blood vessel],” and that the ring 16 may be expanded and the hooks 14 may pierce the blood vessel after the graft 10 is in position); <i>see also</i> annotated Fig. 9 below (illustrating that the hooks 14 engage the interior surface of the blood vessel when the ring 16 and the struts 12 are in the expanded state to secure the graft 10 in place).</p>  <p style="text-align: right;">FIG. 9 Fluid Flow</p>
<p>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.</p>	<p>Kornberg discloses that the device (“graft 10”) is an endovascular graft where the endovascular graft additionally comprises a graft sleeve (“cylindrical, hollow, bifurcated sleeve”). 2:62-65. As shown by annotated Fig. 9 above, the graft sleeve (“cylindrical, hollow, bifurcated sleeve”) is coupled to the stent (“struts 12 and 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”) to apply the force (e.g., blood pressure) to the projections (“hooks 14”).</p>

The '417 Patent	Appendix A3: Anticipation by US 5,397,355 to Marin (Exh. 1007)
<p>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,</p>	<p>To the extent that the preamble is a limitation, Marin discloses an intraluminal medical device (“stented graft”) for securement within a vessel, duct, or lumen of a living being, where the vessel, duct, or lumen has an interior surface. Abstract.</p>
<p>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,</p>	<p>Marin discloses that the device (“stented graft”) comprises a tubular member in the form of a tubular mesh-like member 10, and anchoring means in the form of barbs 18 adapted to engage the interior surface of a vessel, duct, or lumen. 1:60-62, 2:39-40; <i>see also</i> annotated Figs. 1 and 2 below (illustrating a stent of the stented graft in a compacted state and an expanded state, respectively). As shown by annotated Fig. 2 below, the tubular member 10 has a passageway extending therethrough and an outer periphery.</p> <div data-bbox="670 1010 1349 1486" data-label="Image"> </div> <p>As shown by annotated Fig. 2 below, the tubular member 10 is arranged to have a body fluid (e.g., blood) flow through the passageway in a first direction when the device (“stented graft”) is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member 10. <i>See also</i> 2:54-59 (stating that the tubular member 10 “must be strong enough to withstand any pressure applied by the blood vessel . . .</p>

The '417 Patent	Appendix A3: Anticipation by US 5,397,355 to Marin (Exh. 1007)
	<p>in which it is placed”).</p>  <p style="text-align: center;">FIG. 2</p>
<p>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,</p>	<p>As shown by annotated Fig. 2 above, the anchoring means (“barbs 18”) are located adjacent the outer periphery of the tubular member 10 and comprising plural projections (“plural barbs 18”) that are arranged for engagement with the interior surface of the vessel, duct, or lumen. <i>See also</i> 3:11-15 (stating that the barbs 18 engage the interior surface of the blood vessel to anchor the stent in place).</p>
<p>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,</p>	<p>As shown by annotated Fig. 2 above, each of the projections (“barbs 18”) has: (i) a leading portion in the form of the upstream portion of each barb 18 (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 barb 18 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow.</p> <p>Marin further discloses that, in one embodiment, each slot/opening 12 can have opposing barbs 18 that extend toward each other in each slot/opening 12 such that two barbs 18 would extend in opposite directions from each circumferential rib 14. 3:26-31. Thus, irrespective of which direction the tubular member 10 is oriented in a body lumen, it would necessarily have at least one of the two barbs 18 in each slot/opening 12 with a trailing portion (downstream portion) that has at least one surface preferentially oriented to extend at an acute</p>

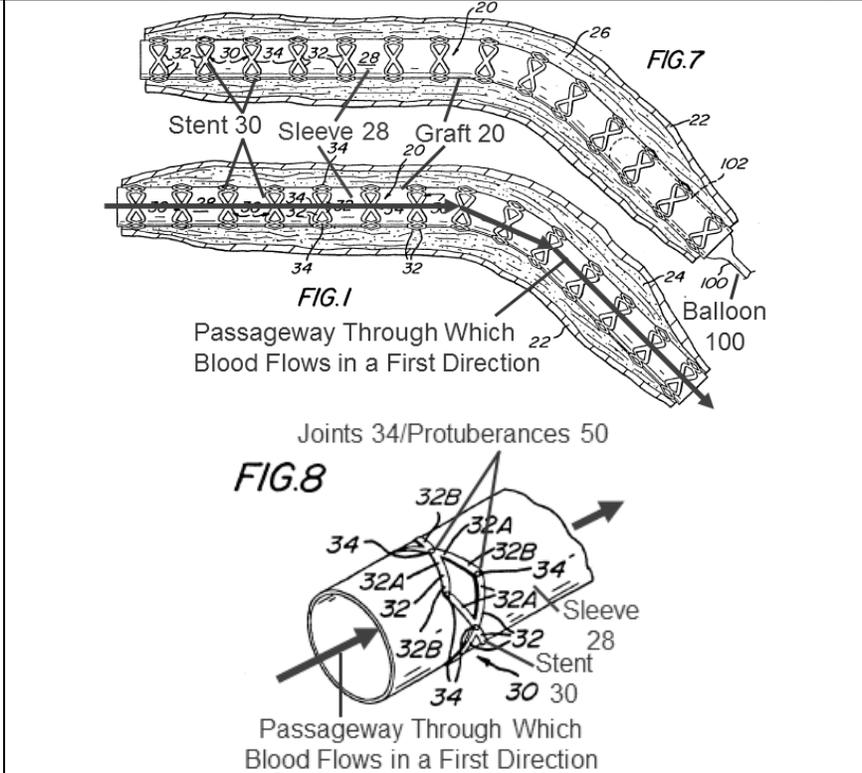
The '417 Patent	Appendix A3: Anticipation by US 5,397,355 to Marin (Exh. 1007)
<p>said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,</p>	<p>angle to the first direction (“fluid flow direction”). As shown by annotated Fig. 2 above, the trailing portion includes at least one surface (a surface of the downstream portion of each barb 18) that is preferentially oriented to extend at an acute angle to the first direction (<i>see</i> direction of fluid flow in annotated Fig. 2 above).</p>
<p>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.</p>	<p>Marin discloses that the force (e.g., blood pressure) applied to the tubular member 10 by the fluid flowing through the passageway of the tubular member 10 produces on each of the projections (“barbs 18”) a force component to cause the at least one surface (a surface of the downstream portion of each barb 18) to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device (“stented graft”) in place. <i>See</i> 1:60-62 (explaining that the barbs 18 are adapted to engage a graft and the interior surface of the blood vessel to mechanically attach the stent to the blood vessel).</p> <p>As explained by Expert Rowe, and shown by annotated Fig. 2 below, the force applied to the tubular member 10 by fluid flowing through the passageway of the tubular member 10 would necessarily and inherently produce a force component on the surfaces of the barbs 18 to cause the surfaces to tightly engage the interior surface of the blood vessel to fixedly secure the stented graft in place. Exh. 1003, pgs. 10-13, ¶¶ 22, 23, 27.</p>  <p>The diagram, labeled FIG. 2, illustrates a tubular member 10 with a series of barbs 18 extending from its outer surface. The tubular member is shown in a perspective view, with fluid flow indicated by a large arrow at the bottom pointing from left to right, labeled 'Fluid Flow' and 'First Direction'. The flow enters from the 'Upstream' end and exits at the 'Downstream' end. The barbs 18 are shown in a staggered arrangement. Arrows labeled '4' point from the barbs towards the interior of the tubular member, representing the forces exerted by the fluid flow. A vertical dimension line labeled 'D' indicates the diameter of the tubular member. The barbs are shown to be oriented such that their trailing surfaces engage the interior surface of the vessel or duct.</p>
<p>2. The device of claim 1 wherein said at least one</p>	<p>As shown by annotated Fig. 2 below, at least one surface of the trailing portion of each projection (“barb</p>

The '417 Patent	Appendix A3: Anticipation by US 5,397,355 to Marin (Exh. 1007)
surface is inclined upward in the first direction.	<p>18”) is inclined upward in the first direction (“fluid flow direction”).</p> 
9. The device of claim 1 wherein said tubular member is a stent.	<p>As shown by annotated Fig. 2 above, the tubular member 10 is a stent. <i>See also 2:39-40.</i> In Marin, the tubular member 10 is able to withstand the pressure applied on the tubular member by a blood vessel in which the tubular member 10 is placed to keep open the blood vessel. <i>See 2:54-59.</i></p>
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.	<p>As shown by annotated Figs. 1 and 2 above, the stent (“tubular member 10”) is expandable from a contracted state (Fig. 1) to an expanded state (Fig. 2), where the anchoring means (“barbs 18”) engage the interior surface of the vessel, duct, or lumen when the stent (“tubular member 10”) is in the expanded state to secure the device (“stented graft”) in place. <i>See also 3:8-15</i> (stating that expansion of the tubular member 10 causes the barbs 18 to move radially outwardly from the surface of the tubular member 10 to engage the interior surface of the blood vessel to secure the stent in place).</p>
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	<p>Marin discloses that the device (“stented graft”) is an endovascular graft where the endovascular graft additionally comprises a graft sleeve. <i>See 2:20-25</i> (disclosing that the stent comprising the tubular member 10 may be used as part of a stented graft), and 1:14-17 (disclosing that the stented graft may be made of dacron, expanded polytetrafluorethylene (ePTFE), or a natural substitute such as a vein or artery taken from another portion of the body). Marin further discloses that the graft sleeve is coupled to the stent.</p>

The '417 Patent	Appendix A3: Anticipation by US 5,397,355 to Marin (Exh. 1007)
<p>which the body fluid flows in the first direction to apply the force to said projections.</p>	<p><i>See</i> 1:60-62 (stating that the barbs 18 are adapted to engage the graft of the stented graft).</p> <p>As explained by Expert Rowe, the graft sleeve of the stented graft would inherently and necessarily have an outer surface and inner passageway through which the body fluid (e.g., blood) flows in a first direction (“fluid flow direction”) to apply the force (e.g., blood pressure) to the projections. Exh. 1003, pg. 13, ¶ 27.</p>

The '417 Patent	Appendix A4: Obvious Based on US 5,122,154 to Rhodes (Exh. 1008) in View of Lazarus (Exh. 1005)
<p>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,</p>	<p>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.</p>
<p>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,</p>	<p>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. <i>See</i> 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 (<i>see</i> 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.</p>

The '417 Patent **Appendix A4: Obvious Based on US 5,122,154 to Rhodes (Exh. 1008) in View of Lazarus (Exh. 1005)**

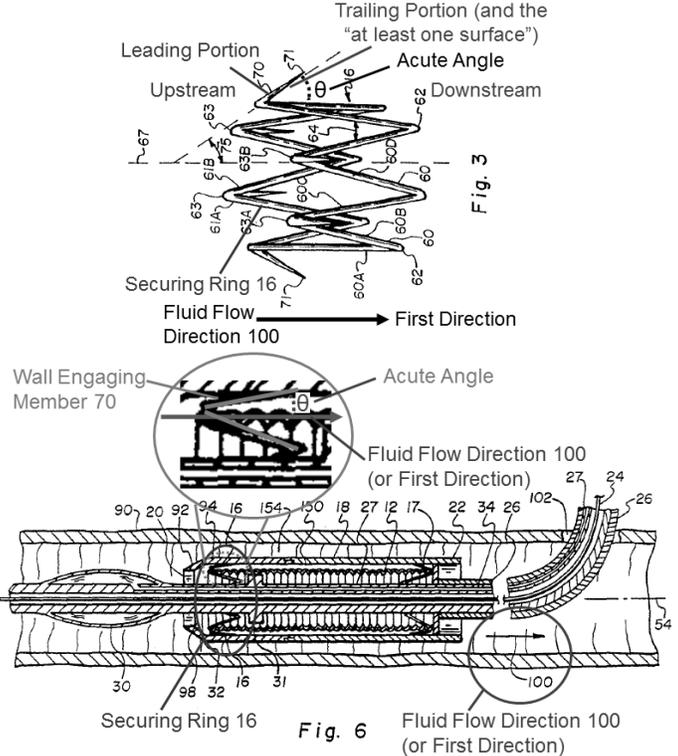


said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen,

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 having a leading portion located in the upstream direction of the fluid

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

The '417 Patent	Appendix A4: Obvious Based on US 5,122,154 to Rhodes (Exh. 1008) in View of Lazarus (Exh. 1005)
<p>flow and a trailing portion located in the downstream direction thereof,</p>	<p>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. <i>See also</i> 5:47-51.</p> 
<p>said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,</p>	<p>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 oriented to extend at an acute angle to the first direction (“fluid flow direction 100”). The acute angle (<i>see</i> 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.</p>
<p>whereupon the force applied to said tubular member by the fluid</p>	<p>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</p>

The '417 Patent	Appendix A4: Obvious Based on US 5,122,154 to Rhodes (Exh. 1008) in View of Lazarus (Exh. 1005)
<p>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.</p>	<p>(“stent 30”) produces on each of the projections (“protuberances”) 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. <i>See</i> 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”).</p> <p>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. 10-13, ¶¶ 22, 23, 28.</p> <p>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. Thus, 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).</p> <p>Rhodes utilizes the projections (“protuberances 50”) to secure the device (“graft 20”) in place within a vessel, duct, or lumen. Exh. 1008, 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. Thus, a 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</p>

The '417 Patent	Appendix A4: Obvious Based on US 5,122,154 to Rhodes (Exh. 1008) in View of Lazarus (Exh. 1005)
	members 70”) that each have at least one surface preferentially oriented to extend 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. Exh. 1004, pgs. 10-11, ¶¶ 26-29.
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. 1008, 5:61-66, and Exh. 1005, 5:4-23.
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.	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 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. <i>See</i> Exh. 1005, 9:38-42.
13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft	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

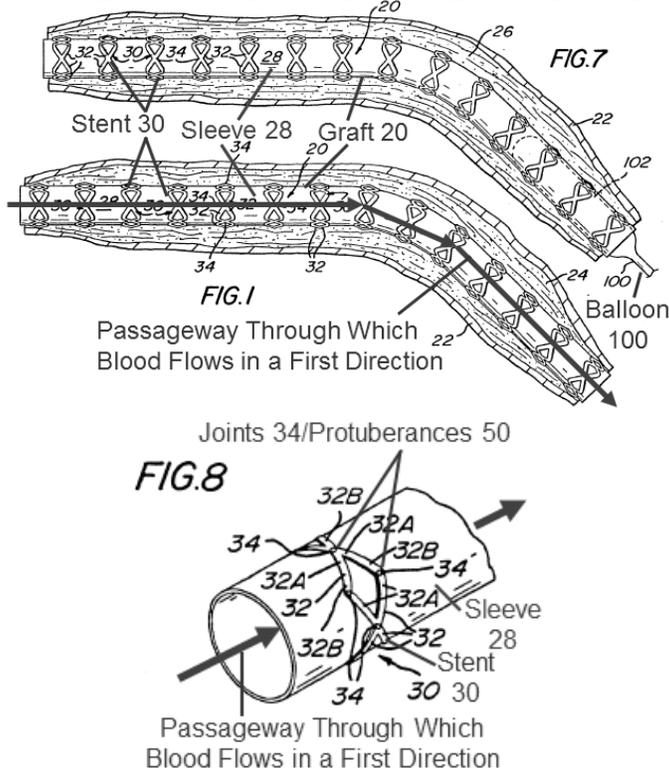
The '417 Patent	Appendix A4: Obvious Based on US 5,122,154 to Rhodes (Exh. 1008) in View of Lazarus (Exh. 1005)
<p>additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.</p>	<p>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; <i>see also</i> annotated Figs. 1 and 8 of Rhodes above.</p> <p>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. Thus, 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).</p>

The '417 Patent	Appendix A5: Obvious Based on Rhodes (Exh. 1008) in View of Kornberg (Exh. 1006)
<p>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,</p>	<p>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.</p>
<p>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</p>	<p>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. <i>See</i> 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 (<i>see</i> annotated Figs. 1, 7, and 8 below) when</p>

The '417 Patent	Appendix A5: Obvious Based on Rhodes (Exh. 1008) in View of Kornberg (Exh. 1006)
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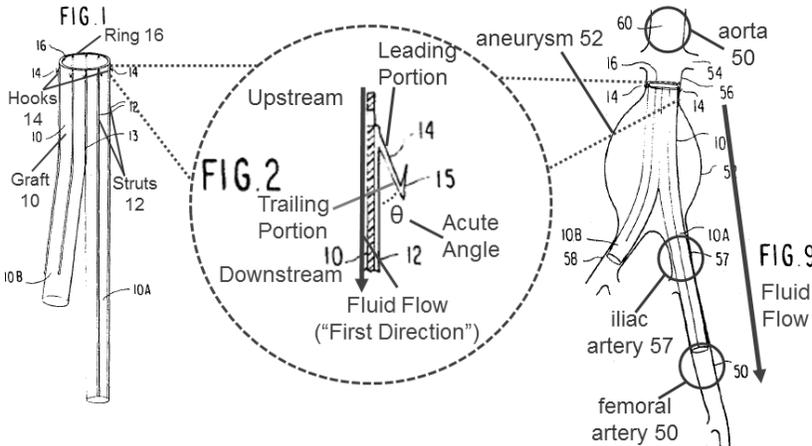
the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,

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,

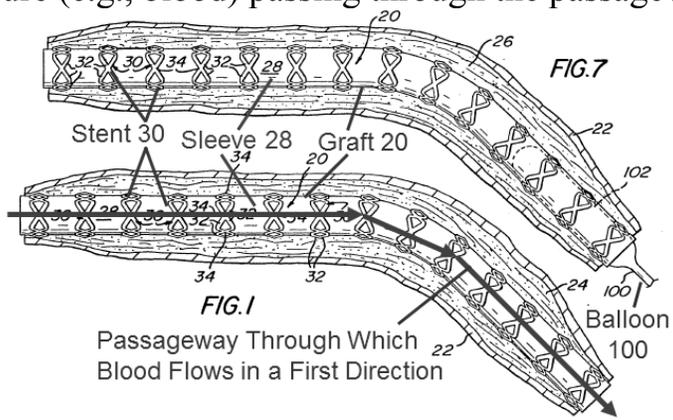
As shown by annotated Fig. 8 above, the anchoring means (“protuberances 50”) are located adjacent the outer periphery of the tubular member (“stent 30”) and comprising plural projections (“plural protuberances 50”) that are arranged for engagement with the interior surface of the vessel, duct, or lumen. *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 joints 34 of the various stents.”)

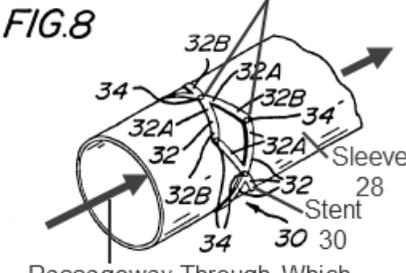
The '417 Patent	Appendix A5: Obvious Based on Rhodes (Exh. 1008) in View of Kornberg (Exh. 1006)
<p>each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof,</p>	<p>Kornberg teaches, as shown by annotated Figs. 1, 2, and 9 below, each of the projections (“hooks 14”) has: (i) a leading portion in the form of the upstream portion of each hook 14 (e.g., a surface that faces the upstream direction of the fluid flow); and (ii) a trailing portion in the form of a downstream portion of each hook 14 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow. <i>See also</i> Exh. 1003, pg. 7, ¶ 16 (noting that blood flows from the aorta 60 to femoral artery 50).</p> 
<p>said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,</p>	<p>Kornberg teaches, as shown by annotated Figs. 1, 2, and 9 of Kornberg above, the trailing portion includes at least one surface (a surface of the downstream portion of each hook 14) that is preferentially oriented to extend at an acute angle to the first direction (<i>see</i> direction of fluid flow in annotated Figs. 2 and 9 above). Each hook 14 may, for example, be “oriented downward at an angle of about 10° to 45° [] with respect to the vertical.” Exh. 1005, 3:62-67; <i>see also</i> Exh. 1003, pg. 7, ¶ 16 (noting that blood flows from the aorta 60 to femoral artery 50).</p>
<p>whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on</p>	<p>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”) a force component to cause the at</p>

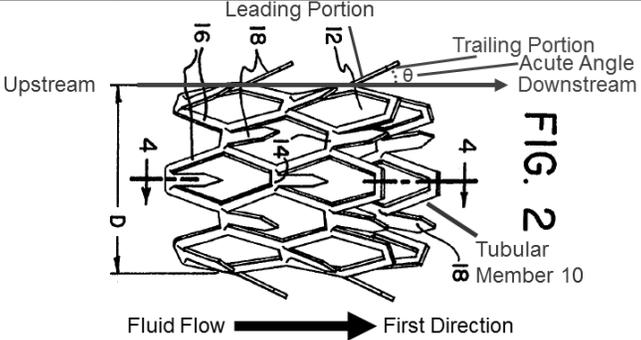
The '417 Patent	Appendix A5: Obvious Based on Rhodes (Exh. 1008) in View of Kornberg (Exh. 1006)
<p>each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.</p>	<p>least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device (“graft 20”) in place. <i>See</i> 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”).</p> <p>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/projections 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. 10-13, ¶¶ 22, 23, 28.</p> <p>Rhodes utilizes the projections (“protuberances 50”) to secure the device (“graft 20”) in place within a vessel, duct, or lumen. Exh. 1008, 7:18-24. Kornberg also utilizes the projections (“hooks 14”) to secure the device (“graft 10”) in place within a vessel, duct, or lumen. Exh. 1006, Abstract, 3:60-65. Thus, a 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 Kornberg (“hooks 14”) that each have at least one surface preferentially oriented to extend 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. Exh. 1004, pgs. 11-13, ¶¶ 30-33.</p>
<p>2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.</p>	<p>Kornberg teaches, as shown by annotated Fig. 2 of Kornberg above, at least one surface of the trailing portion of each projection (“hook 14”) is inclined upward in the first direction (“fluid flow direction”) when the device (“graft 10”) is placed in a vessel, duct,</p>

The '417 Patent	Appendix A5: Obvious Based on Rhodes (Exh. 1008) in View of Kornberg (Exh. 1006)
	or lumen.
9. The device of claim 1 wherein said tubular member is a stent.	Rhodes and Kornberg 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. 1008, 5:61-66, and Exh. 1006, 2:62-65, 6:35-37.
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.	<p>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 50 engage the interior surface of the vessel, duct, or lumen to secure the graft 20 in place).</p> <p>Kornberg similarly teaches that the stent 16 is expandable from a contracted state to an expanded state, where the anchoring means 14 engage the interior surface of the vessel, duct, or lumen when the stent 16 is in the expanded state to secure the device 10 in place. Exh. 1006, 4:6-12.</p>
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.	<p>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; <i>see also</i> annotated Figs. 1 and 8 of Rhodes above.</p> <p>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. Thus, 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).</p>

The '417 Patent	Appendix A6: Obvious Based on Rhodes (Exh. 1008) in View of Marin (Exh. 1007)
<p>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,</p>	<p>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.</p>
<p>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,</p>	<p>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. <i>See</i> 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 (<i>see</i> 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.</p>



The '417 Patent	Appendix A6: Obvious Based on Rhodes (Exh. 1008) in View of Marin (Exh. 1007)
	<p style="text-align: center;">Joints 34/Protuberances 50</p> <p style="text-align: center;">FIG.8</p>  <p style="text-align: center;">Passageway Through Which Blood Flows in a First Direction</p>
<p>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,</p>	<p>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. <i>See also 7:18-30</i> (“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.”)</p>
<p>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,</p>	<p>Marin teaches, as shown by annotated Fig. 2 of Marin below, that each of the projections (“barbs 18”) has: (i) a leading portion in the form of the upstream portion of each barb 18 (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 barb 18 (e.g., a surface that faces the downstream direction) that is located in the downstream direction of the fluid flow.</p>

The '417 Patent	Appendix A6: Obvious Based on Rhodes (Exh. 1008) in View of Marin (Exh. 1007)
	 <p>Marin further discloses that, in one embodiment, each slot/opening 12 can have opposing barbs 18 that extend toward each other in each slot/opening 12 such that two barbs 18 would extend in opposite directions from each circumferential rib 14. 3:26-31. Thus, irrespective of which direction the tubular member 10 is oriented in a body lumen, it would necessarily have at least one of the two barbs 18 in each slot/opening 12 with a trailing portion (downstream portion) that has at least one surface preferentially oriented to extend at an acute angle to the first direction (“fluid flow direction”).</p>
said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction,	Marin teaches, as shown by annotated Fig. 2 of Marin above, that the trailing portion includes at least one surface (a surface of the downstream portion of each barb 18) that is preferentially oriented to extend at an acute angle to the first direction (<i>see</i> direction of fluid flow in annotated Fig. 2 of Marin above).
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”) 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. <i>See</i> 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”).

The '417 Patent	Appendix A6: Obvious Based on Rhodes (Exh. 1008) in View of Marin (Exh. 1007)
	<p>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. 10-13, ¶¶ 22, 23, 28. 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. Thus, 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 '154 and/or to the Marin projections when used with Rhodes '154.</p> <p>Rhodes utilizes the projections (“protuberances 50”) to secure the device (“graft 20”) in place within a vessel, duct, or lumen. Exh. 1008, 7:18-24. Marin also utilizes the projections (“wall engaging members 70”) to secure the device (“graft 12”) in place within a vessel, duct, or lumen. Exh. 1007, Abstract, 3:11-15, 3:29-31. Thus, a 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 Marin (“barbs 18”) that each have at least one surface preferentially oriented to extend 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. Exh. 1004, pgs. 13-14, ¶¶ 34-37.</p>
<p>2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.</p>	<p>Marin teaches, as shown by annotated Fig. 2 of Marin above, that at least one surface of the trailing portion of each projection (“barb 18”) is inclined upward in the first direction (“fluid flow direction”).</p>

The '417 Patent	Appendix A6: Obvious Based on Rhodes (Exh. 1008) in View of Marin (Exh. 1007)
9. The device of claim 1 wherein said tubular member is a stent.	Rhodes and Marin 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. 1008, 5:61-66, and Exh. 1007, 2:39-40, 2:54-59.
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.	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 50 engage the interior surface of the vessel, duct, or lumen to secure the graft 20 in place). Marin similarly teaches that the stent 10 is expandable from a contracted state to an expanded state, where the anchoring means 18 engage the interior surface of the vessel, duct, or lumen when the stent 10 is in the expanded state to secure the device (“stented graft”) in place. Exh. 1007, 3:8-15.
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; <i>see also</i> 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 projections in Rhodes '154 and/or to the Marin projections when used with Rhodes '154.

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

I hereby certify that a true copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 and all exhibits/attachments thereto (Exhs. 1001-1008 and Appendices A1-A6) were served in their entirety by EXPRESS MAIL this 31ST day of OCTOBER, 2013 on the attorney of record of Valentine J. Rhodes, owner of the subject patent, as indicated below:

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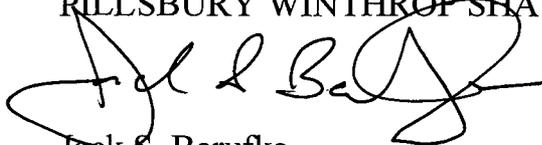
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