UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC,

Petitioners

v.

Medtronic Vascular, Inc.,

Patent Owner

Patent No. 8,206,427
Issue Date: June 26, 2012

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,206,427

Case No. IPR 2018-01571

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1031	Declaration of Brian Durrance
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Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively "Petitioners") respectfully request *inter partes* review of claims 1-42 of U.S. Patent No. 8,206,427 ("the '427 patent") (Ex. 1001). The USPTO assignment records show that the Patent Owner is Medtronic Vascular, Inc. ("Medtronic").

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

A. Real Parties-in-Interest

Petitioners are the real parties-in-interest.

B. Related Matters

This Petition is being filed and served concurrently with petitions for *inter partes* review in IPR No. 2018-01569 and IPR No. 2018-01570. Each of these petitions individually challenges the patentability of claims 1-42 of the '427 patent.

U.S. Application No. 15/349,758 is related to the '427 patent, and is currently pending before the U.S. Patent Office.

C. Lead And Back-Up Counsel

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D. Service Information (§ 42.8(b)(4))

Service on Petitioners may be made by mail or hand-delivery to the lead and back-up counsel at the addresses specified above. Petitioners also consent to service by e-mail at addresses specified above.

II. ADDITIONAL REQUIREMENTS

A. Timing (37 C.F.R. §§ 42.101 And 42.102)

The '427 patent issued on June 26, 2012. Neither Petitioners, nor any of their privies: (1) own the '427 patent; (2) were served with a complaint alleging infringement of the '427 patent; (3) filed a civil action challenging the validity of any claim of the '427 patent; or (4) are barred or estopped from challenging the claims of the '427 patent.

B. Fee For Inter Partes Review (37 C.F.R. § 42.103)

The Office is authorized to charge the required fees specified by 37 C.F.R. § 42.15(a), as well as any other necessary fees, to Deposit Account No. 23-1925.

C. Certification Of Standing (§ 42.104(a))

Petitioners certify that the '427 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

D. Identification Of Challenge, Precise Relief Requested, Specific Art And Statutory Grounds On Which The Challenge Is Based (§ 42.104(b))

The precise relief requested is that claims 1-42 of the '427 patent (Ex. 1001) be found unpatentable, and canceled.

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. § 103(a):[1]

No.	Grounds
1	Claims 1-42 are obvious in view of Mirich[2] (Ex. 1011) and Dumon[3] (Ex. 1007).

[1] The '427 patent issued from U.S. Patent Application No. 08/463,836, filed June 5, 1995. Accordingly, the pre-AIA section of 35 U.S.C. § 103 applies here.

[2] Mirich *et al.*, *Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study*, 170 RADIOLOGY, pp. 1033-1037 (1989).

[3] U.S. Patent No. 5,236,446.

No.	Grounds
2	Claims 1-3, 5-7, 9-11, 13-17, 25-26, 29, 31, and 35 are obvious in view of Barone[4] (Ex. 1005), and one or both of the following: • Parodi 1991[5] (Ex. 1009), and • Parodi 1993[6] (Ex. 1010).
3	Claims 4, 8, 12, 18-24, 27-28, 30, 32-34, and 36-42 are obvious in view of Barone, and one or both of the following: • Parodi 1991, and • Parodi 1993, and in further combination with Mirich.

[4] U.S. Patent No. 5,360,443.

[5] Parodi *et al.*, *Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms*, 5 ANNALS VASCULAR SURGERY, pp. 491-499 (1991).

[6] Parodi, *Endovascular Repair of Abdominal Aortic Aneurysms*, ADVANCES IN VASCULAR SURGERY, Vol. 1, Mosby Year Book, pp. 85-106 (1993).

III. BACKGROUND

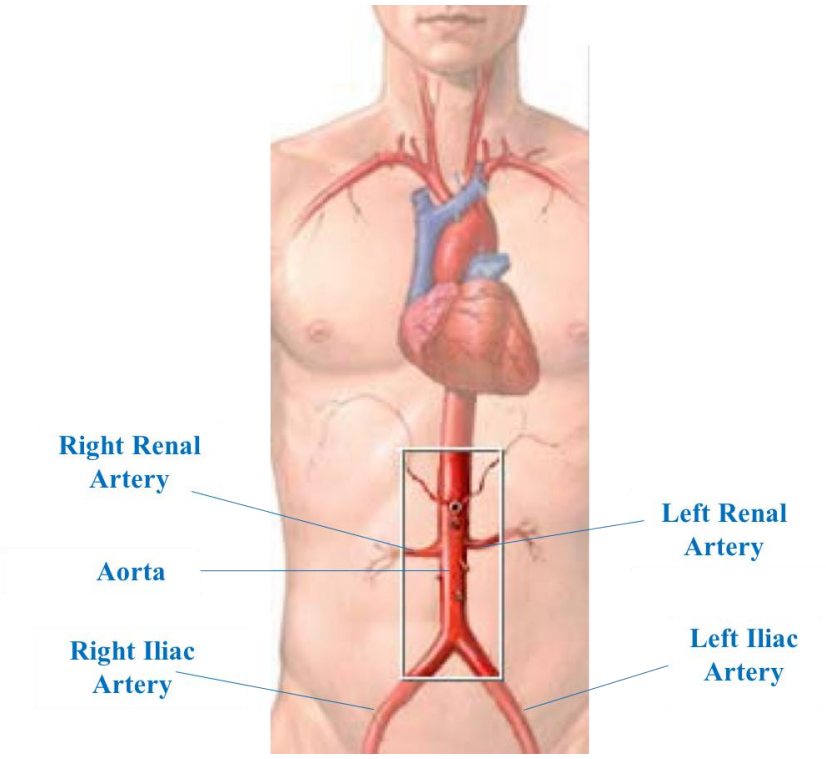
A. Endoluminal Grafts

The '427 patent is entitled "Apparatus and Methods for Endoluminal Graft Placement." (Ex. 1001 at Title). The patent issued from U.S. Patent Application Serial No. 08/463,836 ("the Ryan Application"), filed June 5, 1995, and claims priority to U.S. Patent Application Serial No. 08/255,681 ("the Priority Application"), filed June 8, 1994. (*Id.*, 1:4-5; *see also* Ex. 1003 at 5-47; Ex. 1029, ¶¶27, 40-50). The '427 Patent names as inventors Timothy J. Ryan, Thomas J. Fogarty, Jay A. Lenker, and Kirsten Freislinger (individually and collectively "the Named Inventors"). (Ex. 1029, ¶27).

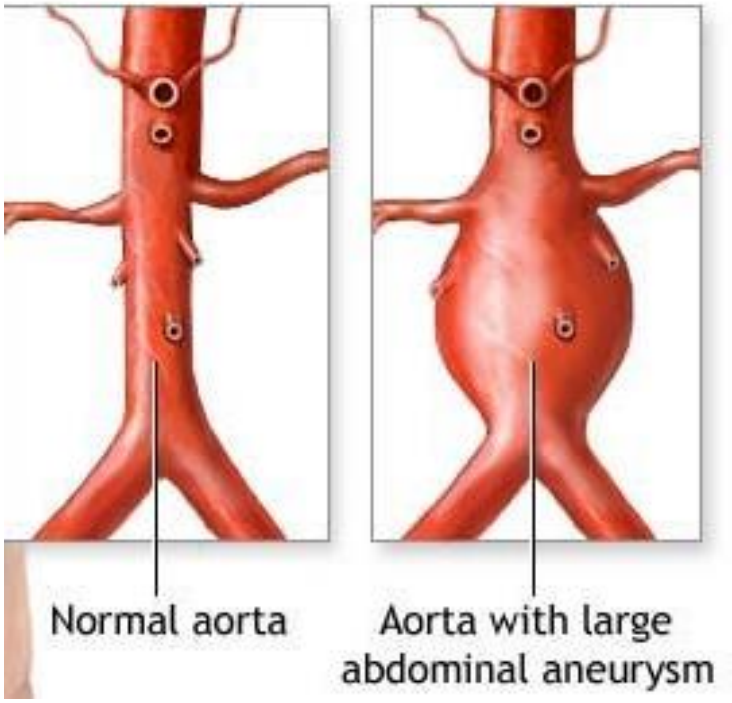
The "Field of the Invention" of the '427 Patent generally includes "apparatus and methods for endoluminal placement of grafts, stents, and other structures." (Ex. 1001 at 1:10-12). The devices and methods of the "invention" are directed to a variety of clinical uses, including "treatment of abdominal and other aneurysms," and for treating "the ureter, urethra, biliary tract, and the like." (*Id.*, 1:12-15, 2:55-57; *see also id.*, 4:66-5:6 (The disclosed devices may be used to treat any condition that would "benefit from the introduction of a reinforcing or protective structure in the lumen."); Ex. 1029, ¶28).

The preferred embodiments of the '427 patent are directed to endoluminal grafts for treating diseases of the vasculature, including aortic aneurysms.

(Ex. 1001 at 1:12-15, 2:31-33, 2:48-55, 10:23-11:7). The aorta is the largest blood vessel in the body, which carries blood from the heart toward the arms, legs, and head. The aorta, and branch vessels (including renal and iliac arteries) are illustrated below:

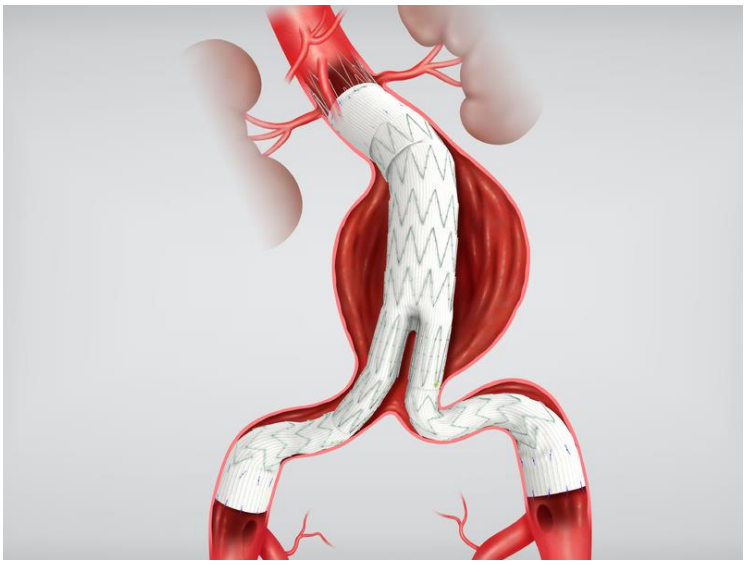


(Ex. 1029, ¶29). Aortic aneurysms occur when the wall of the aorta (and sometimes branch vessels), loses elasticity, causing the vessel to increase in diameter, or "balloon," as shown below.



(*Id.*, ¶30).

Endoluminal grafts are used by physicians to repair aortic aneurysms. The graft is inserted into the lumen of the aorta, typically using a series of catheters and sheaths inserted remotely, either through the patient's arms or legs. The following image depicts an endoluminal graft used to treat an abdominal aortic aneurysm.



(*Id.*, ¶31).

B. The ’427 Patent

1. Disclosed Method

The ’427 patent describes the method of the “present invention” as introducing into the body three components, one at a time, as shown below in annotated Figures 8, 10, and 12 (depicting “bifurcated base structure” (highlighted in green), “first tubular graft” (highlighted in red), and “second tubular graft” (highlighted in red) components).

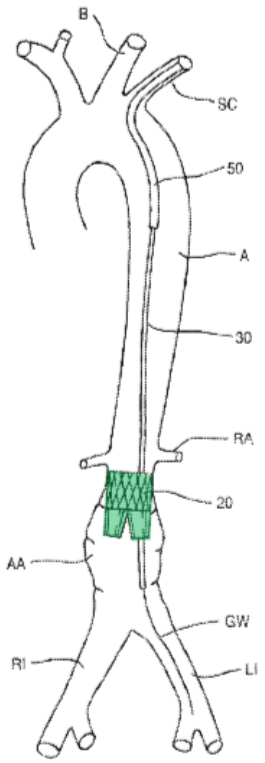


FIG. 8

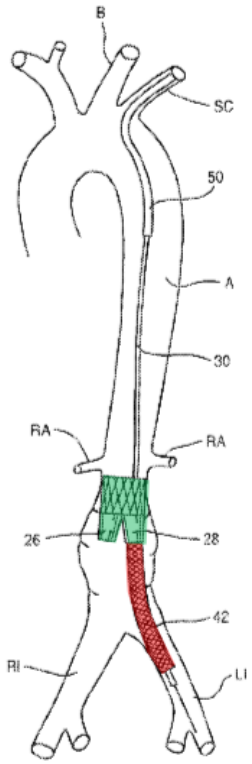


FIG. 10

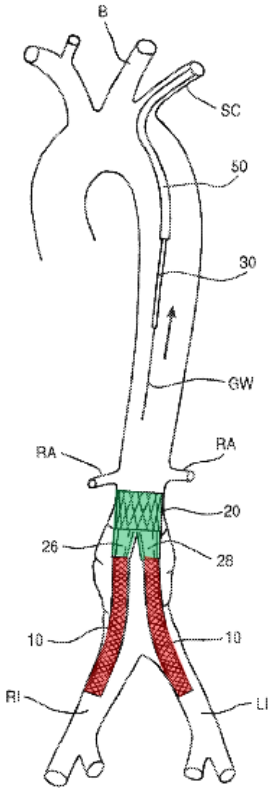


FIG. 12

(Ex. 1029, ¶¶33-35; Ex. 1001 at 3:37-62).

2. Claims

The ’427 patent includes two independent claims: claims 1 and 15. Each claim recites a “method” for “introducing a vascular graft into a primary artery which [divides/branches] into first and second branch arteries.” (Ex. 1001 at 11:14-16, 12:7-9). The method of claim 1 recites three “introducing” steps – one each for a “bifurcated structure,” a “first tubular graft,” and a “second tubular graft.” (Ex. 1001 at 11:14-32; Ex. 1029, ¶37). The method of claim 15, on the other hand, recites only one “introducing” step. (Ex. 1001 at 12:7-15; Ex. 1029, ¶38). Claims 2-14 depend from independent claim 1 and recite all of the limitations of claim 1. Claims 16-42 depend from claim 15 and recite all of the limitations of claim 15. (*Id.*, ¶39).

3. Prosecution History

The Ryan Application was filed as a divisional of the June 8, 1994 Priority Application. (Ex. 1029, ¶¶40-41). During prosecution, the Named Inventors attempted to establish an invention date earlier than June 8, 1994, based on invention disclosures purportedly created by named inventors Lenker and Ryan. (*See* Ex. 1002 at 2202-2213; Ex. 1026 at 5-8 ("Ryan Disclosure"), 9-12 ("Lenker Disclosure"); Ex. 1029, ¶45). The Patent Office never addressed whether these disclosures describe any "invention," or whether the Named Inventors are entitled to an earlier invention date. (Ex. 1029, ¶46). Patent Owner has since told the Patent Office that the Lenker Disclosure does *not* disclose the subject matter of the claims. (*Id.*, ¶50; Ex. 1002 at 2095-2097). As Petitioners' expert, Dr. Criado, explains, neither Disclosure discloses all of the limitations of independent claims 1 or 15, and neither demonstrates an "invention" of the claimed methods prior to June 8, 1994. (Ex. 1029, ¶¶51-61).

During prosecution, the Patent Office issued an Office Action rejecting application claim 27 (ultimately issued as claim 1), as anticipated by Barone (Ex. 1005). (Ex. 1002 at 2000-2001; Ex. 1029, ¶49). The Patent Office's rejection, and Patent Owner's response, are discussed below in Section IV.C.2. (Ex. 1029, ¶49).

C. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art ("PHOSITA") as of the time of the filing of the Priority Application, (and generally in the 1993-1994 timeframe), would have included a mechanical or biomedical engineer with experience developing and making stents, grafts, or stent grafts; or is a physician with experience in both developing and making stents, grafts, or stent grafts and in the intraluminal placement of stent grafts or stents, with the understanding that such experience may come from education or training. (Ex. 1029, ¶¶16-17).[7] With respect to the '427 patent, the BPAI previously found that the PHOSITA "is presumed to possess some logic and skill that is independent of what is disclosed in an item of prior art." (Ex. 1002 at 219; Ex. 1027 at 65).

Petitioners submit the Declaration of Enrique Criado, M.D. (Ex. 1029). Dr. Criado is a vascular surgeon, and Chief of Vascular Surgery at MidMichigan Health, which is affiliated with the health care division of the University of Michigan. (Ex. 1029, ¶4). As reflected in his *curriculum vitae* (included in Ex. 1029), Dr. Criado had extensive experience in the 1993-1994 timeframe with

[7] The same definition of a person having ordinary skill in the art, as well as the analysis of the prior art references discussed in this petition, would apply anytime in the 1993-1994 timeframe. (Ex. 1029, ¶17).

endoluminal devices and methods. (*Id.*, ¶¶4-12, 18, Exhibit B). Dr. Criado qualified as a PHOSITA in the 1993-1994 timeframe, and his Declaration addresses the '427 patent and prior art from the perspective of a PHOSITA at that time. (*Id.*, ¶¶18-19).

D. State Of The Prior Art

The prior art disclosed devices and methods for treating damaged or diseased vessels. (Ex. 1029, ¶¶62-79). For example, the prior art disclosed using vascular grafts, (*id.*, ¶¶62-64), and stents, (*id.*, ¶¶65-69), for treating vessels.

By the 1993-1994 timeframe, two types of stents had emerged: (1) balloon-expandable stents; and (2) self-expanding stents. Balloon-expandable stents cannot expand on their own, and require an external force to expand – typically provided by a balloon. (*See* Ex. 1023 (describing balloon-expandable "Palmaz stent")). Self-expanding stents, on the other hand, are capable of expanding on their own due to mechanical and/or thermal resilience of the material from which they are manufactured.[8] (*See* Ex. 1019 (describing self-expanding "Z-stent")). Both types of stents were considered viable candidates for treating damaged or diseased vessels. (Ex. 1029, ¶¶65-69).

The prior art also disclosed stent grafts (or covered stents), for treating vessels. (*Id.*, ¶¶70-73). The prior art disclosed that stents and stent grafts can be

[8] The '427 patent distinguishes self-expanding and balloon-expandable stents using the terms "resilient" (self-expanding), and "malleable" (balloon-expandable). (*See* Ex. 1001 at 6:47-7:17). A PHOSITA would have recognized that "resilient" stents are self-expanding, and "malleable" stents are balloon-expandable. (Ex. 1029, ¶66).

formed in the body by inserting multiple devices, one after the other, and connecting the devices within the body. (Ex. 1029, ¶¶74-78; Ex. 1004 at 2:65-67; Ex. 1006 at 12:36-41; Ex. 1008 at 10; Ex. 1010 at 99, 103-104; Ex. 1019 at 5:17-22; Ex. 1009 at 495). The prior art disclosed using straight and/or bifurcated devices, depending on the shape of the vessel being treated. (Ex. 1029, ¶79; Ex. 1004 at Figure 10; Ex. 1005 at Figure 12; Ex. 1006 at Figure 20; Ex. 1007 at Figure 5).

E. Claim Construction (§ 42.104(b)(3))

A claim subject to *inter partes* review receives the "broadest reasonable construction [("BRI")] in light of the specification of the patent in which it appears." 37 C.F.R. §42.100(b). *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278-79 (Fed. Cir. 2015), *aff'd, Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). For the purposes of this *inter partes* review only, Petitioners adopt the following BRI constructions, consistent with the understanding of a PHOSITA.

1. "Simultaneously"

Certain dependent claims describe anchoring a graft "simultaneously" within: (1) a connector or anchor; and (2) a branch artery. (*See, e.g.*, Ex. 1001 at 11:51-55). The term "simultaneously" does not appear in the specification of the '427 patent. (Ex. 1029, ¶81).

The word "simultaneous" ordinarily means "at the same time." (Ex. 1029, ¶82). However, there is no disclosure in the specification of anchoring a graft within a connector/anchor *and* a branch artery "*at the same time*." In the preferred embodiments of the '427 patent, this would require that both ends of the graft expand "at the same time." However, the '427 patent discloses expanding self-expanding grafts from a sheath, by "withdraw[ing]" the sheath from the graft. (Ex. 1001 at 10:37-47). A PHOSITA would have recognized that withdrawing the

sheath from the graft necessarily results in one end of the graft expanding before the other end of the graft (*i.e.* not "at the same time"). (Ex. 1029, ¶82).

In view of this, a PHOSITA would have understood that "simultaneously" means *in the same procedural step*. (*Id.*, ¶83).

2. "Introducing"

Claim 15 recites a step of "*introducing* into a patient's vasculature" two elements: (1) an "anchor section"; and (2) a "first tubular graft."[9] (Ex. 1001 at 12:10-11). During prosecution, the BPAI determined that claim 15 does not require that these two elements "be introduced '*in a single step*' or *simultaneously*." (Ex. 1002 at 202; Ex. 1027 at 48; Ex. 1029, ¶84). Claim 15 is "broadly recited and *imposes no particular manner* for the insertion of the anchor section and the first t[u]bular graft." (Ex. 1027 at 57; Ex. 1029, ¶84). Thus, the "introducing" step in claim 15 includes introducing the anchor section and first tubular graft, *in one or more steps*. (Ex. 1029, ¶84).

[9] All emphases added unless otherwise noted.

3. "Antegrade" / "Retrograde"

Certain claims of the '427 patent state that a component is introduced through an artery in an "*antegrade* direction," (*see, e.g.*, Ex. 1001 at 11:44-45), or a "*retrograde* direction," (*see, e.g.*, *id.*, at 11:47-48). "Antegrade direction" is a direction that is *forward* moving, or in a forward direction *with respect to flow within the vessel*. (Ex. 1029, ¶85). "Retrograde direction" is a direction that is *backward* moving, or in a backward direction *with respect to flow within the vessel*. (*Id.*; Ex. 1001 at 10:25-28, 51-53). In the context of the vasculature, "antegrade" is a direction *away from the heart*, whereas "retrograde" is a direction *towards the heart*, as shown below.

Antegrade (Introduction in the *same direction* as blood flow)

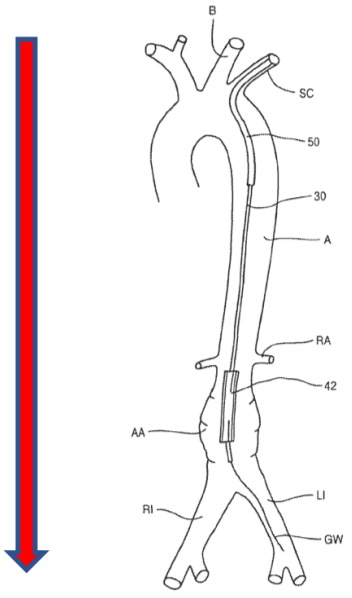


FIG. 7

Retrograde (Introduction in an *opposite direction* with respect to blood flow)

(Ex. 1029, ¶¶36, 85).

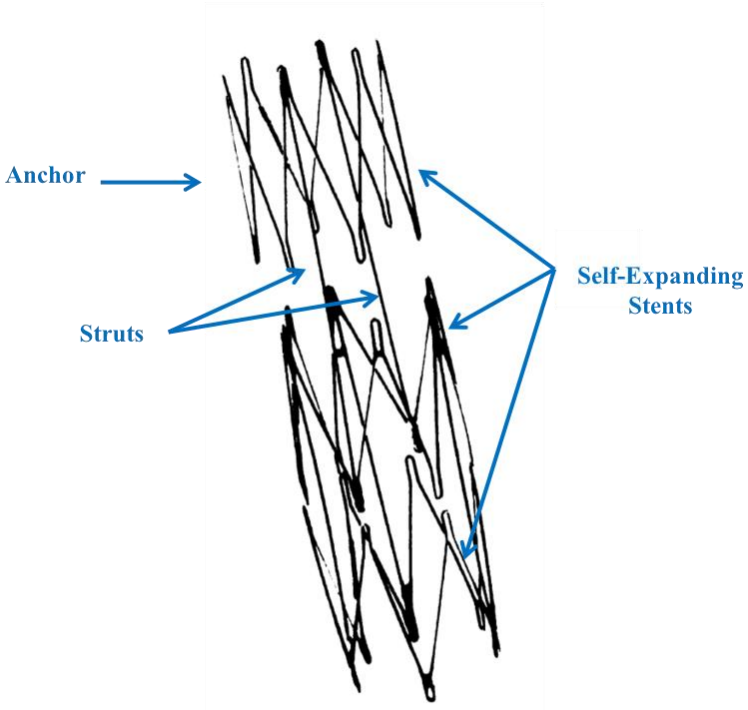
The ’427 patent describes antegrade and retrograde approaches as “conventional.” (Ex. 1001 at 5:12-18; Ex. 1029, ¶36). The decision to use a retrograde approach, versus an antegrade approach, lies within the discretion of the physician. (Ex. 1029, ¶36; Ex. 1017 at 3:20-23; Ex. 1021 at 6:58-60).

IV. SPECIFIC PRIOR ART REFERENCES FORMING THE BASIS FOR UNPATENTABILITY

A. Mirich (Ex. 1011)

Mirich published in 1989 (Ex. 1029, ¶86; Ex. 1031, ¶7), and qualifies as prior art under 35 U.S.C. §§ 102(a) and (b). Mirich is included in the list of "References Cited" in the '427 patent. (*See* Ex. 1001 at 10). Mirich was listed in an IDS dated October 19, 2007, along with hundreds of other references (and thousands of pages of foreign references and non-patent literature). (Ex. 1002 at 1876). Mirich was not substantively addressed on the record during prosecution. (Ex. 1029, ¶86).

Mirich describes a study addressing the feasibility of treating aneurysms with endoluminal grafts. (Ex. 1011 at 1033; Ex. 1029, ¶87). As shown below, the graft "consisted of three or four small, self-expanding Gianturco stents connected in tandem with two stainless steel struts," and a "[n]ylon material…formed into cylinders approximately 7 mm in diameter" (nylon material not illustrated).



(Ex. 1011 at 1033-1034; Ex. 1029, ¶88). The graft was "compressed and advanced through [a] catheter with a blunt-tipped, 8-F introducer wire." (Ex. 1011 at 1034). Once the graft was positioned at the treatment site, "the introducer wire was held tight and the catheter was slowly withdrawn, releasing the graft and allowing it to expand." (*Id.*). The authors disclosed that "it was essential to locate the aneurysm

exactly and bridge it completely" with the graft, because "[o]nce the graft was deployed, it could not be repositioned or retrieved." (*Id.*; Ex. 1029, ¶89). The authors reported that "[i]n all cases, the endovascular graft was successfully placed across the aneurysm." (Ex. 1011 at 1034; *see also id.*, 1033-1037; Ex. 1029, ¶90).

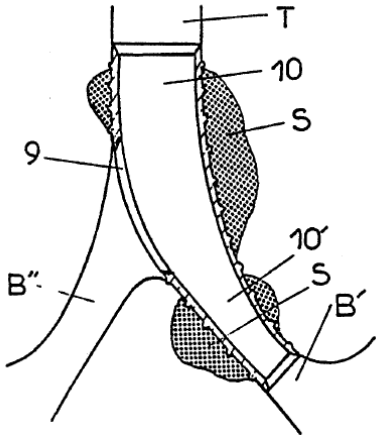
B. Dumon (Ex. 1007)

Dumon issued on August 17, 1993 from a PCT application filed March 2, 1989. (Ex. 1029, ¶91). Dumon qualifies as prior art under 35 U.S.C. §§ 102(a) and (e). Dumon is included in the list of "References Cited" in the '427 patent. (*See* Ex. 1001 at 2). Dumon was listed in an IDS dated October 19, 2007, along with hundreds of other references (and thousands of pages of foreign references and non-patent literature). (Ex. 1002 at 834). Dumon was not substantively addressed on the record during prosecution. (Ex. 1029, ¶91).

Dumon discloses "tubular endoprosthes[e]s for anatomical conduits or channels." (Ex. 1007 at 1:8-9). The endoprostheses "can, as a function of the shape of the anatomical conduit or channel inside which it is intended to be installed, affect a variety of shapes." (*Id.*, 2:30-33; *see also id.*, 2:40-44; Ex. 1029, ¶92).

Dumon discloses in Figure 12 (below) a tubular endoprosthesis including "a major part 10 extended by a second part of smaller diameter 10'," and an "opening 9 laterally placed at the juncture point of the major part 10 and the secondary part 10'." (Ex. 1007 at 3:31-47).

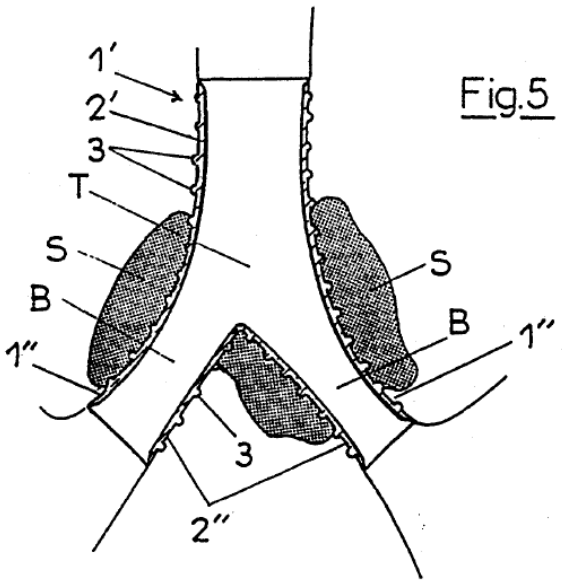
Fig.12



The opening 9 is "intended to be placed at the entry of a second healthy branch," as shown above. (*Id.*, 3:42-43; *see also id.*, 4:64-68; Ex. 1029, ¶93).

Dumon discloses that the opening 9 may "allow and favor the installation of a second independent tubular branch." (Ex. 1007 at 3:47-50). The resulting device would resemble the bifurcated endoprosthesis depicted in Figure 5 of Dumon

(below), including "a principle tube extending into two divergent tubular branches." (*Id.*, 2:37-40).



(Ex. 1029, ¶94).

Dumon's discloses that the endoprostheses are "advantageously made in a material with an elastic deformation capacity," and "may be reinforced by an internal reinforcement capable of being well-tolerated by the organism." (Ex. 1007 at 2:44-50). A PHOSITA would have understood the reference to "internal reinforcement" to include stents. (Ex. 1029, ¶95). Dumon describes using endoprostheses for treating "conduits such as the trachea or bronchus." (Ex. 1007 at 1:9-14). A PHOSITA would have recognized that the techniques described in Dumon would have other clinical applications, including treating aortic aneurysms. (Ex. 1029, ¶96).

C. Barone (Ex. 1005)

Barone issued on November 1, 1994 from a U.S. patent application filed on June 11, 1990. (Ex. 1029, ¶97). Barone qualifies as prior art under 35 U.S.C. § 102(e). Barone names as inventors Hector Barone, Julio Palmaz, and Juan Parodi (individually and collectively, "Barone Inventors"). (Ex. 1005 at 1).

Barone discloses "an aortic graft for intraluminal delivery, and a method and apparatus for repairing an abdominal aortic aneurysm." (Ex. 1005 at 1:6-8; *see also id.*, Abstract). Barone discloses endoluminal grafts and procedures as an alternative to conventional surgery, which has numerous "disadvantages," including "considerable mortality and morbidity" and "high mortality rate," among other things. (*Id.*, 1:32-2:22; Ex. 1029, ¶98).

1. Barone Embodiments

Embodiment #1: As shown below in annotated Figure 6, Barone discloses in a *first* embodiment a graft 150' deployed within aorta 152 and iliac arteries 153, including aneurysms 151 (aortic) and 190 (iliac). (Ex. 1005 at 8:8-22).

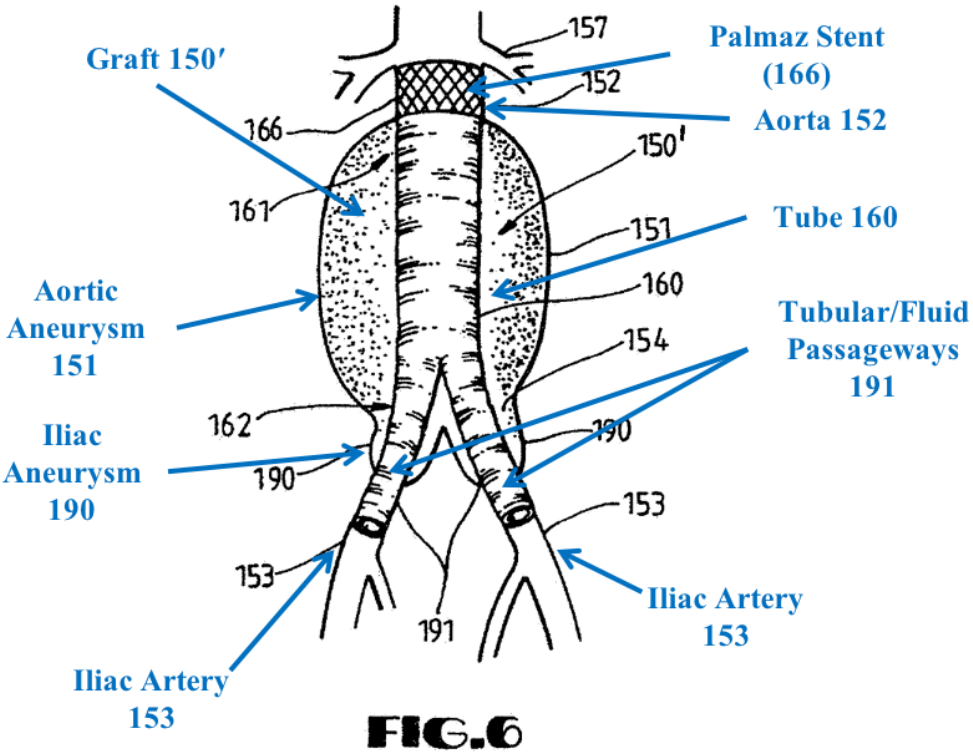
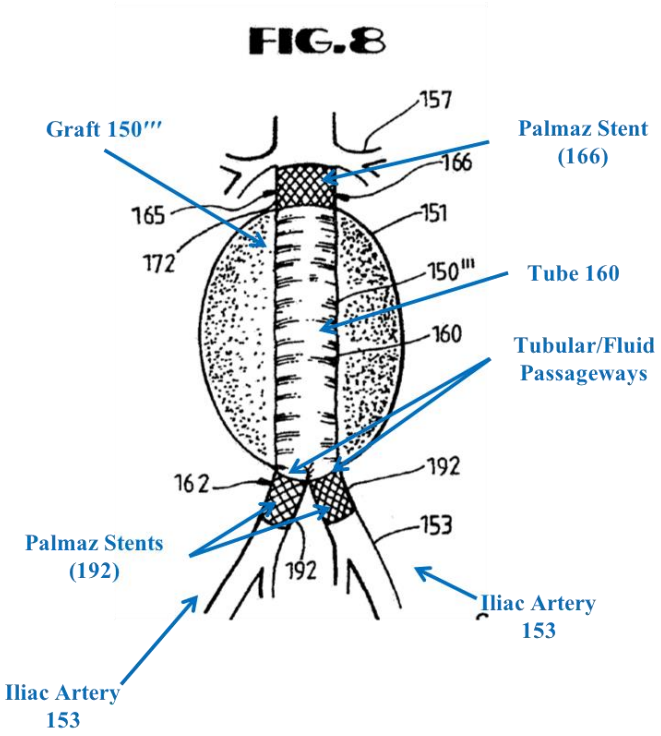


FIG.6

The graft 150' includes tube 160, which "may be made from a variety of materials," such as knitted or woven "Dacron®," or "TEFLON® (polytetrafluoroethylene)," among other things. (*Id.*, 6:55-7:19; 8:11-14). The distal end of tube 160 (furthest away from the heart) is "bifurcated, so that two tubular passageways 191 are formed, which are each in fluid communication with the first end 161 of tube 160, and the fluid passageways 191 are mated with and

disposed within the two iliac arteries 153." (*Id.*, 8:17-22). The graft 150' is secured by a "securing means," or "thin-walled member 166," which a PHOSITA would have recognized may include a Palmaz stent. (*Id.*, 8:11-14, 6:32-47; Ex. 1023; Ex. 1029, ¶99; *see also* Section III.D.). Barone discloses that the securing means may be coated, for example with "TEFLON® or porous polyurethane." (Ex. 1005 at 7:16-19; Ex. 1029, ¶99).

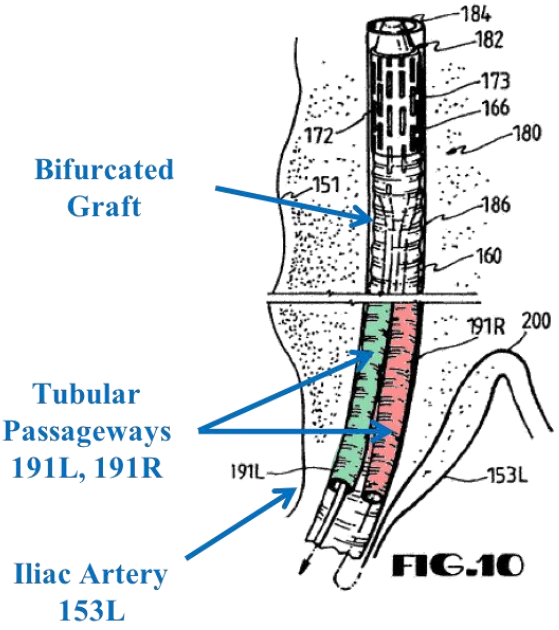
Embodiment #2: Barone discloses in a *second* embodiment "securing means 192," which "insure no movement of passageways 191, caused by body movements." (Ex. 1005 at 8:23-53, 9:13-18, Figure 8). As shown below in annotated Figure 8, bifurcated graft 150''' of Embodiment #2 includes a tube 160 deployed within the aorta, tubular/fluid passageways extending toward the iliac arteries 153, and stents 166, 192 securing tube 160 and each fluid passageway to the aorta and iliac arteries, respectively.



(*Id.*; Ex. 1029, ¶100).

Barone discloses intraluminally delivering vascular grafts within the "sheath" of a "conventional catheter insertion device." (Ex. 1005 at 9:19-51). The vascular grafts may be delivered "through a femoral artery," in a *retrograde* direction, or "through an axillary artery," in an *antegrade* direction. (*Id.*, 4:44-49, 9:19-51, 10:14-36, Figures 1-3, 9-10, 13; *see also id.*, 10:24-29; Ex. 1029, ¶101).

As shown below in annotated Figure 10, Barone discloses introducing bifurcated grafts into the body through a patient's iliac artery 153L.



(Ex. 1005 at 9:19-51; Ex. 1029, ¶102). Both tubular passageways (191L (highlighted in green) and 191R (highlighted in red)) are introduced into the body at the same time, through the same iliac artery–artery 153L. (*Id.*). The overall goal of the procedure, however, is to deploy the graft so that only *one* of the

tubular passageways, (191L (highlighted in green)), is inserted in iliac artery 153L, and the *other* of the tubular passageways, (191R (highlighted in red)), is inserted in the other iliac artery 153R. To accomplish this, Barone discloses using catheters and surgical wires to move tubular passageway 191R: (1) out of iliac artery 153L; (2) up and over the bifurcation of the vessel; and (3) down into iliac artery 153R, as shown below in Figure 11.

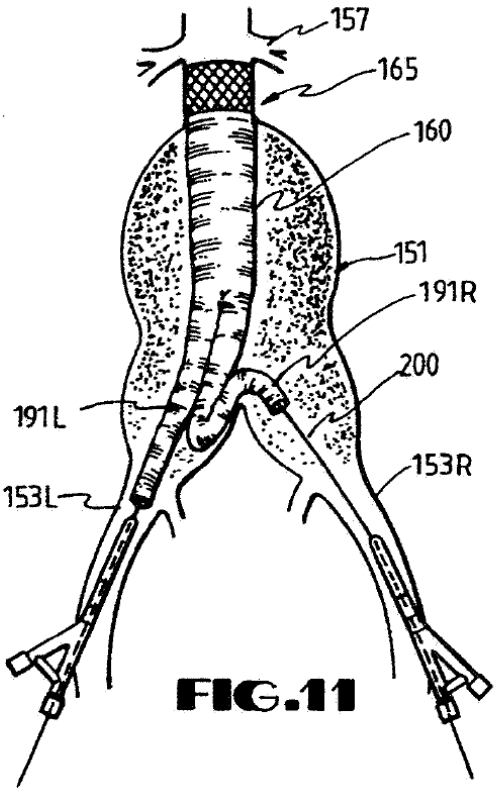


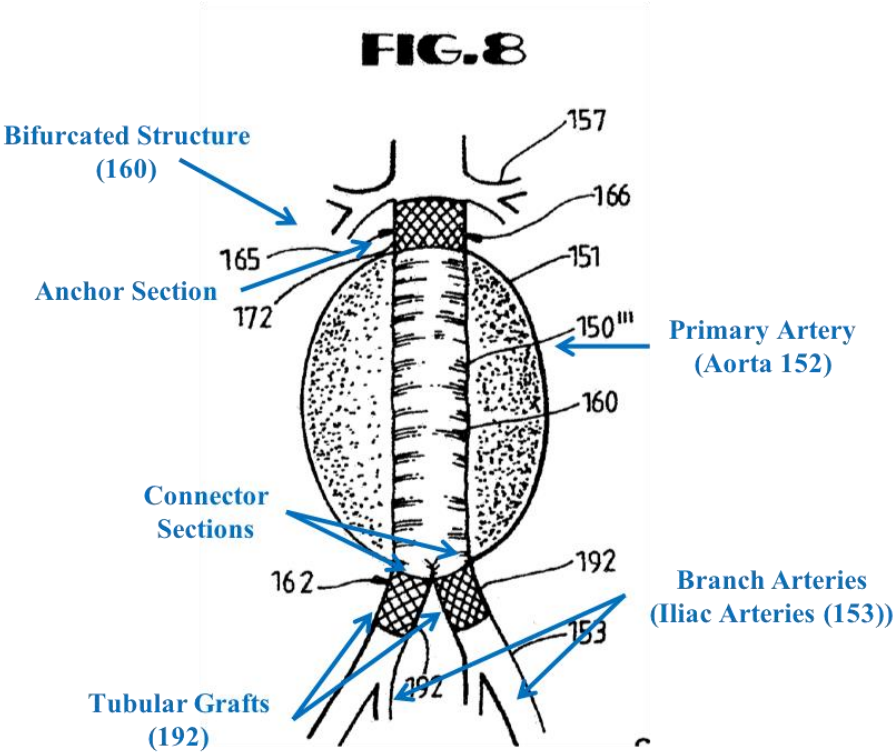
FIG.11

(Ex. 1029, ¶102). A PHOSITA would have recognized that moving tubular passageway 191R from one iliac artery 153L to another iliac artery 153R was a relatively complex procedure, involving relatively advanced catheterization

techniques and a high level of skill, and was beyond the level of skill possessed by most vascular surgeons in the 1993-1994 timeframe. (Ex. 1029, ¶200).

2. Prosecution History

During prosecution, the Patent Office rejected application claim 27 (ultimately issued claim 1), and certain depending claims, as anticipated by Barone *Embodiment #2*. (Ex. 1029, ¶103; Ex. 1002 at 2000-2001). As shown below, Barone Embodiment #2 discloses all of the structural elements recited in claim 1.[10] (Ex. 1002 at 2001).



(Ex. 1029, ¶104).

In response to the Office Action, Patent Owner did not dispute that Barone Embodiment #2 discloses all of the structural elements described in application

[10] Illustration prepared to demonstrate Dr. Criado's opinion.

claim 27. Instead, Patent Owner amended the claim to "clarify" that the introducing step for the "bifurcated structure" is performed "prior to" the introducing steps for the first and second "tubular graft[s]." (Ex. 1002 at 2098 (emphasis in original); *see also id.*, 2087). In its remarks, Patent Owner identified a *single* alleged difference between Barone Embodiment #2 and the amended claim–that Barone Embodiment #2 does not "teach or suggest *separately introducing* first and second grafts into *a previously deployed bifurcated structure*," but instead "introduces the aortic graft (150") into the aorta (152) with stent-like securing means (192) *already attached, i.e., in a single step*." (Ex. 1002 at 2098-2099). Based on Patent Owner's arguments, the Patent Office withdrew its rejection. (Ex. 1029, ¶105).

The Patent Office never addressed on the record whether issued claim 1 (or any other issued claim) would have been obvious in view of Barone.[11] The Patent

[11] "[I]t involves *no invention* to cast in one piece an article which has formerly been cast in two pieces and put together…." *Howard v. Detroit Stove Works*, 150 U.S. 164, 170 (1893). Of course, the inverse is also true. *See Laclede-Christy Clay Prods. Co. v. St. Louis*, 280 F. 83, 85 (8th Cir. 1922) ("Ordinarily, the making of two or more parts out of a thing that had heretofore been used in one part, and using the separate parts to serve the purpose that had been served before the division is not invention.") (*citing Howard*, 150 U.S. 164).

Office also never addressed on the record whether the issued claims would have been invalid in view of Barone *Embodiment #1*.

D. Parodi 1991 (Ex. 1009)

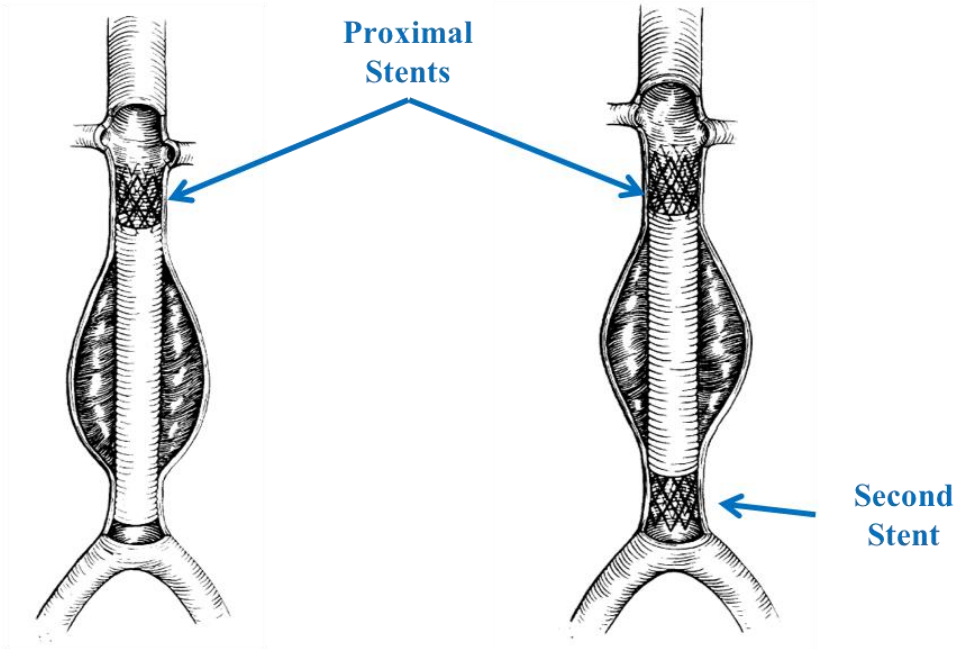
Parodi 1991 published in 1991, (Ex. 1029, ¶107; Ex. 1009 at 1; Ex. 1031, ¶8), and qualifies as prior art under 35 U.S.C. §§ 102(a) and (b). Parodi 1991 names as authors each of the Barone Inventors. Parodi 1991 is included in the list of "References Cited" in the '427 patent. (*See* Ex. 1001 at 12). Parodi 1991 was listed in an IDS dated October 19, 2007, along with hundreds of other references (and thousands of pages of foreign references and non-patent literature). (Ex. 1002 at 1918). Parodi 1991 was not substantively addressed on the record during prosecution. (Ex. 1029, ¶107).

Parodi 1991 describes introduction in patients of "intraluminal, stent-anchored, Dacron prosthetic graft[s]," like the grafts described in Barone. (Ex. 1009 at 491; *see also id.*, 492). The grafts included "either one or two aortic balloon-expandable [Palmaz] stents" sutured to a Dacron graft. (*Id.*, 493). Each patient had "an individually tailored device," with dimensions "determined by data obtained from sonograms, computed tomographic (CT) scans, and arteriograms." (*Id.*, 494; Ex. 1029, ¶108).

In one patient, "the Dacron graft was overly long and the caudal end of the prosthesis lay within the right common iliac artery….effectively exclud[ing] the

contralateral iliac artery from the circulation." (Ex. 1009 at 495). This was a "patently unsatisfactory situation," requiring the patient to be "taken to the operating room where a standard AAA resection [(*i.e.*, conventional surgery)] was performed." (*Id.*; Ex. 1029, ¶109).

In another patient who initially received a graft with only one stent (*see, e.g.*, below left), "reflux was noted at the distal end of the graft" (*i.e.*, the unstented end). (Ex. 1009 at 495).



In this case, "a second stent was [subsequently] placed," (*see, e.g.*, above right). (*Id.*; Ex. 1029, ¶110).

E. Parodi 1993 (Ex. 1010)

Parodi 1993 is a chapter from a book entitled ADVANCES IN VASCULAR SURGERY, Vol. 1, Mosby Year Book (1993). (Ex. 1032, ¶9). According to U.S. Copyright Office registration records, (and consistent with Dr. Criado's recollection), Parodi 1993 published in October 1993. (Ex. 1029, ¶111; Ex. 1030; Ex. 1032, ¶¶9, 25; Ex. 1010-0002). Parodi 1993 qualifies as prior art under 35 U.S.C. § 102(a). *See Celorio Garrido v. Holt*, No. 2013-1194, 2013 U.S. App. Lexis 21363, *12-13 (Fed. Cir. Oct. 22, 2013) (copyright registration of published document sufficient to establish prior art date); *Flir Sys., Inc. v. Leak Surveys, Inc.*, IPR2014-00411, Paper 9 at 19 (PTAB Sept. 5, 2014) ("Copyright notice prima facie establishes a prior art date…."). Parodi 1993 names as the author Barone Inventor Parodi. Parodi 1993 was not cited during prosecution of the '427 patent. (Ex. 1029, ¶111).

Parodi 1993 describes "endovascular treatment for abdominal aortic aneurysms (AAAs) and other arterial diseases." (Ex. 1010 at 85). Treatment included introducing and deploying in patients vascular grafts, like the grafts described in Barone. (*Id.*, 90). The dimensions of the grafts were "tailored to fit the individual patient." (*Id.*; Ex. 1029, ¶112).

In one patient, there was leakage through the proximal stent of the first deployed graft. This was resolved by "successfully deploy[ing] another

stented…graft within the lumen of the [first] graft," resulting in "no further complications." (Ex. 1010 at 99; *see also id.*, 103-104; Ex. 1029, ¶113).

In another patient, "the first graft…implanted was too short to reach the distal neck of the AAA." This was resolved by successfully "deploy[ing] a second stented graft of appropriate length within the lumen of the original graft." (Ex. 1010 at 99; *see also id.*, 104; Ex. 1029, ¶114).

Parodi 1993 concludes that "technical problems related to endovascular grafting probably should be corrected by secondary endovascular procedures whenever possible." (Ex. 1010 at 103 (emphasis in original)). Further, "[i]nadequate graft length" can be resolved by "deploying a second endovascular graft of appropriate length within the lumen of the first one," (*see, e.g.*, Figure below), to extend the length of the graft. (*Id.*, 96, 104).

(Ex. 1029, ¶115).

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO THE CHALLENGED CLAIMS (§§ 42.104(b)(4) AND (b)(5))

There is a reasonable likelihood that Claims 1-42 are unpatentable in view of the grounds identified above in Section II.D.

A. Ground 1: Claims 1-42 Are Obvious In View Of Mirich And Dumon

The '427 patent is directed to endoluminal devices and methods for treating conditions in a variety of vessels, including the aorta, urethra, biliary tract, and the like. (Section III.A.; Ex. 1029, ¶¶28, 117). Mirich and Dumon each relate to the same field of endeavor described in the '427 patent, including "endoluminal placement of grafts, stents, and other structures." (Ex. 1001 at 1:9-12). A PHOSITA would have understood that the devices and methods described in each of these prior art references are pertinent to a problem identified in the '427 patent–providing improved intraluminal methods. (Ex. 1001 at 1:61-64; Ex. 1029, ¶118). A PHOSITA interested in improving intraluminal methods for introducing a vascular graft into an artery would have considered each of these references, in view of the common structures, techniques, and goals described in these references, and would have been motivated to combine these references. (Ex. 1029, ¶118).

In determining whether to institute *inter partes* review, the Board considers whether "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). As explained above in Sections IV.A.–B., Mirich and Dumon each were independently cited to the Patent Office in a lengthy IDS. However, neither of these references was substantively addressed on the record, either alone or in combination as described below. (Ex. 1029, ¶¶86, 91). Further, the Patent Office never considered Dr. Criado's testimony that claims 1-42 would have been obvious in view of Mirich and Dumon, as described below. Thus, the Board should institute *inter partes* review here. *See Pure Storage, Inc. v. Realtime Data LLC*, IPR2018-00549, Paper 7 at 11 (July 23, 2018) (instituting review where "[t]here is no evidence of record that [the cited art] w[as] substantively considered by the Examiner"); *St. Jude Med., LLC v. Snyders Heart Valve LLC*, IPR2018-00106, Paper 15 at 12 (May 3, 2018) ("The evidence of record does not demonstrate that the Examiner considered the references in the combinations relied upon by Petitioner or addressed arguments similar to those Petitioner now presents before the Board as the basis for the unpatentability of the challenged claims."); *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00483, Paper 10 at 15 (July 15, 2015) (instituting review based on prior art disclosed in a "lengthy Information Disclosure Statement,"

where "reference was not applied against the claims and there is no evidence that the Examiner considered the particular disclosures cited by [Petitioner]").

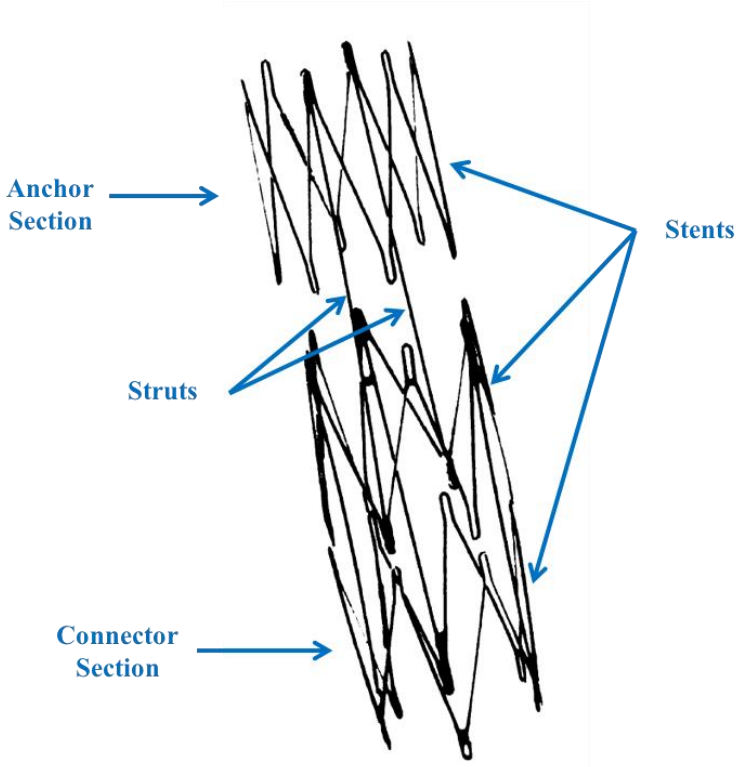
1. Claim 1

a. "A method for introducing a vascular graft into a primary artery which divides into first and second branch arteries, said method comprising"

The preamble is not limiting. Nonetheless, Mirich discloses the "method" described in the preamble. (Ex. 1029, ¶119; Ex. 1011 at 1033, 1035).

b. *"introducing and deploying a bifurcated structure including an anchor section and first and second connector sections so that the anchor section is disposed within the primary artery and the first and second connector sections extend toward the first and second branch arteries"*

As illustrated below, Mirich discloses a graft structure including an anchor section and a connector section.



The graft structure "consist[s] of three or four small, self-expanding Gianturco [Z-] stents connected in tandem with two stainless steel struts," and a nylon graft material. (Ex. 1011 at 1033). A PHOSITA would have recognized that these structures are capable of being overlapped to increase the overall length of the

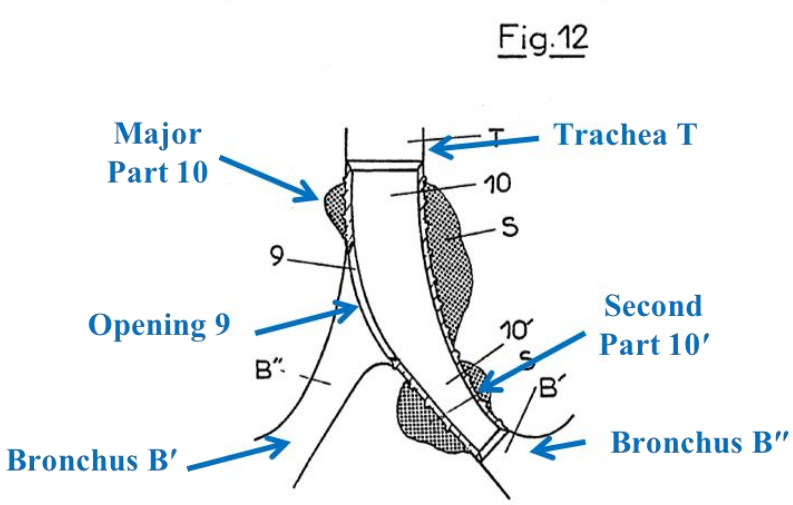
graft, as was well known in the prior art for Z-stents. (Ex. 1029, ¶120; Ex. 1019 at 2:24-27, 5:17-22, Figure 8; Ex. 1008 at 10).

Mirich does not explicitly disclose a bifurcated structure, however this is not a patentable distinction. (Ex. 1029, ¶121). A PHOSITA would have understood that the shape and size of a vascular graft should conform to the shape and size of the damaged or diseased vessel. (Ex. 1029, ¶121; Ex. 1004 at 2:59-3:4, 10:28-40; Ex. 1006 at 12:36-41; Ex. 1007 at 2:30-33, 2:40-44; Ex. 1008 at 10).

A PHOSITA would have been motivated to use a bifurcated graft, rather than a mere straight graft, if the aortic aneurysm being treated extends beyond the aorta into one or both of the iliac arteries (a so-called aortoiliac aneurysm). (Ex. 1029, ¶122). In such cases, it would have been obvious to construct the Mirich graft in a bifurcated configuration, and to introduce and deploy the bifurcated structure so that the anchor section is disposed within the aorta (a primary artery), and first and second connector sections extend toward the first and second iliac arteries (branch arteries). (*Id.*). Constructing the Mirich graft in a bifurcated configuration would have been considered obvious and routine to a PHOSITA, and would have involved simple and well-known mechanical components disclosed in Mirich (including self-expanding Z-stents and a nylon graft material). (*Id.*).

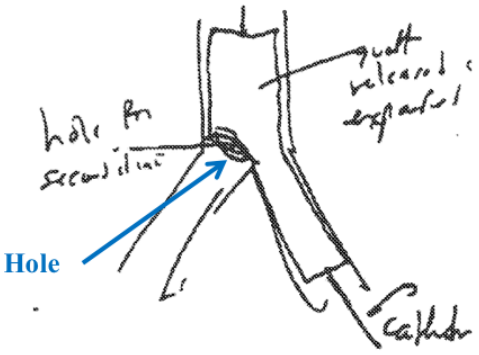
As explained above in Section IV.B., Dumon discloses a method of introducing a bifurcated endoprosthesis, by separately introducing and deploying multiple prosthesis components. (Ex. 1029, ¶123; Ex. 1007 at 3:31-50, Figures 5, 12). The Dumon method, (assembling a bifurcated device *in situ* from multiple, individually inserted components), would have been considered simple and easy to perform. A PHOSITA would have recognized that the Dumon method could easily be applied to the Mirich grafts. (Ex. 1029, ¶124).

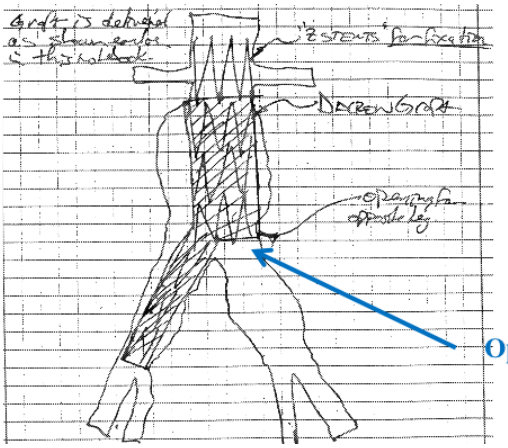
For example, it would have been obvious to construct a modified Mirich graft, including a major part 10, secondary part 10', and opening 9 laterally placed at the juncture point of the major part 10 and the secondary part 10', as depicted in annotated Dumon Figure 12, below.



It would have been obvious to introduce and deploy the modified Mirich graft, so that: (1) the major part 10 (anchor section) is disposed within the aorta (a primary artery); (2) the secondary part 10' (a connector section) is disposed within the first iliac artery (a first branch artery); and (3) the opening 9 is placed at the branching point between the aorta and the second iliac artery (a second branch artery). (Ex. 1029, ¶124).

The Named Inventors argued during prosecution that the '427 patent is entitled to an invention date based on invention disclosures depicting connector sections in the form of a hole, or an opening, as illustrated below.





(Ex. 1026 at 6, 10; Section III.B.3). For purposes of this ground, Petitioners accept the Named Inventors' interpretation of claim 1 as encompassing the hole and opening above. The hole and opening above are analogous to opening 9 in the modified Mirich graft. Under the Named Inventors' interpretation, opening 9 in modified Mirich is a "connector section" that, when introduced and deployed "extend[s] toward" the second branch artery. (Ex. 1029, ¶125).

Alternatively, it would have been obvious to add to the modified Mirich graft a short (*e.g.*, one Z-stent in length) fabric-covered leg extending distally from opening 9 toward the iliac artery. A PHOSITA would have been motivated to make this modification, for example, to increase the surface area of contact at the connection between the bifurcated structure and first tubular graft. Increasing the

contact surface area would predictably increase the friction between the components, thereby providing a more secure connection to prevent inadvertent separation. (Ex. 1029, ¶126). This would have been considered an obvious and routine modification, involving simple mechanical components disclosed in Mirich. (*Id.*).

The above-described modifications involve application of a known technique (described in Dumon), to improve a similar method ready for improvement (*i.e.*, minimally invasive procedure described in Mirich), to yield the predictable result of forming continuous flow paths from a primary artery (aorta) to branch arteries (iliac arteries). *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). The modular technique described in Dumon was an obvious, common sense solution taught in the prior art, and would have been considered routine to a PHOSITA. (Ex. 1029, ¶¶127, 261-272; *see also* Section VII. (describing others within the 1993-1994 timeframe that independently arrived at the claimed technique of assembling a bifurcated endoluminal graft *in situ* from multiple individually inserted components)).

Applying the Dumon method to Mirich would satisfy the "introducing…" requirement here. (Ex. 1029, ¶128).

c. *"and thereafter; introducing a first tubular graft into the first connector section and anchoring said first tubular graft to extend between the first connector section and the first branch artery to form a first continuous flow path from the primary artery to the first branch artery"*

It would have been obvious to secure a first branch graft (*e.g.*, another Mirich graft) to the opening 9 in the previously-placed modified Mirich graft, and anchor the first branch graft to extend between the opening 9 and the second iliac artery to form a continuous flow path from the aorta to the second iliac artery. This would satisfy the requirement "introducing…" requirement here. (Ex. 1029, ¶129).

d. *"introducing a second tubular graft into the second connector section and anchoring said second tubular graft to extend between the second connector section and the second branch artery to form a second continuous flow path from the primary artery to the second branch artery"*

Mirich discloses that "it [is] essential to locate the aneurysm exactly and bridge it completely" with the graft, because "[o]nce the graft [is] deployed, it could not be repositioned or retrieved." (Ex. 1011 at 1034). A PHOSITA would have recognized that, despite best efforts, it was not possible for a physician to measure and calculate with absolute certainty the dimensions of a vascular graft required to treat a patient. (Ex. 1029, ¶130). Variations in vessel visualization and measurement techniques, as well as changes in the patient's disease state over time, made it difficult to know before the procedure exactly what size vascular graft was needed. (*Id.*).

A PHOSITA would have been motivated to avoid potential problems associated with improper graft sizing. (Ex. 1029, ¶131; Ex. 1004 at 2:65-67; Ex. 1006 at 12:36-41; Ex. 1009 at 494; Ex. 1018 at 3:53-55). A graft sized too long could potentially cover and occlude branch vessels, cutting off circulation to parts of the body. (Ex. 1009 at 495). Thus, a PHOSITA would have been motivated to size a bifurcated graft to ensure that the graft does not extend so far

distally into an iliac artery that it occludes a branch artery (*e.g.*, the internal iliac artery). (Ex. 1029, ¶131).

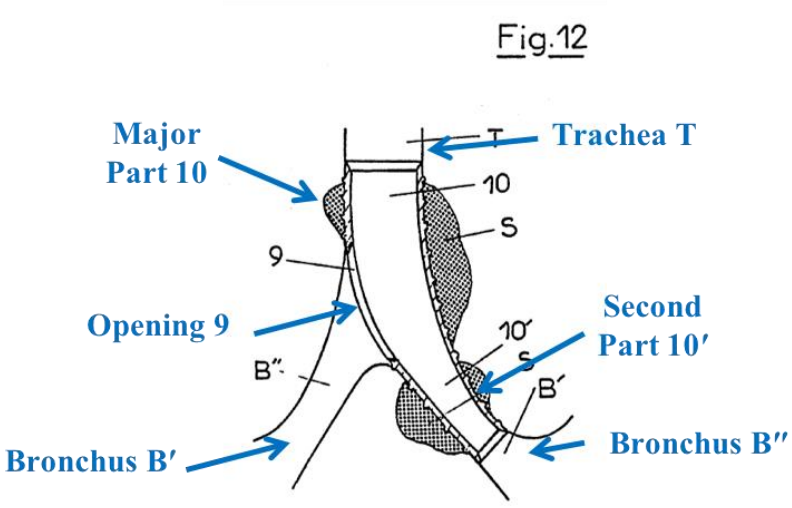
One of the risks of sizing a bifurcated graft too long is that it may not be possible to correct the sizing using an intraluminal procedure. Instead, the procedure may need to be converted from a minimally invasive approach to a conventional surgical procedure. (Ex. 1009 at 495). Converting to a conventional surgical procedure would undermine the goals of Mirich, including providing a "less invasive alternative," and "enabl[ing] a significant reduction in the morbidity and mortality associated with," conventional surgery. (Ex. 1011 at 1035, 1037; Ex. 1029, ¶132).

On the other hand, if a graft is sized too short it could form an insufficient seal with the vessel, resulting in incomplete exclusion of the aneurysm. (Ex. 1029, ¶133; Ex. 1009 at 495; Ex. 1010 at 99; Ex. 1008 at 9). A PHOSITA would have been motivated to size a bifurcated graft to ensure that the graft extends far enough into the iliac arteries that it forms a seal with the arteries. (Ex. 1029, ¶133).

Given these considerations, a PHOSITA would have erred on the side of sizing the Mirich bifurcated graft so that it is relatively short, rather than relatively long. (Ex. 1029, ¶134). This would not have been a concern, however, as a PHOSITA would have recognized that if the Mirich bifurcated graft was sized too

short, the graft could easily be extended using another endoluminal graft, as was well known for self-expanding Z-stents. (*Id.*; *see* Sections III.D. and V.A.1.b.).

It would have been obvious to introduce a second tubular graft into the secondary part 10' (second connector section) of the modified Mirich graft (*see* annotated Figure 12, below), and anchor the second tubular graft to extend between the secondary part 10' and the first iliac artery to form a continuous flow path from the aorta to the first iliac artery.



(Ex. 1029, ¶135).

The claimed "introducing" step merely uses a known technique (described in Mirich and known in the art), to improve a similar method ready for improvement (*i.e.*, minimally invasive procedures described in Mirich), to yield the predictable result of forming a first continuous flow path from the primary artery (aorta) to a branch artery (iliac artery). *See KSR*, 550 U.S. at 417. The overlapping technique

was an obvious, common sense solution taught in the prior art, and would have been considered routine to a PHOSITA. (Ex. 1029, ¶¶135-136).

Introducing a second tubular graft into the secondary part 10' of the modified Mirich graft using the overlapping technique would satisfy the "introducing…" requirement here. (Ex. 1029, ¶136).

2. Claim 2

Claim 2 depends from claim 1 and states "wherein the primary artery is an aorta, the first branch artery is a right iliac, and the second branch artery is a left iliac." Claim 2 would have been obvious, for the reasons in Section V.A.1. (Ex. 1029, ¶137).

3. Claim 3

Claim 3 depends from claim 1 and states "wherein the anchor section of the bifurcated structure is radially compressed while being introduced." Mirich discloses this limitation. (Ex. 1011 at 1034 (the graft was "compressed and advanced through [a] catheter with a blunt-tipped, 8-F introducer wire….[T]he introducer wire was held tight and the catheter was slowly withdrawn, releasing the graft and allowing it to expand."); Ex. 1029, ¶138).

4. Claim 4

Claim 4 depends from claim 3 and states "wherein the anchor section is composed of a resilient material, said method further comprising releasing the radially compressed anchor section at a target location with the primary artery."

As explained above in Section III.D., the '427 patent uses the term "resilient" to refer to self-expanding stents (versus the term "malleable," which is used to refer to balloon-expandable stents). Mirich discloses that the anchoring section may include self-expanding stents. (Ex. 1011 at 1033). Thus, Mirich discloses that the anchoring section is "composed of a resilient material." (Ex. 1029, ¶140).

Mirich also discloses releasing the radially compressed anchor section at a target location with the primary artery. (Ex. 1011 at 1034 ("When the nylon-covered portion of the graft had bridged the aneurysm, the introducer wire was held tight and the catheter was slowly withdrawn, releasing the graft and allowing it to expand.")). Further, claim 4 would have been obvious, for the reasons in Section V.A.1.c. (Ex. 1029, ¶141).

5. Claim 5

Claim 5 depends from claim 1 and states "wherein the bifurcated structure is introduced through the primary artery in an antegrade direction." Mirich discloses that the graft may be inserted either in an antegrade direction (through the carotid artery), or in a retrograde direction (through the femoral artery). (Ex. 1011 at 1034; Ex. 1029, ¶142).

Even if Mirich did not explicitly describe an antegrade direction (or retrograde direction), a PHOSITA would not have considered such a limitation to be a patentable distinction. (Ex. 1029, ¶143). A physician attempting to introduce the Mirich graft into the abdominal aorta has two choices of direction: (1) retrograde (*e.g.*, through the patient's leg); or (2) antegrade (*e.g.*, through the patient's arm or neck). The decision to introduce an endoluminal vascular device in a retrograde direction, versus an antegrade direction, is generally up to the discretion of the physician, based on the physician's knowledge and experience, the design of the device, and a patient's particular vasculature and ease of access. There is nothing about the design of the Mirich graft that would prevent the graft from being introduced in either a retrograde direction, or an antegrade direction. Thus, it would have been obvious to introduce the Mirich graft in either direction, whichever the physician chooses. (Ex. 1029, ¶143).

Dr. Criado's opinion is supported by the '427 patent, which describes retrograde and antegrade introductions as "conventional." (Ex. 1001 at 5:12-17; Ex. 1029, ¶144; *see also* Section III.E.3.).

6. Claim 6

Claim 6 depends from claim 1 and states "wherein the bifurcated structure is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 6 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶145).

7. Claim 7

Claim 7 depends from claim 1 and states "wherein the first tubular graft is radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.3. (Ex. 1029, ¶146).

8. Claim 8

Claim 8 depends from claim 7 and states "wherein the first tubular graft is composed of a resilient material, said method further comprising releasing the radially compressed graft to anchor simultaneously within the first connector and the first branch artery." As explained in Section III.E.1., "simultaneously" means in the same procedural step. Mirich discloses tubular grafts that are self-expanding, such that the entire length of the graft expands in the same procedural step (*i.e.*, the step of removing the constraining sheath). Using the Mirich graft as a "first tubular graft" would satisfy "releasing the radially compressed graft to anchor *simultaneously* within the first connector and the first branch artery. (Ex. 1029, ¶147).

9. Claim 9

Claim 9 depends from claim 1 and states "wherein the first tubular graft is introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 9 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶148).

10. Claim 10

Claim 10 depends from claim 1 and states "wherein the first tubular graft is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 10 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶149).

11. Claim 11

Claim 11 depends from claim 1 and states "wherein the second tubular graft is radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.7. (Ex. 1029, ¶150).

12. Claim 12

Claim 12 depends from claim 11 and states "wherein the second tubular graft is composed of a resilient material, said method further comprising releasing the radially compressed graft to anchor simultaneously within the second connector and the second branch artery." Claim 12 would have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶151).

13. Claim 13

Claim 13 depends from claim 1 and states "wherein the second tubular graft is introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 13 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶152).

14. Claim 14

Claim 14 depends from claim 1 and states "wherein the second tubular graft is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 14 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶153).

15. Claim 15

a. *"A method for treating an aneurysm by introducing a vascular graft into a primary artery which branches into first and second branch arteries, said method comprising"*

The preamble is not limiting. Nonetheless, Mirich discloses the "method" described in the preamble, for the reasons in Section V.A.1. (Ex. 1029, ¶154; Ex. 1011 at 1033).

b. *"introducing into a patient's vasculature an anchor section and first tubular graft of the vascular graft so that the anchor section is disposed within the primary artery and the first tubular graft is at least partially disposed within the first branch artery to form a first continuous flow path from the primary artery to the first branch artery"*

It would have been obvious to construct a bifurcated Mirich graft using the Dumon method, for the reasons in Section V.A.1.b. In particular, it would have been obvious to construct a graft including a major part 10, secondary part 10', and opening 9 laterally placed at the juncture point of the major part 10 and the secondary part 10', as described in Dumon. Introducing the modified Mirich graft in the manner described in Section V.A.1.b. satisfies the "introducing…" requirement here. (Ex. 1029, ¶¶155-156).

c. "securing a second tubular graft to the anchor section via a connector leg of the anchor section to form a second continuous flow path from the primary artery to the second branch artery"

It would have been obvious to secure a second tubular graft to the anchor section of the modified Mirich graft via a connector leg[12] of the anchor section (*e.g.*, either via opening 9, as depicted in Dumon, or as an extended opening 9 (*i.e.*, a short connector leg)), to form a second continuous flow path from the aorta to the second iliac artery, for the reasons in Sections V.A.1.b – V.A.1.d. (Ex. 1029, ¶157).

d. "wherein each of the grafts comprises a tubular frame and a liner"

Mirich discloses grafts comprising a tubular frame (self-expanding Z-stents) and a liner (nylon). (Ex. 1011 at 1033; Ex. 1029, ¶158).

[12] The Named Inventors argued during prosecution that the '427 patent should be entitled to an invention date based on invention disclosures depicting connectors in the form of a hole, or an opening. (*See* Section V.A.1.b.). For purposes of this ground, Petitioners accept the Named Inventors' interpretation of claim 15 as encompassing a hole or opening. Under the Named Inventors' interpretation, the opening 9 in the modified Mirich graft is a "connector leg." (Ex. 1029, ¶¶45, 157).

16. Claim 16

Claim 16 depends from claim 15 and states "wherein the primary artery is an aorta, the first branch artery is a right iliac, and the second branch artery is a left iliac." Claim 16 would have been obvious, for the reasons in Section V.A.2. (Ex. 1029, ¶159).

17. Claim 17

Claim 17 depends from claim 15 and states "wherein the anchor section and first tubular graft of the vascular graft are radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.3. (Ex. 1029, ¶160).

18. Claim 18

Claim 18 depends from claim 17 and states "wherein the anchor section and first tubular graft of the vascular graft are resilient, said introducing step comprising releasing the radially compressed anchor section and first tubular graft at a target location with the vasculature." Mirich discloses this limitation, and claim 18 would have been obvious, for the reasons in Section V.A.4. (Ex. 1029, ¶161).

19. Claim 19

Claim 19 depends from claim 18 and states "wherein the anchor section and first tubular graft of the vascular graft are introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 19 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶162).

20. Claim 20

Claim 20 depends from claim 18 and states "wherein the anchor section and first tubular graft of the vascular graft are introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 20 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶163).

21. Claim 21

Claim 21 depends from claim 18 and states "wherein the second tubular graft is radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.7. (Ex. 1029, ¶164).

22. Claim 22

Claim 22 depends from claim 21 and states "wherein the second tubular graft is resilient, said method further comprising releasing the radially compressed second tubular graft to anchor within the connector leg on the anchor section." Claim 22 have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶165).

23. Claim 23

Claim 23 depends from claim 22 and states "wherein the second tubular graft is introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 23 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶166).

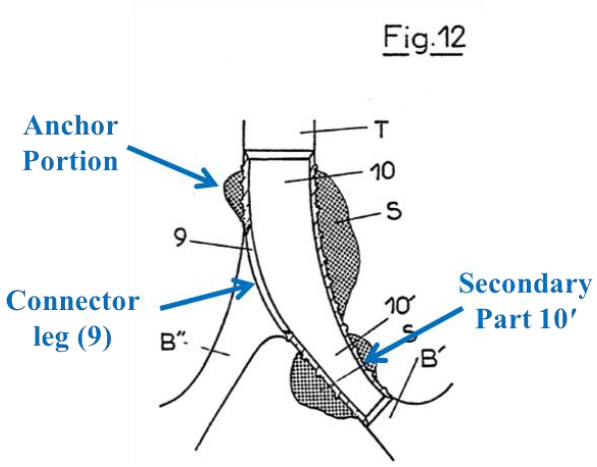
24. Claim 24

Claim 24 depends from claim 22 and states "wherein the second tubular graft is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 24 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶167).

25. Claim 25

Claim 25 depends from claim 15 and states "wherein the introducing step comprises securing the first tubular graft to the anchor section of the vascular graft after the anchor section has been disposed within the primary artery." Claim 25 would have been obvious, for the reasons in Sections V.A.1. and V.A.15. (Ex. 1029, ¶168).

As explained above in Section V.A.15 and depicted below in annotated Figure 12, Dumon discloses a graft including a secondary part 10', which may be considered a first tubular graft, and an opening 9, which may be considered a "connector leg," at least as the Named Inventors applied the term "leg" during prosecution. (*See* Section V.A.15).



Further, as explained above in Sections V.A.1.b–V.A.1.d, it would have been obvious to a PHOSITA, if necessary during a procedure, to extend one *or both* of: (1) opening 9 of the modified Mirich graft (with or without a "short" extension);

and (2) secondary part 10' of the modified Mirich graft.[13] Extending the secondary part 10' using a tubular graft (a "first tubular graft") would satisfy the requirement of "the introducing step comprises securing the first tubular graft to the anchor section of the vascular graft after the anchor section has been disposed within the primary artery." In particular, the "first tubular graft" is secured to the anchor section via secondary part 10', *after* the anchor section has been disposed within the primary artery. (Ex. 1029, ¶169).

[13] Referred to above in claim 1 as "connector sections."

26. Claim 26

Claim 26 depends from claim 25 and states "wherein the first tubular graft is secured to the anchor section via a second connector leg of the anchor section." Claim 26 would have been obvious, for the reasons in Section V.A.25. In particular, the secondary part 10' is a "second connector leg of the anchor section." (Ex. 1029, ¶170).

27. Claim 27

Claim 27 depends from claim 26 and states "wherein the first tubular graft is resilient and wherein the securing of the first tubular graft to the anchor section comprises releasing the first tubular graft from a compressed configuration to expand within the second connector leg and the first branch artery." Claim 27 would have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶171).

28. Claim 28

Claim 28 depends from claim 27 and states "wherein the second tubular graft is resilient and wherein the securing of the second tubular graft to the anchor section comprises releasing the second tubular graft from a compressed configuration to expand within its respective connector leg and the second branch artery." Claim 28 would have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶172).

29. Claim 29

Claim 29 depends from claim 25 and states "wherein the primary artery is an aorta, the first branch artery is a right iliac, and the second branch artery is a left iliac." Claim 29 would have been obvious, for the reasons in Section V.A.2. (Ex. 1029, ¶173).

30. Claim 30

Claim 30 depends from claim 29 and states "wherein the second tubular graft is resilient and wherein the securing of the second tubular graft to the anchor section comprises releasing the second tubular graft from a compressed configuration to expand within the connector leg and the left iliac." Claim 30 would have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶174).

31. Claim 31

Claim 31 depends from claim 25 and states "wherein the anchor section of the vascular graft is radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.3. (Ex. 1029, ¶175).

32. Claim 32

Claim 32 depends from claim 31 and states "wherein the anchor section is resilient, said introducing step comprising releasing the radially compressed anchor section at a target location with the vasculature." Mirich discloses this limitation, and claim 32 would have been obvious, for the reasons in Section V.A.4. (Ex. 1029, ¶176).

33. Claim 33

Claim 33 depends from claim 32 and states "wherein the anchor section of the vascular graft is introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 33 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶177).

34. Claim 34

Claim 34 depends from claim 32 and states "wherein the anchor section of the vascular graft is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 34 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶178).

35. Claim 35

Claim 35 depends from claim 25 and states "wherein the first tubular graft is radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.7. (Ex. 1029, ¶179).

36. Claim 36

Claim 36 depends from claim 35 and states "wherein the first tubular graft is resilient, said introducing step comprising releasing the radially compressed first tubular graft to anchor within a second connector leg on the anchor section." Claim 36 would have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶180).

37. Claim 37

Claim 37 depends from claim 36 and states "wherein the first tubular graft is introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 37 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶181).

38. Claim 38

Claim 38 depends from claim 36 and states "wherein the first tubular graft is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 38 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶182).

39. Claim 39

Claim 39 depends from claim 25 and states "wherein the second tubular graft is radially compressed while being introduced." Mirich discloses this limitation, for the reasons in Section V.A.7. (Ex. 1029, ¶183).

40. Claim 40

Claim 40 depends from claim 39 and states "wherein the second tubular graft is resilient, said method further comprising releasing the radially compressed second tubular graft to anchor simultaneously within the connector leg on the anchor section and the second branch artery." Claim 40 would have been obvious, for the reasons in Section V.A.8. (Ex. 1029, ¶184).

41. Claim 41

Claim 41 depends from claim 40 and states "wherein the second tubular graft is introduced through the primary artery in an antegrade direction." Mirich discloses this limitation, and claim 41 would have been obvious, for the reasons in Section V.A.5. (Ex. 1029, ¶185).

42. Claim 42

Claim 42 depends from claim 40 and states "wherein the second tubular graft is introduced through a branch artery in a retrograde direction." Mirich discloses this limitation, and claim 42 would have been obvious, for the reasons in Sections V.A.5. and V.A.6. (Ex. 1029, ¶186).

B. Ground 2: Claims 1-3, 5-7, 9-11, 13-17, 25-26, 29, 31, And 35 Are Obvious In View Of Barone And One Or Both Of: (1) Parodi 1991 And (2) Parodi 1993

Barone, Parodi 1991, and Parodi 1993 relate to the same subject matter–the Barone Inventors' development of a vascular graft and methods for repairing abdominal aortic aneurysms. (*See* Sections IV.C.–IV.E.). Each of these references is directed to "endoluminal placement of grafts, stents, and other structures" (Ex. 1001 at 1:9-12), and, therefore, these references are within the "Field of the Invention" of the '427 patent. A PHOSITA interested in improving intraluminal methods for introducing a vascular graft into an artery would have considered each of these references, in view of the common structures, techniques, and goals described in these references. A PHOSITA would have been motivated to combine these references, at least because they are each directed to the common goal of providing improved intraluminal methods for treating damaged or diseased vessels. (Ex. 1029, ¶187).

The Patent Office previously cited Barone *Embodiment #2* as an *anticipatory* reference against certain claims of the '427 patent. (*See* Section IV.C.2.). The Patent Office never addressed on the record Barone *Embodiment # 1*, or whether the claims of the '427 patent would have been *obvious*

in view of this embodiment in combination with Parodi 1991 and/or Parodi 1993.[14] Further, the Patent Office never considered Dr. Criado's testimony that claims 1-42 would have been obvious in view of these references, as described below in Grounds 2 and 3. Thus, the Board should institute *inter partes* review here. *See Pure Storage*, IPR2018-00549, Paper 7 at 11 (prior consideration under § 102 "should [not] preclude using [the reference] in an obviousness challenge combined with three other references"); *Edwards Lifesciences Corp. v. Boston Scientific Scimed, Inc.*, IPR2017-01295, Paper 9 at 27 (PTAB October 25, 2017) (declining to deny institution where "although the same art may have been before the Examiner during prosecution,…the Petition's and the Examiner's reliance on [the reference] is substantially different").

[14] Parodi 1993 was never cited to the Patent Office during prosecution. (Section IV.E.). While Parodi 1991 appeared in a lengthy IDS, it was never substantively addressed on the record, (Section IV.D.), and there is no evidence that Parodi 1991 was substantively considered by the Examiner. *See Pure Storage*, IPR2018-00549, Paper 7 at 11 (instituting review where "[t]here is no evidence of record that [the cited art] w[as] substantively considered by the Examiner").

1. Claim 1

a. "A method for introducing a vascular graft into a primary artery which divides into first and second branch arteries, said method comprising"

The preamble is not limiting. Nonetheless, Barone discloses the "method" described in the preamble. (Ex. 1029, ¶188; Ex. 1005 at Abstract, 1:6-8, 9:19-10:36, Figures 9-13).

b. *"introducing and deploying a bifurcated structure including an anchor section and first and second connector sections so that the anchor section is disposed within the primary artery and the first and second connector sections extend toward the first and second branch arteries"*

Barone Embodiment #1 discloses introducing and deploying in a body a bifurcated structure (160), including an anchor section and first and second connector sections (tubular/fluid passageways 191), as shown below.

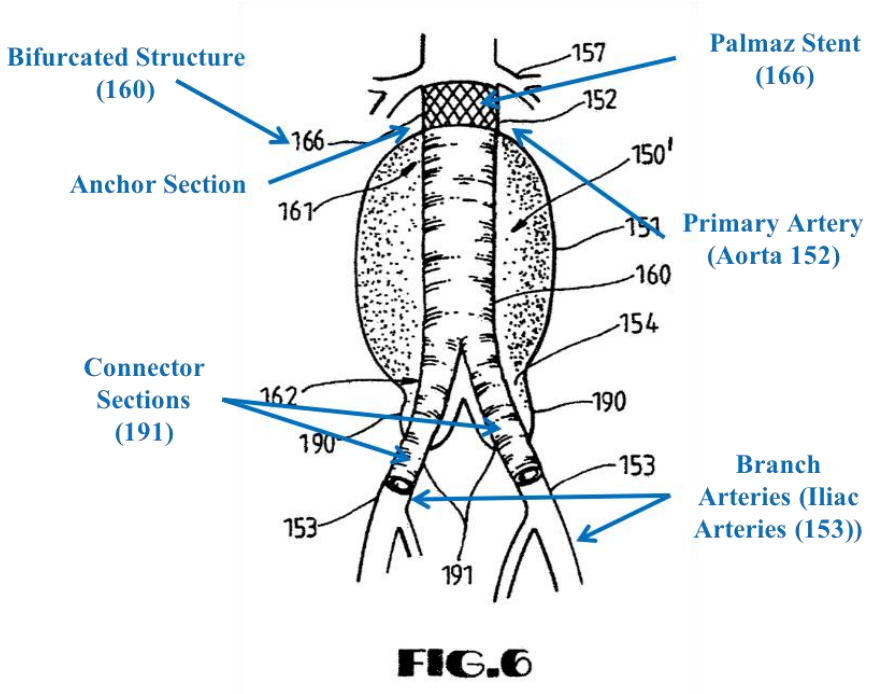


FIG.6

(Ex. 1005 at 6:32-7:19, 8:8-22). As shown above, the anchor section is disposed within a primary artery (abdominal aorta 152) and the first and second connector sections (191) extend toward the first and second branch arteries (iliac arteries 153). The anchor section includes a "securing means" (166). (*Id.*, 6:32-47, 8:11-14; Ex. 1029, ¶189).

c. *"and thereafter; introducing a first tubular graft into the first connector section and anchoring said first tubular graft to extend between the first connector section and the first branch artery to form a first continuous flow path from the primary artery to the first branch artery"*

Barone Embodiment #1 does not explicitly describe a step, performed *after* introducing and deploying the bifurcated structure, of introducing into a connector section a tubular graft and anchoring the tubular graft to extend between the connector section and the first branch artery. This is not a patentable distinction, however. (Ex. 1029, ¶190); *Laclede-Christy*, 280 F. at 85 ("Ordinarily, the making of two or more parts out of a thing that had heretofore been used in one part, and using the separate parts to serve the purpose that had been served before the division is not invention.") (*citing Howard*, 150 U.S. 164).

A PHOSITA would have been motivated to avoid potential problems associated with improper graft sizing, for the reasons in Section V.A.1.d. (*See also* Ex. 1029, ¶¶191-197). Thus, a PHOSITA would have been motivated to size the Barone Embodiment #1 graft to ensure that the graft does not extend so far into the

iliac artery that it undesirably occludes other branching arteries from the iliacs, as illustrated below.

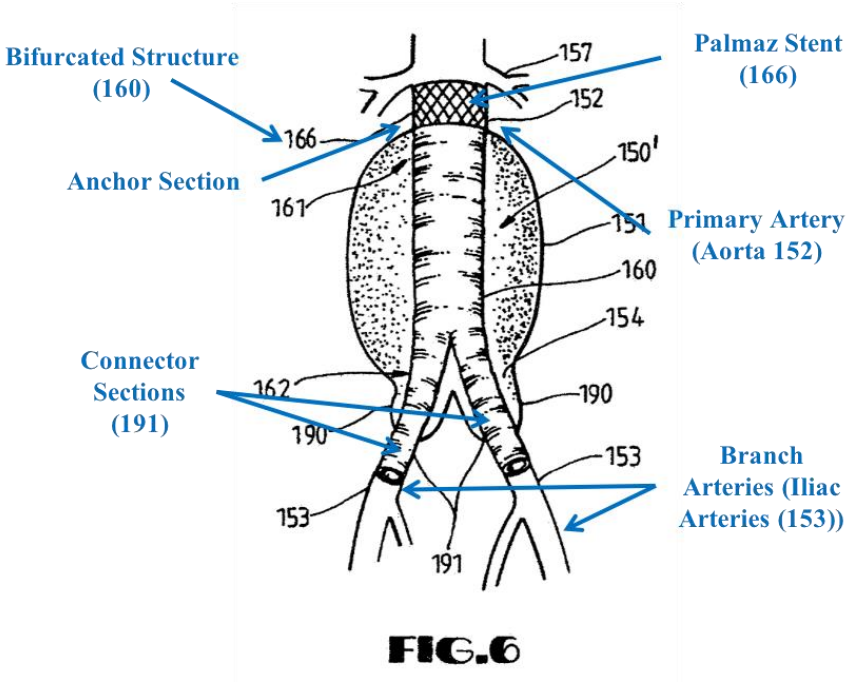


FIG.6

(*Id.*, ¶193). The Barone Inventors described this very concern in Parodi 1991. (*Id.*, ¶194; Ex. 1009 at 495 (describing an "overly long" graft as a "patently unsatisfactory situation")).

On the other hand, a PHOSITA would have been motivated to ensure that the graft extends far enough into the iliac arteries to properly seal within the arteries. (Ex. 1029, ¶195). The Barone Inventors described this issue both in Parodi 1991 and Parodi 1993. (*Id.*; Ex. 1009 at 495 (describing "reflux…at the distal end of [a] graft" that was too short); Ex. 1010 at 99 ("the first graft…implanted was too short to reach the distal neck of the AAA")).

Given these competing considerations, a PHOSITA would have erred on the side of sizing the bifurcated graft so that it is relatively short, rather than relatively long, and would have planned for the possibility that the Embodiment #1 bifurcated graft, by itself, may be insufficient to exclude a patient's aneurysm. (Ex. 1029, ¶196). This would not have been a concern, however, as a PHOSITA would have recognized that if the bifurcated graft was too short, the graft could easily be extended using another endoluminal graft, as described in the prior art by the Barone Inventors. (Ex. 1029, ¶¶196-197; Ex. 1009 at 495; Ex. 1010 at 99, 103-104; Sections IV.D.-IV.E.).

Thus, it would have been obvious to extend one or both of the connector legs of the Barone Embodiment #1 bifurcated graft (illustrated below), by introducing

and deploying a tubular graft in an overlapping configuration to form continuous flow paths from the primary artery to the branch arteries.

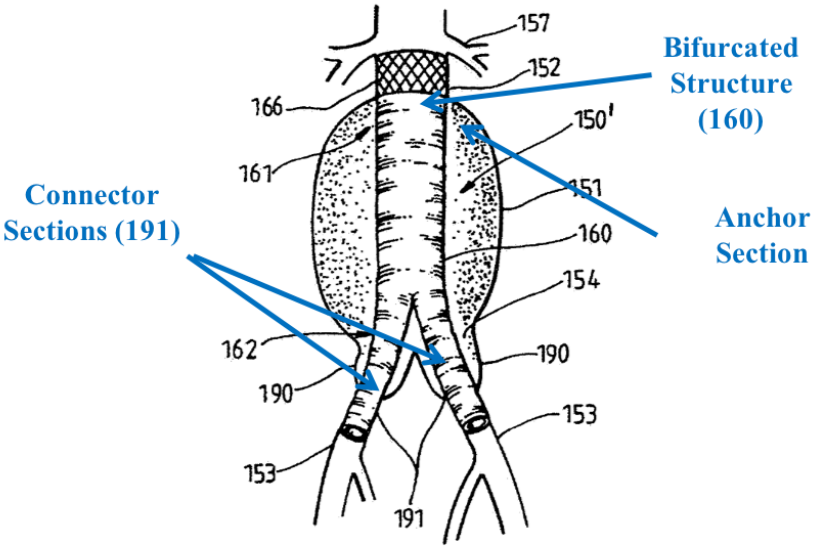
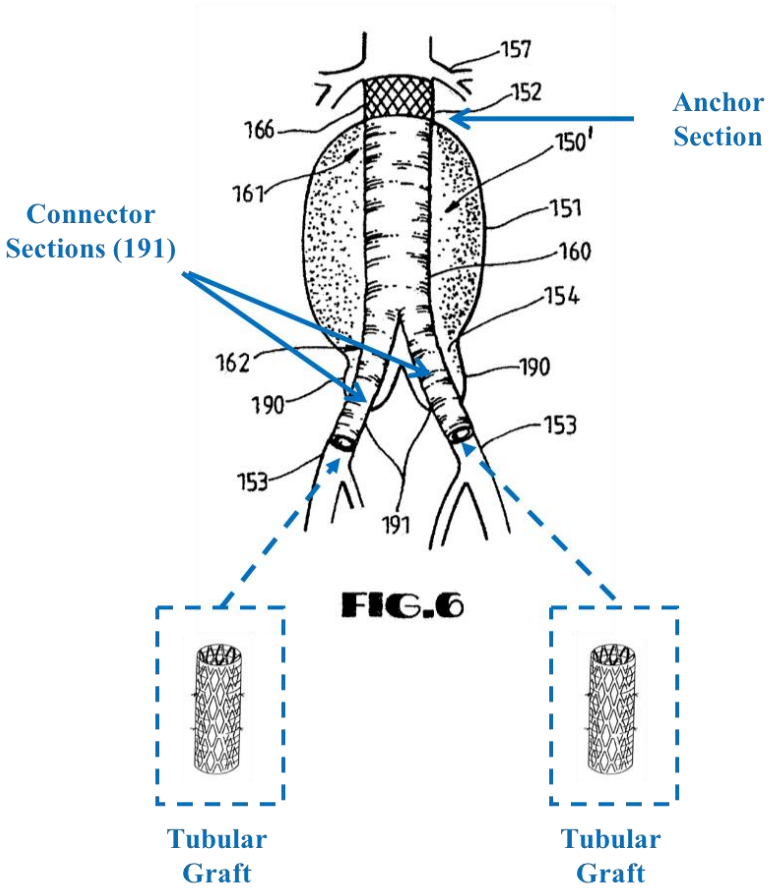


FIG.6

It would have been obvious to use as the tubular graft any of the coated or uncoated stents, or tubular sleeve-covered stents described in Barone, Parodi 1991, and Parodi 1993, depending on the application. (*Id.*; Ex. 1005 at 6:32-7:19, 8:11-14). For example, it would have been obvious to use as a tubular graft a short "stent covered by a Dacron graft," as disclosed in Figure 12 of Parodi 1993 (reproduced below).

(Ex. 1010 at 96). Alternatively, it would have been obvious to use as a tubular graft a Dacron or Teflon covered stent, as described in Barone or Parodi 1991. (Ex. 1005 at 6:32-7:19; Ex. 1009 at 491-499; Ex. 1029, ¶198).

Thus, it would have been obvious to extend one or both of the connector sections in the Barone Embodiment #1 graft, as illustrated below.



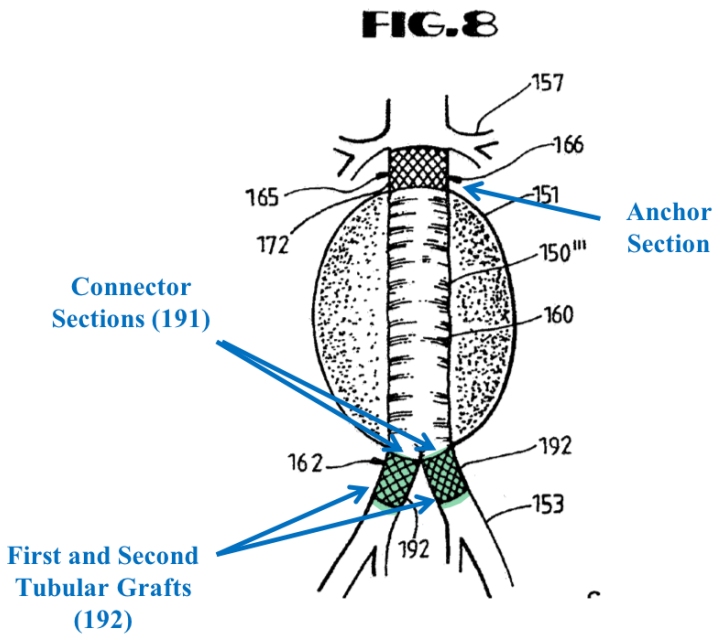
(Ex. 1029, ¶199).

It also would have been obvious to *intentionally* size the graft too short, in order to simplify the procedure for introducing and deploying the graft. As explained above in Section IV.C.1, Barone discloses a complex procedure for

introducing a bifurcated graft into the body. A PHOSITA would have recognized that the disclosed procedure would present the risk of undesirable twisting and/or kinking of the device, leading to restriction or occlusion of blood flow. (Ex. 1029, ¶200). A PHOSITA would have been motivated to simplify and improve the method of introducing and deploying the Barone graft. (*Id.*).

It would have been obvious to size the Embodiment #1 graft too short so that, when introduced and deployed, each of the connector sections (191L, 191R) extend toward, but not into, a respective iliac artery 153L, 153R. This would eliminate the need to perform the complicated step of moving connector section 191R from iliac artery 153L into iliac artery 153R. (Ex. 1029, ¶201). It would have been obvious thereafter to extend both of the connector legs, by introducing and deploying a tubular graft in an overlapping configuration to form continuous flow paths from the primary artery to the iliac arteries.

The resulting device would resemble the graft depicted in Figure 8 (reproduced and annotated below, with first and second tubular grafts 192 highlighted in green).



(*Id.*, ¶¶201-202).

A PHOSITA would have been motivated to introduce and deploy first and second tubular grafts, as described above, to ensure that the Embodiment #1 graft is sized according to the patient's specific anatomy, to ensure that the aortic aneurysm is completely excluded, to avoid potential complications from an improperly-sized bifurcated graft, to avoid the potential for converting from an intraluminal procedure to a conventional surgical procedure, and to simplify the procedure for introducing and deploying the graft. (*Id.*, ¶203). The claimed "introducing" step is merely a known technique (described by the Barone Inventors in Parodi 1991 and Parodi 1993), to improve a similar method ready for

improvement (*i.e.*, endovascular procedure described in Barone), to yield the predictable result of forming a first continuous flow path from the primary artery (aorta) to a branch artery (iliac artery). *See KSR*, 550 U.S. at 417.

The "introducing" step is an obvious, common sense solution taught in the prior art, and would have been considered routine to a PHOSITA. (Ex. 1029, ¶¶203-204, 261-272; *see also* Section VII. (describing others within the 1993-1994 timeframe that independently arrived at the claimed technique of assembling a bifurcated endoluminal graft *in situ* from multiple individually inserted components)). Introducing a tubular graft into one of the connector legs using the overlapping technique would satisfy the "introducing…" requirement here. (Ex. 1029, ¶204).

d. *"introducing a second tubular graft into the second connector section and anchoring said second tubular graft to extend between the second connector section and the second branch artery to form a second continuous flow path from the primary artery to the second branch artery"*

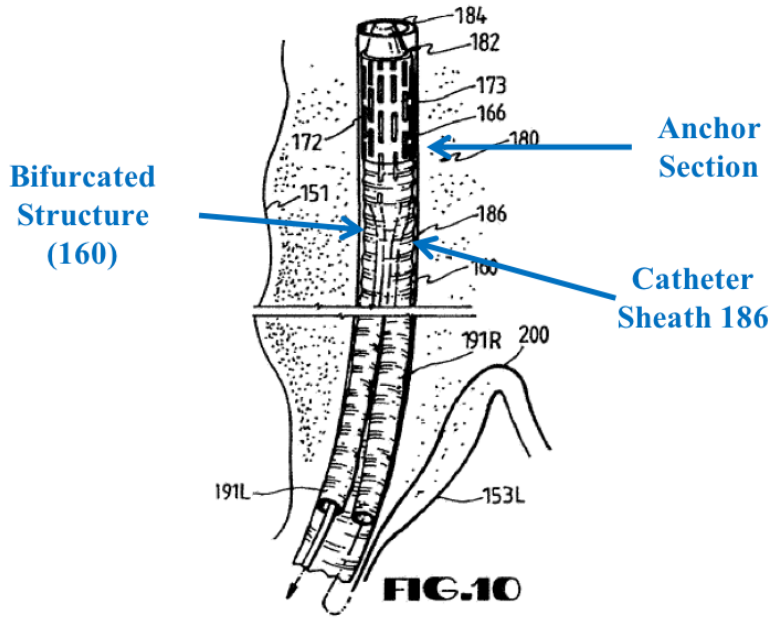
A method with this limitation would have been obvious, for the reasons in Section V.B.1.c. Introducing a *second* tubular graft (*i.e.*, when *both* connector sections are extended) satisfies the "introducing…" requirement here. (Ex. 1029, ¶205).

2. Claim 2

Claim 2 depends from claim 1 and states "wherein the primary artery is an aorta, the first branch artery is a right iliac, and the second branch artery is a left iliac." Barone discloses this limitation, for the reasons in Section V.B.1.b. (Ex. 1029, ¶206).

3. Claim 3

Claim 3 depends from claim 1 and states "wherein the anchor section of the bifurcated structure is radially compressed while being introduced." Barone discloses this limitation, as shown below.



As shown above, the anchor section of bifurcated structure (160) is radially compressed within catheter sheath 186. (Ex. 1005 at 7:66-8:3, 9:19-51, Figures 1, 14; Ex. 1029, ¶207).

4. Claim 5

Claim 5 depends from claim 1 and states "wherein the bifurcated structure is introduced through the primary artery in an antegrade direction." Barone discloses that the vascular graft may be introduced in a *retrograde* direction, or an *antegrade* direction. (Ex. 1005 at 4:44-49, 9:19-51, 10:14-36, Figures 1-3, 9-10, 13; Ex. 1029, ¶208).

An "antegrade" (or "retrograde") direction is not a patentable distinction, for the reasons in Section V.A.5. There is nothing about the design of the Barone graft that would prevent the graft from being introduced in either an antegrade direction, or a retrograde direction. (Ex. 1029, ¶¶209-210).

5. Claim 6

Claim 6 depends from claim 1 and states "wherein the bifurcated structure is introduced through a branch artery in a retrograde direction." Barone discloses this limitation, and claim 6 would have been obvious, for the reasons in Section V.B.4. (Ex. 1029, ¶211).

6. Claim 7

Claim 7 depends from claim 1 and states "wherein the first tubular graft is radially compressed while being introduced." Barone discloses this limitation, for the reasons in Section V.B.3. (Ex. 1029, ¶212).

7. Claim 9

Claim 9 depends from claim 1 and states "wherein the first tubular graft is introduced through the primary artery in an antegrade direction." Barone discloses this limitation, and claim 9 would have been obvious, for the reasons in Section V.B.4. (Ex. 1029, ¶213).

8. Claim 10

Claim 10 depends from claim 1 and states "wherein the first tubular graft is introduced through a branch artery in a retrograde direction." Barone discloses this limitation, and claim 10 would have been obvious, for the reasons in Sections V.B.4. and V.B.5. (Ex. 1029, ¶214).

9. Claim 11

Claim 11 depends from claim 1 and states "wherein the second tubular graft is radially compressed while being introduced." Barone discloses this limitation, for the reasons in Section V.B.6. (Ex. 1029, ¶215).

10. Claim 13

Claim 13 depends from claim 1 and states "wherein the second tubular graft is introduced through the primary artery in an antegrade direction." Barone discloses this limitation, and claim 13 would have been obvious, for the reasons in Section V.B.4. (Ex. 1029, ¶216).

11. Claim 14

Claim 14 depends from claim 1 and states "wherein the second tubular graft is introduced through a branch artery in a retrograde direction." Barone discloses this limitation, and claim 14 would have been obvious, for the reasons in Sections V.B.4. and V.B.5. (Ex. 1029, ¶217).

12. Claim 15

a. "A method for treating an aneurysm by introducing a vascular graft into a primary artery which branches into first and second branch arteries, said method comprising"

The preamble is not limiting. Nonetheless, Barone discloses the "method" described in the preamble, for the reasons in Section V.B.1. (Ex. 1029, ¶218).

b. *"introducing into a patient's vasculature an anchor section and first tubular graft of the vascular graft so that the anchor section is disposed within the primary artery and the first tubular graft is at least partially disposed within the first branch artery to form a first continuous flow path from the primary artery to the first branch artery"*

For the reasons in Section V.B.1.c, it would have been obvious to a PHOSITA: (1) to first deploy the Embodiment #1 graft in the body; and (2) thereafter to extend both of the connector legs of the Embodiment #1 bifurcated graft, by introducing and deploying a tubular graft in an overlapping configuration to form continuous flow paths from the primary artery to the branch arteries. (Ex. 1029, ¶219).

As illustrated below, introducing and deploying the Embodiment #1 graft (either as illustrated, or intentionally sized too short) and a first tubular graft (first tubular graft not illustrated, but location highlighted in green) satisfies the limitation of introducing into a patient's vasculature an anchor section and first tubular graft, so that the anchor section is disposed within the primary artery (aorta 152) and the first tubular graft (highlighted in green) is at least partially disposed within the first branch artery (iliac artery 153L) to form a first continuous flow path from the primary artery to the first branch artery.

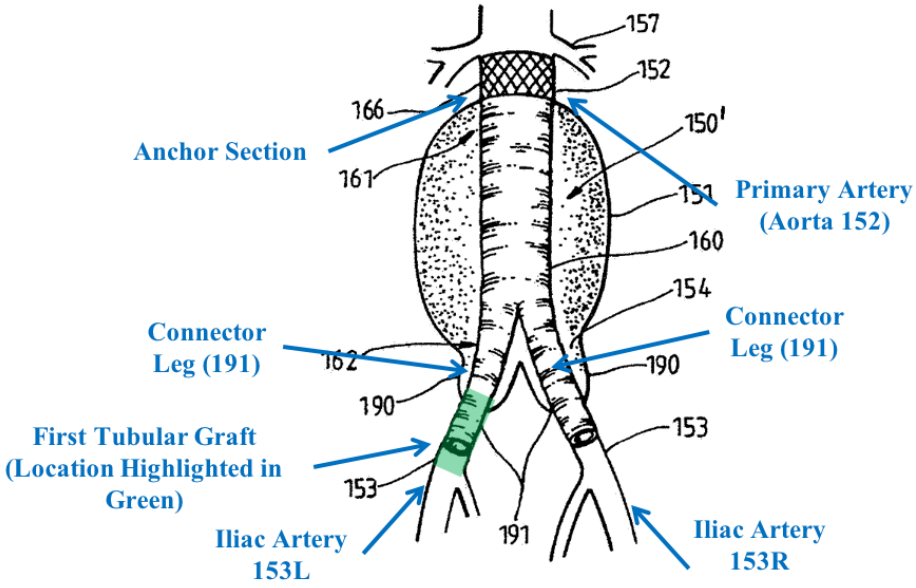
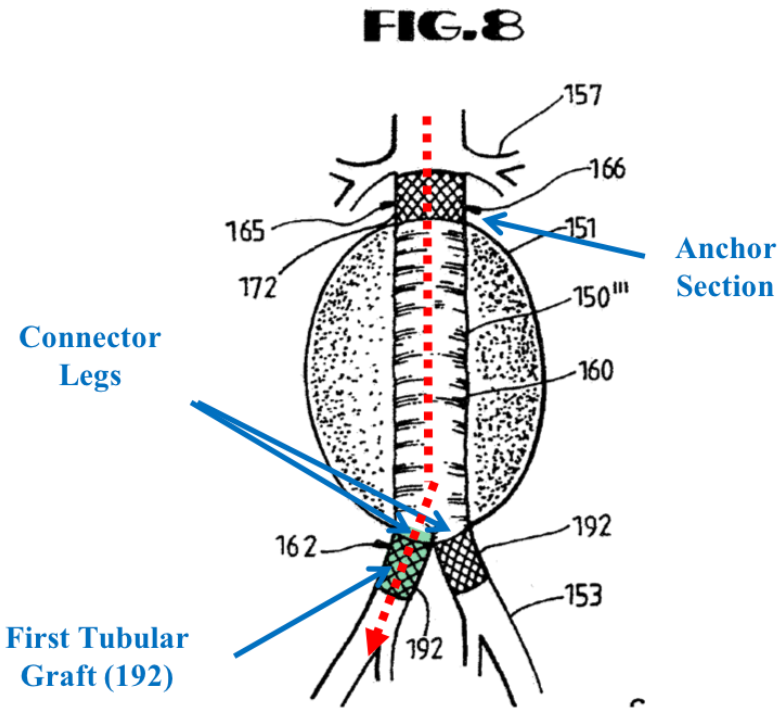


FIG.6

(Ex. 1029, ¶220).

Where the graft was *intentionally* sized too short (*see* Section V.B.1.c.), the resulting device would resemble the graft illustrated below, with first tubular graft 192 highlighted in green (first continuous flow path identified by red-dashed arrow).



(*Id.*, ¶221).

c. "securing a second tubular graft to the anchor section via a connector leg of the anchor section to form a second continuous flow path from the primary artery to the second branch artery"

It would have been obvious to extend the connector legs of the Embodiment #1 bifurcated graft, for the reasons in Section V.B.1.c. As illustrated below, extending the tubular/fluid passageway 191 (a connector leg) in iliac artery 153R using a second tubular graft (graft not illustrated, but location highlighted in green), satisfies the limitation of securing a second tubular graft to the anchor section via a connector leg (191) of the anchor section to form a second continuous flow path from the primary artery (152) to the second branch artery (153R).

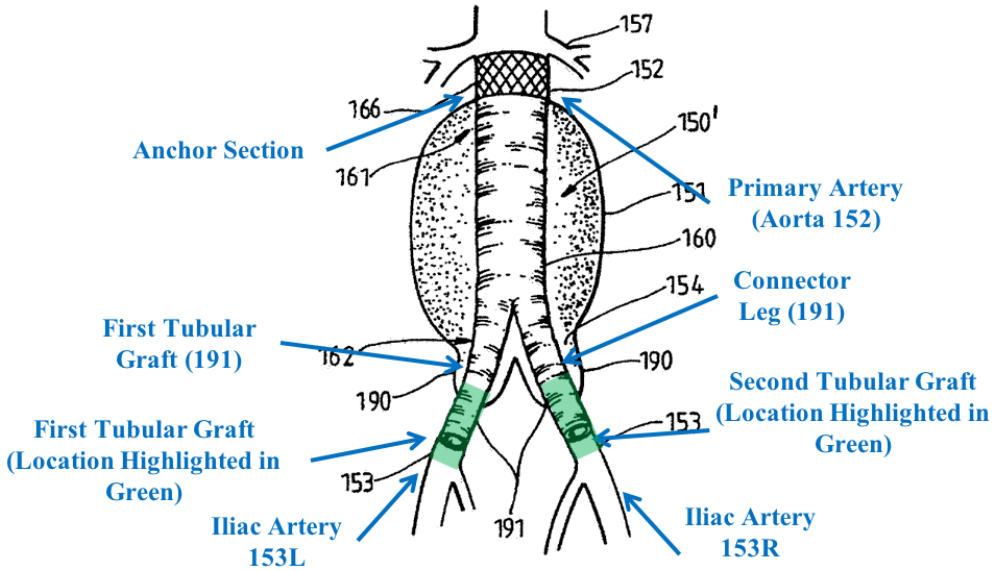
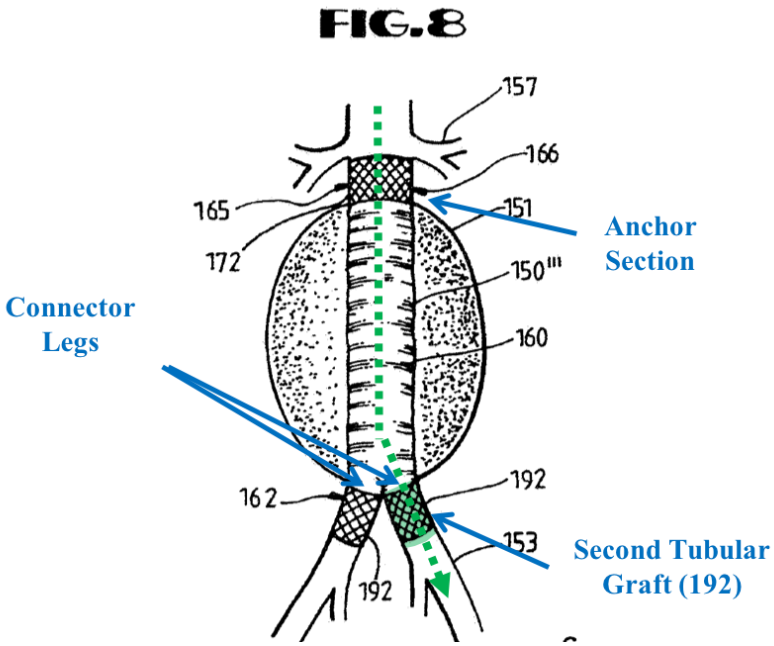


FIG.6

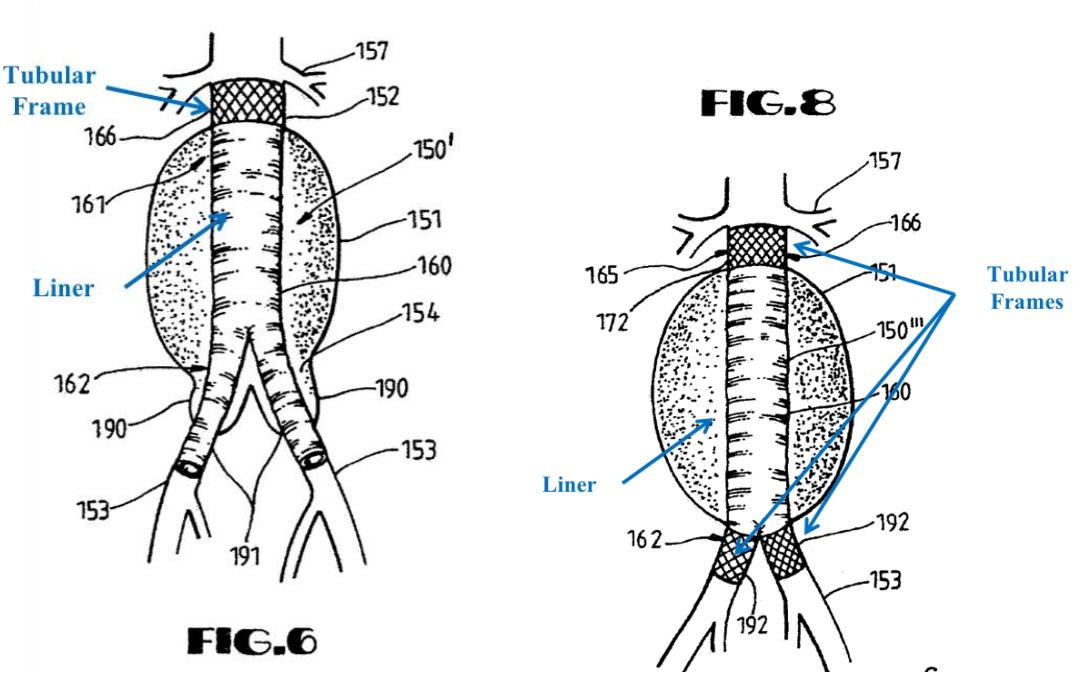
(Ex. 1029, ¶222). Where the graft was *intentionally* sized too short (*see* Section V.B.1.c.), the resulting device (including first and second tubular grafts), would resemble the graft illustrated below, with second tubular graft 192 highlighted in green (second continuous flow path identified by green-dashed arrow).



(*Id.*, ¶223).

d. "wherein each of the grafts comprises a tubular frame and a liner"

Barone discloses this limitation, as illustrated below.



(Ex. 1005 at 6:32-7:19, 8:8-14). It would have been obvious to use first and second tubular grafts, each including a tubular frame (stent) and liner (graft material), for the reasons in Section V.B.1.c. (Ex. 1029, ¶224).

13. Claim 16

Claim 16 depends from claim 15 and states "wherein the primary artery is an aorta, the first branch artery is a right iliac, and the second branch artery is a left iliac." Barone discloses this limitation, for the reasons in Section V.B.2. (Ex. 1029, ¶225).

14. Claim 17

Claim 17 depends from claim 15 and states "wherein the anchor section and first tubular graft of the vascular graft are radially compressed while being introduced." Barone discloses this limitation, for the reasons in Section V.B.3. (Ex. 1029, ¶226).

15. Claim 25

Claim 25 depends from claim 15 and states "wherein the introducing step comprises securing the first tubular graft to the anchor section of the vascular graft after the anchor section has been disposed within the primary artery." Claim 25 would have been obvious, for the reasons in Section V.B.12. (Ex. 1029, ¶227).

16. Claim 26

Claim 26 depends from claim 25 and states "wherein the first tubular graft is secured to the anchor section via a second connector leg of the anchor section."

Claim 26 would have been obvious, for the reasons in Section V.B.12. (Ex. 1029, ¶228).

17. Claim 29

Claim 29 depends from claim 25 and states "wherein the primary artery is an aorta, the first branch artery is a right iliac, and the second branch artery is a left iliac." Barone discloses this limitation, for the reasons in Section V.B.2. (Ex. 1029, ¶229).

18. Claim 31

Claim 31 depends from claim 25 and states "wherein the anchor section of the vascular graft is radially compressed while being introduced." Barone discloses this limitation, for the reasons in Section V.B.3. (Ex. 1029, ¶230).

19. Claim 35

Claim 35 depends from claim 25 and states "wherein the first tubular graft is radially compressed while being introduced." Barone discloses this limitation, for the reasons in Section V.B.6. (Ex. 1029, ¶231).

C. Ground 3: Claims 4, 8, 12, 18-24, 27-28, 30, 32-34, And 36-42 Are Obvious In View Of Barone And One Or Both Of: (1) Parodi 1991 And (2) Parodi 1993, In Further Combination With Mirich

1. Claim 4

Claim 4 depends from claim 3 and states "wherein the anchor section is composed of a resilient material, said method further comprising releasing the radially compressed anchor section at a target location within the primary artery." Claim 3 would have been obvious, for the reasons in Section V.B.3. (Ex. 1029, ¶232).

The term "resilient" means self-expanding. (*See* Section III.D.). Barone discloses balloon-expandable Palmaz-type stents (*see* Section IV.C.), however this is not a patentable distinction. (Ex. 1029, ¶233). There were *two* types of stents in the 1993-1994 timeframe: resilient, self-expanding stents, and malleable, balloon-expandable stents. (*See* Section III.D.). Both were considered viable candidates for treating diseased or damaged vessels. (*Id.*). It would have been obvious to a PHOSITA developing an intraluminal grafting method to use either self-expanding *or* balloon-expandable stents, depending on their particular preference. (Ex. 1029, ¶¶65-69, 234).

Thus, it would have been obvious to substitute resilient, self-expanding stents for the Palmaz-type stents described in Barone. Self-expanding stents were one of a finite number of types of stents available in the 1993-1994 timeframe (*i.e.*,

two). A PHOSITA would have recognized that substituting self-expanding stents would provide potential benefits, including greater flexibility, and smaller delivery catheter size. A PHOSITA would have been motivated to substitute self-expanding stents to take advantage of these potential benefits. (Ex. 1029, ¶¶65-69, 235).

For example, resilient, self-expanding Z-stents had been used successfully in prior art intraluminal grafting methods, for excluding abdominal aortic aneurysms. (*See, e.g.*, Ex. 1011 ("Mirich") at 1034-1036). A PHOSITA would have been motivated to substitute self-expanding Z-stents for the Palmaz-type stents disclosed in Barone, in order to obtain the advantages described in Mirich. Substituting self-expanding stents for balloon-expandable stents would have been considered obvious and routine to a PHOSITA, and would have involved simple and well-known mechanical components disclosed in Mirich. The resulting graft would include an anchor section composed of a resilient material. (Ex. 1029, ¶236).

Barone discloses releasing the radially compressed anchor section at a target location within the primary artery, for the reasons in Section V.B.1. (*Id.*, ¶237).

2. Claim 8

Claim 8 would have been obvious, for the reasons in Section V.C.1. (Ex. 1029, ¶238 (substitute self-expanding stents)). Using a modified device as a "first tubular graft" would satisfy "releasing the radially compressed graft to anchor *simultaneously* within the first connector and the first branch artery." That is, the entire length of each self-expanding graft expands in the same procedural step (*i.e.*, the step of removing the constraining sheath or catheter). (Ex. 1029, ¶239; Section III.E.1.).

3. Claim 12

Claim 12 would have been obvious, for the reasons in Section V.C.2. (Ex. 1029, ¶240).

4. Claim 18

Claim 18 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶241).

5. Claim 19

Barone discloses the limitation of claim 19, and claim 19 would have been obvious, for the reasons in Sections V.B.4. and V.C.1. (Ex. 1029, ¶242).

6. Claim 20

Barone discloses the limitation of claim 20, and claim 20 would have been obvious, for the reasons in Sections V.B.4., V.B.5., and V.C.1. (Ex. 1029, ¶243).

7. Claim 21

Barone discloses the limitation of claim 21, and claim 21 would have been obvious, for the reasons in Sections V.B.6. and V.C.1. (Ex. 1029, ¶244).

8. Claim 22

Claim 22 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶245).

9. Claim 23

Barone discloses the limitation of claim 23, and claim 23 would have been obvious, for the reasons in Sections V.B.4. and V.C.1. (Ex. 1029, ¶246).

10. Claim 24

Barone discloses the limitation of claim 24, and claim 24 would have been obvious, for the reasons in Sections V.B.4., V.B.5., and V.C.1. (Ex. 1029, ¶247).

11. Claim 27

Claim 27 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶248).

12. Claim 28

Claim 28 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶249).

13. Claim 30

Claim 30 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶250).

14. Claim 32

Claim 32 would have been obvious, for the reasons in Section V.C.1. (Ex. 1029, ¶251).

15. Claim 33

Barone discloses the limitation of claim 33, and claim 33 would have been obvious, for the reasons in Sections V.B.4. and V.C.1. (Ex. 1029, ¶252).

16. Claim 34

Barone discloses the limitation of claim 34, and claim 34 would have been obvious, for the reasons in Sections V.B.4., V.B.5., and V.C.1. (Ex. 1029, ¶253).

17. Claim 36

Claim 36 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶254).

18. Claim 37

Barone discloses the limitation of claim 37, and claim 37 would have been obvious, for the reasons in Sections V.B.4. and V.C.1. (Ex. 1029, ¶255).

19. Claim 38

Barone discloses the limitation of claim 38, and claim 38 would have been obvious, for the reasons in Sections V.B.4., V.B.5., and V.C.1. (Ex. 1029, ¶256).

20. Claim 39

Barone discloses the limitation of claim 39, and claim 39 would have been obvious, for the reasons in Sections V.B.6. and V.C.1. (Ex. 1029, ¶257).

21. Claim 40

Claim 40 would have been obvious, for the reasons in Sections V.C.1. and V.C.2. (Ex. 1029, ¶258).

22. Claim 41

Barone discloses the limitation of claim 41, and claim 41 would have been obvious, for the reasons in Sections V.B.4. and V.C.1. (Ex. 1029, ¶259).

23. Claim 42

Barone discloses the limitation of claim 42, and claim 42 would have been obvious, for the reasons in Sections V.B.4., V.B.5., and V.C.1. (Ex. 1029, ¶260).

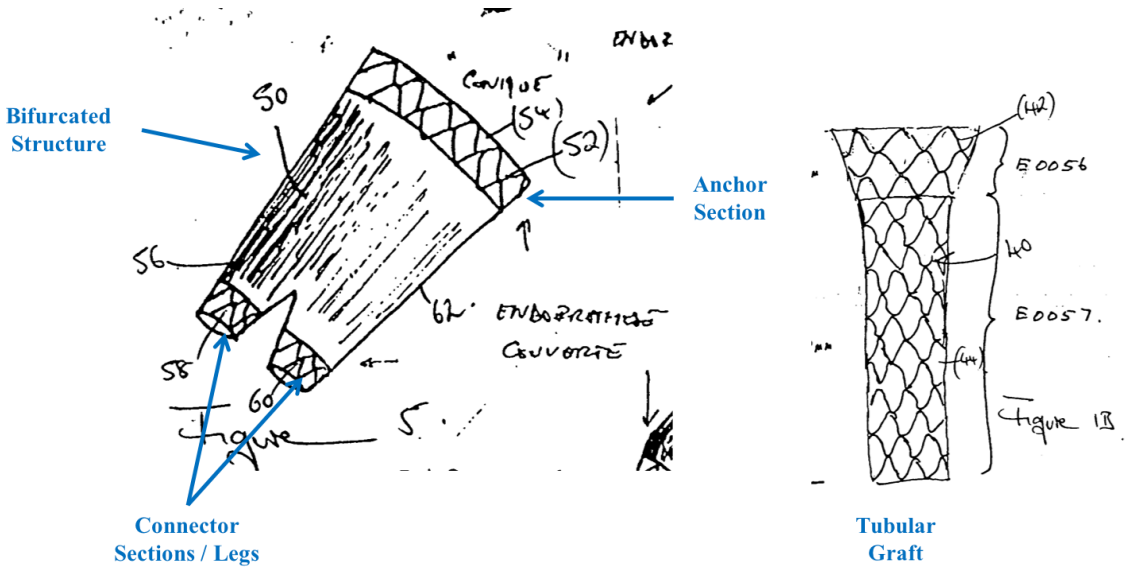
VI. NO REDUNDANCY

The grounds are not redundant as each ground is based on a distinctive and different prior art combination.

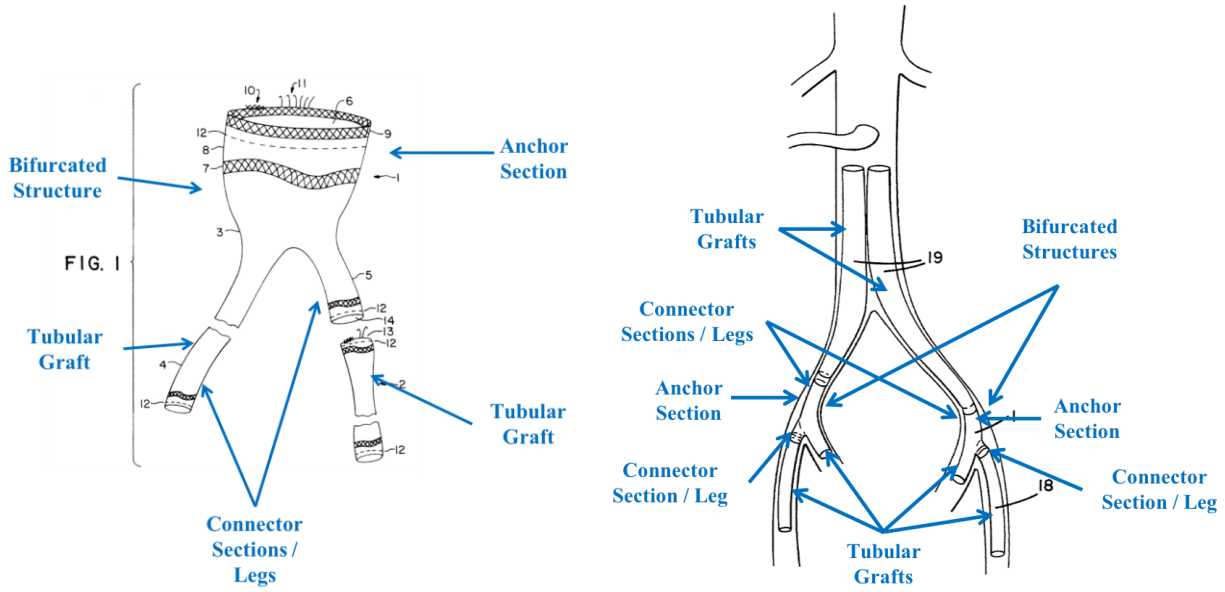
VII. SECONDARY CONSIDERATIONS

Petitioners reserve the right to address any secondary considerations of nonobviousness that Patent Owner may assert.

With respect to *obviousness*, Dr. Criado explains that numerous others independently "invented" within the same time period methods of assembling a bifurcated endoluminal graft *in situ* from multiple, individually inserted components, as illustrated below.



Goicoechea *et al.* "Invention" (At Least By February 1994)



Martin "Invention" (At Least By August/September 1994)

(Ex. 1029, ¶¶261-269; *see also id.*, ¶¶270-272 (describing White *et al.* "invention" at least by September 1994); Exs. 1012-1015; Ex. 1025 at 63-132). These "simultaneous inventions" further demonstrate that the subject matter described in the claims of the '427 patent would have been obvious. *See Geo M. Martin Co. v. Alliance Machine Sys. Int'l LLC*, 618 F.3d 1294, 1306 (Fed. Cir. 2010); *ZTE (USA) Inc. v. Evolved Wireless LLC*, IPR2016-00757, Paper 42 at 28-29 (PTAB Nov. 30, 2017).

VIII. CONCLUSION

There is a reasonable likelihood that at least one of the challenged claims is unpatentable. Therefore, Petitioners respectfully request the PTAB to grant this petition for *inter partes* review.

Dated: September 4, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 13,937 words as calculated by the "Word Count" feature of Microsoft Word, the word processing program used to create it.

The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: September 4, 2018

Respectfully submitted,

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Dominic P. Zanfardino (Reg. No. 36,068)
Lead Attorney for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,206,427, as well as the accompanying Power of Attorney, and Exhibits 1001-1015, 1017-1027, and 1029-1032, have been served in their entirety on September 4, 2018, by Federal Express (Overnight Delivery) on:

MEDTRONIC VASCULAR, INC. IP Legal Department 3576 Unocal Place Santa Rosa, California 95403
Counsel of Record for Medtronic Vascular, Inc. at the U.S. Patent & Trademark Office with respect to U.S. Patent No. 8,206,427

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