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Paper 7
Entered: March 4, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK INCORPORATED, COOK GROUP INCORPORATED, AND COOK MEDICAL LLC,
Petitioner,

v.

MEDTRONIC VASCULAR, INC.,
Patent Owner.

Case IPR2018-01571
Patent 8,206,427 B1

Before JAMESON LEE, KEN B. BARRETT, and MICHAEL L. WOODS, *Administrative Patent Judges.*

WOODS, *Administrative Patent Judge.*

DECISION

Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC, (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–42 of U.S. Patent No. 8,206,427 B1 ("the '427 patent"). Pet. 4. Medtronic Vascular, Inc., ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.") to the Petition, contending that the Petition should be denied as to all challenged claims. Prelim. Resp. 2–3.

We have jurisdiction under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the arguments and the evidence presented, for the reasons described below, we do not institute an *inter partes* review of any challenged claim.

A. Related Proceedings

Petitioner represents that the '427 patent is at issue in IPR2018-01569 and IPR2018-01570 and that related U.S. Pat. App. No. 15/349,758 is currently pending before the Office. Pet. 1. Patent Owner represents that IPR2018-01569 and IPR2018-01570 are related. Paper 3, 1.

B. The '427 Patent (Ex. 1001)

The '427 patent, titled "Apparatus and Methods for Endoluminal Graft Placement," describes an apparatus and methods for the placement of graft structures within the vascular system for treatment of aneurysms,

among other conditions. Ex. 1001, [54], 4:66–5:2. The grafts are placed endovascularly using a catheter over a guidewire with fluoroscopic guidance. *Id.* at 5:9–12. Specifically, the '427 patent describes a method for placing "a bifurcated graft structure in an abdominal aortic aneurysm . . . of a patient." *Id.* at 10:23–25. To describe the creation of this bifurcated graft structure, we begin with a reproduction of Figure 5, below:

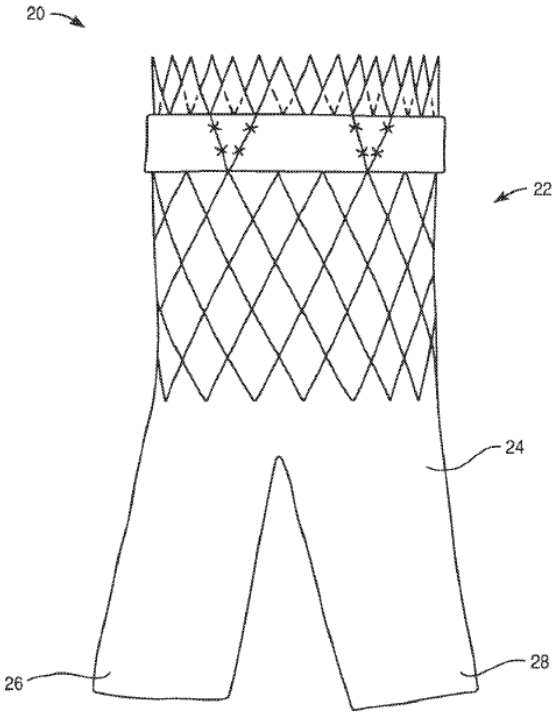


FIG. 5

According to the '427 patent, Figure 5 depicts a bifurcated base structure used for forming a bifurcated graft structure *in situ*. *Id.* at 4:54–55. In particular, the figure shows bifurcated base structure 20 comprising anchor segment 22 (or frame), which will typically be a radially-compressible perforate frame. *Id.* at 9:27–36. Liner 24 is disposed within anchor segment/frame 22 and has divergent flow lumens in each of its two legs 26, 28. *See id.* at 9:35–44. Legs 26, 28 are preferably not covered by frame 22 of the anchor. *Id.* at 9:44–45.

Figures 7, 8, 10, and 12, reproduced below, illustrate placement of the bifurcated graft in an abdominal aortic aneurysm (*id.* at 10:23–25):

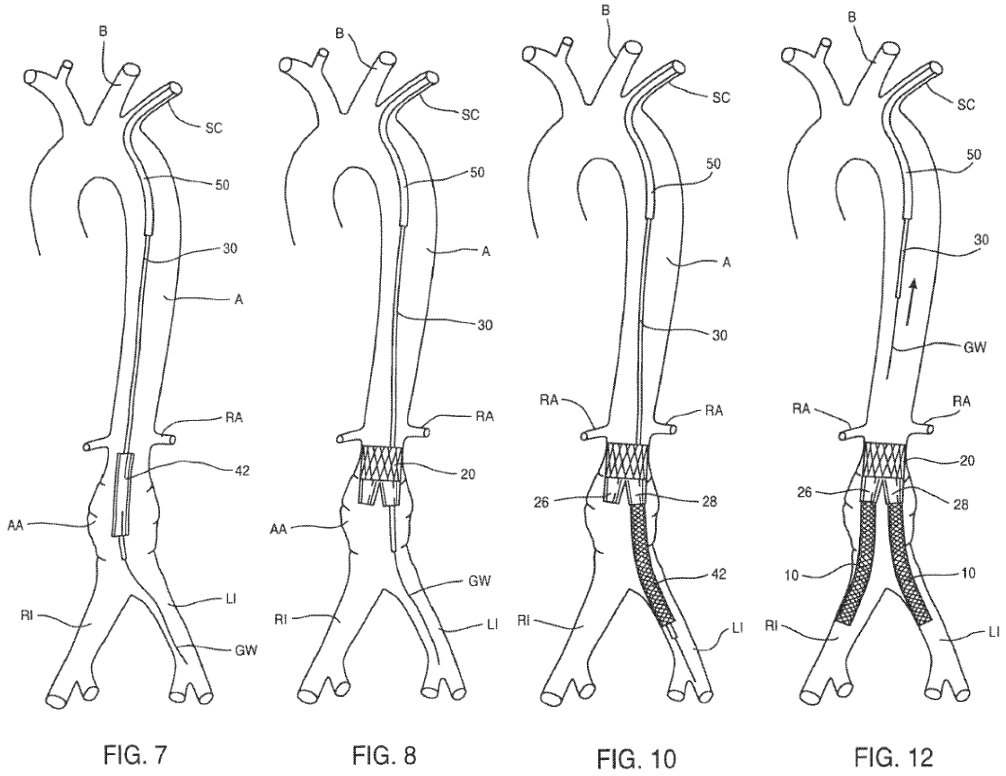


FIG. 7 FIG. 8 FIG. 10 FIG. 12

According to the ’427 patent, delivery catheter 30 is introduced through introducer sleeve 50, with bifurcated base structure 20 radially compressed within sheath 42, as shown in Figure 7. *Id.* at 10:25–30. Compressed bifurcated base structure 20 is then positioned and, once positioned, sheath 42 is withdrawn and base structure 20 expands in place, as shown in Figure 8. *Id.* at 10:28–32. Catheter 30 may then be withdrawn, leaving guidewire GW in place. *Id.* at 10:32–33. Vascular graft 10 is then compressed (within sheath 42), mounted on catheter 30, and positioned so that one end of graft 10 lies within fabric liner leg 28, as shown in Fig. 10. *Id.* at 10:33–37. Sheath 42 is then withdrawn so that vascular graft 10 expands within leg 28 and within left iliac artery LI. *Id.* at 10:37–39. Catheter 30 is then withdrawn and reintroduced in right iliac artery RI to

deliver second vascular graft 10 within second leg 26 of the fabric liner and RI, as shown in Figure 12. *Id.* at 10:44–49.

C. Illustrative Claims

Claims 1 and 15 are independent and recite a "method for introducing a vascular graft into a primary artery" and a "method for treating an aneurysm," respectively. *Id.* at 11:14–12:21. The independent claims are illustrative of the subject matter at issue and are reproduced below with emphases added to certain limitations addressed in this decision:

> 1. A method for introducing a vascular graft into a primary artery which divides into first and second branch arteries, said method comprising:
>
> 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 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; and
>
> 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*.
>
> 15. 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:
>
> 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; and
>
> 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*, wherein each of the grafts comprises a tubular frame and a liner.

Id. at 11:14–12:20 (emphases added).

D. References Relied Upon

Petitioner's challenges rely on the following references (Pet. 4–5):

Name	Reference	Ex. No.
Barone	US 5,360,443, issued Nov. 1, 1994.	Ex. 1005
Dumon	US 5,236,446, issued Aug. 17, 1993.	Ex. 1007
Schaer	*Schaer et al.*, Treatment of Malignant Esophageal Obstruction with Silicone-Coated Metallic Self-Expanding Stents, 38 GASTROINTESTINAL ENDOSCOPY, pp. 7–11 (1992).	Ex. 1008
Parodi 1991	*Parodi et al.*, Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms, 5 ANNALS VASCULAR SURGERY, pp. 491–99 (1991).	Ex. 1009
Parodi 1993	*Parodi*, Endovascular Repair of Abdominal Aortic Aneurysms, ADVANCES IN VASCULAR SURGERY, Vol. 1, Mosby Year Book, pp. 85–106 (1993).	Ex. 1010
Mirich	*David Mirich, M.D., et al.*, Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study, 170 RADIOLOGY, pp. 1033–1037 (1989).	Ex. 1011

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 1–42 of the '427 patent are unpatentable under the following grounds:

References	Basis	Claim(s)
Mirich and Dumon	§ 103(a)	1–42
Barone and (Parodi 1991 and/or Parodi 1993)	§ 103(a)	1–3, 5–7, 9–11, 13–17, 25, 26, 29, 31, and 35
Barone, Mirich, and (Parodi 1991 and/or Parodi 1993)	§ 103(a)	4, 8, 12, 18–24, 27, 28, 30, 32–34, and 36–42

Pet. 4–5.

Petitioner also relies on the declaration testimony of Dr. Enrique Criado, M.D., (Ex. 1029) in support of its Petition. Pet. xi.

II. ANALYSIS

A. Claim Construction

As a first step in our analysis, we determine the meaning of a claim using the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach). Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Although Petitioner and Patent Owner disagree about the interpretation of the claimed terms "simultaneously," "introducing," and "antegrade/retrograde," we determine that the only limitations that require construction for purposes of this Decision are: "to form a first continuous flow path" and "to form a second continuous flow path," as recited in independent claim 1; and "to form a second continuous flow path," as

recited in independent claim 15. *See* Prelim. Resp. 24 ("Petitioner's propos[ed interpretation of these terms is] an attempt to limit the scope of the claims beyond their broadest reasonable interpretation"); *see also Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

1. "to form a first continuous flow path" / "to form a second continuous flow path" (claim 1)

Independent claim 1 recites, "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*" and "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*. Ex. 1001, 11:23–32 (emphases added).

The plain language of the claim clearly requires that the flow paths are not formed between the branch arteries and the primary artery until *after* the first tubular graft is introduced into the first connector section and the second tubular graft is introduced into the second connector section. This construction is also consistent with the Specification. *See, e.g., id.* at Figs. 7–12 (depicting the method of connecting vascular grafts 10 to anchor section 20 (and connectors 26, 28) to form a flow path between the primary artery and the branch arteries (RI, LI) *after* vascular grafts 10 are implanted).

Accordingly, we interpret the claim limitations to require the first and second flow paths to be formed between the primary artery and the first and second branch artery *after* the first and second tubular grafts are introduced into the first and second connector sections, respectively. *Id.* at 11:14–32.

2. "to form a second continuous flow path" (claim 15)

Independent claim 15 recites, "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*." Ex. 1001, 12:16–19 (emphasis added).

As distinguished from claim 1, claim 15 does not require, *inter alia*, the first tubular graft to be "introduced" or "secured" to a first connector section. *Compare id.* at 11:23–27, *with id.* at 12:10–14. Claim 15 is similar to claim 1, however, in that claim 15 requires the second tubular graft to be secured to a connector leg of the anchor section "to form a second continuous flow path from the primary artery to the second branch artery." *Compare id.* at 11:28–32, *with id.* at 12:16–19.

As discussed above (*supra* Part II.A.1), the plain and ordinary meaning of this limitation, which is consistent with the Specification, requires the second continuous flow path between the primary artery and the second branch artery to be formed *after* the second tubular graft is secured to the connector leg of the anchor section.

Accordingly, we interpret the claim limitation to require the second flow path to be formed between the primary artery and the second branch artery *after* the second tubular graft is secured to the connector leg of the anchor section.

3. Other Claim Terms

We determine that no other claimed limitation requires express construction for purposes of this Decision. *See Wellman*, 642 F.3d at 1361.

B. Prosecution History

During prosecution, the examiner rejected, *inter alia*, independent claim 27 as anticipated by Barone. Ex. 1002, 2000–01. To overcome the rejection, the appellant amended the claims

> to clarify that the step of introducing and deploying a bifurcated structure including an anchor section and first and second connector sections extending toward the first and second branch arteries is performed prior to the subsequent steps of introducing a first tubular graft into the first connector section and introducing a second tubular graft into the section connector section.

Id. at 2098. The appellant further argued that

> Barone does not teach or suggest separately introducing first and second grafts into a previously deployed bifurcated structure so that the respective grafts extend between the respective connector section and the respective branch artery *to form a continuous flow path from the primary artery to the respective branch artery*, as recited in independent claim 27.

Id. at 2098-99 (emphasis added).

The Examiner issued a Notice of Allowance explaining that the prior art fails to disclose or fairly suggest the claimed limitations. *Id.* at 2247–49. Claim 27 issued as independent claim 1 and claim 41 issued as independent claim 15.

C. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, *i.e.*, secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

D. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17.

Petitioner relies upon the declaration of Dr. Criado (Ex. 1029) and contends that a person of ordinary skill in the art ("PHOSITA") would have been either "a mechanical or biomedical engineer with experience developing and making *stents, grafts, or stent grafts*" or "a physician with

experience in both developing and making *stents, grafts, or stent grafts* and in the intraluminal placement of stent grafts or stents." Pet. 13 (citing Ex. 1029 ¶¶ 16–17 (emphases added)).

Patent Owner, similarly, but more broadly, contends that a POSITA "would be a mechanical or biomedical engineer with experience in an academic or industrial laboratory focusing on *medical device development*, or a physician with experience in *medical device development* and the introduction or implantation of medical devices into a patient." Prelim. Resp. 23 (emphases added). Patent Owner alternatively proposes that a POSITA would have had "significant experience in an academic or industrial laboratory focusing on development of *medical devices*." *Id.* (emphasis added).

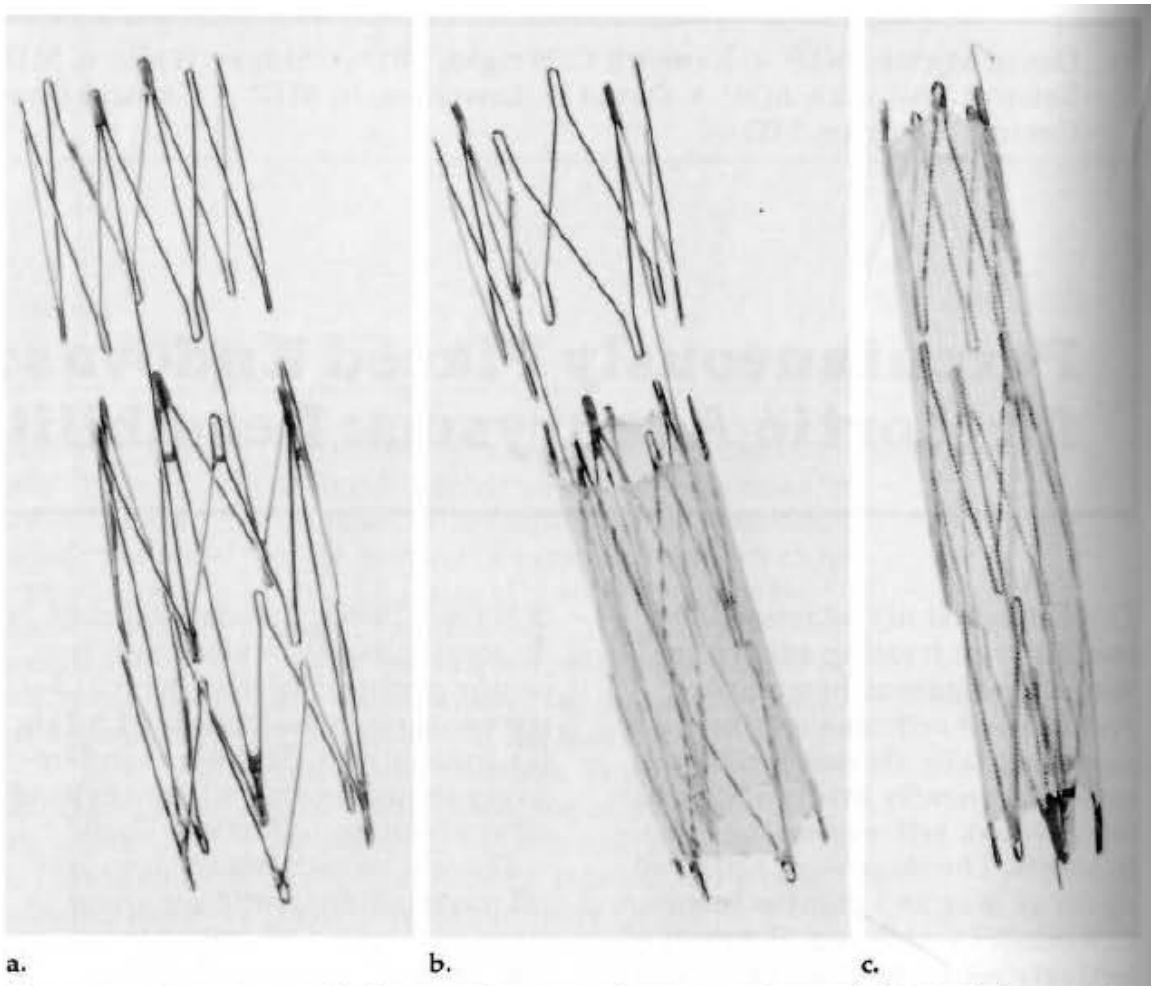
We find that the level of ordinary skill as proposed by both Petitioner and Patent Owner to be excessively vague. Neither meaningfully specifies the extent of applicable working experience and neither specifies the appropriate level of education. Based on our review of the '427 patent, the types of problems and solutions described in the '427 patent and applied prior art, for purposes of this decision, we determine that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

E. Mirich and Dumon

Petitioner contends that claims 1–42 are unpatentable over Mirich and Dumon. Pet. 40.

1. Mirich (Ex. 1011)[1]

Mirich is a technical publication from the 15th Annual Meeting of the Society of Cardiovascular & Interventional Radiology, San Diego, March 20–23, 1989. Ex. 1011, cover page. Mirich is titled, "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" and describes a "limited study address[ing] the feasibility of treating aneurysms with a new transcatheter endoprosthesis." *Id.* at 1033. We reproduce Figure Figures 1a–c of Mirich, below:



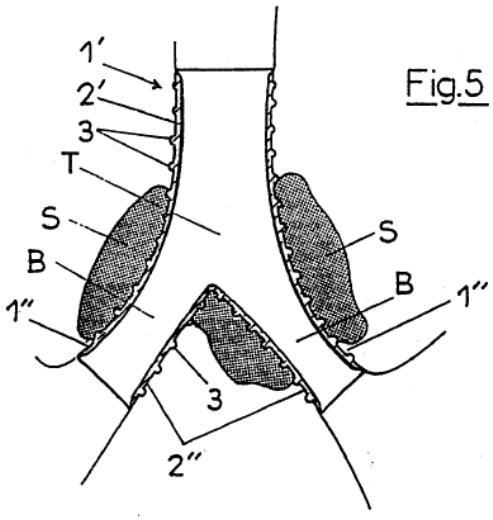
[1] Our citations to Mirich are to the native page numbers.

According to Mirich, Figures 1a–c depict a self-expanding arterial endovascular graft. Ex. 1011, 1034. Figure 1a depicts graft framework consisting of three self-expanding metallic zig-zag stents connected in tandem. *Id.* Figure 1b depicts a completed graft, the lower two stents being covered in nylon. *Id.* Figure 1c depicts barbs attached at both ends to anchor the graft.

Mirich discloses that it is "essential to locate the aneurysm exactly and bridge it completely" because "[o]nce the graft was deployed, it could not be repositioned or retrieved." *Id.*

2. Dumon (Ex. 1007)

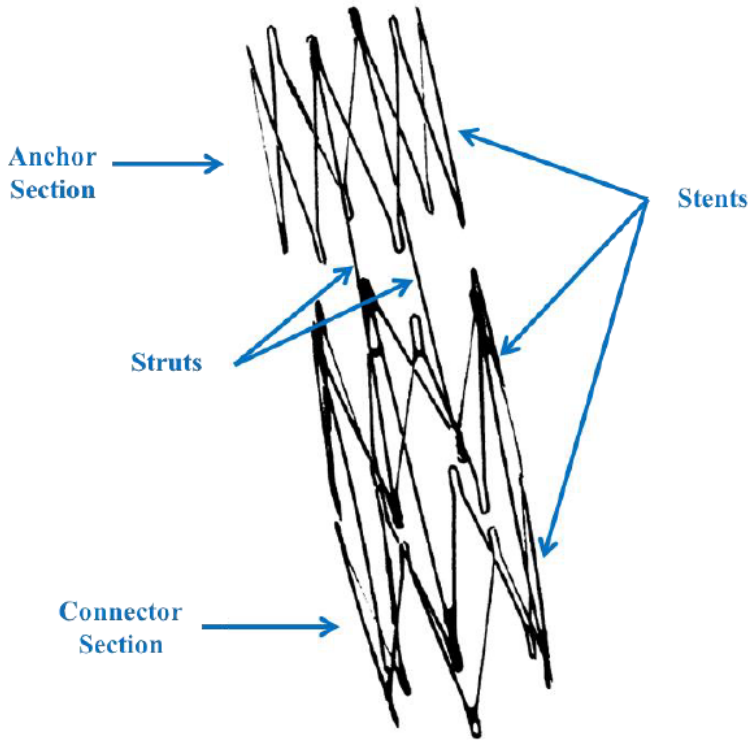
Dumon is a U.S. Patent titled "Tubular Endoprosthesis for Anatomical Conduits" and discloses a tubular endoprosthesis for anatomical conduits. Ex. 1007, [54], [57]. Dumon discloses that its endoprostheses is intended to be installed in "a variety of shapes" and "can have any shape and any diameter adapted to the shape and the diameter of the conduits, channels or vessels inside which it is to be placed." *Id.* at 2:30–44. We reproduce Figure 5 of Dumon, below:



Dumon describes Figure 5 as depicting a prosthesis with principal tubular body **1**' extended by two divergent tubular branches **1**." Ex. 1007, 3:15–22. Dumon further discloses that the "lateral opening **9** can also allow and favor the installation of a second independent tubular branch similar to the secondary part **10'**, in order to create an endoprosthesis like the one shown" above. *Id.* at 3:47–51.

3. Petitioner's Challenge

In challenging independent claim 1, Petitioner submits that Mirich discloses a method for introducing a vascular graft including the step of introducing a graft structure including an anchor section and a connector section. Pet. 43–44. Petitioner submits an annotated version of Mirich's Figure 1a (*id.* at 44), which we reproduce below:

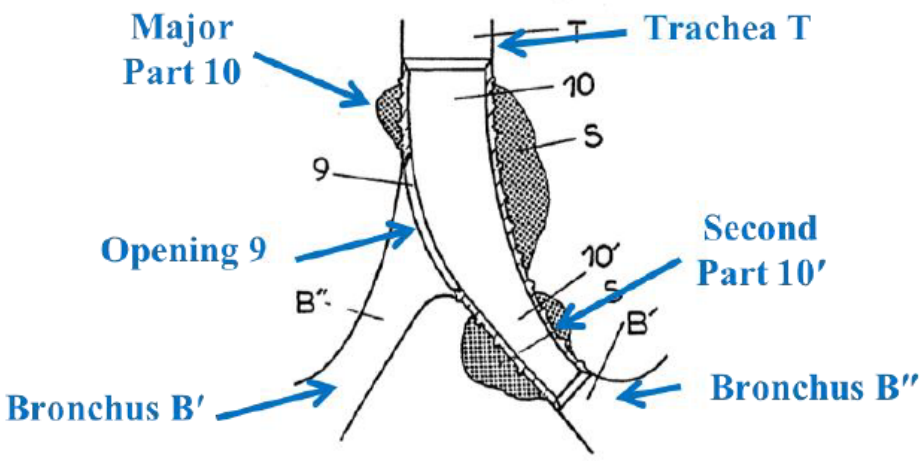


According to Petitioner, and as shown in the annotated Figure 1a, a POSITA "would have recognized that these structures are capable of being overlapped to increase the overall length of the graft, as was well known in the prior art for Z-stents." Pet. 44–45 (citations omitted). Petitioner also asserts that a POSITA "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." *Id.* at 45 (citations omitted).

Petitioner further asserts that a POSITA "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." *Id.* (citing Ex. 1029 ¶ 122). Dr. Criado testifies that "it would have been obvious to construct the Mirich graft in a bifurcated configuration" and that "[c]onstructing 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)." Ex. 1029 ¶ 122 (emphasis added).

Petitioner also relies on Dumon for disclosing "a method of introducing a bifurcated endoprosthesis, by separately introducing and deploying multiple prosthesis components" and asserts that a POSITA "would have recognized that the Dumon method could easily be applied to the Mirich grafts." Pet. 46 (citing Ex. 1029 ¶¶ 123, 124; Ex. 1007, 3:31–50). Petitioner submits an annotated version of Dumon's Figure 12, which we reproduce (*id.* at 47), below:

Fig.12



According to Petitioner, and as shown above in annotated Figure 12, "it would have been obvious to construct a modified Mirich graft, including 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'" *Id*. at 47.

In the alternative, Petitioner reasons that "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 iliac artery . . . to increase the surface area of contact at the connection between the bifurcated structure and first tubular graft . . . thereby providing a more secure connection to prevent inadvertent separation." *Id*. at 48–49 (citing Ex. 1029 ¶ 126).

To satisfy the claim limitation, "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," Petitioner reasons that 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." Pet. 50 (italics omitted) (citing Ex. 1029 ¶ 129).

To address the claimed "introducing a second tubular graft into the second connector section . . . to form a second continuous flow path," Petitioner reasons that a POSITA "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" (*id.* at 51 (citing Ex. 1029 ¶ 130)) and that a POSITA "would have erred on the side of sizing the Mirich bifurcated graft so that it is relatively short, rather than relatively long" (*id.* at 52 (citing Ex. 1029 ¶ 134)).

4. Patent Owner's Response

Patent Owner argues, *inter alia*, that "Petitioner relies on several unsubstantiated leaps in reasoning to assert that a POSA would have been motivated to modify Mirich and combine Mirich with Dumon to arrive at the claimed methods." Prelim. Resp. 31–32.

We agree.

5. Analysis

Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Mirich and Dumon render obvious claims 1–42.

First, we are not persuaded that "it would have been obvious to construct the Mirich graft in a bifurcated configuration," as Petitioner reasons. Pet. 45 (citing Ex. 1029 ¶ 122). The Federal Circuit has stated that

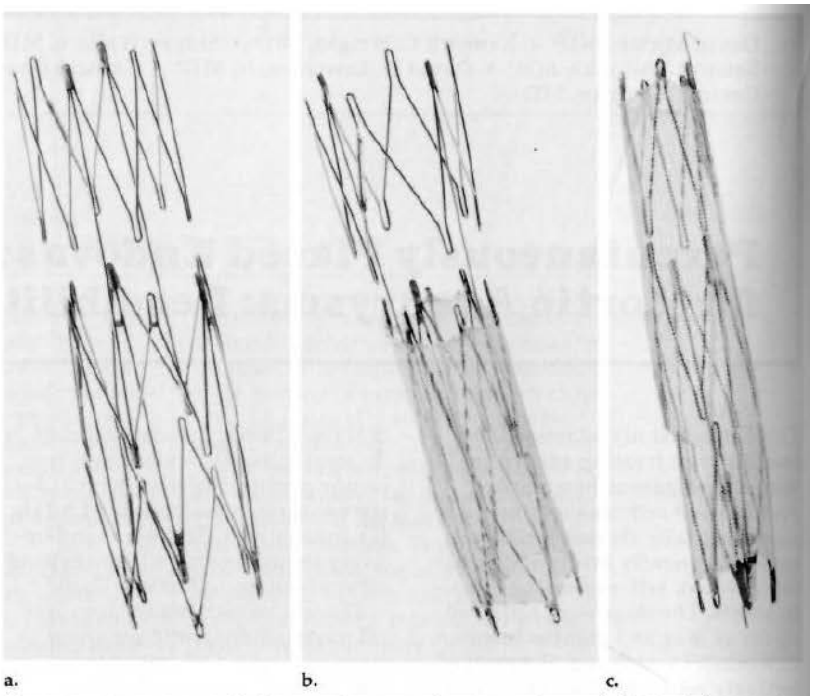
"rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR*, 550 U.S. at 418.

In support of Petitioner's reasoning, Dr. Criado testifies that "[c]onstructing 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)." Ex. 1029 ¶ 122 (emphasis added). Because Dr. Criado's testimony does not disclose the underlying facts or data on which this opinion is based, however, it is entitled to little or no weight. 37 C.F.R. § 42.65(a).

Although Dr. Criado testifies that "[b]ifurcated endoluminal devices and methods . . . were well known" at the time of the invention, and submits several figures in support of this assertion (Ex. 1029 ¶ 79), we do not find the cited figures have structure that remotely resembles the self-expanding stents that Mirich utilizes. Absent evidence and explanation, we are not persuaded that reconfiguring Mirich's cylindrical graft to be bifurcated would have been obvious, *let alone routine*, as Petitioner argues. Pet. 45 ("Constructing the Mirich graft in a bifurcated configuration would have been considered *obvious and routine* to a PHOSITA" (emphasis added)).

Indeed, Mirich does not disclose bifurcated grafts at all, instead disclosing straight, self-expanding, cylindrical grafts that are radially compressed about its axis and within a catheter to advance the graft to a position that bridges the aneurysm. Ex. 1011, 1034 (Graft Placement and

Follow-up, Figure 1). Upon withdrawal of the catheter, the graft expands in position to bridge the aneurysm. *Id.* To further illustrate Mirich's stents, we reproduce its Figures 1a–c, below:

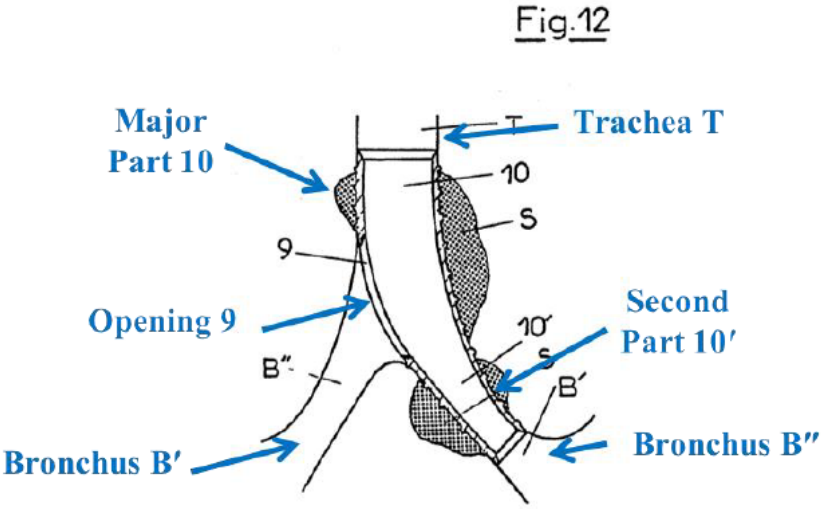


According to Mirich, and as shown in the above Figures 1a-c, its grafts have a framework that "consist[s] of three self-expanding metallic zigzag stents connected in tandem." Ex. 1011, 1034 (referencing Figure 1a).

Notwithstanding Dr. Criado's testimony, we are not persuaded that "[c]onstructing the Mirich graft in a bifurcated configuration would have been considered obvious and *routine* to a PHOSITA." Ex. 1029 ¶ 122 (emphasis added). *Even if* we accept as true Dr. Criado's assertion that bifurcated endoluminal grafts for treating aortic aneurysms were well known at the time of the invention (*id.* n.16, ¶ 79), we are not persuaded that it would have been routine to construct Mirich's straight, tubular, radially-compressible graft with self-expanding metallic zigzag stents connected in tandem to form a radially-compressible, self-expanding *bifurcated graft*.

Stated differently, we are not persuaded that it would have been obvious—*let alone routine*, as Petitioner argues (Pet. 45)—to reconfigure Mirich's stent, which compresses radially about a single axis, into a bifurcated stent that has two divergent axes.

Second, Petitioner relies on the "Dumon method" for "disclos[ing] a method of introducing a bifurcated endoprosthesis, by separately introducing and deploying multiple prosthesis components." Pet. 46 (citing Ex. 1029 ¶ 123; Ex. 1007, 3:31–50, Fig. 5). Petitioner further asserts that the "Dumon method [is] assembling a bifurcated device *in situ* from multiple, individually inserted components." *Id.* Petitioner submits an annotated version of Dumon's Figure 12, which we reproduce, below:



The figure shows a modified Mirich graft. According to Petitioner, "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 *junction point* of the major part 10 and the secondary part 10', as depicted in annotated Dumon Figure 12." Pet. 47.

However, we do not see any "junction point" between major part 10 and secondary part 10'. Furthermore, we do not find Dumon as disclosing

any such method for "assembling a bifurcated device *in situ*," as Petitioner asserts. Rather, Dumon merely discloses, "The lateral opening **9** can also allow and favor the installation of a second independent tubular branch similar to the secondary part **10'**, in order to create an endoprosthesis like the one shown in **FIG. 5**." Ex. 1007, 3:47–51. Upon reviewing Figures 5 and 12 in light of this disclosure, we find that Dumon is ambiguous as to how the second tubular branch is installed, and we are mindful not to read into Dumon that which is not disclosed. Such hindsight bias has no role in an obviousness analysis. Because Dumon does not disclose or depict any method for assembling a bifurcated endoprosthesis in parts, we are not persuaded that a POSITA would have implanted Mirich's bifurcated graft with the "Dumon method" to meet the claims, as Petitioner proposes.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Mirich and Dumon render obvious claims 1–42.

F. Barone and (Parodi 1991 and/or Parodi 1993)

Petitioner contends that claims 1–42 are unpatentable over Barone in view of "one or both of" Parodi 1991 and Parodi 1993. Pet. 75 (bolding omitted).

1. Barone (Ex. 1005)

Barone is a U.S. Patent titled "Aortic Graft for Repairing an Abdominal Aortic Aneurysm" and discloses a "method and apparatus for repairing an abdominal aortic aneurysm." Ex. 1005, [54], [57]. Barone discloses a unitary bifurcated vascular graft that is introduced in one piece

and maneuvered within a patient to be positioned in the aorta and iliac arteries. *Id.* at 9:19–51, Figs. 9–12. To illustrate Barone's method of implanting its graft, we reproduce Figures 9–12, below:

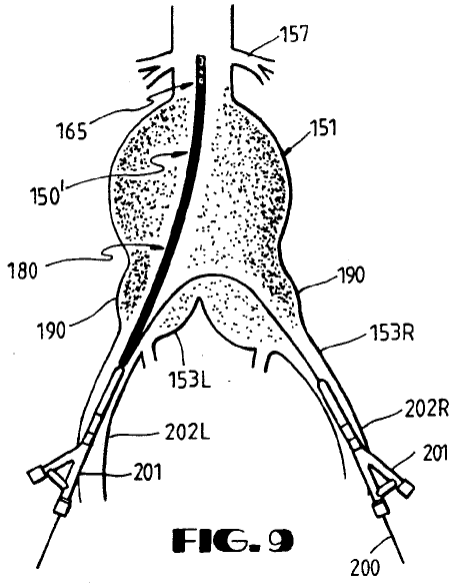


FIG. 9

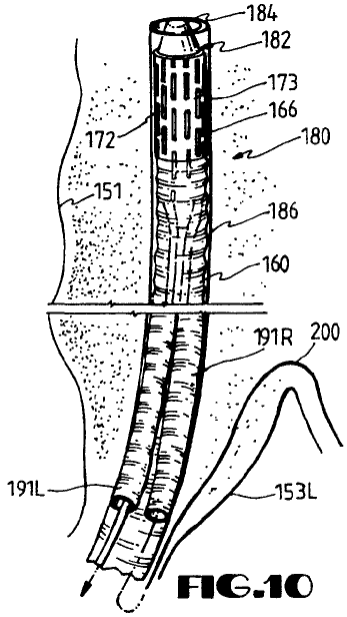


FIG.10

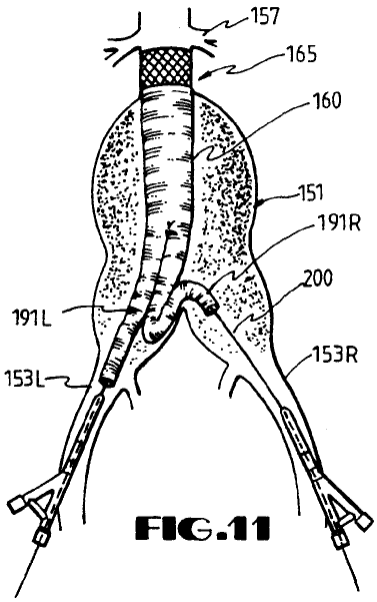


FIG.11

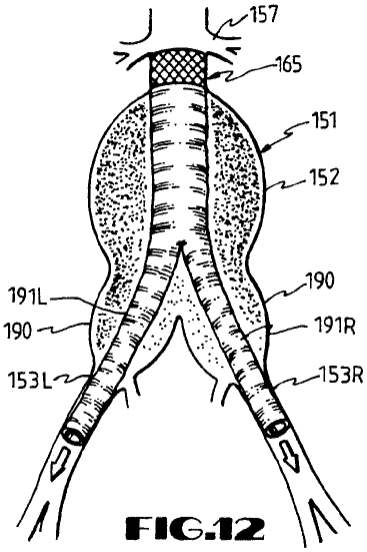


FIG.12

According to Barone, Figures 9–12 "are partial cross-sectional views of an abdominal aortic aneurysm, illustrating one embodiment of the method of the present invention for repairing an abdominal aortic aneurysm and iliac

aneurysm." *Id.* at 5:16–19. Securing means 165 is disposed in aorta and positioned as shown in Figure 9. *Id.* at 9:37–39. Sheath 186 is removed and surgical wire 200 may then be sutured to right passageway 191R of tube 160, as shown in Figure 10. *Id.* at 9:39–43. Wire 200 can then be withdrawn and pulled, so as to pull right passageway 191R of tube 160 downwardly into right iliac artery 153R until it assumes the position shown in Figure 12. *Id.* at 9:45–49.

During prosecution, the Examiner rejected, but subsequently withdrew, several claims as being anticipated by Barone. *See supra* Part II.B.

2. Parodi 1991 (Ex. 1009)[2]

Parodi 1991 is a technical publication titled "Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms." Ex. 1009, 491. Parodi 1991 describes grafts with one or two balloon-expandable stents (*id.* at 493) and describes one patient who received a graft with one stent with a second stent placed on the unstented end (*id.* at 495). To illustrate this structure, we reproduce Parodi 1991's Figures 8 and 10 (*id.* at 496, 498), below:

[2] Citations to Parodi 1991 will be to the native page numbers.

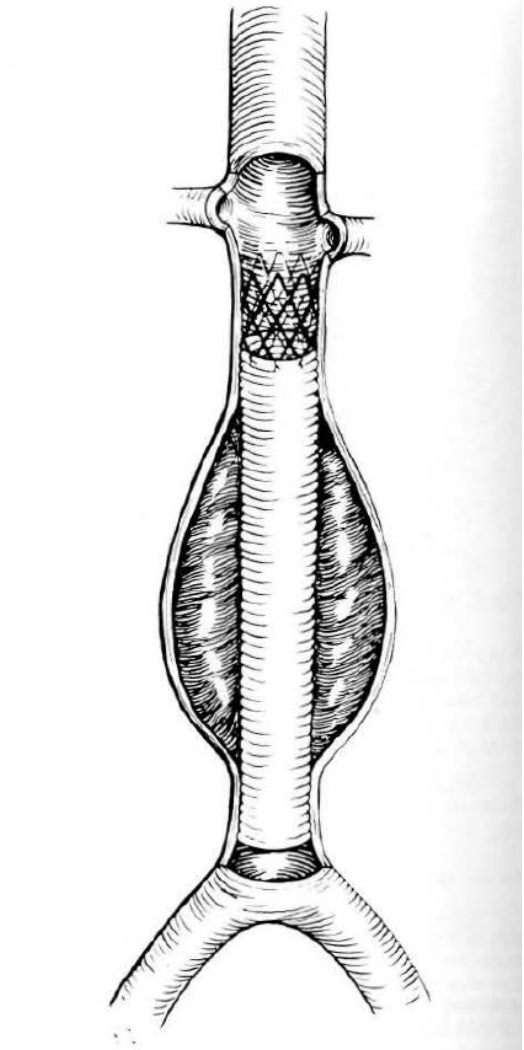


Fig. 8. Graft-stent combination with cephalic stent.

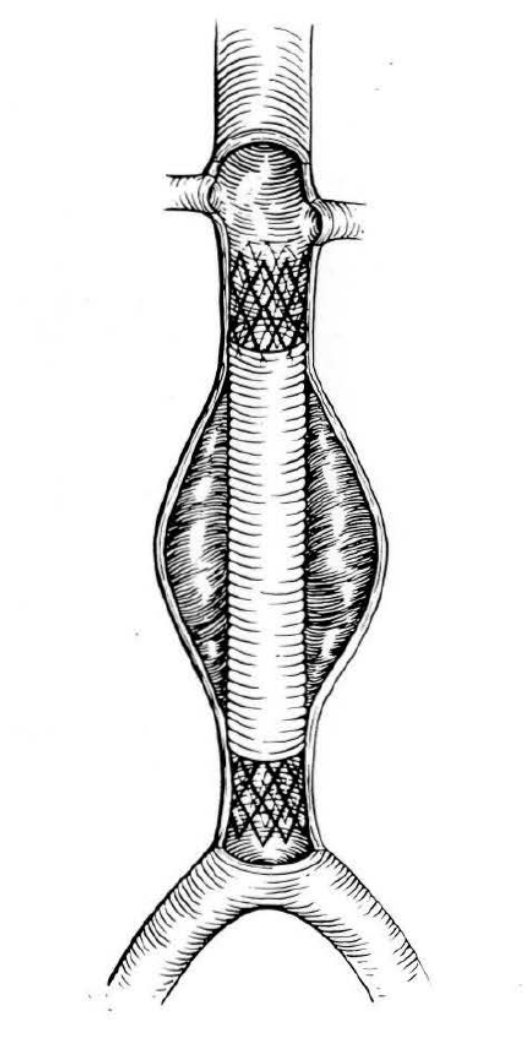


Fig. 10. Graft-stent combination with both cephalic and caudal stent.

According to Parodi 1991, the above-left Figure 8 depicts a graft-stent combination with a cephalic stent (*id.* at 496) while the above-right Figure 10 depicts a graft-stent combination with both a cephalic and a caudal stent (*id.* at 498).

3. Parodi 1993 (Ex. 1010)[3]

Parodi 1993 is a chapter titled, "Endovascular Repair of Abdominal Aortic Aneurysms," from a technical book titled, "Advances in Vascular Surgery." Ex. 1010, 85. Parodi 1993 describes the treatment of abdominal aortic aneurysms with vascular grafts that are tailored to fit the individual patient. *Id.* at 85, 90.

Parodi 1993 discloses that a second endovascular graft may be deployed within the lumen of a first graft to extend the length of the original graft. *Id.* at 96, 104. In particular, Parodi 1993 describes leakage through a proximal stent of a deployed graft, which was resolved by deploying a second stented graft within the lumen of the first graft. *Id.* at 99. Parodi 1993 also describes deploying a second stented graft within the lumen of a first graft, which was too short. *Id.*

4. Petitioner's Challenge

Petitioner relies on Barone for disclosing a method for introducing a vascular graft and the step of "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." Pet. 77–78 (addressing claim 1); *see also id.* at 92–95 (addressing similarly claim 15). To illustrate this finding, Petitioner submits an annotated version of Barone's Figure 6 (*id.* at 78), which we reproduce, below:

[3] Citations to Parodi 1993 are to the native page numbers.

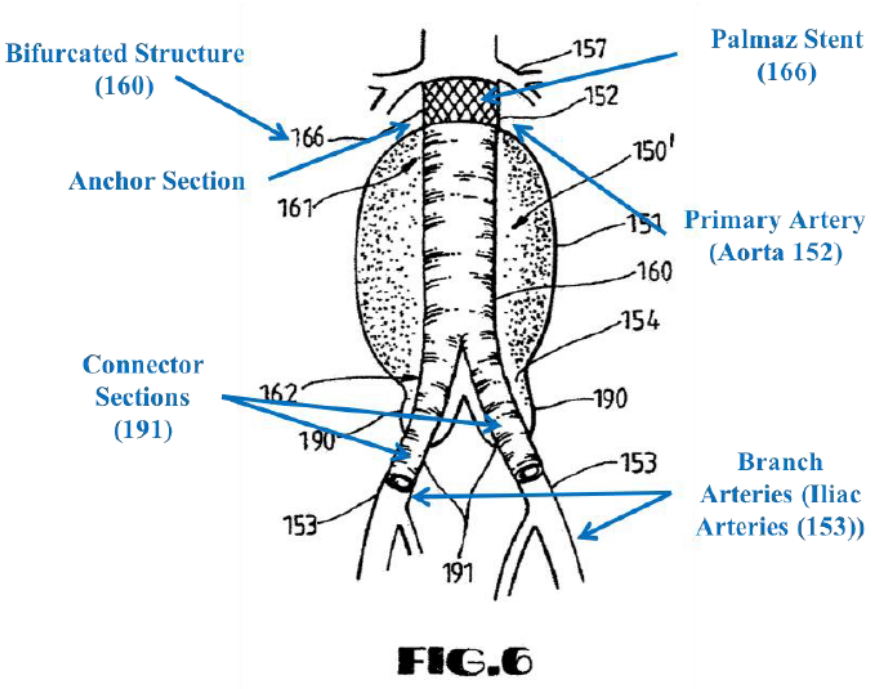


FIG.6

According to Petitioner, the above annotated figure 6 shows "anchor section" disposed within primary artery/aorta 152, with "first and second connector sections" 191 extending toward the first and second branch arteries/iliac arteries 153. Pet. 78 (citations omitted).

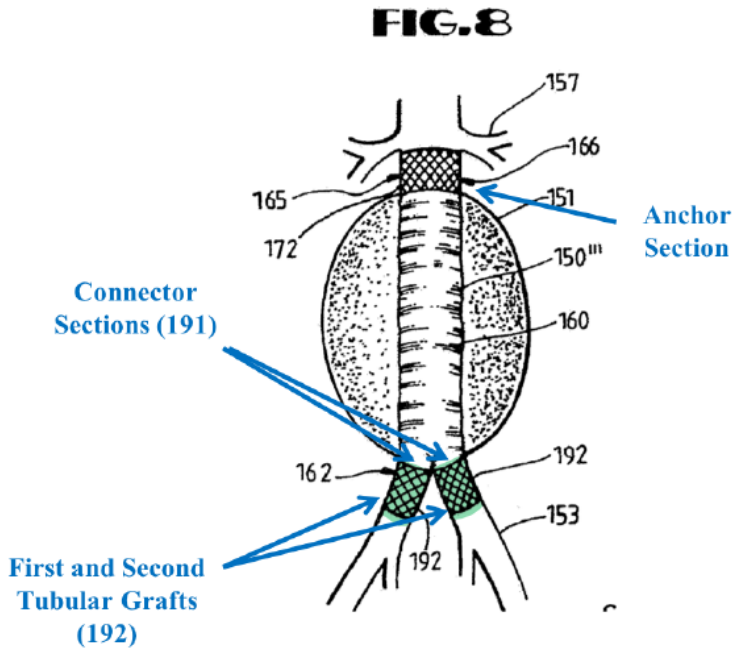
To address the claimed "and thereafter; introducing a first tubular graft into the first connector section and anchoring said first tubular graft to extend between the first connector section and the first branch artery to form a first continuous flow path from the primary artery to the first branch artery," Petitioner relies on a combination of Barone and (Parodi 1991 and/or Parodi 1993). Pet. 79–86; *see also id.* at 96–98 (addressing similarly claim 15).

Petitioner acknowledges that Barone does not disclose the step of introducing a connector section after the bifurcated structure is deployed, but asserts that "[t]his is not a patentable distinction." Pet. 79 (citing in-part *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 theretofore been used in one part, and using the separate parts to serve the purpose that had been served before the division is not invention" (internal citation omitted)).

Petitioner reasons that a POSITA "would have erred on the side of sizing the bifurcated graft so that it is relatively short, rather than relatively long" (*id.* at 81 (citing Ex. 1029 ¶ 196)) so that the graft does not "undesirably occlude[] other branching arteries" (*id.* at 80).

Petitioner further reasons that it would have been obvious to size Barone's "connector sections" so that they "extend toward, but not into" the respective iliac arteries. *Id.* at 84. Petitioner submits another annotated version of Barone's Figure 8 (*id.* at 85) to illustrate this structure, below:



The figure illustrates a modified Barone graft. According to Petitioner, modifying Barone as Petitioner proposes "would resemble the graft depicted in Figure 8 . . . with first and second tubular grafts highlighted in green." *Id.* (citing Ex. 1029 ¶¶ 201, 202). Petitioner asserts that a

POSITA would have sized Barone's "connector sections" to "extend toward, but not into" iliac arteries 153 so as to "eliminate the need to perform the complicated step of moving connector section 191R from the iliac artery 153L into iliac artery 153R." *Id.* at 84.

Petitioner reasons that a POSITA would have been motivated to introduce and deploy the first and second tubular grafts, as called for in the claims, in order: to ensure that the 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.* at 85 (citing Ex. 1029 ¶ 203).

To address the claimed "introducing a second tubular graft . . .," Petitioner relies on the same analysis and reasoning discussed above regarding the "introducing a first tubular graft . . . ." *See* Pet. 87.

5. Patent Owner's Response

Patent Owner responds that Petitioner's reasoning is flawed because it is premised on either a length problem (Prelim. Resp. 56) and a complexity problem (*id.* at 62) that simply do not exist. Patent Owner asserts that the supposed length and complexity problems are "born solely out of speculation and hindsight." *Id.* at 54.

We agree.

6. Analysis

For several reasons, Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Barone and (Parodi 1991 and/or Parodi 1993) render obvious claims 1–42.

First, we are not persuaded that a person having ordinary skill in the art would have *wholly redesigned* Barone's graft and its disclosed surgical method, as Petitioner proposes. Specifically, we are not persuaded that a POSITA would have shortened Barone's graft only to perform a subsequent procedure to add second grafts.

During prosecution, the appellant amended the claims to overcome the examiner's anticipation rejection under Barone. *See supra* Part II.B. The appellant argued that "Barone does not teach or suggest separately introducing first and second grafts into a previously deployed bifurcated structure" (Ex. 1002, 2098–99), which the examiner found persuasive (*id.* at 2247–48).

Notwithstanding the prosecution history, Petitioner asserts that a POSITA would have "erred on the side of sizing [Barone's] bifurcated graft so that it is relatively short" only to later "extend one or both of the connector legs." Pet. 81. Petitioner's reasoning for modifying Barone, however, is a bridge too far, and is not supported by the evidence of record.

In particular, Petitioner's proposed modification of shortening Barone's legs so that they extend toward, but not into the branch arteries, lacks rational underpinnings. *See* Pet. 84 ("it would have been obvious to size [Barone's] 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"); Ex. 1029 ¶ 201.

Dr. Criado's testimony in support of this reasoning (Ex. 1029 ¶ 201) is premised on an unfounded assertion that doing so would "eliminate the need to perform the *complicated step* described in Barone." Ex. 1029 ¶ 201 (emphasis added). We are not persuaded, however, that Barone's method is so complicated that a POSITA would have wholly redesigned Barone's graft by shortening its "legs" only to later perform a wholly different procedure to add second grafts. Because Dr. Criado's testimony as to Barone's "complexity" is not supported by facts or evidence, it is given little weight. 37 C.F.R. § 42.65(a). We find that the proposed combination is based on improper hindsight in light of the disclosure of the '427 patent, and is made to satisfy the claimed steps of "introducing a first tubular graft . . . to form a first continuous flow path" and "introducing a second tubular graft . . . to form a second continuous flow path," as recited in claim 1, and the claimed step of "securing a second tubular graft . . . to form a second continuous flow path," as recited in claim 15. *See supra* Parts II.A.1, II.A.2.

Furthermore, Petitioner's assertion that the claimed step involves "no invention" misconstrues the law. *See* Pet. 79 (citations omitted). Petitioner argues that "the making of two or more parts out of a thing that had heretofore been used in one part, and using separate parts to serve the purpose that had been served before the division is not invention." *Id.* (citing *Laclede-Christy*, 280 F. at 85). Petitioner's reliance on *Laclede-Christy*, however, is misplaced.

As pointed out correctly by Patent Owner, in *Laclede-Christy*, the 8th Circuit further explained, "where a discovery embodies co-acting elements, although they be old, yet, if when brought together in a way not theretofore known, they produce by their interaction a new and useful result, the

combination is patentable . . . . [A]nd if one of the elements in the combination be removed or changed so that their interaction is then in another way . . . there is nevertheless invention, although the same result is attained." Prelim. Resp. 61 (citing *Laclede-Christy*, 280 F. at 85). The claims at issue are *method claims* and Petitioner's analysis focuses overly on the structure of a multi-part graft while discounting the importance of the claimed steps of implanting a multi-part graft, including the step of forming continuous flow paths between the primary and branch arteries once the tubular grafts are introduced (claim 1) or secured (claim 15) in the branch arteries. *See supra* Part II.A.1.

Because Petitioner's reasoning for modifying Barone is not supported by the record, Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Barone and (Parodi 1991 and/or Parodi 1993) render obvious claims 1–42.

G. Barone, (Parodi 1991 and/or Parodi 1993), and Mirich

Petitioner relies on Barone, (Parodi 1991 and/or Parodi 1993), and Mirich to address *dependent claims* 4, 8, 12, 18–24, 27, 28, 30, 32–34, and 36–42. Pet. 101. These claims depend directly or indirectly from independent claim 1 or 15. Ex. 1001, 11:14–14:21.

Petitioner relies on Mirich to address dependent claims not challenged under Barone and (Parodi 1991 and/or Parodi 1993), alone. *Id.* Petitioner does not rely on Mirich to address any of the deficiencies discussed above (*supra* Part II.F.6) in the combination of Barone and (Parodi 1991 and/or Parodi 1993).

For the same reasons we are not persuaded that independent claims 1 and 15 are unpatentable over Barone and (Parodi 1991 and/or Parodi 1993), we are not persuaded that claims 4, 8, 12, 18–24, 27, 28, 30, 32–34, and 36–42 are unpatentable over Barone, (Parodi 1991 and/or Parodi 1993), and Mirich.

III. ORDER

For the reasons given, it is:

ORDERED that no *inter partes* review is instituted.

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