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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 IPR2018-01570
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. 1. 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.

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 IPR2018-01571 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 IPR2018-01571 are related. Paper 4, 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 reproduce Figure 5, below:

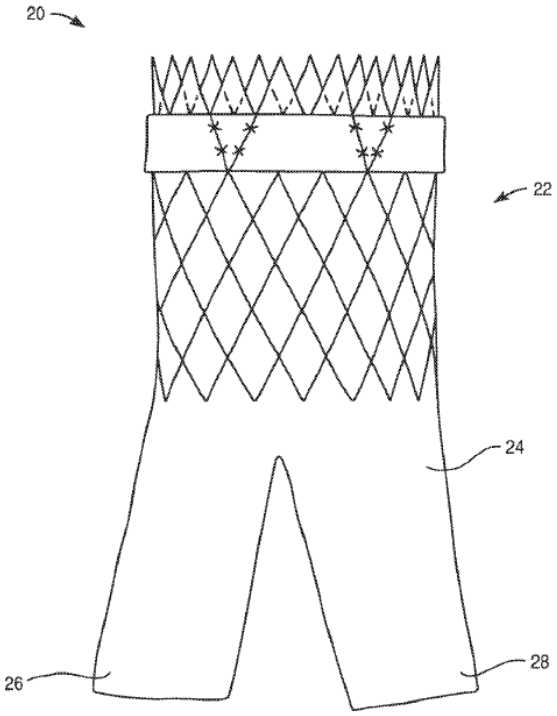


FIG. 5

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):

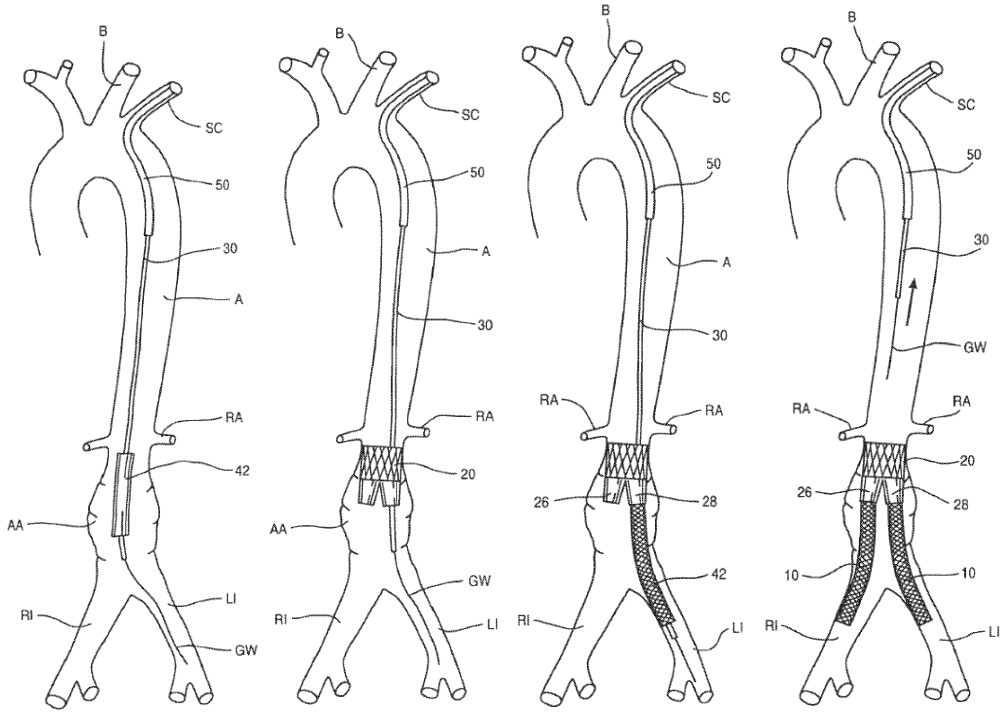


FIG. 7 FIG. 8 FIG. 10 FIG. 12

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 11:14–14:21. 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):

Name	Reference	Ex. No.
Plaia	US 5,571,169, issued Nov. 5, 1996	Ex. 1006
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

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)
Plaia and Schaer	§ 103(a)	1–42
Plaia and Dumon	§ 103(a)	1–42

Pet. 4.

Petitioner also relies on the declaration testimony of Dr. Enrique Criado, M.D., (Ex. 1028) 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. 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).

C. 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. 1028) and contends that a person of ordinary skill in the art ("POSITA") 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. 14 (citing Ex. 1028 ¶¶ 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).

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).

D. Plaia and Schaer

Petitioner contends that claims 1–42 are unpatentable over Plaia and Schaer. Pet. 30.

1. Plaia (Ex. 1006)

Plaia is a U.S. patent titled "Anti-Stenotic Method and Product for Occluded and Partially Occluded Arteries" (Ex. 1006, [54]) and discloses "[m]ethods of artificially lining a vessel, especially an artery, of a medical patient to address the existence of a flow-inhibiting atheroma" (*id.* at [57]). Plaia discloses vascular grafts and states that its grafts advantageously

provide a conduit for blood flow for preventing aneurysms and preserving the area for blood flow. *Id.* at 13:22–31.

To illustrate an embodiment of a graft disclosed in Plaia, we reproduce its Figure 20, below:

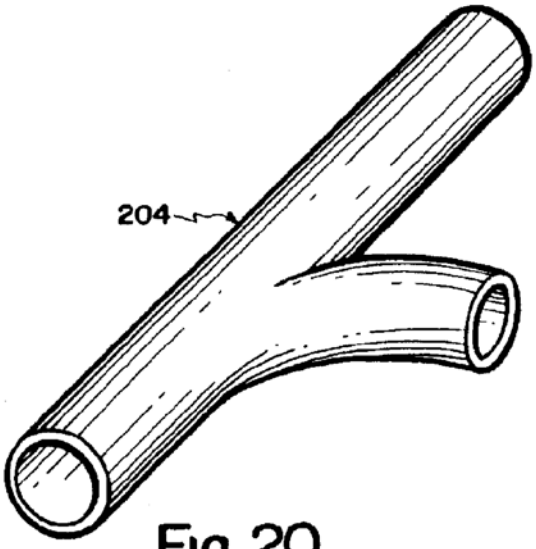


Fig. 20

According to Plaia, Figure 20 depicts vascular graft 204, which is "adapted to conform specifically to the nature of the shape, size, and disposition of the branched artery subjected to treatment." Ex. 1006, 12:36–41.

Plaia further discloses that its grafts, "once correctly positioned and contiguous with the interior vascular wall, [are] usually inherently secure against inadvertent migration within the artery or other vessel due to friction and infiltration of weeping liquid accumulation on the inside artery wall." *Id.* at 7:31–35. Plaia further discloses that stents may be used to hold open the grafts (*id.* at 7:45–46) and that the stents may be expanded to bias the graft against the treated arterial surface (*id.* at 13:13–17).

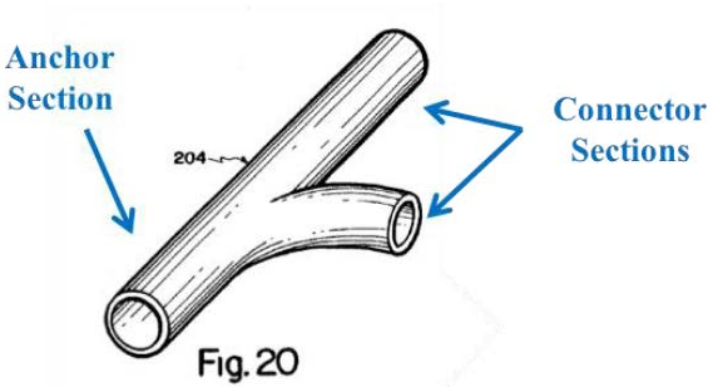
Plaia does not disclose a method for implanting its graft in a bifurcated artery.

2. Schaer (Ex. 1008)

Schaer is a technical publication titled "Treatment of Malignant Esophageal Obstruction With Silicone-Coated Metallic Self-Expanding Stents." Ex. 1008, 1. Schaer discloses a self-expanding stent placed in the *esophagus* to create a passageway for food and beverages when a patient's throat has been *blocked by tumors*. *Id.* at 7. Schaer further discloses that "an overlapping stent can be placed at either end of the original stent to, in effect, extend the stented region." *Id.* at 10.

3. Petitioner's Challenge

In challenging independent claim 1, Petitioner submits that Plaia discloses a "method for introducing a vascular graft into a primary artery which divides into first and second branch arteries" (Pet. 32) and the step of "introducing and deploying a bifurcated structure including an anchor section and first and second anchor sections . . ." (*id.* at 33). Petitioner relies on similar findings in addressing independent claim 15 and further reasons that it would have been obvious to dispose Plaia's tubular graft within a primary artery and first iliac artery. *See id.* at 55–56. In support of these assertions, Petitioner submits an annotated version of Plaia's Figure 20 (*id.* at 33), which we reproduce below:



Plaia's Figure 20 depicts a line drawing diagrammaticlaly illustrating in perspective a bifurcated vascular graft. Ex. 1006, 3:58:60.

According to Petitioner, and as shown in the above annotated figure 20, Plaia's "anchor section" is introduced and deployed within the primary artery, and the first and second "connector sections" "extend toward the first and second branch arteries." *Id.* (citing in part Ex. 1028 ¶ 106).

Petitioner reasons that a POSITA "would have been motivated to use the Plaia graft to repair branching arteries in the body, (including the aorta and iliac arteries), to take advantake of the many disclosed benefits of the Plaia vascular graft." *Id.* at 34 (citing Ex. 1028 ¶ 107).

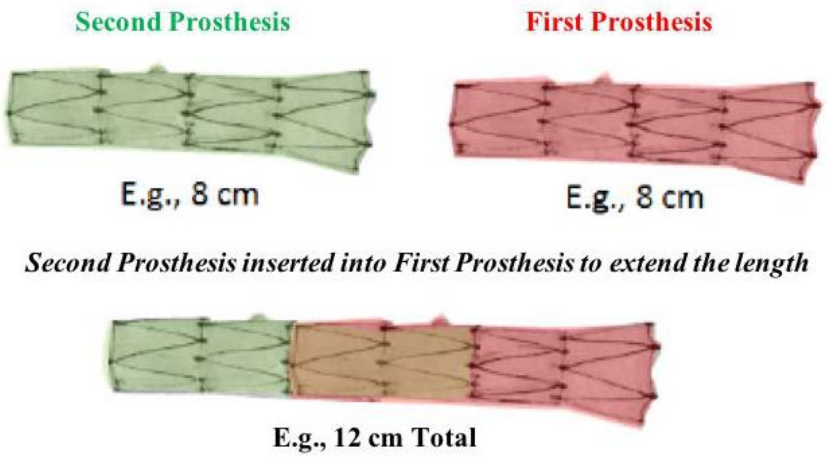
To address the claim limitations " introducing a first tubular graft into the first connector section and anchoring said first tubular graft to extend between the first connector section and the first branch artery to form a first continuous flow path from the primary artery to the first branch artery," Petitioner relies on a combination of Plaia and Schaer. *Id.* at 36–43.

Petitioner acknowledges that "Plaia does not explicitly describe introducing tubular grafts into the connector sections, however, this is not a patentable distinction." *Id.* at 36 (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 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" (internal citation omitted)).

Petitioner explains that a POSITA "would have been motivated to avoid potential problems associated with improper graft sizing" (Pet. 37) by identifying problems caused by grafts that are either too short or too long. Specifically, Petitioner reasons that a POSITA would have been motivated to size Plaia's bifurcated graft long enough "to ensure that the graft extends far enough into the iliac artery . . . that it forms a seal with artery" (*id.* at 39 (citing Ex. 1028 ¶ 113)), while also ensuring that the graft is not too long, such that it "extend[s] so far distally into an iliac artery that it occludes a branch artery (e.g., the internal iliac artery)." *Id.* at 37–38 (citing Ex. 1028 ¶ 111). Weighing these competing concerns, Petitioner reasons that a POSITA "would have erred on the side of sizing the Plaia bifurcated graft so that it is *relatively short*, rather than relatively long." *Id.* at 39 (emphasis added).

Petitioner then reasons that a POSITA "would have recognized that if the Plaia bifurcated graft was sized *too short*, the graft could easily be extended using *another endoluminal graft*, as described in the prior art" (*id.* (citing Ex. 1028 ¶ 114) (emphases added)). Petitioner then relies on Schaer and submits the following annotated figures (*id.* at 40), which we reproduce below:



According to Petitioner, and as shown above in the annotated figures, Schaer "discloses that the solution to a first endoluminal graft sized too short (highlighted in red), is to introduce and deploy a *second* endoluminal graft (highlighted in green), in overlapping configuration with the first graft (overlap highlighted in orange)." Pet. 44 (citing Ex. 1028 ¶ 113; Ex. 1008, 8–10).

Petitioner reasons that "[i]t would have been obvious[,] . . . if necessary, to extend one or both of the connector sections of the Plaia bifurcated graft, by introducing and deploying a tubular graft in an overlapping configuration with the connector section." *Id.* at 40 (citing Ex. 1028 ¶ 116). Petitioner asserts that a POSITA "would have been motivated to introduce and deploy a tubular graft, if necessary, to ensure that the Plaia 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, and to avoid the potential for converting from an intraluminal procedure to a conventional surgical procedure." *Id.* at 42–43.

4. Patent Owner's Response

Patent Owner argues, *inter alia*, that Petitioner's reason for combining Plaia with Schaer is based on impermissible hindsight and is unsupported by the evidence of record. Prelim. Resp. 48. Patent Owner also argues that the proposed combination fails to address the claimed step of introducing a tubular graft "to form a continuous flow path" from the primary artery to the branch artery, as called for in the claims. *See id.* at 38 ("Nor does either reference disclose or suggest the claimed step of ***forming*** continuous flow paths from the primary artery to the branch arteries by adding a tubular graft to a base or anchor structure.").

We agree with Patent Owner.

5. Analysis

For at least the following reasons, Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Plaia and Schaer render obvious claims 1–42.

First, we are not persuaded that a person having ordinary skill in the art would have wholly redesigned Plaia, as Petitioner proposes. Petitioner's reasoning for modifying Plaia is a bridge too far, and is premised on an unsupportable assertion that Plaia's "connectors" would need to be extended. The record does not support Petitioner's assertion that a POSITA would have sized Plaia's connectors too short, thereby requiring a subsequent procedure to add a second graft.

Notably, Plaia discloses that "[i]n cases where the artery being lined is bifurcated . . . , vascular graft **204** (FIG. **20**) may be used, the configuration thereof being adapted to conform specifically to the nature of the shape, size,

and disposition of the branched artery subject to treatment." Ex. 1006, 12:36–41. We are not aware of any disclosure within Plaia that teaches, suggests, or discloses that its grafts may be too short, thereby necessitating subsequent joining of additional grafts. In other words, because Plaia's grafts are already "adapted to conform specifically to the nature of the shape, size, and disposition of the branched artery," we are not persuaded that a surgeon would have encountered a problem with "improper graft sizing" (Pet. 37), thus creating a need to extend Plaia's grafts, as Petitioner proposes (*id.* at 39).

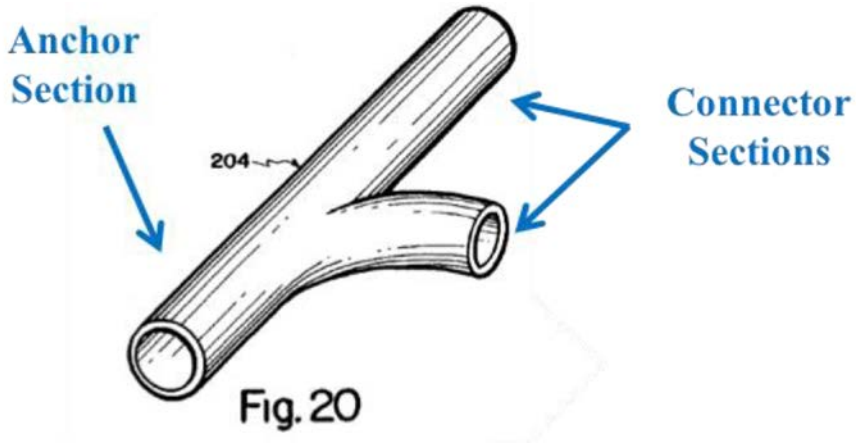
Second, the proposed combination fails to satisfy the claimed step of "forming continuous flow paths" from the primary artery to the branch arteries.

As discussed above, the plain and ordinary meaning of the limitations in claim 1 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. *Supra* Part II.A.1.

Similarly, the plain and ordinary meaning of the limitation in claim 15 requires 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. *Supra* Part II.A.2.

In Petitioner's proposed combination, however, flow paths are formed between the primary artery and the branch arteries *before* the tubular grafts are connected. In particular, the Petition states that a POSITA "would have been motivated to size [Plaia's] . . . bifurcated graft to ensure that the graft does not extend so far distally into the iliac artery 90 that it occludes a

branch artery (e.g., the internal iliac artery)." Pet. 37–38. To illustrate this point, we reproduce Petitioner's annotated version of Plaia's Figure 20 (*id.* at 33), below:



According to Petitioner, and as shown in the above-annotated version of Plaia's Figure 20, a POSITA would have sized Plaia's bifurcated graft so that each "graft" or "connector section" "extends far enough into the iliac arteries that it forms a seal with the arteries." *See* Pet. 39 (citing Ex. 1028 ¶ 113).

Because Petitioner's proposed combination results in Plaia's "connector sections" extending into and forming a seal with the branch arteries before Schaer's graft extensions are joined, the continuous flow path between the primary artery and the branch arteries are formed *before* Schaer's tubular grafts are introduced (claim 1) or secured (claim 15); thus, Petitioner's proposed combination does not meet either claim limitation.

Third, Petitioner's assertion that the claimed step involves "no invention" misconstrues the law. *See* Pet. 36 (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, "However, 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. 54–55 (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.

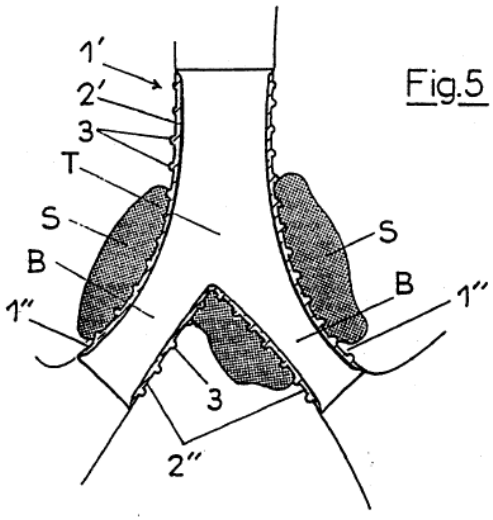
Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Plaia and Schaer render obvious claims 1–42.

E. Plaia and Dumon

Petitioner contends that claims 1–42 are unpatentable over Plaia and Dumon. Pet. 73.

1. Dumon (Ex. 1007)

Dumon is a U.S. Patent titled "Tubular Endoprosthesis for Anatomical Conduits" and discloses tubular endoprosthesis for anatomical conduits. Ex. 1007, [54], [57]. Dumon discloses that its endoprosthesis are 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.

2. Petitioner's Challenge

As with the challenge based on Plaia and Schaer, Petitioner relies on Plaia for disclosing a method of "introducing and deploying a bifurcated

structure including an anchor section and first and second connector sections." Pet. 75 (addressing independent claim 1); *see also id.* at 85–86 (addressing similarly independent claim 15).

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 acknowledges that Plaia does not explicitly describe using a combination of stent grafts to construct a vascular graft *in situ*, but asserts that "this is not a patentable distinction." *See* Pet. 76; *see also id.* at 87 (addressing similarly claim 15).

Petitioner also acknowledges that Plaia does not disclose a procedure for deploying a bifurcated graft into three vessels (*id.* at 77), instead asserting that a POSITA "would have recognized that the Dumon method (assembling a bifurcated device in situ from multiple, relatively straight components), is simpler and easier to perform than other known methods" (*id.* at 78). Petitioner then reasons that it would have been obvious to introduce a second branch graft into the "connector" section of Plaia's graft (*id.* at 78–80) in order to: (1) ensure that the graft is sized according to the patient's specific anatomy; (2) to ensure that the aortic aneurysm is completely excluded; (3) to avoid potential complications from an improperly-sized bifurcated graft; and (4) to avoid the potential for converting from an intraluminal procedure to a conventional surgical procedure (*id.* at 80). *See also id.* at 87 (addressing similarly claim 15).

3. Patent Owner's Response

Patent Owner responds that Petitioner relies "entirely on hindsight . . . [and] fails to offer any reasoned analysis why the supposed 'Dumon method' would satisfy the claimed method." Prelim. Resp. 57–58. Patent Owner asserts that "Dumon adds little more" (*id.* at 56) and "says nothing about the method by which the second independent tubular branch is introduced" (*id.* at 57).

We agree with Patent Owner.

4. Analysis

As with the prior ground, we are not persuaded that a person having ordinary skill in the art would have looked to Dumon to arrive at a surgical method involving the attachment of additional grafts to Plaia's "connectors," as Petitioner proposes.

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 the present case, Petitioner relies on the "Dumon method" for teaching "assembling a bifurcated device *in situ* from multiple, relatively straight components." Pet. 77–78 (citing Ex. 1028 ¶ 185–1866; Ex. 1007, 3:31–50, Figs. 5, 12). We do not find, however, 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 Plaia's graft with the "Dumon method" to meet the claims, as Petitioner proposes.

Moreover, Petitioner's proposed modification of shortening Plaia's connectors so that they extend toward, but not into the branch arteries, lacks rational underpinnings. *See* Pet. 78 ("it would have been obvious to introduce and deploy the Plaia graft . . . so that . . . the 'short' connector section extends toward, but not into, the second iliac artery"); Ex. 1028 ¶ 188.

Dr. Criado's testimony in support of this reasoning (Ex. 1028 ¶ 188) is not supported by facts or evidence, and is given little weight. 37 C.F.R. § 42.65(a). Petitioner's reasoning is also belied by Plaia's explicit disclosure that "where the artery being lined is bifurcated . . . vascular graft **204** (FIG. **20**) may be used, the configuration thereof being adapted to *conform specifically to the nature of the shape, size, and disposition of the branched artery* subjected to treatment." Ex. 1006, 12:36–41 (emphasis added). Because Plaia's bifurcated graft conforms specifically to the shape of the branched artery, Petitioner's reasoning that a POSITA would extend its graft so that it does not extend into the branched arteries contradicts Plaia's explicit teaching.

Rather, we find that the proposed combination is based on improper hindsight in light of the disclosure of the '427 patent 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.

Because Petitioner's reasoning for modifying Plaia is not supported by the record, Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Plaia and Dumon render obvious claims 1–42.

III. ORDER

For the reasons given, it is

ORDERED that no *inter partes* review is instituted.

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