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Paper 7
Entered: March 1, 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 IPR2018-01569
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 IPR2018-01570 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 IPR2018-01570 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 begin with a reproduction of Figure 5, below:

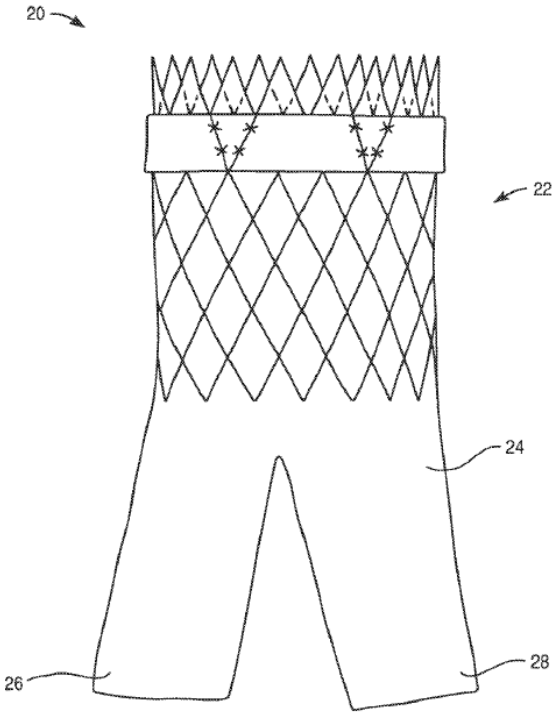


FIG. 5

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):

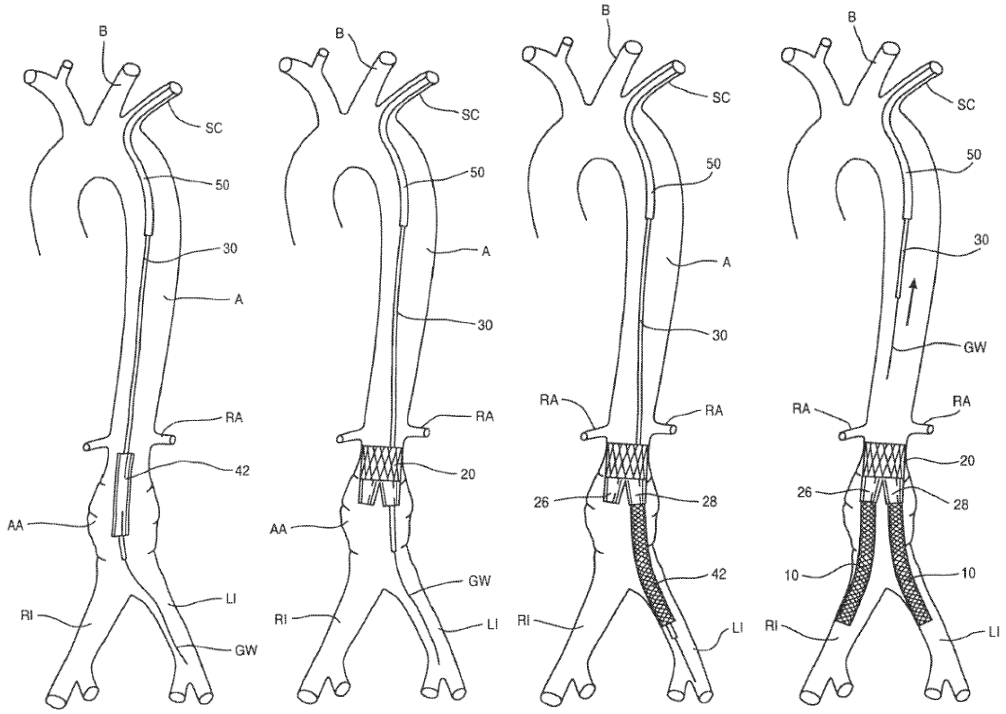


FIG. 7 FIG. 8 FIG. 10 FIG. 12

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 11:14–14:21. 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.
Lazarus	US 5,871,536, issued Feb. 16, 1999	Ex. 1004
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)
Lazarus and Schaer	§ 103(a)	1–42
Lazarus and Dumon	§ 103(a)	1–42

Pet. 4.

Petitioner also relies on the declaration testimony of Dr. Enrique Criado, M.D., (Ex. 1016) in support of its Petition. Pet. 11.

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. 23 ("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 claimed 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. 1016) 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. 1016 ¶¶ 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. 22–23 (emphases added). Patent Owner alternatively proposes that a POSITA would have "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).

D. Lazarus and Schaer

Petitioner contends that claims 1–42 are unpatentable over Lazarus and Schaer. Pet. 32.

1. Lazarus (Ex. 1004)

Lazarus is a U.S. patent titled "Intraluminal Vascular Graft and Method" (Ex. 1004, [54]) and discloses a vascular graft with one or more leg

portions suitable for repairing bifurcated vessels (*id.* at [57]). To illustrate an embodiment of Lazarus's graft, we reproduce its Figure 11, below:

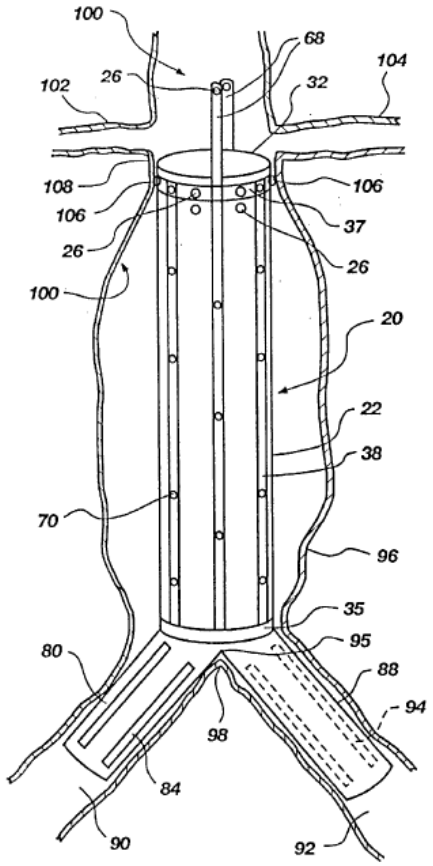
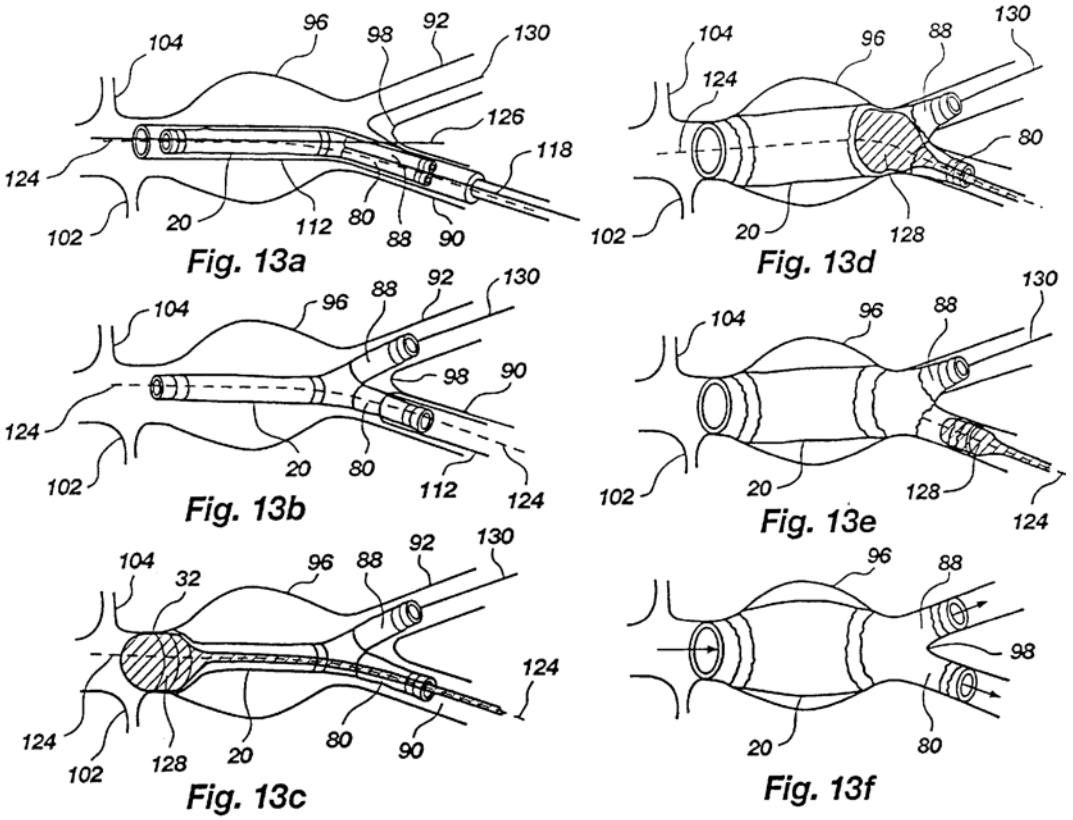


Fig. 11

According to Lazarus, Figure 11 depicts a vascular graft 20 with two leg portions positioned within a diseased abdominal aorta and bifurcating iliac arteries. Ex. 1004, 8:21–24, 12:42–44. In particular, Figure 11 illustrates expandable caudal ring 35 "seated upon and supported by the bifurcation of the vessel, otherwise referred to as the crotch **98** of the bifurcation." *Id.* at 12:45–47. Longitudinal support structures 38 extend the length of tubular body 22 and support vascular graft 20 in position within vessel 96. *Id.* at 12:47–50. First leg portion 80 and second leg portion 88 are each positioned within one of the iliac arteries that bifurcate from aorta 96. *Id.* at 13:11–13.

Lazarus also discloses deployment of vascular graft 20. *Id.* at 13:18–19; *see id.* at 8:28–31 (referencing Figures 13a-13f as illustrating deployment of a vascular graft and Figure 14 as illustrating an alternative implantation procedure.). To illustrate one disclosed deployment procedure, we reproduce Lazarus's Figures 13a-13f, below:



According to Lazarus, Figures 13a depicts vascular graft and leg portions 20 radially compressed within capsule 112 and introduced in iliac artery 90. *See id.* at 13:18–61. Guide wire 124 facilitates placement of vascular graft 20 within the vessel. *Id.* at 13:49–51. Once vascular graft 20 is correctly positioned within vessel 96, stabilizer rod 118 maintains graft 20 in place while capsule is withdrawn, as shown in Figures 13a, 13b. *Id.* at 13:57–61. Upon removal of capsule 112, the compressed force is removed and vascular graft 20 expands radially outward. *Id.* at 13:65–14:3. As

shown in Figure 13c, balloon catheter 128 may be used to "expand[] the more distal regions of the vascular graft 20 until the vascular graft is fully expanded," as shown in Figures 13c, 13d, and 13e. *Id.* at 14:6–21. In order to position second leg portion 88 into other iliac artery 92, "additional procedures must be performed." *Id.* at 14:36–42. Lazarus discloses one such method as inserting a guide wire "into the femoral artery *which is not used for transport of the device* into the vessel 96." *Id.* at 14:43–47 (emphasis added). Figures 13a–13f show guide wire 130 inserted iliac artery 92 and the end of guide wire 130 is sutured to second leg portion 88. *Id.* While stabilizer rod 118 is in-place maintaining vascular graft 20 in position, guide wire 130 is withdrawn from iliac artery 92, which brings second leg portion 88 over crotch 98 and into iliac artery 92. *Id.* at 14:64–15:1.

Lazaraus also discloses an alternative method for deploying vascular graft, shown in Figure 14 (*id.* at 14:10–12), which we reproduce, below:

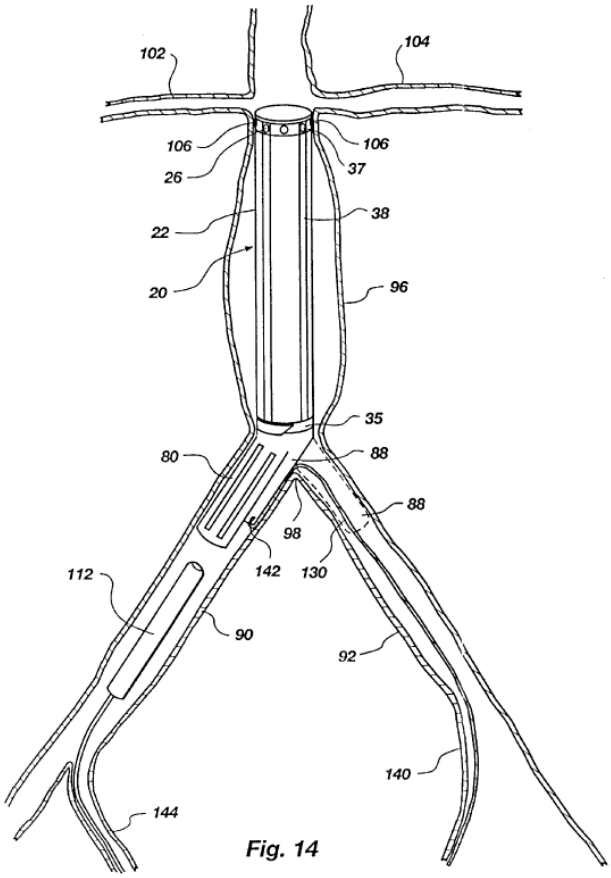


Fig. 14

According to Lazarus, Figure 14 depicts guide wire introduced into iliac artery 92 and urged across crotch 98 and into right iliac artery 90. *Id.* at 15:10–16. Guide wire is formed with hook 142, or other device capable of grasping second leg portion 88. *Id.* at 15:16–18. Second leg portion 88 is secured by hook 142 and as guide wire 130 is withdrawn, second leg portion is urged over crotch 98 and into iliac artery 92. *Id.* at 15:19–22.

Lazarus further discloses that "the longitudinal support structures 38 may be adjustable in length to modify the length of the vascular graft 20" (*id.* at 10:19–21) and further discloses that "once deployed in the diseased vessel, the length of the longitudinal support structure 38 may be modified to provide an optimal fit within the vessel." *Id.* at 10:37–41.

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 Lazaraus discloses a "method for introducing a vascular graft into a primary artery which divides into first and second branch arteries" (Pet. 35) and the step of "introducing and deploying a bifurcated structure including an anchor section and first and second connector sections . . ." (*id.* at 36). Petitioner relies on similar contentions in addressing independent claim 15. *See id.* at 59–62. In support of these assertions, Petitioner submits an annotated version of Lazarus's Figure 1 (*id.*), which we reproduce, below:

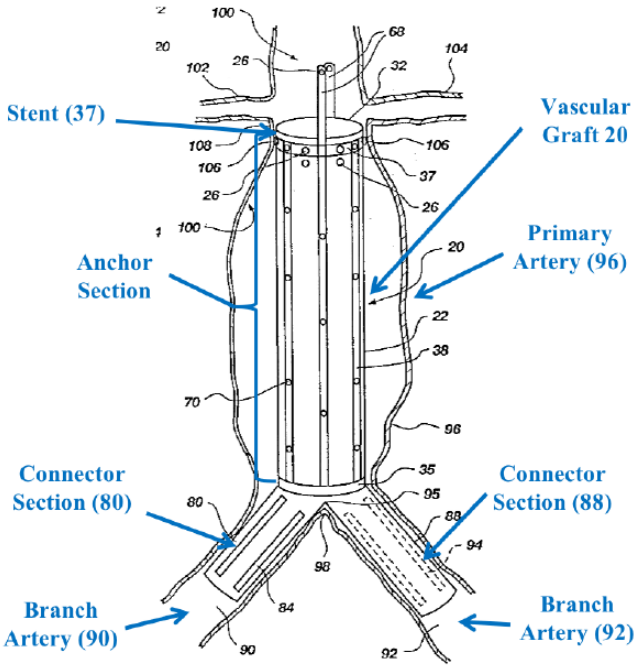


Fig. 11

According to Petitioner, Figure 11 depicts Lazarus's "vascular graft" 20, including an anchor section that is disposed within the primary artery (abdominal aorta 96) and includes first and second "connector sections" 80, 88 that are disposed in branch arteries 90, 92, respectively. Pet. 36–37.

To address the claimed steps of "and thereafter" "introducing a first tubular graft into the first connector section . . . 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 . . . to form a second continuous flow path from the primary artery to the second branch artery," Petitioner relies on a combination of Lazarus and Schaer. Pet. 40–49.

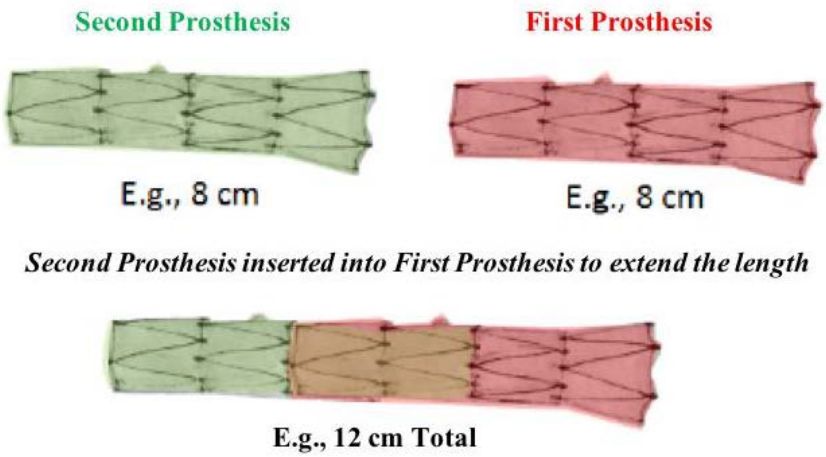
Petitioner acknowledges that "Lazarus does not explicitly describe introducing tubular grafts into the connector sections" and instead asserts that "this is not a patentable distinction." *Id.* at 40 (citing in-part *Laclede-Christy Clay Prods. Co. v. St. Louis*, 280 F. 83, 85 (8th Cir. 1922) ("Ordinarily, 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," *(id.* at 41), 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 Lazarus'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 43 (citing Ex. 1016 ¶ 111)), while also ensuring that the graft is not too long, such that it "extend[s] so far distally into the iliac artery 90 that it occludes a branch artery (e.g., the internal iliac artery)." *Id.* at 41. Weighing these competing concerns, Petitioner reasons that a POSITA "would have erred on the side of sizing Lazarus's bifurcated graft so that it is *relatively short*, rather than relatively long." *Id.* at 43 (emphasis added).

Petitioner then asserts that a POSITA "would have recognized that if the Lazarus bifurcated graft was sized *too short* (and could not easily be extended using techniques described in Lazarus), the graft could easily be extended using *another endoluminal graft*, as described in the prior art" (*id.* (citing Ex. 1016 ¶ 112) (emphases added)).

Petitioner then relies on Schaer and submits the following annotated figures (*id.* at 44), reproduced, below:



According to Petitioner, and as shown above, 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. 1016 ¶ 113; Ex. 1008, 8–10).

Petitioner reasons that "[i]t would have been obvious, if necessary during a procedure, to extend one or both of Lararus' connector sections, by introducing and deploying a tubular graft in an overlapping configuration with the connector sections." *Id.* at 45. Petitioner asserts that a POSITA "would have been motivated to introduce and deploy a tubular graft, if necessary, to ensure that the Lazarus 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 48.

4. Patent Owner's Response

Patent Owner argues, *inter alia*, that Petitioner's reason for combining Lazarus with Schaer is based on impermissible hindsight and is unsupported

by the evidence of record. Prelim. Resp. 45. Patent Owner also argues that the proposed combination fails to address the claimed step of introducing tubular grafts "to form a continuous flow path" from the primary artery to the branch artery, as called for in the claims. *See id.* at 36 ("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 Lazarus 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 Lazarus as Petitioner proposes. Petitioner's reasoning for modifying Lazarus is a bridge too far, and is premised on an unsupportable assertion that Lazarus's grafts would need to be extended. In other words, the record does not support Petitioner's assertion that a POSITA would have sized Lazarus's graft too short, thereby requiring a subsequent procedure to add a second graft.

Notably, Lazarus discloses that "once deployed in the diseased vessel, the length of the longitudinal support structure 38 may be modified to provide an optimal fit within the vessel." Ex. 1004, 10:37–40. Indeed, if the surgeon needed to adjust the length of Lazarus's graft after it was deployed, we are not persuaded that he or she would perform the seemingly complex procedure of "introducing" (claim 1) or "securing" (claim 15) additional

grafts to Lazarus's structure 38, rather than modifying the length of support structure 38, as Lazarus itself discloses. *Id.* Moreover, Dr. Criado's testimony that Lazarus's bifurcated graft "could not otherwise be extended by [those very] techniques described in Lazarus," is not persuasive as it is conclusory. Ex. 1016 ¶ 112. In other words, Dr. Criado does not explain or cite evidence as to why the length of Lazarus's longitudinal support structure 38 could not be extended, despite Lazarus's explicit disclosure otherwise. *Compare id., with* Ex. 1004, 10:37–40

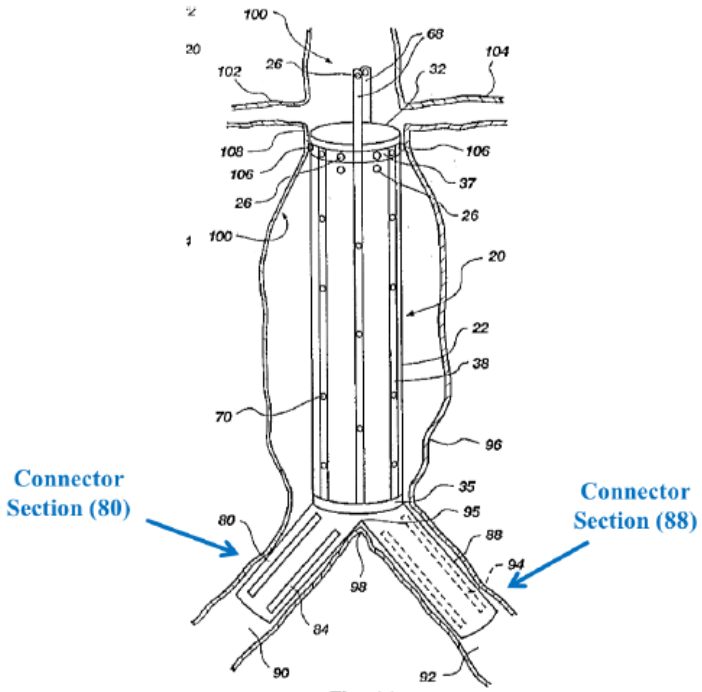
Second, the proposed combination fails to satisfy the claimed step of "forming continuous flow paths" from the primary artery to the branch arteries by introducing a first tubular graft into a first connection section and introducing a second tubular graft into a second connector section, as recited in claim 1, or securing a second tubular graft to an anchor section, as recited in claim 15.

As discussed above, the plain and ordinary meaning of the claimed 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 claimed 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. Specifically, the Petition states that a POSITA "would have

been motivated to size [Lazarus'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. 41; *see also id.* at 43 ("a PHOSITA would have been motivated to size a bifurcated graft to ensure that the graft extends far enough into the iliac artery 90 that it forms a seal with artery 90"). To further illustrate this point, we reproduce Petitioner's annotated version of Lazarus's Figure 11, below:



As shown above, Petitioner's combination proposes to extend Lazarus's bifurcated graft (along with its attached "connectors") into the branch arteries, thereby forming a continuous flow path between the primary artery and the both branch arteries *before* Schaer's endoluminal grafts are attached.

Accordingly, Petitioner's proposed combination fails to satisfy the claimed "to form a first continuous flow path" and "to form a second

continuous flow path," as required by claim 1, and fails to satisfy the claimed "to form a second continuous flow path," as required by claim 15.

Third, Petitioner's assertion that the claimed step involves "no invention" misconstrues the law. *See* Pet. 40 (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. 51–52 (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.

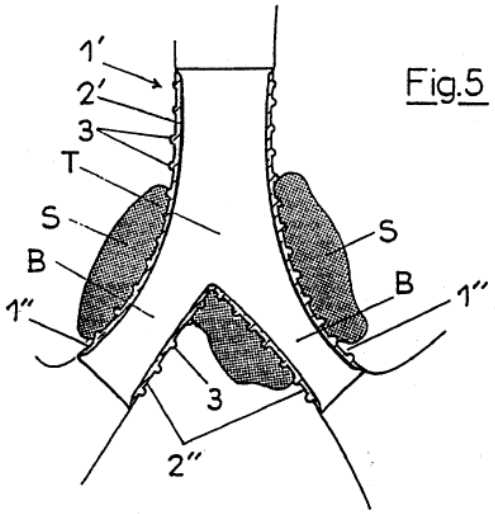
Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Lazarus and Schaer render obvious claims 1–42.

E. Lazarus and Dumon

Petitioner contends that claims 1–42 are unpatentable over Lazarus and Dumon. Pet. 4.

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 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 places." *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 Lazarus and Schaer, Petitioner relies on Lazarus for disclosing a method of "introducing and deploying a bifurcated structure including an anchor section and first and second connector sections." Pet. 81 (addressing independent claim 1); *see also id.* at 96–97 (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 Lazarus 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. 81; *see also id.* at 97 (addressing similarly claim 15). Petitioner explains that the procedure disclosed in Lazarus is "a relatively complex procedure" and that a POSITA "would have been motivated to simplify and improve the method of introducing and deploying the Lazarus graft." *Id.* at 83 (citations omitted).

Petitioner asserts that "Dumon discloses a method of introducing a bifurcated endoprosthesis, by separately introducing and deploying multiple prosthesis components" and that a POSITA "would have recognized that the Dumon method could easily be applied to Lazarus in order to simplify the procedure." *Id.* at 84 (citing Ex. 1016 ¶¶ 186, 187). Petitioner then reasons that it would have been obvious to either add a second branch graft to the

long connector section, which extends into the iliac artery (*id.* at 87), or, *alternatively*, add a branch graft to a short connector section that "extends toward, but not into, the right iliac artery" (*id.* at 89).

Petitioner explains that a POSITA "would have been motivated to apply the Dumon method . . . to simplify the method of introducing the Lazarus graft, 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, and to avoid the potential for converting from an intraluminal procedure to a conventional surgical procedure." *Id.* at 91; *see also id.* at 99 (addressing claim 15).

3. Patent Owner's Response

Patent Owner argues that the combination of Lazarus and Dumon is based entirely on impermissible hindsight. Prelim. Resp. 59.

We agree with Patent Owner, including its assessment that Petitioner's combination results in a "whole cloth reconstruction of Lazarus." *Id.* at 60. Indeed, Petitioner's modification of Lazarus completely changes its graft design *and* surgical method.

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 completely redesign Lazarus's graft and surgical method 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 proposes a complete redesign of Lazarus because Lazarus describes a "relatively complex procedure." Pet. 83. Petitioner further explains that because of Lazarus's surgical complexity, a POSITA would have simplified it by shortening Lazarus's "connectors" only to later add subsequent grafts. *Id.* at 84–91.

Although Dr. Criado testifies at great length as to why a POSITA would have completely redesigned Lazarus (Ex. 1016 ¶¶ 184–192), we find that his testimony lacks the facts or data needed to support it, and we are not persuaded that Lazarus's graft and surgical method were so complex that a POSITA would have redesigned them by making its one-piece graft into a multi-piece graft, assembled *in-situ*. 37 C.F.R. § 42.65(a). For example, Dr. Criado's testimony that Lazarus's procedure may result in "undesirable twisting and/or kinking of leg portion 88" (Ex. 1016 ¶ 185) lacks evidentiary support and his testimony that it would be "simpler and easier to perform" a surgical procedure implanting and joining together multiple components (*id.* ¶ 187) is also not supported by the record.

Petitioner also relies on the "Dumon method" for disclosing a "method of introducing a bifurcated endoprosthesis, by separately introducing and deploying multiple prosthesis components." Pet. 84 (citing Ex. 1016 ¶ 186; Ex. 1007, 3:31–50, Figs. 5, 12). We do not find, however, Dumon as disclosing any such method for "introducing a bifurcated endoprosthesis, by separately introducing and deploying multiple prosthesis components," as Petitioner asserts. *Id.* 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 agree with Patent Owner and read Dumon as most likely disclosing the insertion of a longer tubular graft into the original tubular graft. *See* Prelim. Resp. 57 (citing Ex. 1007, Fig. 12 ("the alleged 'Dumon method' involves the insertion of a second tube into a hole (9) in the *anchor section, not the connector section*" (emphasis added))). Because Dumon does not disclose or depict a bifurcated endoprosthesis assembled in parts, we are not persuaded that a POSITA would have combined Lazarus with Dumon to meet the claims.

Because Petitioner's reasoning for modifying Lazarus is not supported by the record, Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Lazarus 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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