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Paper 7
Entered: June 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 IPR2019-00205
Patent 7,264,632 B2

Before JAMESON LEE, KEN B. BARRETT, and JAMES A. TARTAL,
Administrative Patent Judges.

TARTAL, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–4, 7, 8, and 12 of U.S. Patent No. 7,264,632 B2 (Ex. 1001, "the '632 patent"). Medtronic Vascular, Inc. ("Patent Owner") did not file a preliminary response to the Petition. We have authority to determine whether to institute an *inter* partes review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Moreover, a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Applying that standard, and upon consideration of the Petition and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we authorize an *inter partes* review to be instituted as to all challenged claims of the '632 patent on all grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

II. BACKGROUND

A. The '632 Patent

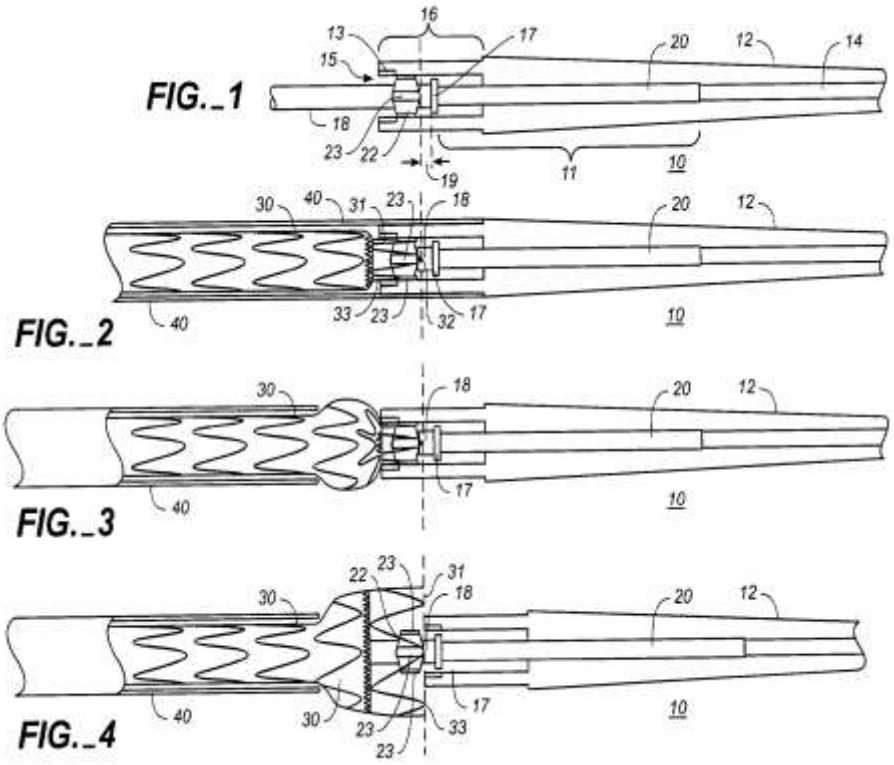
The '632 patent, titled "Controlled Deployment Delivery System," issued September 4, 2007, from U.S. Application No. 10/455,978, filed June 5, 2003. Ex. 1001, [21], [22], [45], [54]. The '632 patent generally relates to a "controlled stent-graft deployment delivery system." *Id.* at Abstract.

With regard to the background of the apparatus, the '632 patent explains that prosthetic vascular grafts were known to be used to "bypass damaged or occluded natural blood vessels." *Id.* at 1:20–24. A "stent-graft" or "endoluminal graft" consists of "graft material supported by framework." *Id.* at 1:24–25. "Self-expanding" stent-grafts are "inserted into the vascular system in a compressed or contracted state and permitted to expand upon removal of a restraint." *Id.* at 1:24–32. Stent-grafts preferably are deployed through an intraluminal delivery, using, for example, "a delivery catheter with coaxial inner (plunger) and outer (sheath) tubes arranged for relative movement." *Id.* at 1:40–50. "The proximal end of the stent-graft is the end closest to the heart whereas the distal end is the end furthest away from the heart during deployment." *Id.* at 1:65–67. By contrast, "the distal end of the catheter is usually identified to the end that is farthest from the operator while the proximal end of the catheter is the end nearest the operator." *Id.* at 2:1–2:3.

In use, the stent-graft is compressed at the distal end of the outer catheter tube and maneuvered through a vessel until positioned at the point of treatment. *Id.* at 1:50–56. While holding the inner tube of the catheter stationary, the self-expanding stent-graft is gradually exposed and expands

as the outer tube of the catheter is withdrawn. *Id.* at 1:56–65. "The proximal end of the stent-graft is typically designed to fixate and seal the stent graft to the wall of the vessel during deployment," leaving "little room for error in placement since re-positioning . . . is usually difficult if possible at all." *Id.* at 2:10–16. The '632 patent explains that a need exists for a deployment system "that enables partial deployment of a stent-graft," that "enables re-deployment of the stent-graft," and "further reduces deployment forces during advancement of the stent-graft." *Id.* at 2:38–44; *see also* Pet. 5–10 (providing a summary of the background of the apparatus of the '632 patent).

Figures 1–4 of the '632 patent, reproduced below, illustrate an embodiment of the claimed invention.



Figures 1–4 illustrate stent-graft deployment delivery system 10 "as elements of the delivery system are manipulated to at first partially deploy

and then fully deploy the proximal end of the stent graft 30." Ex. 1001, 4:12–18. Figure 1 illustrates distal tapered tip 12 of delivery system 10 without a stent-graft, whereas Figures 2–4 illustrate tip portion 12 loaded with stent-graft 30, "with progressive figures showing deployment from within a retractable primary sheath 40." *Id.* at 4:19–24. Tip 12 includes lumen 14 for passage of a guidewire. *Id.* at 4:30–32.

As shown in Figure 2, sheath 40 contains stent-graft 30 in a constrained diameter. Within sheath 40 and stent-graft 30 is outer tube 18. Within outer tube 18 is inner tube 20, which serves as a guidewire lumen. Cap 15, coupled to end portion 11 of inner tube 20, retains "at least a portion of a proximal end of the stent-graft 30 in a radially compressed configuration." *Id.* at 4:34–47. Actuating members at the operator's end of the catheter (not shown) provide for "a controlled relative axial movement between the outer tube 18 and the inner tube 20 to precisely control the release of the proximal end of the stent-graft . . . from the cap and from the radially compressed configuration." *Id.* at 4:47–53. Proximal lock 22 is coupled to a distal portion of outer tube 18 and preferably includes ribs 23 that, together with cap shroud portion 16, serve as an axial constraint for the proximal end of stent-graft 30. *Id.* at 5:35–40. "The proximal end (or the proximal springs 31, 32, and 33) of the stent-graft 30 cannot deploy until the proximal end of the ribs of the proximal lock clear the end of the shroud portion 16 of the tip." *Id.* at 5:40–43.

Figure 3 illustrates sheath 40 partially retracted with the proximal end of stent-graft 30 constrained but the portion of stent-graft 30 exposed due to the partial retraction is partially deployed. Such a configuration allows "longitudinal" re-positioning of the stent-graft before releasing the proximal

end of the stent-graft. *Id.* at 4:58–5:4. In Figure 4, the proximal end of stent-graft 30 has been deployed "by the controlled relative axial movement between the inner tube 20 and the outer tube 18." *Id.* at 5:15–17; *see also* Pet. 11–16 (summarizing the apparatus disclosed by the '632 patent).

B. Illustrative Claim

Challenged claims 1, 7, and 12 are independent, claims 2–4 depend from claim 1, and claim 8 depends from claim 7. Claim 1, reproduced below, is illustrative of the claimed subject matter.

> 1. A controlled stent-graft deployment delivery system, comprising:
>
> a stent-graft;
>
> a retractable primary sheath containing said stent-graft in a first constrained diameter configuration;
>
> an outer tube within the retractable primary sheath and within the stent-graft;
>
> an inner tube within the outer tube, wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;
>
> a cap coupled to a distal end of the inner tube and configured to retain at least a portion of a proximal portion of the stent-graft in a radially compressed configuration, wherein a controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the radially compressed configuration.

Ex. 1001, 9:33–49.

C. Related Proceedings

The Parties state that Petitioner concurrently filed a petition in IPR2019-00206 challenging the patentability of claims 1, 2, 4, 5, 7–9, and 12 of the '632 patent. Pet. 1; Paper 3, 1.

D. Real Parties in Interest

Petitioner identifies Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC as real parties-in-interest. Pet. 1. Patent Owner, under the heading "Real Party-In-Interest," states that Medtronic, Inc., is the owner of the '632 patent and that "Medtronic plc is the ultimate parent of Medtronic, Inc." Paper 3, 1–2.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–4, 7, 8, and 12 of the '632 patent on the following grounds:

Reference(s)	Basis	Claims Challenged
Hartley[1] "Embodiment #1"	§ 102	1, 2, 4, 7, 8, and 12
Hartley "Embodiment #1" and Lindenberg[2]	§ 103	1–4
Hartley "Embodiment #1" and Olson[3]	§ 103	1–4
Hartley "Embodiment #1," Lindenberg, and Olson	§ 103	1–4
Hartley "Embodiment #2"	§ 102	1, 2, 4, 7, 8, and 12
Hartley "Embodiment #2" and Lindenberg	§ 103	1–4
Hartley "Embodiment #2" and Olson	§ 103	1–4
Hartley "Embodiment #2," Lindenberg, and Olson	§ 103	1–4

[1] WO 98/53761 (published December 3, 1998) (Ex. 1005, "Hartley") (citations are to the original page number at the top of each page).
[2] US 5,433,723 (issued July 18, 1995) (Ex. 1007, "Lindenberg").
[3] US 5,906,619 (issued May 25, 1999) (Ex. 1004, "Olson").

Pet. 4.[4] Petitioner supports its challenge with a Declaration by Enrique Criado M.D., dated November 12, 2018. Ex. 1014.

III. ANALYSIS

A. Principles of Law

A claim is unpatentable for anticipation under 35 U.S.C. § 102 if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). Moreover, "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1383 (Fed. Cir. 2011) (citations omitted); *see also Net MoneyIN v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (holding that "it is not enough [for anticipation] that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention") (citing *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972)). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

[4] Petitioner lists grounds based on "Hartley," but provide analysis of two embodiments disclosed by Hartley. *See, e.g.*, Pet. 41–42 (asserting that the "stent-graft" recited by claim 1 of the '632 patent is disclosed "in Embodiment #1" as prosthesis 20 and "in Embodiment #2" as prosthesis 171).

A claim is unpatentable for obviousness under 35 U.S.C. § 103 if the differences between the claimed subject matter 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 such subject matter pertains." 35 U.S.C. § 103(a). The question of obviousness under 35 U.S.C. § 103 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).

B. Level of Ordinary Skill in the Art

At this stage of the proceeding, and without opposition from Patent Owner at this time, we determine that the level of ordinary skill in the art described by Petitioner is supported by the current record (*see* Ex. 1014 ¶ 17). For purposes of this Decision, we find that a person of ordinary skill in the art to which the '632 patent pertains would have included a medical device engineer or similar professional with an undergraduate degree in engineering and experience with endoluminal devices and methods, or a vascular surgeon or similar physician with two years equivalent experience with endoluminal devices and methods, with the understanding that such experience may come from education and/or training. Pet. 17. We further find that the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of appropriate skill reflected in these references is consistent with the definition of a person of

ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Claim Construction

In an *inter partes* review based on a petition filed prior to November 13, 2018, "[a] claim in an unexpired patent . . . shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2018)[5]; *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). In determining the broadest reasonable construction, we presume that claim terms carry their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may define a claim term in a manner that differs from its ordinary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "proximal" and "distal"

Consistent with the description of the background of the apparatus of the '632 patent provided above, Petitioner contends that when referring to a component of a stent-graft, "distal" and "proximal" are defined relative to the patient, with the "proximal" end of a stent-graft being the end closest to

[5] Although the claim construction standard applied in *inter partes* review was recently changed to the federal court claim construction standard used in a civil action under 35 U.S.C. § 282(b), that change does not apply to this proceeding because the Petition was filed before November 13, 2018, the effective date of the change. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,344 (Oct. 11, 2018).

the patient's heart. Pet. 19 (citing Ex. 1001, 1:65–67). Petitioner further contends that when referring to a component of the delivery catheter, "distal" and "proximal" are defined relative to the operator, with the "proximal" end of a delivery catheter being the end nearest the operator. *Id.* (citing Ex. 1001, 1:67–2:3). Absent any opposition by Patent Owner, we agree with the definitions provided by Petitioner for purposes of this Decision because they are consistent with the specification of the '632 patent.

2. "second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed"

Claim 12 recites "a retention mechanism," as well as "a second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed." Ex. 1001, 10:65–11:6. Petitioner does not propose an express construction for "a second retention mechanism," but instead contends that it "includes an outer sheath that retains a distal end on the stent graft, as depicted in Figure 3A and described in the '632 patent." Pet. 20–21 (citing Ex. 1001, 3:41–49, 4:55–5:14, Fig. 3; Ex. 1014 ¶ 43); *see also id.* at 21 (arguing that "[t]he '632 patent does not disclose any other structure for 'retaining' a distal end of the stent graft undeployed, as described in claim 12"). Petitioner fails to provide any persuasive explanation to show that the meaning of the claim language "second retention mechanism" is informed by directing us to Figure 3A and related references to an outer sheath. To the extent Petitioner appears to implicitly argue that the claim language is not enabled, that issue is not properly before us. *See* 35 U.S.C. § 311(b).

We further find an express construction of this claim language is not necessary for purposes of this Decision because, absent any opposition by Patent Owner, presently there is no dispute in regard to the meaning of this claim language. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (explaining that claim terms need to be construed "only 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))).[6]

D. Scope and Content of the Prior Art

To demonstrate the unpatentability of the challenged claims of the '632 patent, Petitioner relies on Hartley, Lindenberg, and Olson, each of which is briefly summarized below as they pertain to Petitioner's contentions. Pet. 4.

1. Summary of Hartley

Hartley, titled "A Prosthesis and a Method and Means of Deploying a Prosthesis," relates to a self-expanding endovascular prosthesis and an "introducer" for introducing the prosthesis in a lumen of a patient "for the endovascular repair of diseased or damaged vessels." Ex. 1005, [54], [57], 1:7–10.

[6] The parties are encouraged to address in briefing whether either "first retention mechanism" or "second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed" constitutes a means-plus-function limitation under 35 U.S.C. § 112, sixth paragraph, in light of the Federal Circuit's guidance in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc).

Figure 1 of Hartley is reproduced below.

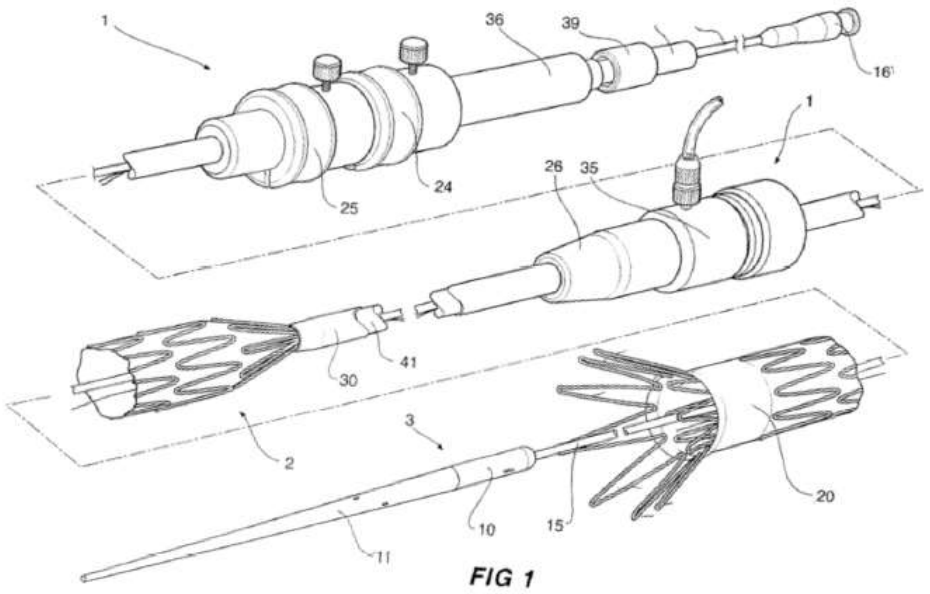


FIG 1

Hartley Figure 1 illustrates "a first embodiment of an introducer . . . in perspective view with the prosthesis partially deployed," including "external manipulation section 1, distal attachment region 2, and proximal attachment region 3."[7] Ex. 1005, 1:11–13, 11:9–10, 12:22–26. Attachment region 3 includes cylindrical sleeve 10, long tapered flexible extension 11, and prosthesis 20. *Id.* at 12:28–13:2, 13:15–16. Thin walled metal tube 15 is fastened to extension 11 and extends through the complete introducer to the

[7] Petitioner states that Hartley uses "proximal" as "a position or direction towards the patient's heart" and "distal" as "a position or direction away from the patient's heart." Pet. 22 n.9 (quoting Ex. 1005, 1:11–13). Petitioner further explains that in the Petition the definitions of "proximal" (i.e., "towards the patient's heart," in reference to a stent graft, but "closest to the operator" in reference to a component of the delivery catheter) and "distal" (the opposite of proximal) from the '632 patent are used when describing Hartley. *Id.* For purposes of this Decision we use the language as set forth in Hartley.

manipulation section and terminates in connection means 16 for a syringe. *Id.* at 13:6–10. Prosthesis 20 "is retained in its compressed condition by means of an external sleeve 30." *Id.* at 13:25–28. "[T]he distal end of the prosthesis 20 is retained in the distal attachment device 40 which is mounted onto a thick-walled plastics tube 41 which extends distally to external of the patient and to the manipulation region 1." *Id.* at 13:31–34. According to Hartley, the delivery system can place and release accurately a prosthesis "by careful positioning before release of the attachment means at a proximal end of the prosthesis and then repositioning if necessary before release of the distal end of the prosthesis." *Id.* at 10:24–31.

Figures 8 and 8A of Hartley are reproduced below.

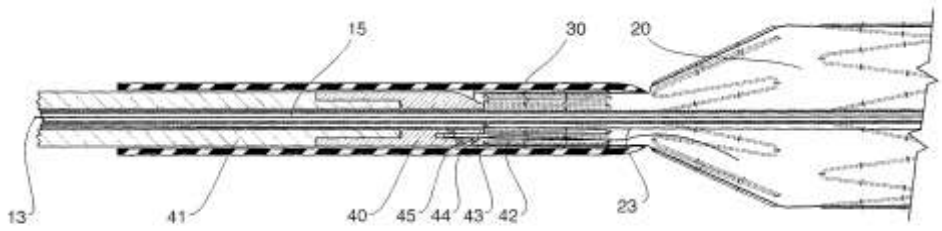


FIG 8

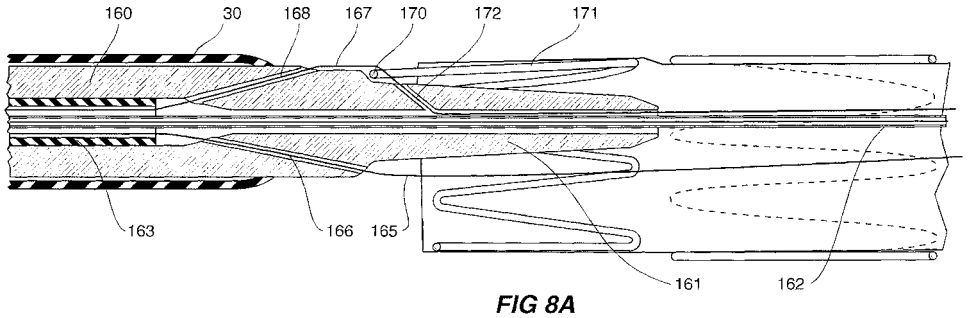


FIG 8A

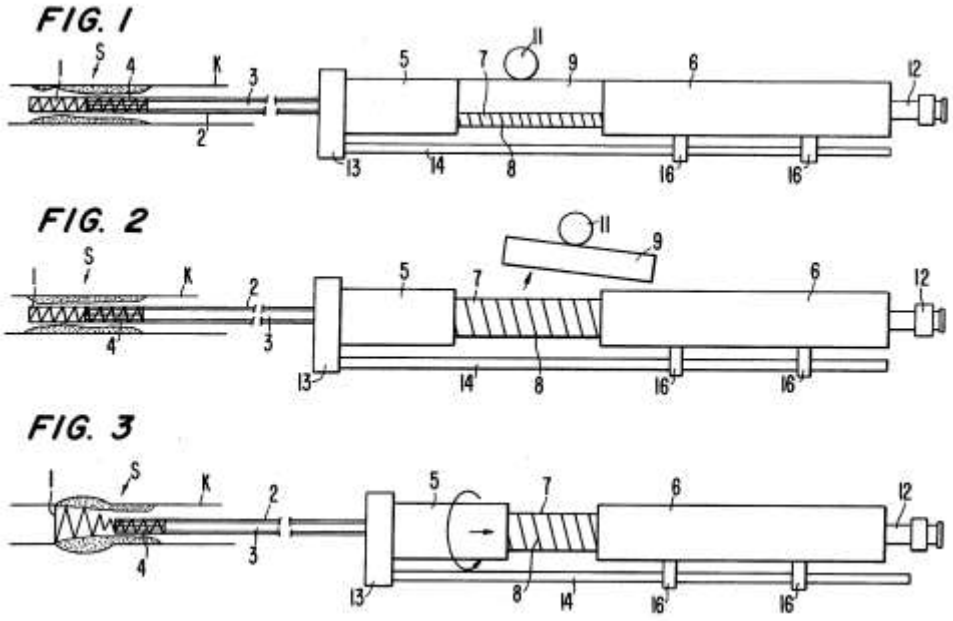
Figure 8 illustrates the part of the introducer "around the distal end of the prosthesis in detail." *Id.* at 11:21–22. Figure 8A illustrates an alternative embodiment of the "part of the introducer around the distal end of the prosthesis in detail." *Id.* at 11:23–24. As explained by Petitioner, in Figure 8 distal attachment region 2 includes distal attachment device 40

formed at the end of tube 41 and the distal end of stent-graft 20 is retained in distal attachment device 40, which is mounted onto tube 41. Pet. 25 (citing Ex. 1005, 13:31–34). "The distal end 42 of the prosthesis 20 has a loop 43 through which a distal trigger wire 44 extends," and distal end 42 of stent-graft 20 is retained within external sheath 30. Ex. 1005, 14:1–8, 15:29–30. As also explained by Petitioner, the embodiment of Figure 8A illustrates the delivery system with thin walled tube 162, thick walled tube 160, and sheath 30. Pet. 27–28. Outer tube 160 is coaxial with and radially outside inner tube 162 and sheath 30 is coaxial with and radially outside outer tube 160. *Id.* (citing Ex. 1005, 13:34–14:1). Inner tube 162 is axially movable with respect to outer tube 160 and sheath 30. *Id.* (citing Ex. 1005, Abstract, 8:1–2, 13:10–14, 14:10–12, 15:14–18:17). The distal end of stent-graft 171 is retained on the distal attachment device and distal trigger wire 167 "passes through the loop 170 in the distal end of the prosthesis 171." *Id.* at 27–28 (quoting Ex. 1005, 14:12–17).

2. Summary of Lindenberg

Lindenberg, titled "Apparatus for Widening a Stenosis," relates to an endoprosthesis made from a memory alloy and an applicator that holds the prosthesis in a compressed position. Ex. 1007, [54], [57].

Figures 1–3 of Lindenberg are reproduced below.



Figures 1–3 illustrate endoprosthesis 1 enveloped by sleeve 2, with applicator 3 within sleeve 2. Ex. 1007, 3:66–4:6, 4:29–32, 4:64–67. Blocking element 9 with grip 11 blocks relative axial movement between first handle 5 and further handle 6 until removed, as shown in Figure 2. By rotating first handle 5 on screw thread 8, sleeve 2 can be retracted to radially release endoprosthesis 1, as shown in Figure 3. *Id.* at 5:42–49.

3. Summary of Olson

Olson, titled "Disposable Delivery Device for Endoluminal Prosthesis," relates to a system for deployment of endoluminal prosthesis within lumens of the body including the use of an actuation mechanism with a variable mechanical advantage to withdraw a sheath from over a tightly compressed prosthesis. Ex. 1004, [54], [57].

Figure 2 of Olson is reproduced below.

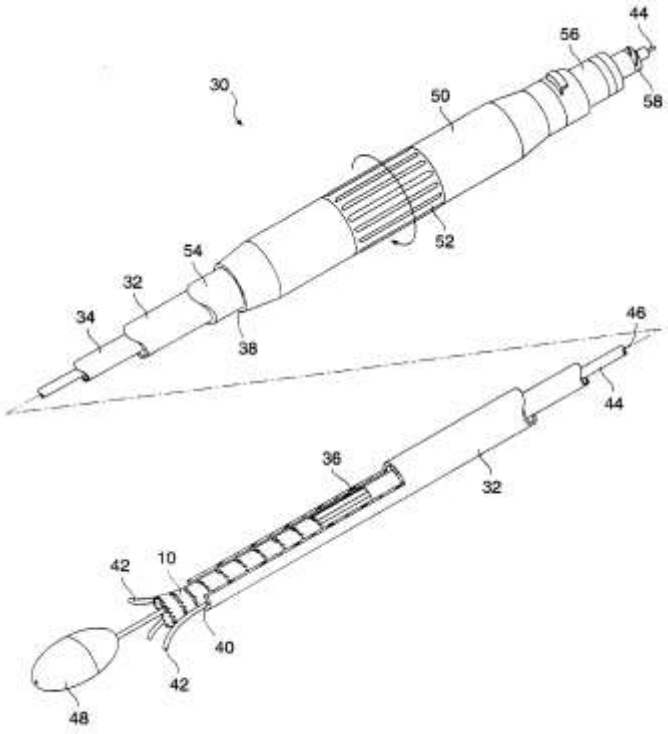


FIG. 2

Figure 2 illustrates delivery system 30, including tubular sheath 32 and shaft 34 slidably received within lumen 36. *Id.* at 5:6–10. "Prosthesis 10 is radially compressed and restrained within runners 42," and "sheath 32 prevents runners 42 from expanding outwardly." *Id.* at 5:19–21. To withdraw sheath 32, handle 52 is rotated about the axis of the sheath. *Id.* at 5:32–34.

E. Alleged Anticipation by Hartley

Petitioner contends that claims 1, 2, 4, 7, 8, and 12 of the '632 patent are anticipated by a first embodiment and also anticipated by a second embodiment disclosed by Hartley. Pet. 39–72. For purposes of our discussion below we focus on Petitioner's contentions with respect to what Petitioner identifies as a first embodiment of Hartley. The primary distinction between the two embodiments relied on by Petitioner appears to

be the part of the inducer around the distal end of the prosthesis, which we discuss above in regard to Figures 8 and 8A of Hartley.

1. Claim 1

Petitioner provides a detailed explanation of how Hartley allegedly discloses each limitation of claim 1. Pet. 39–54. Petitioner's contentions are supported by Dr. Criado. Ex. 1014 ¶¶ 63–73. We briefly summarize how Petitioner contends "Embodiment #1" of Hartley discloses each limitation of claim 1.

A controlled stent-graft deployment delivery system, comprising:

Petitioner contends introducer 1 of Hartley corresponds to a controlled stent-graft deployment delivery system. Pet. 39–40; *see also, e.g.*, Ex. 1005, Abstract ("An introducer (1) adapted for the introduction of a self-expanding endovascular prosthesis (20) in a lumen of a patient.")

a stent-graft;

Corresponding to the recited "stent-graft," Petitioner asserts that prosthesis 20 of Hartley includes a graft component and multiple self-expanding zig-zag stents. Pet. 41 (citing Ex. 1005, Fig. 1; Ex. 1014 ¶ 64); *see also* Ex. 1005, 13:15–16 (stating that "prosthesis 20 is of a self expanding type having resilient stents 19 to enable it to expand after it is released from the introducer").

a retractable primary sheath containing said stent-graft in a first constrained diameter configuration;

Petitioner contends that external sleeve 30 of Hartley discloses the recited "retractable primary sheath," and that it constrains prosthesis 20. Pet. 43–44 (citations omitted); *see also* Ex. 1005,

13:25–28 (stating that "prosthesis 20 is retained in its compressed condition by means of an external sleeve 30").

an outer tube within the retractable primary sheath and within the stent-graft;

According to Petitioner, distal attachment device 40 mounted onto thick-walled plastics tube 41 together correspond to the recited "outer tube" within external sleeve 30. Pet. 45 (citing Ex. 1005, 8:1–2, 13:34–14:1, Figs 8, 9; Ex. 1014 ¶ 66); *see also* Ex. 1005, 13:31–34 (stating that "the distal end of the prosthesis 20 is retained in the distal attachment device 40 which is mounted onto a thick walled plastics tube 41"). Petitioner alleges that the distal end of distal attachment device 40 mounted onto thick-walled plastics tube 41 (which Petitioner calls "outer tube (40+41)") is "disposed within the distal end . . . of the stent graft 20," as purportedly shown in Figure 8 of Hartley. *Id.*

an inner tube within the outer tube, wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;

Corresponding to the recited "inner tube," Petitioner relies on thin walled metal tube 15 of Hartley. *Id.* at 47. Tube 15 is within distal attachment device 40 mounted onto thick-walled plastics tube 41 (corresponding to the "outer tube"). *Id.* (citing Ex. 1005, 13:34–14:1). Petitioner further contends that tube 15 and outer tube (40+41) both move relative to each other and relative to sleeve 30 (corresponding to the "sheath"). *Id.* at 49 (citations omitted).

> *a cap coupled to a distal end of the inner tube and configured to retain at least a portion of a proximal portion of the stent-graft in a radially compressed configuration,*

Petitioner alleges cylindrical sleeve 10 of Hartley discloses the recited "cap," and is coupled to the distal end of tube 15 (the recited "inner tube") via flexible extension 11. Pet. 50. Cylindrical sleeve 10 is configured to retain at least "a portion of a proximal portion" of zigzag stent 21 in a radially compressed configuration, according to Petitioner. *Id.* at 50–51 (citing Ex. 1005 13:16–22, 15:25–30, 16:10–16, Figs. 2–9).

> *wherein a controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the radially compressed configuration.*

Petitioner explains that, as illustrated in Figures 3 and 4 of Hartley, a relative axial movement between distal attachment device 40 mounted onto thick-walled plastics tube 41 (the "outer tube") and tube 15 (the "inner tube") releases the proximal end of zigzag stent 21 from cylindrical sleeve 10 (the "cap") and from the radially compressed configuration. *Id.* at 53. Hartley allegedly discloses that the relative axial movement is controlled by an operator. *Id.* at 54 (citing Ex. 1005, 16:10–14, 15:7–14, 15:31–16:2).

2. Claim 2

Claim 2 depends from claim 1 and further recites "the cap is a shroud portion of a flexible tapered tip fixed to the distal end of the inner tube." Ex. 1001, 9:50–53. Petitioner contends, as shown in Figure 9 of Hartley, that cylindrical sleeve 10 and flexible extension 11 fixed to the distal end of tube 15 correspond to additional limitation of claim 2. *Id.* at 55.

3. Claim 4

Claim 4 depends from claim 1 and further recites the following:

> a proximal lock attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the radially compressed configuration while the plurality of spring apices remain within the cap.

Ex. 1001, 9:59–65. Petitioner asserts that "Hartley discloses in Embodiment #1 a proximal lock (including trigger wire 22)," and provides an annotated version of Figure 11 of Hartley with trigger wire 22 highlighted in red. Pet. 58. Although Petitioner states that trigger wire 22 is included in what Petitioner contends corresponds to the recited "proximal lock" of claim 4, Petitioner does not further explain what else disclosed by Hartley corresponds to the recited "proximal lock" in addition to trigger wire 22.[8]

4. Claims 7 and 8

Independent claim 7 recites, in addition to other limitations similar to features of claim 1, the following:

> a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft, wherein the retention mechanism comprises a proximal lock fixed to the outer tube.

Ex. 1001, 10:15–21. Similar to claim 4, Petitioner argues that Embodiment #1 of Hartley discloses "a proximal lock (including trigger

[8] In regard to Petitioner's contentions based on "Embodiment # 2" of Hartley, Petitioner similarly states that "Hartley discloses in Embodiment #2 a proximal lock (including trigger wire 165)" without explaining what else disclosed by Hartley corresponds to the recited "proximal lock" in addition to trigger wire 165). Pet. 60.

wire 22)," but does not explain what else is disclosed by Hartley that, together with trigger wire 22, corresponds to the recited "proximal lock." Pet. 63.

Claim 8 depends from claim 7 and requires, in part, that "the retention mechanism enables a partial deployment." Petitioner identifies trigger wire 22 as corresponding to the recited "retention mechanism," but does not further address the "proximal lock" requirement of claim 7. *Id.* at 65–66.

5. Claim 12

Independent claim 12, in addition to other limitations similar to features of claim 1, recites "a retractable primary sheath," "a retention mechanism attached to the outer tube" and "a second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed." Ex. 1001, 10:65–11:6. As to the first recited "retention mechanism," Petitioner provides no explanation other than to refer back to portions of the Petition that address other similar, but not identical, limitations in claim 4 (reciting a "proximal lock") and claim 7 (reciting a "proximal lock"). Pet. 67–68. As to the "second retention mechanism," Petitioner relies on sleeve 30 of Hartley, which Petitioner also contends corresponds to the recited "retractable primary sheath." *Id.* at 69–72.

6. Showing of a Reasonable Likelihood

Upon review of the contentions of Petitioner, and of the evidence offered in support thereof, we are persuaded that Petitioner has established a reasonable likelihood of prevailing in showing, at a minimum, that claims 1 and 2 of the '632 patent are anticipated by "Embodiment #1" of Hartley. We also reviewed Petitioner's contentions based on "Embodiment #2" of

Hartley. Pet. 39–72. We further are persuaded that Petitioner has established a reasonable likelihood of prevailing in showing, at a minimum, that claims 1 and 2 of the '632 patent are anticipated by "Embodiment #2" of Hartley.

F. Alleged Obviousness over Combinations of Hartley, Lindenberg, and Olson

Petitioner contends that claims 1–4 of the '632 patent would have been obvious over Hartley (Embodiment #1 or Embodiment #2) in combination with Lindenberg and/or Olson. Pet. 73–84. Petitioner relies on its contentions set forth with respect to the alleged anticipation by Hartley, and further contends that "[t]o the extent claim 1 is interpreted as requiring a distinct structure to enable the claimed 'controlled relative axial movement,' such a requirement is not a patentable distinction." Pet. 73–76 (citing, *e.g.*, Ex. 1014 ¶ 110). In this regard, Petitioner's contentions apply to claim 3, which depends from claim 1, and further recites "a threaded collar coupled to the inner tube and a mating threaded shaft coupled to the outer tube enables the relative axial movement between the inner tube and the outer tube for controlled deployment of the stent graft." Ex. 1001, 9:53–58. Petitioner asserts that Lindenberg and Olson teach this additional limitation. Pet. 76–78 (citations omitted).

Petitioner also asserts that it would have been obvious to apply the teachings of rotary control in Lindenberg and Olson in place of control by "pushing and pulling" taught by Hartley because, among other reasons, rotation was one of a finite number of applicable techniques and would have provided reliable and precise deployment, as well as a mechanical advantage. *Id.* at 77–81. Upon review Petitioner's contentions, and of the evidence offered in support thereof, we are persuaded that Petitioner has

established a reasonable likelihood of prevailing in showing, at a minimum, that claims 1–3 of the '632 patent would have been obvious over either Hartley Embodiment #1 or Embodiment #2, in combination with either, or both, of Lindenberg and Olson.

IV. CONCLUSION

Upon review of the analysis and supporting evidence presented by Petitioner in the Petition, for the reasons provided above, we are persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to at least one of the claims of the '632 patent challenged in the Petition. Accordingly, *inter partes* review shall proceed in this case on all of the grounds raised in the Petition. *See SAS Inst.*, 138 S. Ct. at 1359–60 (a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); Guidance on the Impact of SAS on AIA Trial Proceedings[9] (stating that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–4, 7, 8, and 12 of the '632 patent is instituted with respect to all grounds presented in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of a trial, which commences on the entry date of this Decision.

[9] Available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

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