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571-272-7822

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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 IPR2019-00206
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, 2, 4, 5, 7–9, 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

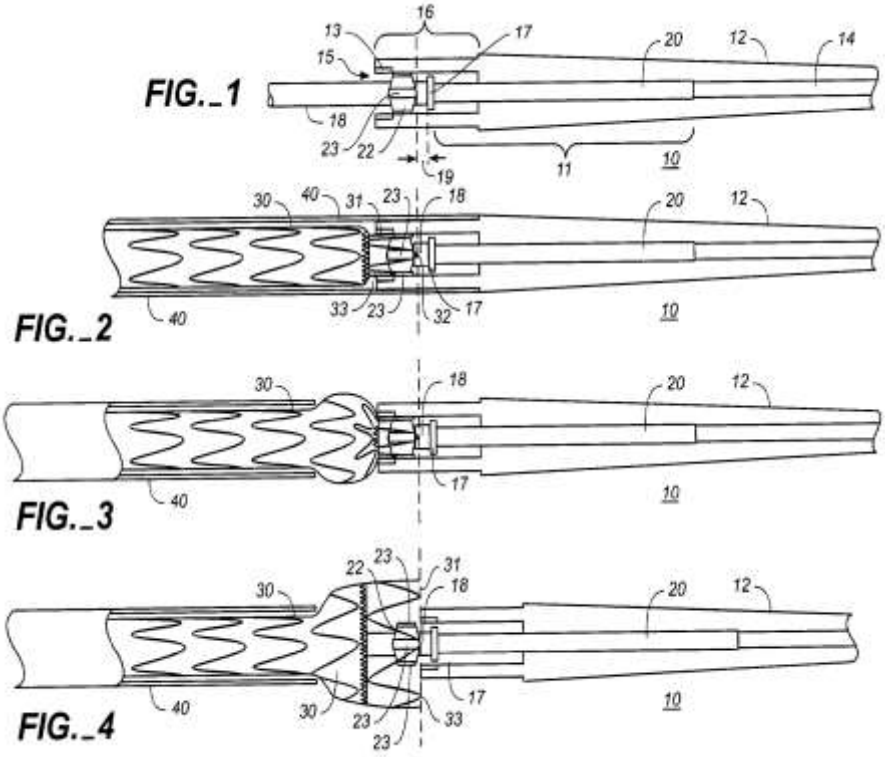
The '632 patent, titled "Controlled Deployment Delivery System," issued September 4, 2007, from U.S. Application No. 10/455,978, filed June 5, 2003. Ex. 1001, [21], [22], [45], [54]. The '632 patent generally relates to a "controlled stent-graft deployment delivery system." *Id.* at Abstract.

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 axial 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, and 5 depend from claim 1, and claims 8 and 9 depend 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 IPR2019-00205 challenging the patentability of claims 1–4, 7, 8, and 12 of the '632 patent. Pet. 1; Paper 3, 2.

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 Vascular, Inc., is the owner of the '632 patent and that "Medtronic plc is the ultimate parent of Medtronic Vascular, Inc." Paper 3, 1–2.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 2, 4, 5, 7–9, and 12 of the '632 patent on the following grounds:

References	Basis	Claims Challenged
Pinchuk[1] (Embodiment #1)	§ 102	1, 4, 7, 8, and 12
Pinchuk (Embodiment #2)	§ 102	1, 2, 4, 7, 8, and 12
Pinchuk (Embodiment #1) and Robinson[2]	§ 103	4, 5, 7–9, and 12
Pinchuk (Embodiment #2) and Robinson	§ 103	4, 5, 7–9, and 12

Pet. 4. Petitioner supports its challenge with a Declaration by Enrique Criado M.D., dated November 12, 2018. Ex. 1015.

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*

[1] US 5,415,664, iss. May 16, 1995, (Ex. 1006, "Pinchuk").
[2] Eur. Pat. App. Pub. No. 0 657 147 A2, pub. Jun. 14, 1995 (Ex. 1008, "Robinson").

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)).

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. 1015 ¶ 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)[3]; *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 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

[3] 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).

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 of 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))).[4]

D. Scope and Content of the Prior Art

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

1. Summary of Pinchuk

Pinchuk, titled "Method and Apparatus for Introducing a Stent or a Stent-Graft," relates "broadly to the delivery and deployment of a transluminal prosthesis." Ex. 1005, [54], 1:7–9. Pinchuk describes an introducer, stent, and sheath that may be moved as one after a portion of the stent is released from the sheath so that the stent may be precisely located before it is deployed. Ex. 1005, [57].

Figure 6 of Pinchuk is reproduced below.

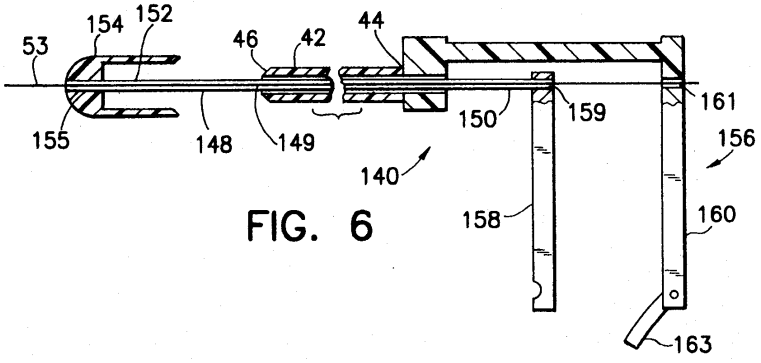


FIG. 6

[4] 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 6 illustrates an embodiment of stent introducer 140 (identified as "Embodiment #1" by Petitioner, but called the "second embodiment" in Pinchuk). Pet. 25, Ex. 1006, 4:44–46, 5:57–59. Introducer 140 includes hollow tube 42, control member 148 with central bore 149, and end cap 154 with central bore 155. *Id.* at 5:57–63. Actuator handle or finger grip means 156 includes inverted L-shaped member 160 coupled to hollow tube 42 and sliding member or finger grip means 158 coupled to control member 148. *Id.* at 5:63–68. As explained by Petitioner, hollow tube 42 and control member 148 move axially relative to one another. Pet. 26 (citing Ex. 1006, 3:40–62, 5:57–6:13, 7:64–9:1; Ex. 1015 ¶ 48).

Figure 5a of Pinchuk is reproduced below.

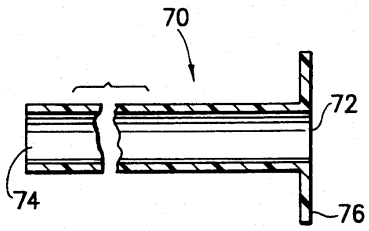


FIG. 5a

Figure 5a illustrates sheath 70, including gripping flange 76, for use with the stent introducer. Ex. 1006, 4:41–43, 5:4–47. Petitioner explains the operation of the introducer disclosed by Pinchuk Embodiment #1 as follows:

> prior to deployment, the proximal end of the stent or stent graft (the end closest to the heart) is "captured and held between the end cap…and the distal end…of the hollow tube [(the end furthest from the operator)]," ([Ex. 1006], 5:35–40 . . .). The inner and outer tubes (42, 148) are then inserted into the sheath 70, and the sheath 70 retains the distal end of the stent or stent graft (the end furthest away from the heart) in a compressed state. (*Id.*, 5:43–48 . . .). During deployment, "the introducer . . . is held stationary while the sheath 70 is partially withdrawn in a proximal direction [(towards the operator)]…, thereby allowing partial diametric expansion" of the stent, or stent graft.

(Ex. 1006, 8:41–47). "[T]he [proximal end] of the stent [or stent graft] remains captured between the cap 154" and the proximal end of the hollow tube 42, and "the [distal end] of the stent [or stent graft] remains covered by the sheath 70." (*Id.*, 8:47–50; Ex. 1015 at ¶49).

Pet. 26–27.[5]

Figures 8, 8a, and 8b of Pinchuk are reproduced below.

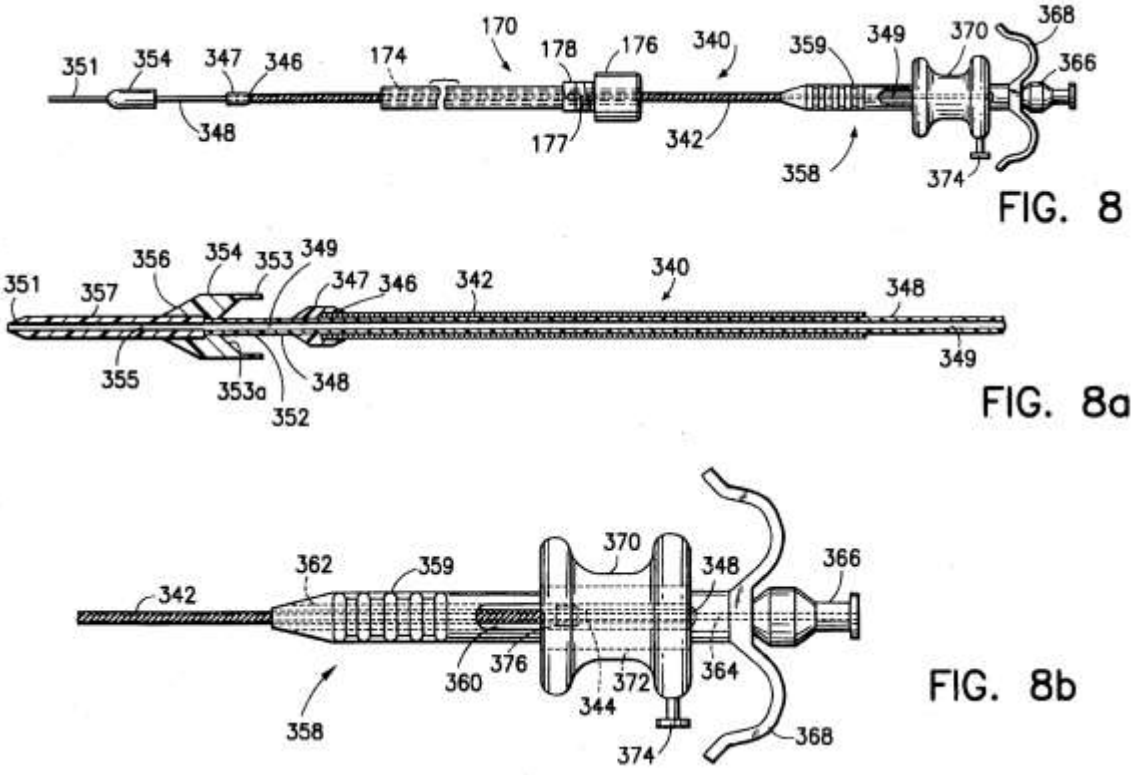


Figure 8, 8a, and 8b illustrate an embodiment of stent introducer 340 (identified as "Embodiment #2" by Petitioner, but called the "fourth

[5] Petitioner states that Pinchuk uses the term "proximal" as "a position or direction towards the operator" and "distal" as "a position or direction away from the operator." Pet. 23 n. 8. 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 Pinchuk. *Id.*

embodiment" in Pinchuk). Pet. 28, Ex. 1006, 4:52–58, 6:55–57. Introducer 340 includes flexible coil 342 "having a frustroconical tapered capturing or locking member 347," and control member 348 with cap 354. Ex. 1006, 7:9–21. Control member 348 is coupled to handle 358 and coil 342 is coupled to spool 370 by cross block 376. *Id.* at 7:44–49. "[M]ovement of the spool 370 relative to the shaft 359 effects a movement of the coil 342 relative to the control member 348, and thereby effects movement of the locking member 347 relative to the cap 354." *Id.* at 7:51–55.

Petitioner explains the operation of the introducer disclosed by Pinchuk Embodiment #2 as follows:

> prior to deployment, the proximal end of a stent or stent graft (end closest to the heart) "is diametrically compressed and inserted into the cylindrical portion 353 of the cap 354." (Ex. 1006 at 8:2-4; . . .). "The cap 354 is then brought into engagement with the frustroconical [sic] tapered locking member 347. . . , thus capturing the distal end 11 of the stent 10." (*Id.*, 8:8–11). "[T]he cap 354 is then inserted into the proximal end . . . of a sheath…as [s]hown in FIG. 10," which retains the distal end of the stent or stent graft (the end furthest away from the heart) in a compressed state. (*Id.*, 8:14–20, Figure 10; . . .). During deployment, "the introducer…is held stationary while the sheath…is partially withdrawn in a proximal direction [(towards the operator)]…, thereby allowing partial diametric expansion" of the stent, or stent graft. (*Id.*, 8:41-47). "[T]he [proximal end] of the stent [or stent graft] remains captured" between the cap 354 and locking member 347, and "the [distal end] of the stent [or stent graft] remains covered by the sheath." (*Id.*, 8:47–50; *see also id.*, 3:50-62; Ex. 1015 at ¶51).

Pet. 29–30.

2. Summary of Robinson

Robinson, titled "Non-migrating vascular prosthesis and minimally invasive placement system therefor," relates to a device for the percutaneous placement of a vascular graft. Ex. 1008, [54], 3:16–19. "The graft assembly can be delivered percutaneously with a catheter-like delivery device that includes an outer sheath and an inner positioning member that extends through the outer sheath." *Id.* at 4:33–36.

Figure 13 of Robinson is reproduced below.

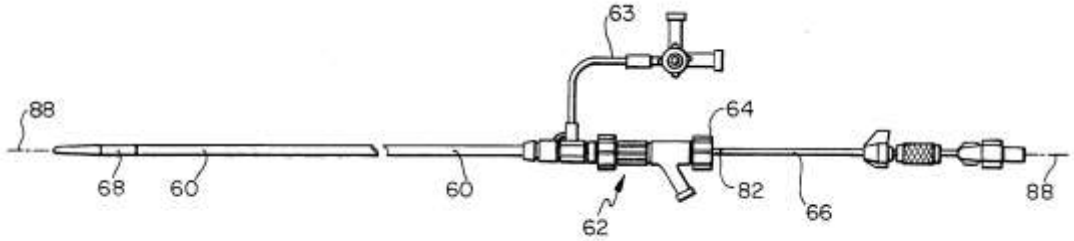


Fig. 13

Figure 13 illustrates the catheter-like delivery device for percutaneously inserting and deploying the implant assembly. *Id.* at 5:41–42, 10:14–17. The delivery device includes sheath 60 adapted to receive positioning tube 66 with dilator 68. *Id.* at 10:17–23.

Figure 16a of Robinson is reproduced below.

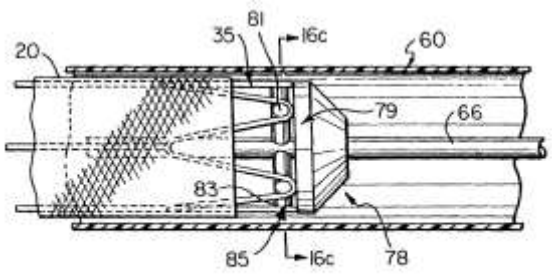


Fig. 16a

Figure 16 illustrates a section of the delivery device which engages the implant. *Id.* at 5:50–52. The delivery device includes stay 78 which operates in conjunction with implant retention device 85 to maintain the

position of implant assembly 10, which includes synthetic vascular graft 20, as sheath 60 is withdrawn. *Id.* at 6:3–5, 11:11–14. When loading the graft assembly on the delivery device, the graft assembly is placed over positioning tube 66 "such that the proximal bends of anchor segment 35 are disposed against the stay 78." *Id.* at 10:45–57. Spokes 81 of retention device 85 engage anchor 30. *Id.* at 11:14–24. As a result, the implant is prevented from moving relative to the stay such that "if removal or repositioning of the implant is desired, the sheath 60 may be advanced distally to recapture the implant assembly." *Id.* at 11:27–32. "[A]s as long as a portion of the implant is maintained within the sheath, the deployment process can be reversed to recapture the implant within the sheath and reposition or remove it." *Id.* at 12:38–42.

E. Alleged Anticipation by Pinchuk

Petitioner contends that claims 1, 4, 7, 8, and 12 of the '632 patent are anticipated by Pinchuk Embodiment #1. Pet. 36–58. Petitioner also contends that claims 1, 2, 4, 7, 8, and 12 of the '632 patent are anticipated by Pinchuk Embodiment #2. Pet. 59–82. For purposes of our discussion below, we focus on the contentions of Petitioner with respect to what Petitioner identifies as Pinchuk Embodiment #1.

1. Claim 1

Petitioner provides a detailed explanation of how Pinchuk Embodiment #1 allegedly discloses each limitation of claim 1. Pet. 36–48. Petitioner's contentions are supported by Dr. Criado. Ex. 1015 ¶¶ 58–69. We briefly summarize how Petitioner contends Pinchuk Embodiment #1 discloses each limitation of claim 1.

A controlled stent-graft deployment delivery system, comprising:

Petitioner contends introducer 140 of Pinchuk Embodiment #1 corresponds to a controlled stent-graft deployment deliver system. Pet. 36; *see also, e.g.*, Ex. 1006, 3:21–26 (describing "the stent delivery and deployment apparatus of the present invention").

a stent-graft;

Corresponding to the recited "stent-graft," Petitioner asserts that Pinchuk Embodiment #1 discloses the use of an introducer to deliver and deploy a stent-graft or endoluminal graft. Pet. 37; *see also, e.g.*, Ex. 1006, 1:14–22 (disclosing that transluminal prosthesis, commonly known as stents, are well known in the medical arts for implantation, and that "[w]hen bio-compatible materials are used as a covering or lining for the stent, the prosthesis is called a stent-graft or endoluminal graft").

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

Petitioner contends that sheath 30 of Pinchuk Embodiment #1 discloses the recited "retractable primary sheath," and that it constrains stent 10. Pet. 38 (citing Ex. 1006, 3:21–32, 3:40–62, 4:41–46, 7:64–8:28, Figs. 5a, 10a; Ex. 1015 ¶ 60).

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

According to Petitioner, Pinchuk Embodiment #1 discloses hollow tube 42 corresponding to the recited "outer tube." Pet. 39. Petitioner also explains that a person of ordinary skill would have understood that, in use, hollow tube 42 is disposed within sheath 70 and within the stent-graft. *Id.* at 39–40 (explaining that a person of

ordinary skill would have understood that the operation of Pinchuk Embodiment #1 is analogous to the operation of the introducer illustrated in Figure 10a of Pinchuk).

> *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 control member 148 within hollow tube 42 (the alleged "outer tube"). Pet. 41 (citing Ex. 1006, 3:21–32, 5:57–6:13, Fig. 6; Ex. 1015 ¶ 63). According to Petitioner, control member 148 and hollow tube 42 move axially relative to each other "by moving sliding member 158 towards, or away from, L-shaped member 160." *Id.* at 42–44 (further contending that person of ordinary skill would have understood that Pinchuk Embodiment #1 operates in the same manner as illustrated in Figures 11, 11a, and 11b of Pinchuk).

> *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 end cap 154 of Pinchuk Embodiment #1, coupled to control member 148, corresponds to the recited "cap" and that it is configured to retain a portion of stent 10 in a compressed configuration. Pet. 45–46 (citing, e.g., Ex. 1006, 3:40–45, 5:57–6:13, Figs. 6, 9, 9a).

> *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 Pinchuk Embodiment #1 discloses a controlled relative axial movement between hollow tube 42 (the "outer tube") and control member 148 (the "inner tube") releases the proximal end of stent 10

from end cap 154 and from the radially compressed configuration. Pet. 47 (citing, e.g., Ex. 1006, 3:21–62, 5:57–6:13, Figure 6; Ex. 1015 ¶ 68).

2. 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 "Pinchuk Embodiment #1 discloses a proximal lock (including end 46) attached to the outer tube 42." Pet. 49. Pinchuk, however, states that "introducer 40 according to the invention includes a hollow tube 42 having a proximal end 44 and a distal end 46." Ex. 1006, 5:6–8. Petitioner does not explain how "distal end 46" is both the recited "proximal lock" and an end of the recited "outer tube." Additionally, although Petitioner states that end 46 is included in what Petitioner contends corresponds to the recited "proximal lock" of claim 4, Petitioner does not further explain what else disclosed by Pinchuk corresponds to the recited "proximal lock" in addition to end 46.[6]

3. 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

[6] In regard to Petitioner's contentions based on "Embodiment # 2" of Pinchuk, Petitioner similarly states that "Pinchuk Embodiment #2 discloses a proximal lock (including locking member 347 . . .)" without explaining what else disclosed by Pinchuk corresponds to the recited "proximal lock" in addition to locking member 347. Pet. 72.

> 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 Pinchuk Embodiment #1 discloses "a proximal lock (including end 46)," but does not explain how "distal end 46" is both the recited "proximal lock" and an end of the recited "outer tube" or what else is disclosed by Pinchuk that, together with end 46, corresponds to the recited "proximal lock." Pet. 53–54.

Claim 8 depends from claim 7 and requires, in part, that "the retention mechanism enables a partial deployment." Petitioner contends that the "retention mechanism" includes the "proximal lock," which includes distal end 46, but does not explain what else is included in each feature and does not further address the "proximal lock" requirement of claim 7. *Id.* at 55–56.

4. 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. 58. As to the "second retention mechanism," Petitioner relies on sheath 70 of Pinchuk, which Petitioner also contends corresponds to the recited "retractable primary sheath." *Id.* at 58.

5. Claim 2 (Alleged Anticipation by Pinchuk Embodiment #2)

Claim 2 further recites "wherein the cap is a shroud portion of a flexible tapered tip fixed to the distal end of the inner tube." Ex. 1001, 9:50–52. Petitioner asserts that "Pinchuk Embodiment #2 discloses that the cap (cylindrical portion 353) is a shroud portion of a flexible tapered tip ('cap 354') fixed to the distal end of the inner tube (control member 348 . . .)." Pet. 71. Pinchuk, however, states that "control member 348 is provided with a rigid cap 354 which has a proximal cylindrical portion 353 . . . and a distally extending soft catheter tip 357." Ex. 1006, 7:17–21. Petitioner does not address how Pinchuk necessarily discloses a cap that is "a shroud portion of a flexible tapered tip" in light of the description of cap 354 as "rigid."

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 claim 1 of the '632 patent is anticipated by Pinchuk Embodiment #1. We also reviewed Petitioner's contentions based on Pinchuk Embodiment #2. Pet. 59–70. We further are persuaded that Petitioner has established a reasonable likelihood of prevailing in showing, at a minimum, that claim 1 of the '632 patent is anticipated by Pinchuk Embodiment #2.

F. Alleged Obviousness over Pinchuk Embodiment #1 or Pinchuk Embodiment #2, in combination with Robinson

Petitioner contends that claims 4, 5, 7–9, and 12 of the '632 patent would have been obvious over Pinchuk Embodiment #1 or Pinchuk Embodiment #2, in combination with Robinson. Pet. 83–99.

1. Claim 4

Claim 4 recites, among other features, that "the stent-graft has a plurality of proximal spring apices." Petitioner argues, again, that Pinchuk Embodiment #1 and Pinchuk Embodiment #2 each disclose the limitations of claim 4, but then proceeds to assert that it would have been obvious to a person of ordinary skill "to use either of the Pinchuk delivery system embodiments to deliver and deploy stent grafts including self-expanding zig-zag type stents, as disclosed in Robinson." Pet. 86–89. Claim 4 does not recite "zig-zag type stents" and Petitioner does not address directly what is deficient in the disclosure of Pinchuk that requires modification by Robinson. *See* Pet. 84–88. Petitioner further argues that it would have been obvious "to modify the shape of Pinchuk's proximal locks in view of Robinson." Pet. 89–94. As noted above, Petitioner does not identify clearly what elements of Pinchuk correspond to the recited "proximal lock" and does not explain why the "proximal lock" allegedly disclosed by Pinchuk requires modification by Robinson to satisfy the requirements of claim 4. For example, Petitioner asserts that it "would have been obvious to modify the shape of the locks disclosed in Pinchuk Embodiment #1 (end 46) and Pinchuk Embodiment #2 (locking member 347) to include radially-extending spokes, as described in Robinson." Pet. 91. Claim 4, however, does not recite "radially-extending spokes."

2. Claim 5

Claim 5 depends from claim 4, and further requires "the proximal lock further comprises a plurality of ribs for retaining a plurality of apices of the proximal spring of the stent-graft." Ex. 1001, 9:66–10:2. Petitioner

contends the radially extending spokes 81 of Robinson correspond to the recited "plurality of ribs." Pet. 94.

3. Claims 7–9 and 12

Petitioner relies in large part on its contentions with respect to anticipation by Pinchuk in support of the asserted obviousness of claims 7–9 over the combination with Robinson. Pet. 95–98. Petitioner asserts, again, that the recited "retention mechanism attached to the outer tube" that "comprises a proximal lock" of claim 7 is disclosed by "Pinchuk Embodiments #1 and #2," and further argues it is disclosed based on "modified Pinchuk Embodiments #1 and #2" addressed in the Petition with respect to claim 4. *Id.* at 95–96. Petitioner makes the same abbreviated argument with regard to claims 8, 9, and 12. *Id.* at 97–99.

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[7] (stating that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

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

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, 2, 4, 5, 7–9, 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.

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