UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cook Incorporated, Cook Group Incorporated and Cook Medical LLC,

Petitioners

v.

Medtronic Vascular, Inc.,

Patent Owner

Patent No. 7,264,632
Issue Date: September 4, 2007

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,264,632

Case No. IPR 2019-00205

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Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively, "Petitioners") respectfully request *inter partes* review of claims 1-4, 7-8, and 12 of U.S. Patent No. 7,264,632 ("the '632 Patent") (Ex. 1001). The USPTO assignment records show that the Patent Owner is Medtronic Vascular, Inc. ("Medtronic" or "Patent Owner").

I. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Parties-in-Interest

Petitioners are the real parties-in-interest.

B. Related Matters

This Petition is being filed and served concurrently with a petition for *inter partes* review in IPR No. 2019-00206, which challenges the patentability of claims 1-2, 4-5, 7-9, and 12 of the '632 patent.

C. Lead And Back-Up Counsel

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D. Service Information

Service on Petitioners may be made by mail or hand-delivery to the lead and back-up counsel at the addresses specified above. Petitioners also consent to service by email at addresses specified above.

II. ADDITIONAL REQUIREMENTS

A. Timing (37 C.F.R. §§ 42.101 And 42.102)

The '632 patent issued on September 4, 2007. Neither Petitioners, nor any of their privies: (1) own the '632 patent; (2) were served with a complaint alleging infringement of the '632 patent; (3) filed a civil action challenging the validity of any claim of the '632 patent; or (4) are barred or estopped from challenging the claims of the '632 patent.

B. Fee for *Inter Partes* Review (37 C.F.R. § 42.103)

The Office is authorized to charge the filing fees specified by 37 C.F.R. § 42.15(a), as well as any other required fees, to Deposit Account No. 23-1925.

C. Certification of Standing (37 C.F.R. § 42.104(a))

Petitioners certify that the '632 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

D. Identification of Challenge, Precise Relief Requested, And Specific Art And Statutory Grounds On Which The Challenge Is Based (37 C.F.R. § 42.104(b))

The precise relief requested is that claims 1-4, 7-8, and 12 of the '632 patent be found unpatentable, and canceled.

Inter partes review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103:[1]

No.	Grounds
1	Claims 1-2, 4, 7-8, and 12 are anticipated by Hartley[2] (Ex. 1005).
2	Claims 1-4 are obvious in view of Hartley (Ex. 1005) in combination with Lindenberg[3] (Ex. 1007) and/or Olson[4] (Ex. 1004).

[1] The '632 patent issued from U.S. Patent Application No. 10/455,978, filed June 5, 2003. The pre-AIA sections of 35 U.S.C. §§ 102 and 103 apply here.

[2] PCT Patent Publication No. WO 98/53761.

[3] U.S. Patent No. 5,433,723.

[4] U.S. Patent No. 5,906,619.

III. BACKGROUND

A. "Background Of The Invention"

The '632 patent is entitled "Controlled Deployment Delivery System." (Ex. 1001 at Title). The '632 patent issued from U.S. Patent Application No. 10/455,978 ("the Wright Application"), filed June 5, 2003, and claims priority to U.S. Provisional Patent Application No. 60/387,278 (Ex. 1003, "Provisional Application"), filed June 7, 2002. (Ex. 1001 at 1:6-8). The '632 patent names as inventors Michael T. Wright, Timothy W. Lostetter, and Alex Ruiz ("the Named Inventors").

The "Field of the Invention" of the '632 patent "relates generally to medical devices and procedures, and more particularly to a method and system of deploying a stent-graft[5] in a vascular system." (Ex. 1001 at 1:12-14). According to the '632 patent, "[p]rostheses for implantation in blood vessels or other similar organs of the living body are, in general, well known in the medical art." (*Id.*,

[5] The specification and claims of the '632 patent use the terms "stent graft" and "stent-graft" interchangeably. (*See, e.g.*, Ex. 1001 at 2:10-12 ("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."); claim 7 ("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"); Ex. 1014 at ¶28).

1:18-20). These include "prosthetic vascular grafts formed of biocompatible materials," as well as "graft material supported by [a] framework" (*i.e.*, "stent-graft[s] or endoluminal graft[s]"). (*Id.*, 1:20-25). The '632 patent acknowledges that, by the time the application for the '632 patent was filed, "the use of stent-grafts for treatment…[of vascular diseases] [was] well known." (*Id.*, 1: 26-29; Ex. 1014 at ¶¶27-28).

A stent is a device, (typically made from biocompatible materials, such as stainless steel or Nitinol (a nickel titanium alloy)), that is used to hold open a natural vessel (*e.g.*, a blood vessel) or an artificial vessel (*e.g.*, a graft) in the body. (Ex. 1014 at ¶¶29). Stents are capable of transitioning from a collapsed smaller diameter to an expanded larger diameter. A stent or stent graft is introduced into the body in a collapsed, smaller diameter inside of a delivery catheter, through a small puncture at a location remote from the vessel portion to be treated (also referred to as an intraluminal delivery). The stent or stent graft is then guided through the vessel to the portion to be treated, where it is expanded to a larger diameter. (*Id.*; Ex. 1001 at 1:40-65). In general, there are two types of stents: (1) balloon-expandable stents; and (2) self-expanding stents. Balloon-expandable stents cannot expand on their own, and require an external force to expand – typically provided by a balloon. Self-expanding stents, on the other hand, are capable of expanding on their own due to mechanical and/or thermal resilience of

the material from which they are manufactured. (Ex. 1014 at ¶29; Ex. 1001 at 1:29-40).

Prior art delivery catheters include coaxial tubes, "arranged for relative axial movement." (Ex. 1001 at 1:48-50). The coaxial tubes are used to compress and restrain the stent graft during insertion of the stent graft in the body. (*Id.*, 1:50-56). The coaxial tubes are manipulated, by relative axial movement, to release and deploy the stent graft from the delivery catheter within the body. (*Id.*, 1:56-65; Ex. 1014 at ¶30).

According to the '632 patent, "[m]any self expanding stent-graft deployment systems" in the prior art were designed to release the proximal end of the stent graft first, as an outer tube or sheath is withdrawn. (Ex. 1001 at 2:8-10). This is illustrated below, for example, in annotated Figures 3 and 4 of U.S. Patent No. 5,824,041 ("Lenker" (Ex. 1009)) (listed as a cited reference on the cover of the '632 patent (Ex. 1001 at p. 1)).

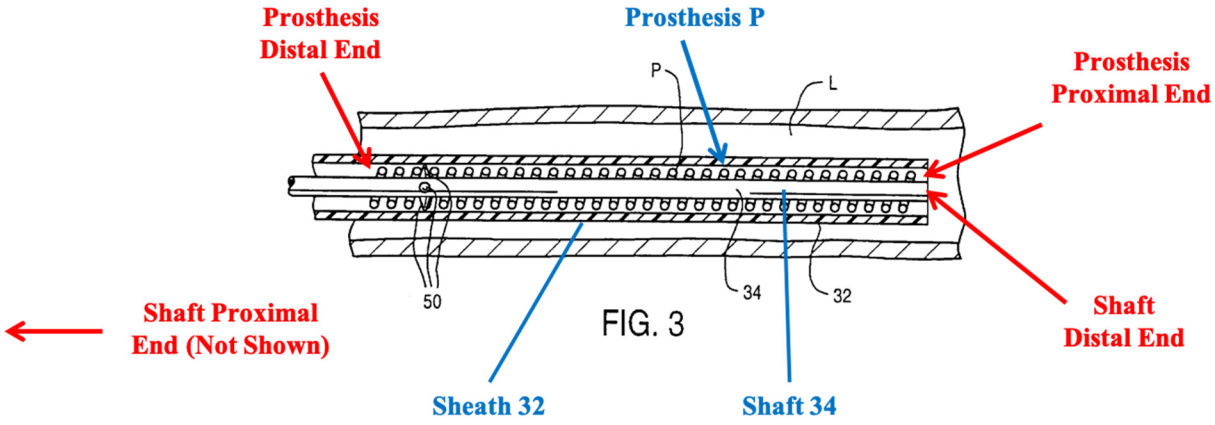


FIG. 3

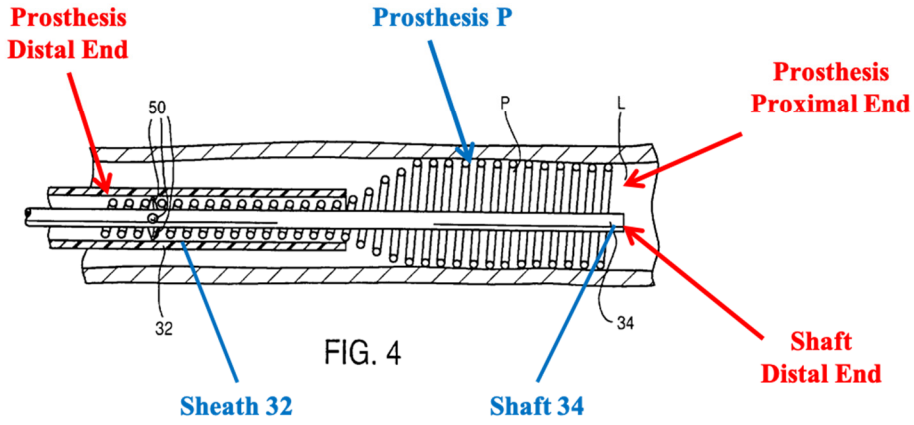


FIG. 4

(Ex. 1014 at ¶31). The annotated figures above depict a delivery catheter 30, including a sheath 32 and coaxial shaft 34. (Ex. 1009 at 7:9-15). The delivery

catheter "receives a radially compressible tubular prosthesis P [(illustrated above as a helical coil)] within the annular space between the outer surface of the shaft 34 and the inner surface of the lumen through sheath 32." (*Id.*, 7:15-23). As shown above, the proximal end of the prosthesis P (the end closest to the heart) expands outwardly from the shaft 34 as the sheath 32 moves proximally (toward the operator) relative to the prosthesis P (from Figure 3 to Figure 4).[6] (Ex. 1014 at ¶31).

The '632 patent describes alleged problems with prior art delivery devices. (Ex. 1001 at 2:8-18). According to the '632 patent, the proximal end of a stent graft "is typically designed to fixate and seal the stent graft to the wall of the vessel during deployment." (*Id.*). Delivery devices that are "configured to have the proximal end of the stent-graft deploy as the outer tube or sheath is pulled back"

[6] The '632 patent defines the proximal end of a stent graft as "the end closest to the heart," and the distal end of the stent graft as "the end furthest away from the heart during deployment." (Ex. 1001 at 1:65-67). *In contrast*, the '632 patent defines the proximal end of the catheter components as "the end nearest the operator," and the distal end of the delivery catheter components as "the end that is farthest from the operator." (*Id.*, 1:67-2:3). As illustrated in annotated Figures 3 and 4 of Lenker, this convention results in seemingly "[in]consistent or opposite" uses of the terms "proximal" and "distal" (*e.g.*, in Figure 3, the *distal* end of the sheath 32 is located at the *proximal* end of the prosthesis P). (*Id.*, 2:3-7).

allegedly "leave[] little room for error in placement since re-positioning the stent-graft after initial deployment, except for a minimal pull down retraction, is usually difficult if possible at all." (*Id.*, 2:8-16). According to the '632 patent, "[d]eploying the proximal end of the stent-graft first makes accurate pre-deployment positioning of the stent-graft critical." (*Id.*, 2:16-18; Ex. 1014 at ¶32).

The '632 patent acknowledges that others in the prior art attempted to overcome this alleged problem in the prior art, by "confin[ing] the proximal end of the stent-graft." (Ex. 1001 at 2:26-27). According to the '632 patent, these prior art attempts "generally fail to provide adequate control in manipulating the stent-graft positioning in both the initial deployment of the stent graft and the re-deployment of the stent-graft (once the stent-graft has been partially deployed)." (*Id.*, 2:26-31). The '632 patent does not identify any of the prior art delivery systems that allegedly "fail to provide adequate control," does not explain why these prior art systems allegedly "fail to provide adequate control," and does not explain what is meant by "*adequate* control"[7] (versus *inadequate* control). (Ex. 1014 at ¶33).

[7] All emphasis is added unless otherwise noted.

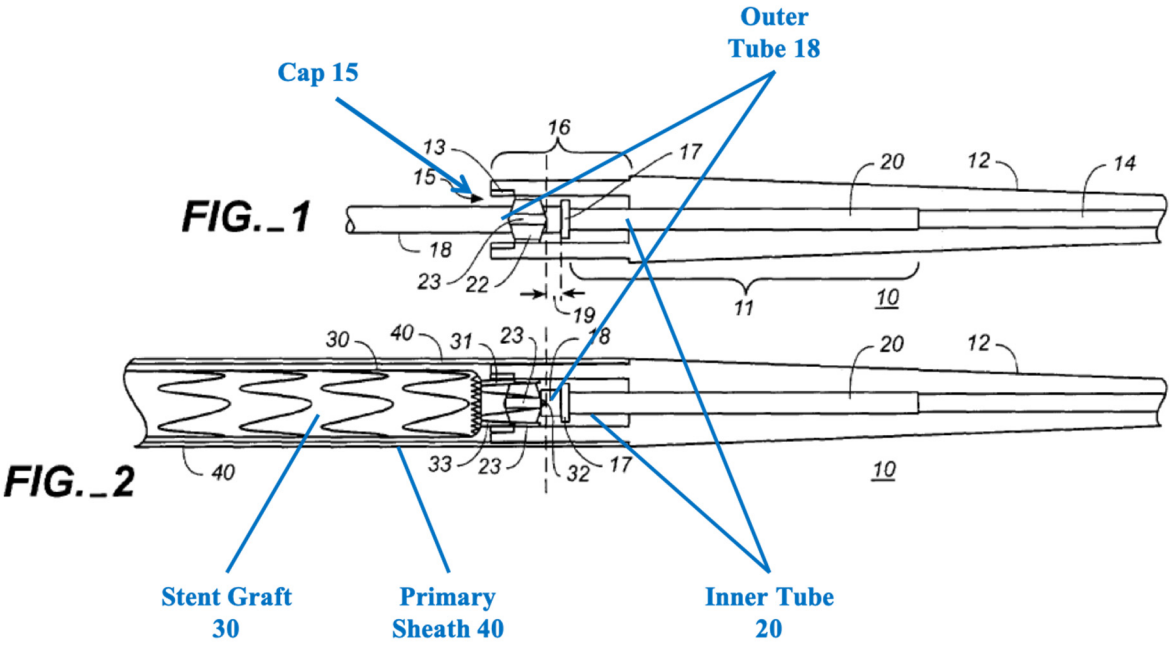
B. "Summary Of The Invention"

The '632 patent discloses as "a first aspect according to the present invention":

> a *stent-graft*, a retractable *primary sheath* containing the 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, where the inner tube and the outer tube both move axially relative to the retractable primary sheath and to each other,….[and] *a cap* coupled to a distal end of the inner tube and *configured to retain at least a portion of a proximal end of the stent-graft in a radially compressed configuration*.

(Ex. 1001 at 2:48-58; Ex. 1014 at ¶34).

Annotated Figures 1 and 2, below, illustrate an embodiment of the '632 patent including each of these elements of "the present invention."

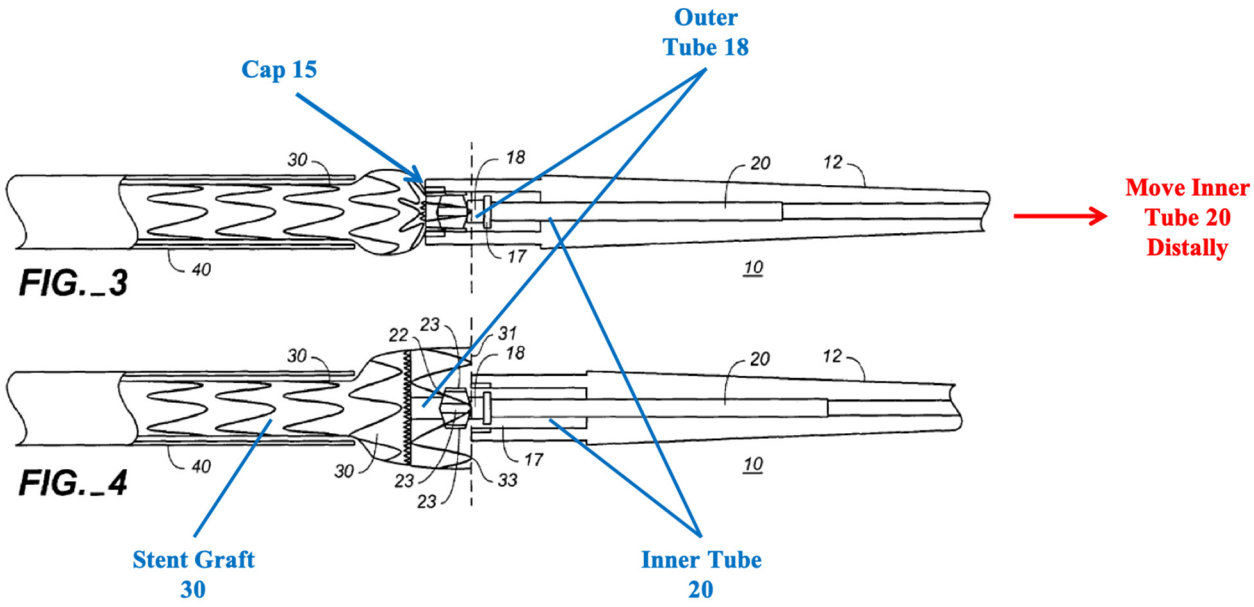


'632 Patent, Fig. 2

(Ex. 1014 at ¶34; Ex. 1001 at 3:35-40, 4:12-57). Annotated Figures 1 and 2 illustrate a stent graft 30, a primary sheath 40 containing the stent graft 30 in a constrained diameter configuration, an outer tube 18, an inner tube 20 that moves axially relative to the primary sheath 40 and outer tube 18, and a cap 15 configured to retain a portion of a proximal end of the stent graft 30 in a radially compressed configuration. According to the '632 patent, in this "aspect of the present invention," "[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 at 2:48-62; *see also id.*, 4:47-53; Ex. 1014 at ¶34).

Annotated Figures 3 and 4, below, illustrate movement (from Figure 3 to Figure 4) of the inner tube 20 distally (away from the operator) relative to the proximal end of stent graft 30 (the end closest to the heart), to release the proximal end of stent graft 30 from cap 15.

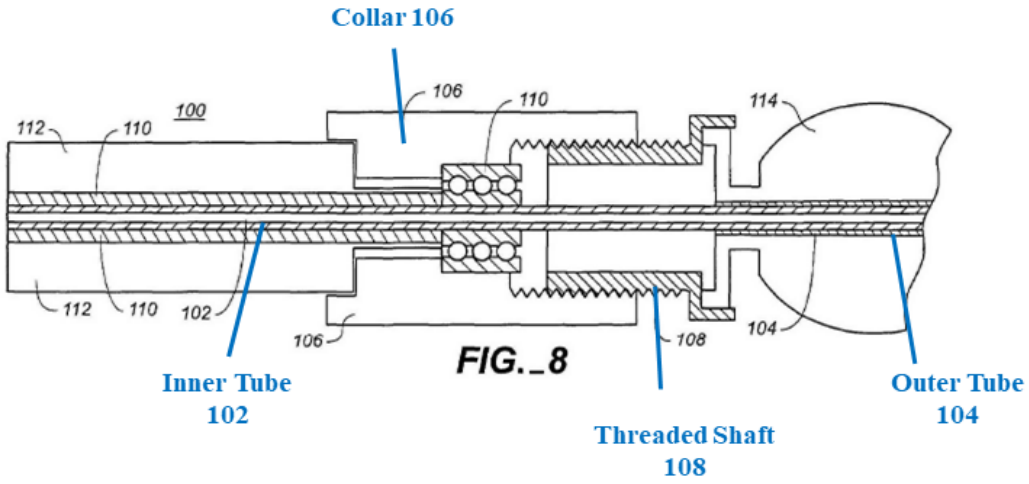


(Ex. 1001 at 3:41-46, 4:58-5:43; Ex. 1014 at ¶35).

According to the "Summary of the Invention," relative axial movement between the inner and outer tubes may be enabled by "a threaded collar coupled to the inner tube and a mating threaded shaft coupled to the outer tube." (Ex. 1001 at 2:66-3:3 ("[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.")).

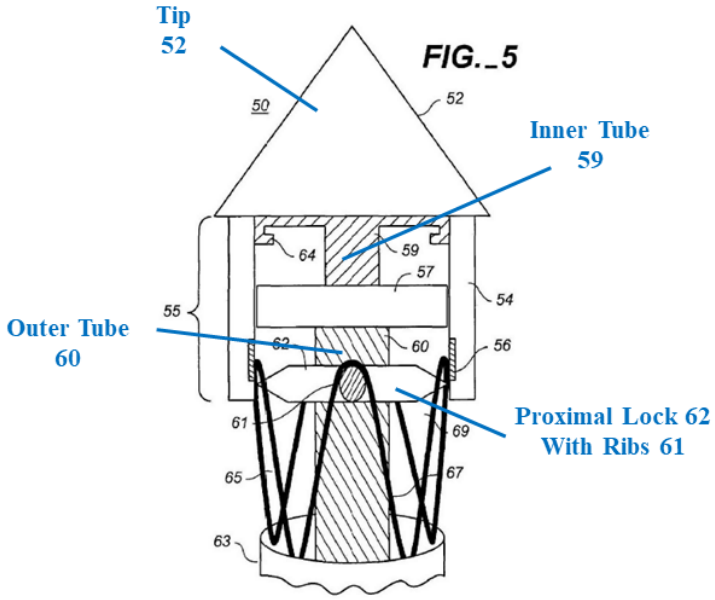
Annotated Figure 8, below, illustrates an embodiment of the '632 patent including "a spinning collar actuation assembly," with a threaded collar 106 coupled to inner tube 102, and a mating threaded shaft 108 coupled to outer tube 104.



(Ex. 1001 at 4:3-5, 8:17-54; Ex. 1014 at ¶36). Inner tube 102 "can advance axially in relation to the outer tube 104 by screwing or spinning the collar 106 down or across the threaded shaft 108." (Ex. 1001 at 8:25-28).

The "Summary of the Invention" further describes a "proximal lock" or "retention mechanism" attached to the outer tube, for retaining a proximal end of the stent graft in a constrained configuration while the proximal end of the stent graft is within the cap. (*Id.,* 3:3-21). The lock may include "a plurality of ribs or splines for retaining [a] plurality of apices of [a] proximal spring of [a] stent-graft."

(*Id.*, 3:3-11). Annotated Figure 5, below, illustrates an embodiment of the '632 patent including a "proximal lock" or "retention mechanism."



(*Id.*, 3:56-58, 5:35-43, 5:56-6:59, Figures 3-5, 5A, 6; Ex. 1014 at ¶37). As shown above in annotated Figure 5, the proximal lock is coupled to a distal end of outer tube 60, and includes a plurality of ribs 61 that retain "a plurality of proximal spring apices 65, 67 and 69 (68 is hidden in this view) of a stent-graft 63…within a cap or shroud portion 55 of a tip 52." (Ex. 1001 at 6:14-18; *see also id.*, 5:35-43 ("Additionally, a proximal lock (retainer) 22 is also coupled to a distal portion of the outer tube 18. The proximal lock 22 preferably includes at least one or a plurality of ribs (or splines) 23 that can together with the shroud portion 16 serve as an axial constraint for the end [of] stent-graft 30. 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.")).

The "Summary of the Invention" describes another "aspect according to the present invention" as "a method for controlled deployment of a stent-graft includ[ing] the steps of":

- "constraining a proximal end of a stent-graft radially under a cap while partially deploying a remaining portion of the stent graft,"
- "evaluating and adjusting as necessary at least one of the axial and radial positions of the stent-graft after the partial deployment of the remaining portion," and
- "releasing the proximal end of the stent-graft by minimal controlled coaxial movement between the cap and a tube retaining the stent-graft within the cap."

(*Id.*, 3:22-31; Ex. 1014 at ¶38).

As further explained below, each of these aspects of the "invention" was known in the art by the time the application for the '632 patent was filed. (Ex. 1014 at ¶39).

C. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art ("PHOSITA") as of the time of the filing of the applications that became the '632 patent (the 2002-2003 timeframe), would have included a medical device engineer or similar professional with at least an undergraduate degree in engineering and experience with endoluminal devices and methods, or a vascular surgeon or similar physician with at least two years equivalent experience with endoluminal devices and methods, with the understanding that such experience may come from education and/or training. (Ex. 1014 at ¶17).[8]

Petitioners submit the Declaration of Enrique Criado, M.D. (Ex. 1014). Dr. Criado is a vascular surgeon, and Chief of Vascular Surgery at MidMichigan Health, which is affiliated with the health care division of the University of Michigan. (Ex. 1014 at ¶4). As reflected in his *curriculum vitae* (included as Exhibit B to Ex. 1014), Dr. Criado had extensive experience in the 2002-2003 timeframe with vascular surgery and with endoluminal devices and methods. (*Id.*, ¶¶4-12, 18, 28, 30, Exhibit B). Dr. Criado qualified as a PHOSITA in the 2002-

[8] The same definition of a person or ordinary skill in the art, as well as the analysis of the prior art references discussed in this petition, would apply anytime in the 2002-2003 timeframe. (Ex. 1014, ¶19).

2003 timeframe, and his Declaration addresses the '632 patent and prior art from the perspective of a PHOSITA at that time. (*Id.*).

D. Claim Construction (37 C.F.R. § 42.104(b)(3))

A claim subject to *inter partes* review receives the "broadest reasonable construction [("BRI")] in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100 (b). *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278-79 (Fed. Cir. 2015), *aff'd, Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). For the purposes of this *inter partes* review only, Petitioners adopt the following constructions, consistent with the understanding of a PHOSITA.

1. "Proximal" / "Distal"

As explained above in Section III.A., the '632 patent defines the "proximal" end of a stent graft as the end "closest to the heart," and the "distal" end of a stent graft as the end "furthest away from the heart during deployment." (Ex. 1001 at 1:65-67). In other words, when referring to a component of a *stent graft*, the terms "proximal" and "distal" are defined with respect to the *patient*.

In contrast, when referring to a component of a *delivery catheter* (*e.g.*, a sheath, tube, or cap), the '632 patent defines the terms "proximal" and "distal" with respect to the *operator, or physician*. In particular, the term "proximal" is defined as "the end nearest the operator," whereas the term "distal" is defined as "the end that is farthest from the operator." (*Id.*, 1:67-2:3). Each of these conventions has been adopted in this Petition, unless otherwise indicated. (Ex. 1014 at ¶¶41-42).

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 "for retaining *a distal end* of the stent-graft undeployed while a remaining portion of the stent-graft is deployed." As shown below in Figure 3A, the '632 patent discloses constraining a distal end of the stent graft (end closest to the operator) within a primary, or outer sheath (*e.g.*, sheath 40).

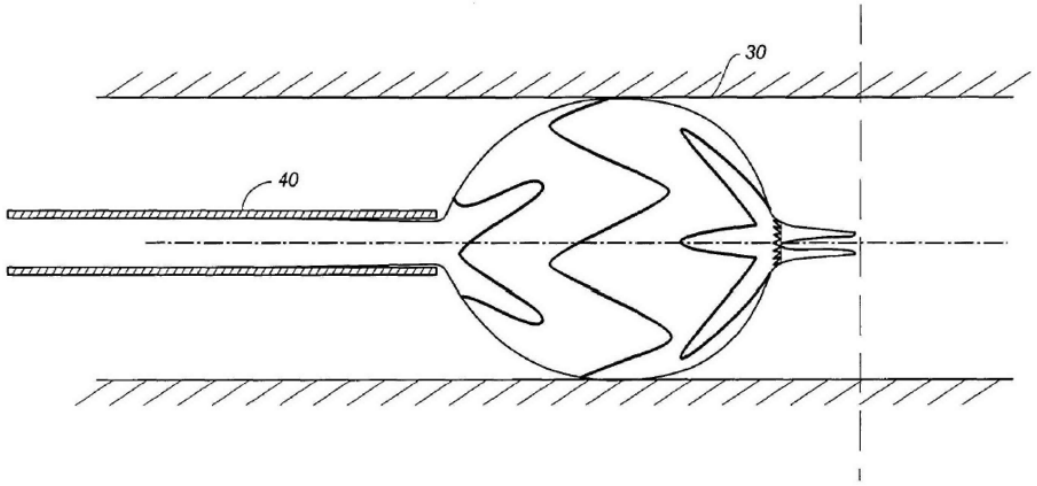


FIG._3A

(Ex. 1014 at ¶43; Ex. 1001 at 2:50-51 ("a retractable primary sheath containing the stent-graft in a first constrained diameter configuration"), 3:41-46 ("FIG. 3 is a close up schematic cross sectional view of [a] deployment system…showing partial deployment of the proximal portion of the stent graft as the proximal end of the stent-graft remains constrained *while the distal end of the stent graft remains loaded in its outer sheath.*"), 3:47-49 ("FIG. 3A is a partial cross sectional view of

the stent graft shown in FIG. 3, but without the distal end of the catheter and retaining shaft which is shown in FIG. 3."), 4:55-5:14).

The '632 patent does not disclose any other structure for "retaining" a distal end of the stent graft undeployed, as described in claim 12. Therefore, as explained in the Criado Declaration, the BRI of "second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed" includes an outer sheath that retains a distal end on the stent graft, as depicted in Figure 3A and described in the '632 patent. (Ex. 1014 at ¶43).

IV. SPECIFIC PRIOR ART REFERENCES FORMING THE BASIS FOR UNPATENTABILITY

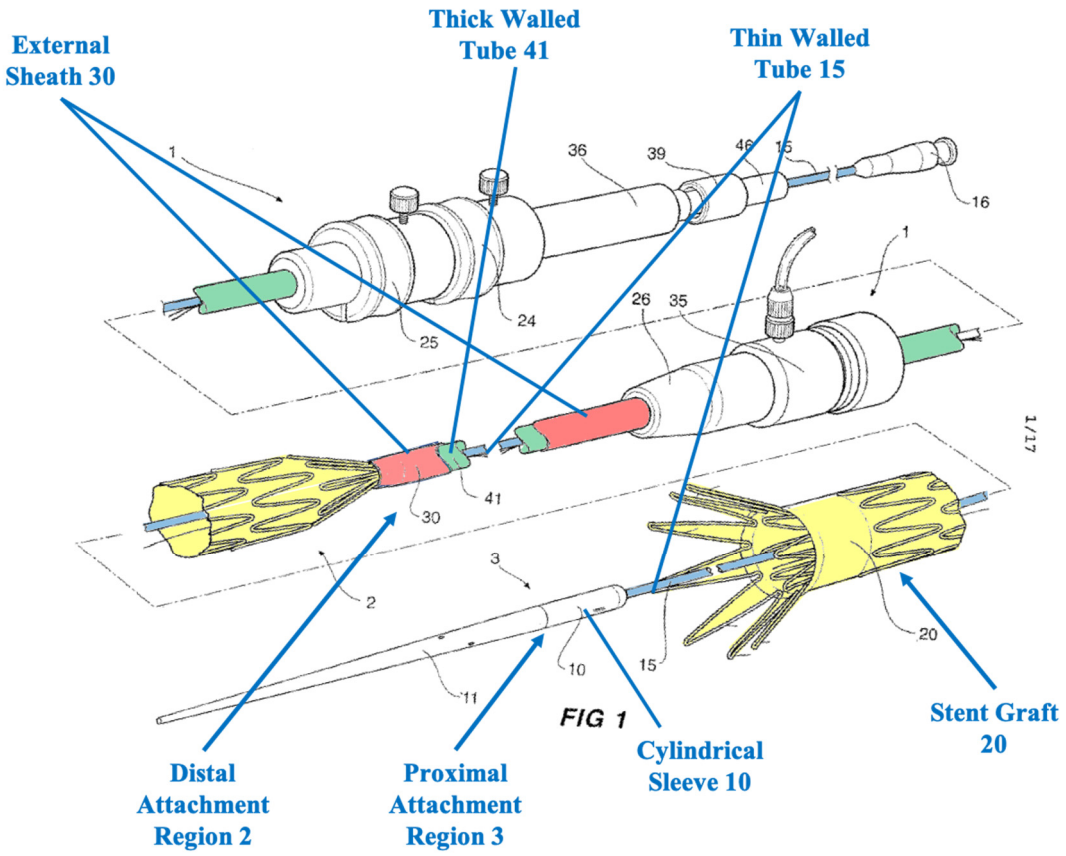
A. Hartley (Ex. 1005)

Hartley published on December 3, 1998. (Ex. 1005 at Cover; Ex. 1014 at ¶44). Hartley qualifies as prior art under 35 U.S.C. §§ 102(a) and 102(b). Hartley was not cited during prosecution of the '632 patent. (Ex. 1014 at ¶44).

Hartley is entitled "A Prosthesis And A Method And Means Of Deploying A Prosthesis." (Ex. 1005 at Title). Hartley "relates to a method and means for introducing a expandable intraluminal prosthesis…intended for the endovascular repair of diseased or damaged vessels…." (*Id.*, 1:7-10). Hartley discloses, in particular, a stent graft deployment delivery system (an "introducer") "adapted for the introduction of a self-expanding endovascular prosthesis…in a lumen of a patient." (*Id.*, Abstract). The delivery system includes "attachment devices (10, 30) to hold each end of the prosthesis[9] so that each can be moved independently." (*Id.*, Abstract; Ex. 1014 at ¶45).

[9] Hartley defines the terms "proximal and proximally" as "a position or direction towards the patient's heart," and the terms "distal and distally" as "a position or direction away the patient's heart." (Ex. 1005 at 1:11-13). To avoid any potential confusion resulting from conflicting definitions between Hartley and the '632 patent, the Petition adopts the definitions of "proximal" and "distal" from the '632 patent when describing Hartley.

Annotated Figure 1, below, illustrates a stent graft and stent graft delivery system disclosed in Hartley in two embodiments.

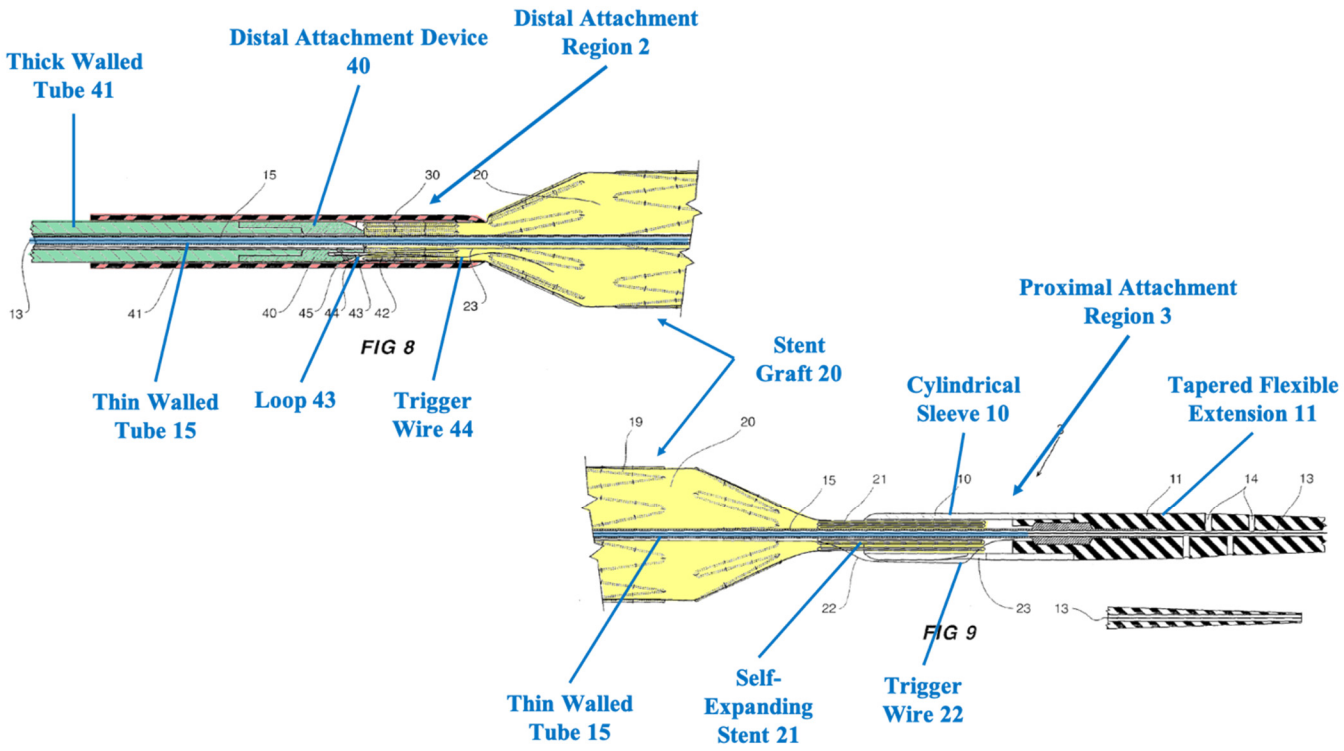


(Ex. 1001 at 11:9-10, 12:22-13:30; Ex. 1014 at ¶46). In a ***first embodiment*** ("Embodiment #1"), the delivery system (introducer 1) has an inner tube (thin walled tube 15 (highlighted in blue)), an outer tube (thick walled tube 41 + distal attachment device 40 (highlighted in green)), and a sheath (external sheath 30 (highlighted in red)). (*Id.*). The outer tube (40+41) "is coaxial with and radially outside the [inner] tube 15 and the sheath 30 is coaxial with and radially outside

the [outer] tube 41." (Ex. 1005 at 13:34-14:1). The inner tube (15, highlighted in blue) is axially movable with respect to the outer tube (40+41, highlighted in green) and the sheath 30 (highlighted in red). (*Id.*, Abstract, 8:1-2, 13:10-14, 14:10-12, 15:14-18:17). The stent graft 20 (highlighted in yellow) is "retained in its compressed condition [(illustrated in Figure 2)] by means of [sheath] 30 which is advanced to be received over the cylindrical sleeve 10 of the proximal attachment device 10 when the device is assembled for insertion." (*Id.*, 13:25-28; Ex. 1014 at ¶46).

The delivery system includes a proximal attachment region 3, for retaining a proximal end of the stent graft 20 (end closest to the heart), and a distal attachment region 2, for retaining a distal end of the stent graft 20 (end furthest from the heart). (Ex. 1005 at 12:22-26; *see also id.*, Abstract (describing "attachment devices…to hold each end of the prosthesis so that each can be moved independently"), 8:23-27 ("Preferably the prosthesis has a proximal end and a distal end and the insertion assembly includes a proximal attachment device and a distal attachment device adapted to retain the proximal and distal ends of the prosthesis respectively…."), 15:19-21 ("The prosthesis 20 is retained at each of its ends by the proximal and distal retaining assemblies respectively…."), 3:15-18, 6:11-30, 7:4-8, 7:14-24; Ex. 1014 at ¶47).

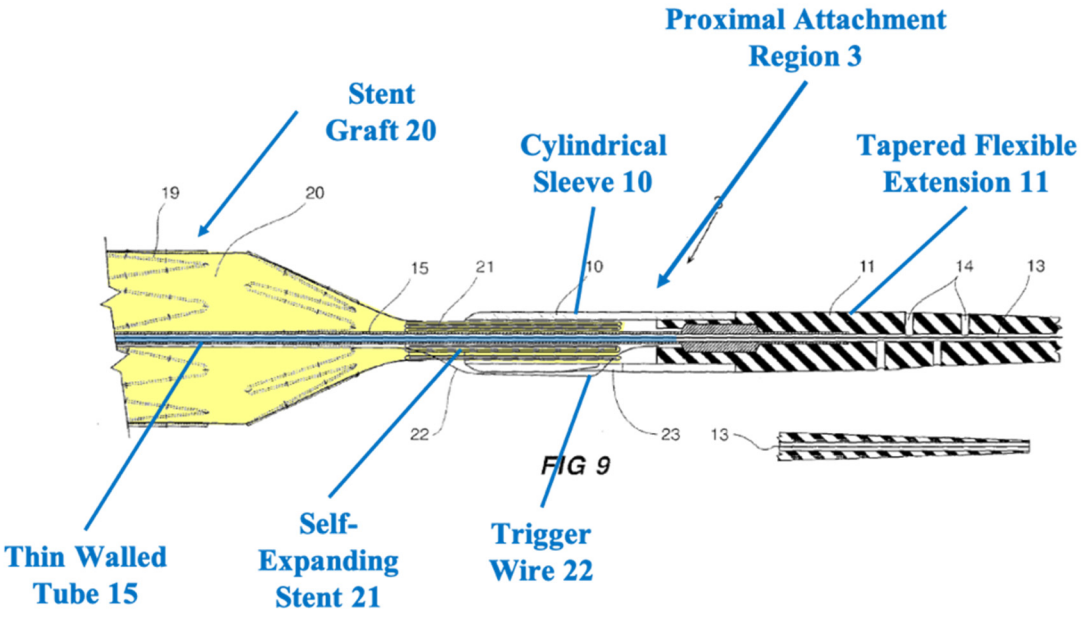
Figures 8 and 9 are reproduced and annotated below, and depict in the first embodiment (Embodiment #1) distal attachment region 2 (Figure 8) and proximal attachment region 3 (Figure 9), respectively.



(Ex. 1014 at ¶48). As shown above in annotated Figure 8, distal attachment region 2 includes a distal attachment device 40 formed at the end of thick walled tube 41 (40 and 41 (highlighted in green)). The distal end (the end furthest from the heart) of the stent graft 20 (highlighted in yellow) is "retained in the distal attachment device 40 which is mounted onto [outer] tube 41." (*Id.*, 13:31-34). "The distal end 42 of the prosthesis 20 has a loop 43 through which a distal trigger wire 44 extends." (*Id.*, 14:1-8). The "distal end 42 [of the stent graft (20)] is

retained within the external sheath 30" (highlighted in red). (*Id.*, 15:29-30; *see also id.*, 3:15-17, 7:4-8, 7:14-19; Ex. 1014 at ¶48).

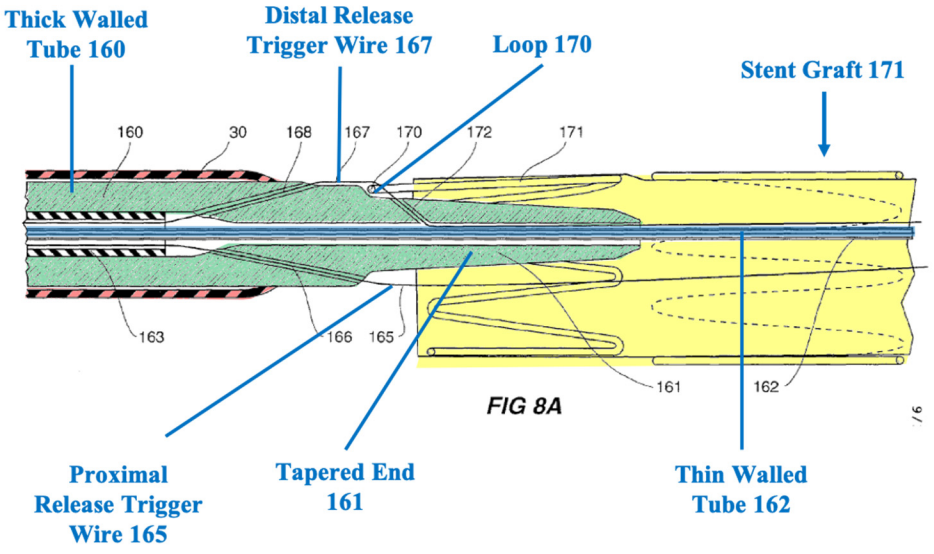
As shown below in annotated Figure 9, the proximal attachment region 3 in Embodiment #1 "includes a cylindrical sleeve 10 with a long tapered flexible extension 11 extending from its proximal end."



(Ex. 1005 at 12:27-13:2; Ex. 1014 at ¶49). Thin walled tube 15 (highlighted in blue) "is fastened to the extension 11 and extends through the complete introducer." (Ex. 1005 at 13:6-14). The proximal end (the end closest to the heart) of the stent graft 20 (highlighted in yellow) includes a self-expanding zigzag stent 21, which is "retained in the cylindrical sleeve 10 of the proximal attachment region 3 and retained in there by means of a trigger wire 22." (*Id.*, 13:16-22,

15:28-30 ("the most proximal zigzag stent 21 is…retained within the proximal attachment device"); Ex. 1014 at ¶49).

Figure 8A is reproduced and annotated below, and depicts in conjunction with Figure 8B (not reproduced below) an alternative embodiment of a distal attachment region for use with the delivery system illustrated in Figure 1 of Hartley (delivery device (1) with alternative attachment regions are referred to as "Embodiment #2").



(Ex. 1005 at 11:23-26, 14:9-17; Ex. 1014 at ¶50). As in the first embodiment, the delivery system has an inner tube (thin walled tube 162[10] (highlighted in blue)), an

[10] Thin walled tube 162 is analogous to thin walled tube 15 from Embodiment #1. (Ex. 1014 at ¶50).

outer tube (thick walled tube 160[11] (highlighted in green)), and a sheath (external sheath 30[12] (highlighted in red)). (*Id.*). The outer tube (160) is coaxial with and radially outside the inner tube (162) and the sheath 30 is coaxial with and radially outside the outer tube (160). (Ex. 1005 at 13:34-14:1). The inner tube (162 (highlighted in blue)) is axially movable with respect to the outer tube (160 (highlighted in green)) and the sheath 30 (highlighted in red). (*Id.*, Abstract, 8:1-2, 13:10-14, 14:10-12, 15:14-18:17). In Embodiment #2, the distal attachment region includes a tapered end 161[13] of thick walled tube 160 (highlighted in green). (Ex. 1005 at 14:9-17; *see also id.*, 8:6-9, 8:28-30). As shown above, the distal end (the end furthest away from the heart) of the stent graft 171 (highlighted in yellow) is retained on the distal attachment device. A distal trigger wire 167[14] "passes

[11] Outer tube (160) is analogous to thick walled tube 41 + distal attachment device 40 from Embodiment #1. (Ex. 1014 at ¶50).

[12] Sheath 30 is analogous to sheath 30 from Embodiment #1. (Ex. 1014 at ¶50).

[13] Tapered end 161 is analogous to distal attachment device 40 from Embodiment #1. (Ex. 1014 at ¶50).

[14] Distal trigger wire 167 is analogous to trigger wire 44 from Embodiment #1. Embodiment #2 also includes a proximal trigger wire 165 and tube 175, which are analogous to the proximal trigger wire 22 and cylindrical sleeve 10 from Embodiment #1, respectively. (Ex. 1014 at ¶50).

through [a] loop 170 in the distal end of the prosthesis 171." (Ex. 1005 at 14:12-17; Ex. 1014 at ¶50).

Hartley discloses that the delivery systems provide controlled and accurate deployment, permitting "careful positioning before release of the attachment means at a proximal end of the prosthesis," as well as "repositioning if necessary before release of the distal end of the prosthesis." (Ex. 1005 at 10:24-31). For example, as shown below in Figure 3, Hartley discloses that the stent graft 20 (highlighted in yellow) may be partially deployed, while retaining the proximal end (end closest to the heart) and distal end (end furthest from the heart) of the stent graft 20 constrained on the delivery system.

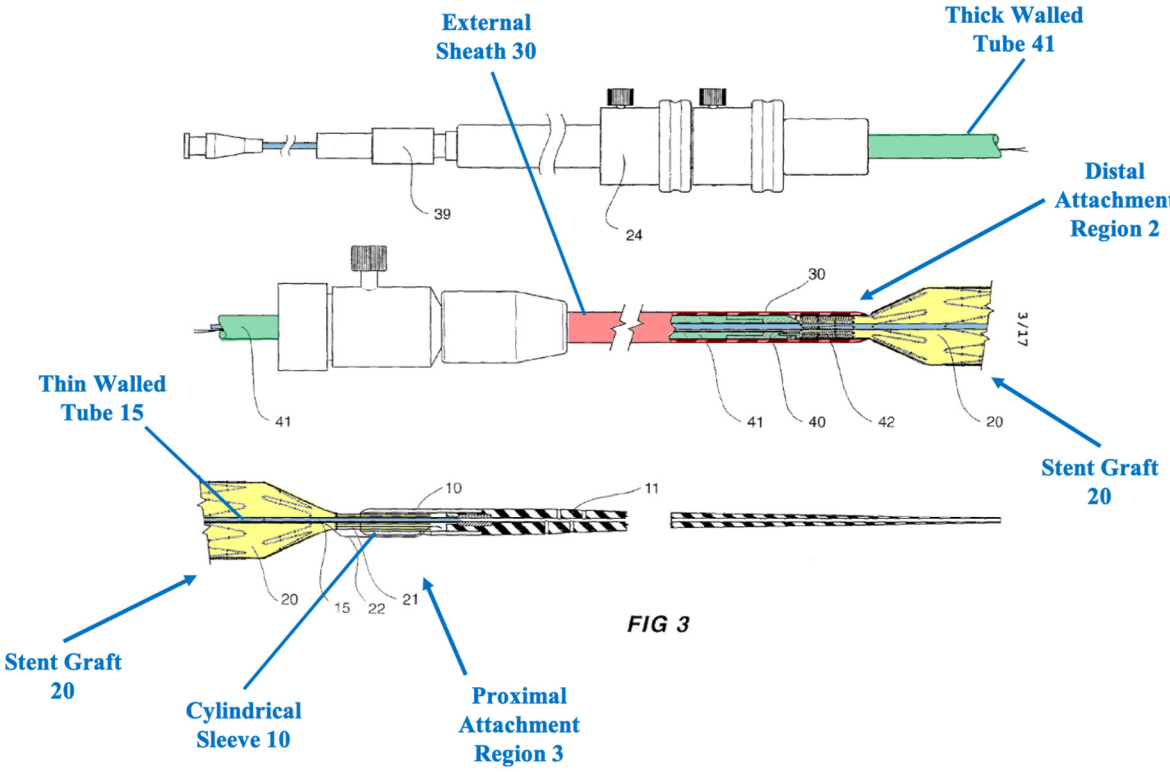


FIG 3

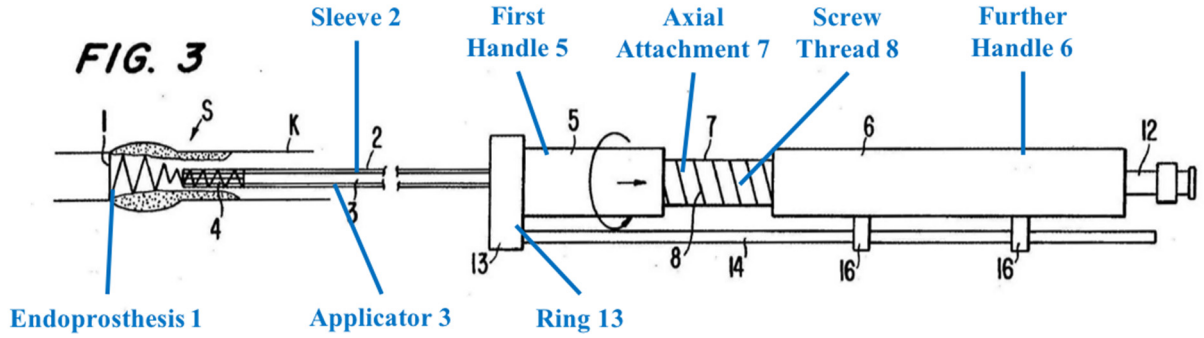
(*Id.*, 15:25-30 ("In FIG 3 it will be seen that once the introducer assembly is in a selected position the external sheath 30 is withdrawn to just proximal of the distal detachment device 40 so that the prosthesis 20 is now released so that it can expand radially except where the most proximal zigzag stent 21 is still retained within the proximal attachment device 10 and where its distal end 42 is retained within the external sheath 30."); Ex. 1014 at ¶51). This allows the stent graft (20) to be moved and repositioned both axially and radially within the body, before the proximal end of the stent graft (20) is released and "hooks or barbs 26 on the zigzag stent 21…grip into the walls of the lumen to hold the prosthesis therein." (Ex. 1005 at 15:31-16:16).

B. Lindenberg (Ex. 1007)

Lindenberg published on July 18, 1995 from a U.S. patent application filed on February 28, 1994. (Ex. 1007 at Cover; Ex. 1014 at ¶52). Lindenberg qualifies as prior art under 35 U.S.C. §§ 102(a), 102(b), and 102(e). Lindenberg was not cited during prosecution of the '632 patent. (Ex. 1014 at ¶52).

Lindenberg discloses "an apparatus for widening a stenosis in a body cavity such as an artery, bile duct, ureter, urethra or the like." (Ex. 1007 at 1:10-12). The apparatus includes an "endoprosthesis," and a delivery device. (*Id.*, 2:10-16, 4:64-67, 5:13-48). The delivery device includes a "sleeve surrounding and radially holding together the endoprosthesis" and an "endoprosthesis applicator." (*Id.*). In operation, the sleeve moves axially relative to the applicator. (*Id.*, 3:30-40, 5:13-68; Ex. 1014 at ¶53).

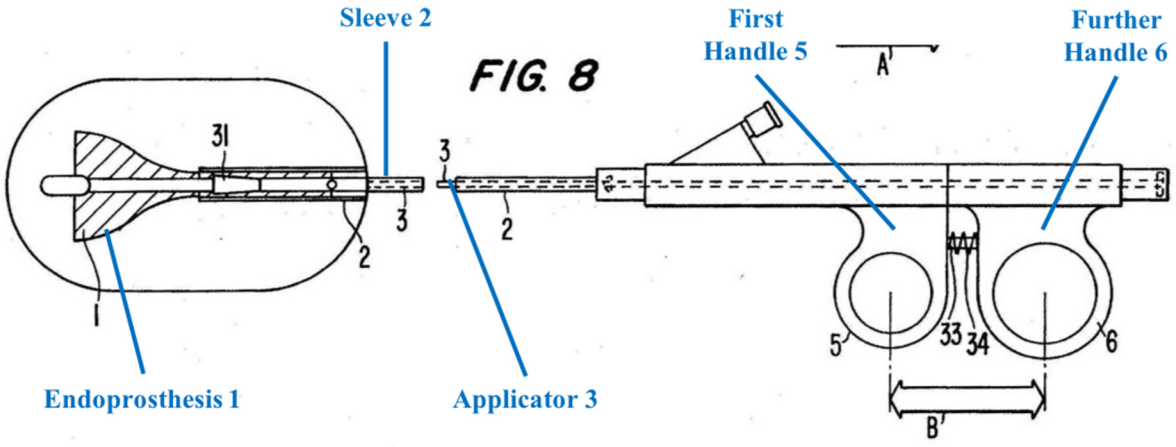
Figure 3 of Lindenberg (annotated and reproduced below) discloses in a first embodiment a device for delivering an endoprosthesis 1 in a patient, including a sleeve 2 and an applicator 3.



(Ex. 1007 at 4:64-67, 5:13-68; *see also id.*, Figures 1-2; Ex. 1014 at ¶54). In this embodiment, the sleeve 2 is moved axially relative to the applicator 3 via a rotating handle mechanism, which allows endoprosthesis 1 to be "precisely…held in position while the sleeve 2…[is] retracted in order to radially release the endoprosthesis 1." (Ex. 1007 at 5:42-48). As shown above, sleeve 2 (an outer tube) is coupled to a "first handle 5," and applicator 3 (an inner tube) is coupled to a "further handle 6." (*Id.*, 5:13-17). The applicator is coupled to further handle 6 via axial attachment 7, which "projects through the first handle 5." (*Id.*, 5:14-17). Axial attachment 7 is a "threadable attachment with a screw thread 8 formed on the outside." (*Id.*, 5:17-20). First handle 5 "has a corresponding internal thread and is consequently received in a threadable manner along the axial attachment 7." (*Id.*, 5:20-23). First handle 5 is "freely rotatably inserted into a ring 13," which is

"firmly axially connected [to the first handle 5], but can still rotate" relative to the sleeve 2. (*Id.*, 5:38-41, 5:64-68). In operation, sleeve 2 moves proximally (towards the operator) relative to the applicator 3, by rotating first handle 5 while holding further handle 6 (and applicator 3) stationary. (*Id.*, Figure 3, 5:13-68). Because of the threaded connection between first handle 5 (and coupled sleeve 2) and axial attachment 7 (and coupled applicator 3), rotating first handle 5 causes the sleeve 2 to move proximally (towards the operator) relative to the applicator 3. (*Id.*; Ex. 1014 at ¶54).

Figure 8 of Lindenberg (annotated and reproduced below) discloses an alternative embodiment for delivering endoprosthesis 1 in a patient.



(Ex. 1007, 7:3-23; Ex. 1014 at ¶55). Unlike the first embodiment, the embodiment illustrated in Figure 8 does not include a rotating handle mechanism for moving sleeve 2 axially relative to applicator 3. Instead, the operator moves sleeve 2 axially relative to the applicator by directly pushing and pulling handles 5, 6

axially, towards and away from one another. (Ex. 1007 at 7:3-53; Ex. 1014 at ¶55).

C. Olson (Ex. 1004)

Olson published on May 25, 1999 from a U.S. patent application filed on July 24, 1997. (Ex. 1007 at Cover; Ex. 1014 at ¶56). Olson qualifies as prior art under 35 U.S.C. §§ 102(a), 102(b), and 102(e). Olson was not cited during prosecution of the '632 patent. (Ex. 1014 at ¶56).

Olson discloses "systems, devices, and methods for deployment of endoluminal prostheses within the lumens of the body." (Ex. 1004 at Abstract; *see also id.*, 1:6-12 ("[I]mproved delivery systems and methods for their use to accurately and safely deploy endoluminal prostheses within the lumens of the body, particularly within the vascular system for treatment of aortic aneurysms, stenoses, and the like."), 4:30-54; Ex. 1014 at ¶57).

According to Olson, prior art delivery devices "suffer from undesirable limitations," such that "accurate delivery and placement of [an] endovascular prosthesis within the vasculature can be problematic." (Ex. 1004 at 1:40-46). This is because endoluminal prostheses can be "tightly compressed within the [delivery] catheter, imposing significant forces against the surrounding catheter sheath." (*Id.*, 1:47-51). In order to overcome this perceived problem, Olson discloses moving the catheter sheath axially relative to the delivery catheter using an actuation

mechanism with a "mechanical advantage." (*Id.*, 2:15-19 ("In a first improvement over known delivery systems, a sheath is withdrawn from over a tightly compressed prostheses using an actuation mechanism having a variable mechanical advantage, which varies with the position of the sheath."), 2:36-48 ("The delivery system comprises a sheath having a proximal end, a distal end, and a lumen….capable of receiving [a] prosthesis near the distal end. The member in the lumen of the sheath is adapted for expelling the prosthesis from the lumen as the sheath moves from a first position to a second position relative to the member. An actuation mechanism is attached to the member, and couples a handle to the sheath with a mechanical advantage that varies as the sheath moves between the first position and the second position."), 2:62-3:24; Ex. 1014 at ¶58).

In particular, Olson discloses a rotating actuation mechanism including a "handle…[that] rotate[s] about an axis parallel to the axis of the sheath," in order to "avoid[] any inadvertent proximal and distal movement imparted by the handle to the prosthesis or delivery system." (Ex. 1004 at 2:24-28; *see also id.*, 3:3-7 ("An actuation mechanism is attached to the member, and couples the sheath to a handle. The handle is rotatable about an axis substantially parallel to the axis of the sheath to effect movement of the sheath…."), 3:8-24, 3:36-43, 3:62-63, 4:10-20, 5:34-39, Figures 2, 8-12; Ex. 1014 at ¶59).

Figure 2 of Olson (annotated and reproduced below) discloses a delivery system 30 for delivering a prosthesis 10 in a patient.

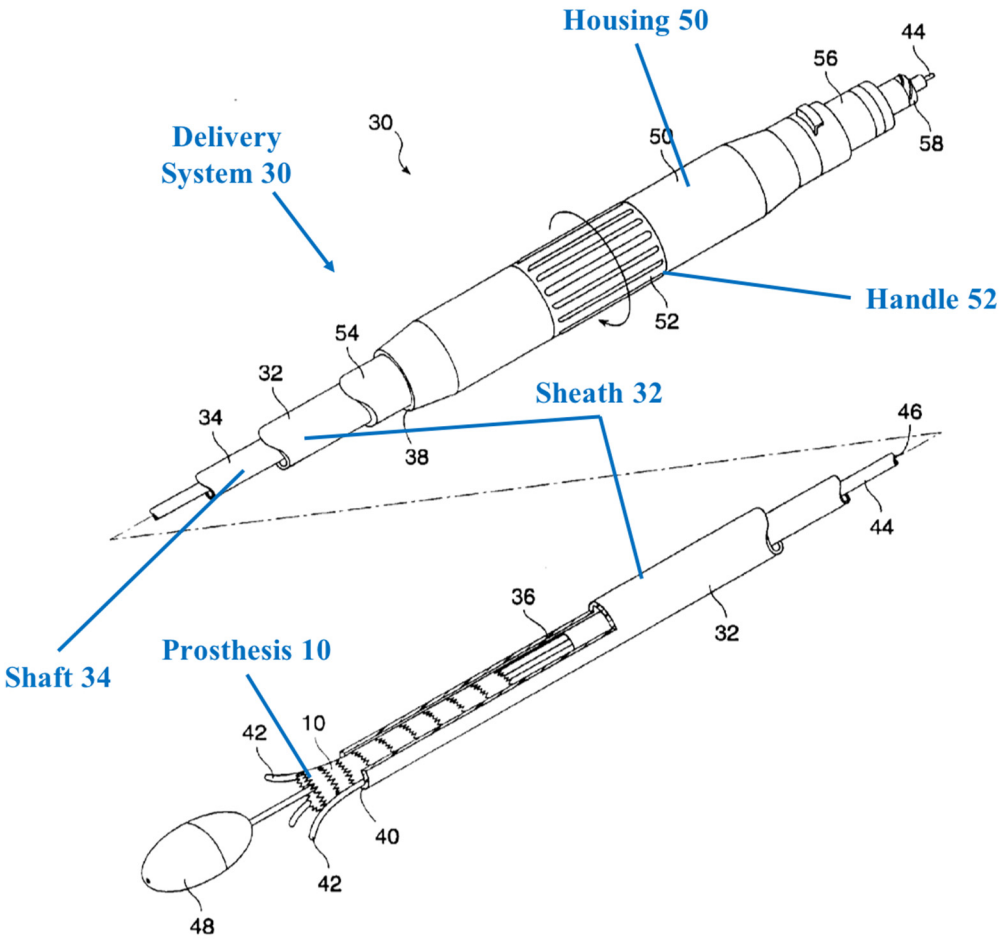


FIG. 2

(Ex. 1004 at 3:62-63, 5:6-55; Ex. 1014 at ¶60). The delivery system 30 includes a tubular sheath 32 (an outer tube) and a shaft 34 (an inner tube) slidably disposed within a lumen of the sheath 32. (Ex. 1004 at 5:6-10). Prosthesis 10 is compressed within the lumen of the sheath 32. (*Id.*, 5:19-21). The delivery system 30 further includes a housing 50, which "contains an actuation mechanism for withdrawing

sheath 32 proximally [(towards the operator)] while prosthesis 10 is axially restrained." (*Id.*, 5:29-32). "To withdraw sheath 32 proximally, a handle 52 [(of the actuation mechanism)] is rotated about the axis of the sheath, as illustrated." (*Id.*, 5:32-34). The actuation mechanism "converts the axial rotation of handle 52 to axial translation of sheath 32." (*Id.*, 7:13-15, 7:21-46, 7:57-8:3; Ex. 1014 at ¶60). Olson discloses that the actuation mechanism allows the end of the prosthesis to be "very gradually released, allowing the physician to verify the accuracy of the deployment position as the prosthesis initially engages the surrounding body lumen." (Ex. 1004, 8:4-8; Ex. 1014 at ¶61).

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO THE CHALLENGED CLAIMS (37 C.F.R. §§ 42.104(b)(4) AND (b)(5))

There is a reasonable likelihood that claims 1-4, 7-8, and 12 are unpatentable in view of one or more of the grounds identified in Section II.D. Each of these grounds includes prior art references that were not cited during prosecution. As demonstrated below, the challenged claims are unpatentable because they are either anticipated by the prior art or are obvious applications of "known technique[s] to…prior art ready for the improvement," and merely state obvious combinations of "familiar elements according to known methods," which "do[] no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416-17 (2007); MPEP § 2143(I). The motivation to combine embodiments would have come from the references themselves, as well as from the knowledge generally available to a PHOSITA.

A. Ground 1: Claims 1-2, 4, 7-8, And 12 Are Anticipated By Hartley (Ex. 1005)

1. Independent Claim 1

a. *"A controlled stent-graft deployment delivery system, comprising:"*

As shown below in annotated Figure 1, Hartley discloses in two embodiments a controlled stent graft deployment delivery system (introducer 1).

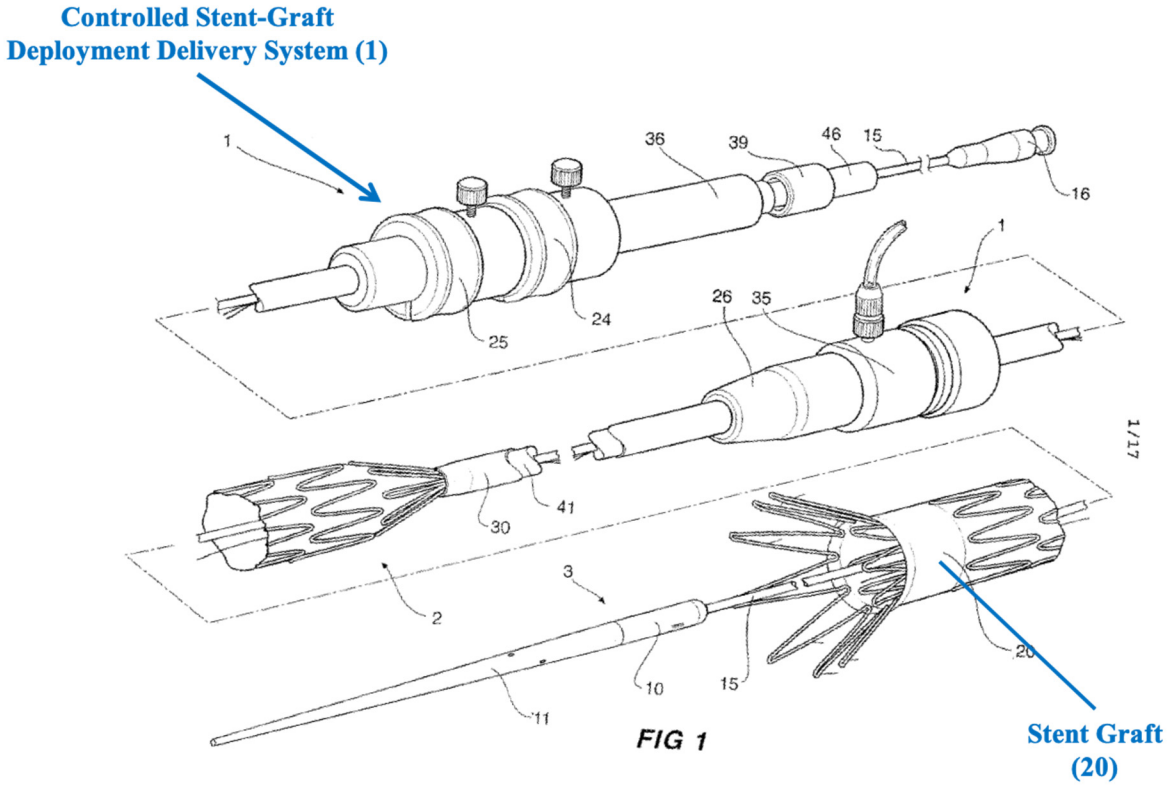


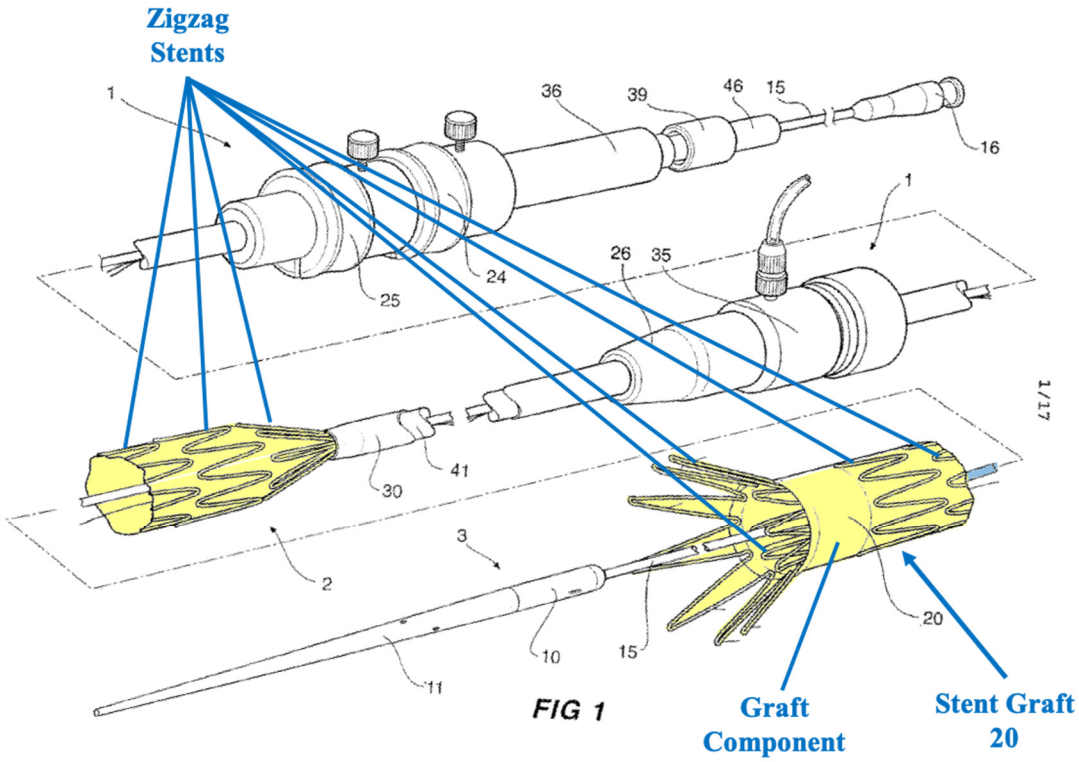
FIG 1

(Ex. 1005 at Abstract ("An introducer (1) adapted for the introduction of a self-expanding endovascular prosthesis (20) in a lumen of a patient. The introducer has

attachment devices (10, 30) to hold each end of the prosthesis so that each can be moved independently."), 1:7-10 ("[A] method and means for introducing a expandable intraluminal prosthesis…intended for the endovascular repair of diseased or damaged vessels…."), 3:7-15 ("[A]n introducer for positioning an expandable endovascular prosthesis in a lumen of a patient…the introducer comprising a prosthesis positioning mechanism selectively releasable from the prosthesis when the prosthesis is positioned at a desired site in the lumen of a patient…."), 3:28-30 ("[A]n endovascular arrangement for positioning an expandable prosthesis at a desired location in a lumen of a patient…."), 6:11-23 ("[A]n introducer adapted for the introduction of a self expanding endovascular prosthesis into a lumen of a patient…."); *see also id.*, *e.g.*, at 3:25-27, 5:1-4; 5:22-31; 8:16-9:2, 10:24-31, 11:9-12:21, 12:22-17:11, Figures 1-13, claims 8 and 23; Section IV.A., above; Ex. 1014 at ¶63).

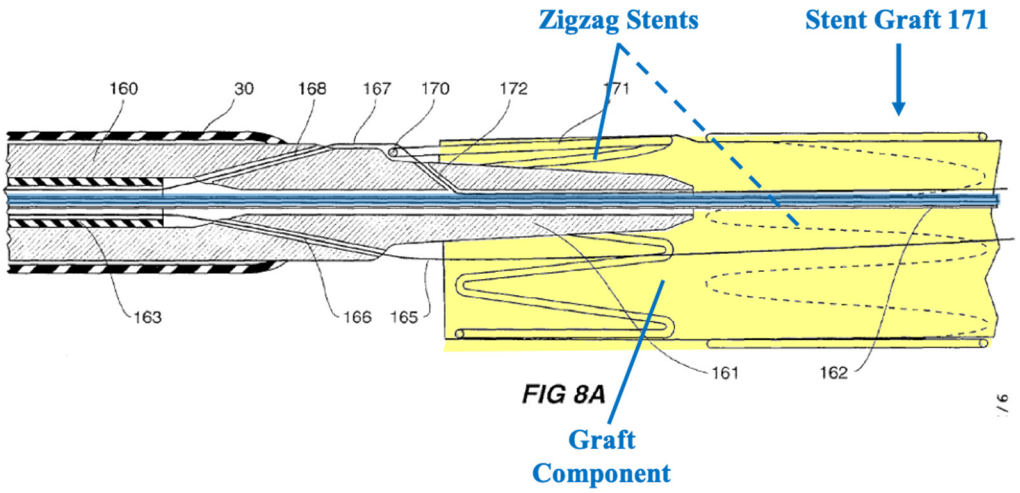
b. *"a stent-graft;"*

As shown below in annotated Figure 1, Hartley discloses in Embodiment #1 a stent graft 20 (highlighted in yellow), including a graft component, and multiple self-expanding zigzag stents.



(Ex. 1014 at ¶64).

Similarly, as shown below in annotated Figure 8A, Hartley discloses in Embodiment #2 a stent graft 171 (highlighted in yellow), including a graft component, and multiple self-expanding zigzag stents.



(Ex. 1005 at Abstract ("An endovascular prosthesis (20)…[includes] stents at the proximal and distal ends being with the graft. The remainder of the stents are positioned on the outside of the graft body."), 3:2-5 ("[A] graft and a method and apparatus to deploy the graft prosthesis…."), 9:26-31 ("[A]n intraluminal prosthesis having a tubular graft and a plurality of self expanding stents along the length of the graft…."), 10:1-2 ("There may be further included a further self expanding stent mounted to the proximal end of the graft and extending beyond the said proximal end."), 10:22-23 ("Each stent of the intraluminal prostheses…may be a zig-zag stent."), 13:15-22 ("The prosthesis is of a self expanding type having resilient stents 19 to enable it to expand after it is released form the introducer.

The prosthesis…includes a self expanding zigzag stent 21 extending from its proximal end….”), Figures 1-9, 13A-C; Ex. 1014 at ¶64).

c. ***“a retractable primary sheath containing said stent-graft in a first constrained diameter configuration;”***

As shown below in annotated Figure 2, Hartley discloses in Embodiment #1 and Embodiment #2 a retractable primary sheath (external sleeve 30 (highlighted in red)) that contains the stent graft[15] (highlighted in yellow) in a first constrained diameter configuration.

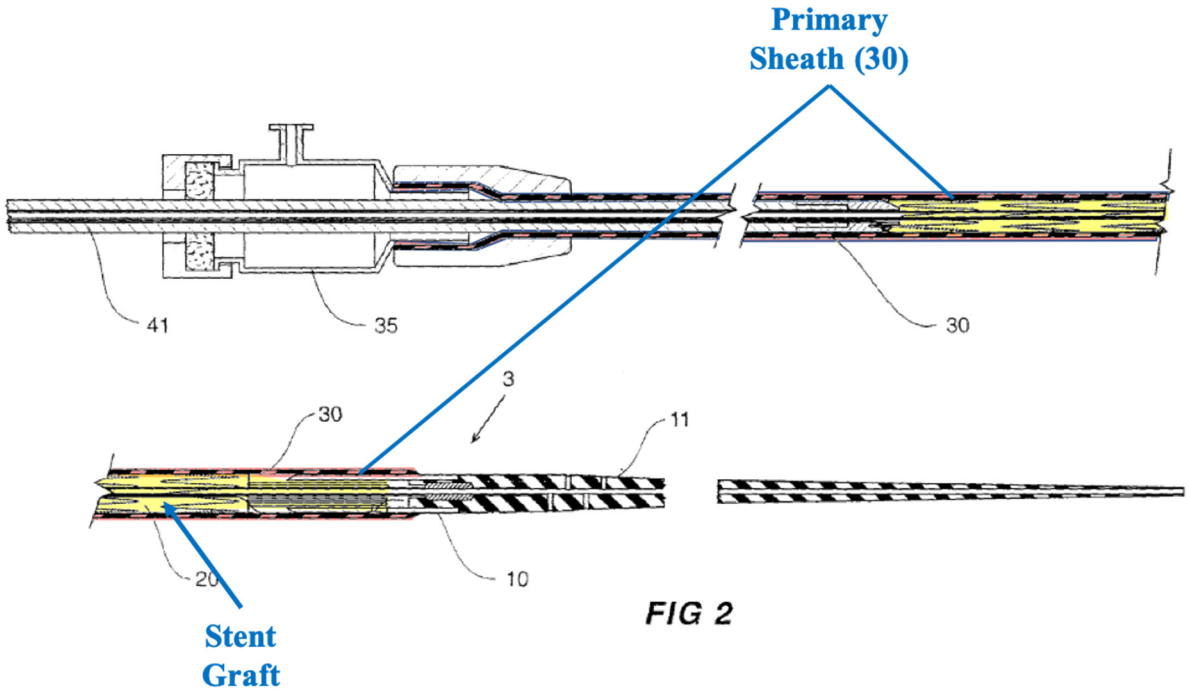


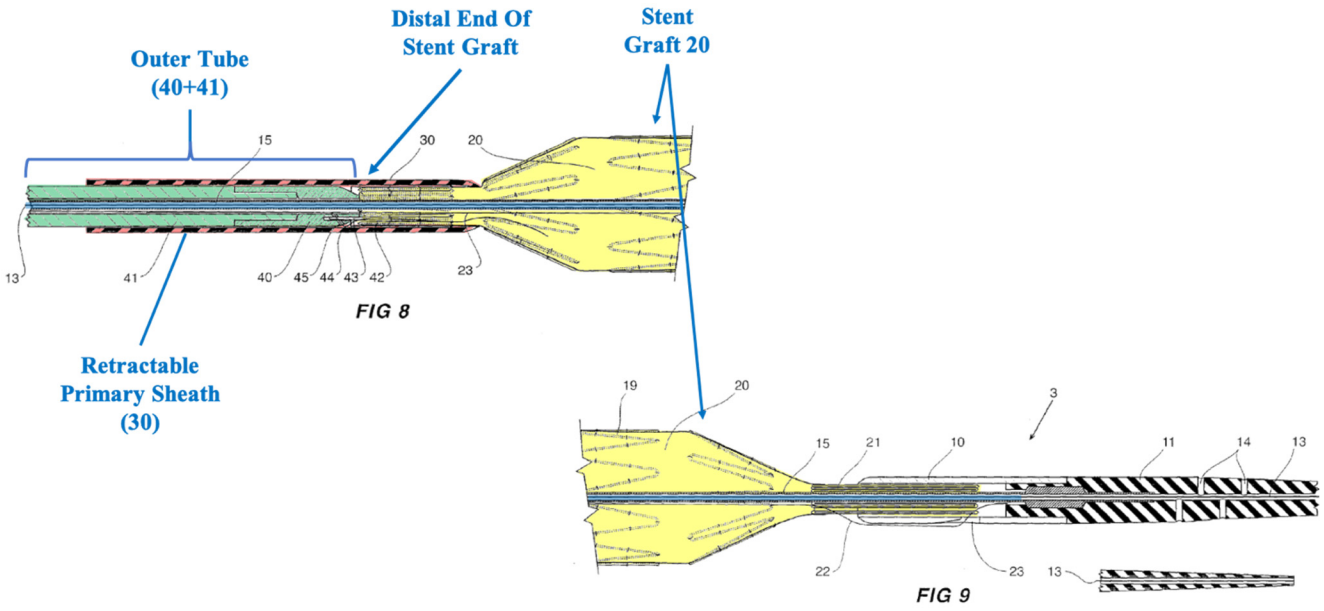
FIG 2

[15] The stent graft is identified by reference number 20 in Embodiment #1, and by the reference number 171 in Embodiment #2. (*See id.*, 11:23-26, 14:9-20, Figures 8A and 8B).

(Ex. 1005 at 13:25-26 ("The prosthesis…is retained in its compressed condition by means of an external sleeve 30…."); *see also id.*, 7:27-30 ("The introducer may also include an external sheath extending from external of the patient to cover and compress the prosthesis during insertion of the introducer into a patient and movable longitudinally from outside the patient to expose the prosthesis."), 15:25-30 ("[O]nce the introducer assembly is in a selected position the external sheath 30 is withdrawn to just proximal of the distal attachment device 40 so that the prosthesis…is now released so that it can expand radially except where the most proximal zigzag stent 21 is still retained within the proximal attachment device 10 and where its distal end 42 is retained within the external sheath 30."), 16:18-20 ("The external sheath 30 has been withdrawn to distal of the distal attachment device 40 to allow the distal end of the attachment device to expand."), 17:17-22, Figures 1, 3, 8, 8A-B, 9-10; Ex. 1014 at ¶65).

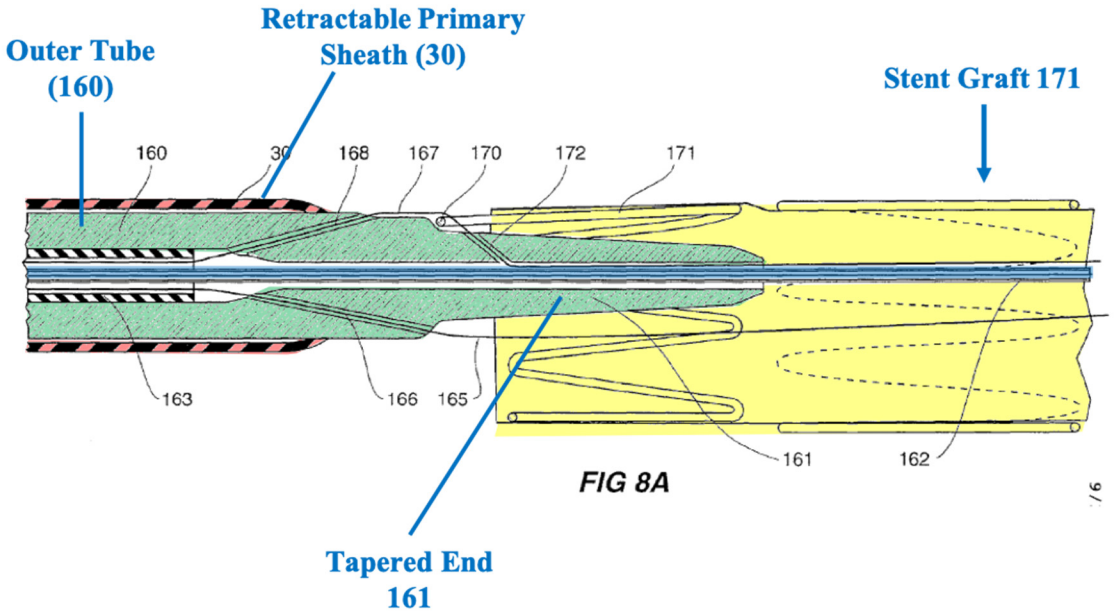
d. ***"an outer tube within the retractable primary sheath and within the stent-graft;"***

As shown below in annotated Figures 8 and 9, Hartley discloses in Embodiment #1 an outer tube (thick walled tube 41 + distal attachment device 40 (collectively highlighted in green)) within the retractable primary sheath (30 (highlighted in red)).



(Ex. 1005 at 8:1-2 ("The external sheath may be coaxial with and a sliding fit on the thick walled tube."), 13:34-14:1 ("The thick walled tube is coaxial with and radially outside the thin walled tube 15 and the sheath 30 is coaxial with and radially outside the thick walled tube 41.")). The distal end (the end furthest from the operator) of the outer tube (40+41) is disposed within the distal end (the end furthest from the heart) of the stent graft 20. (Ex. 1014 at ¶66).

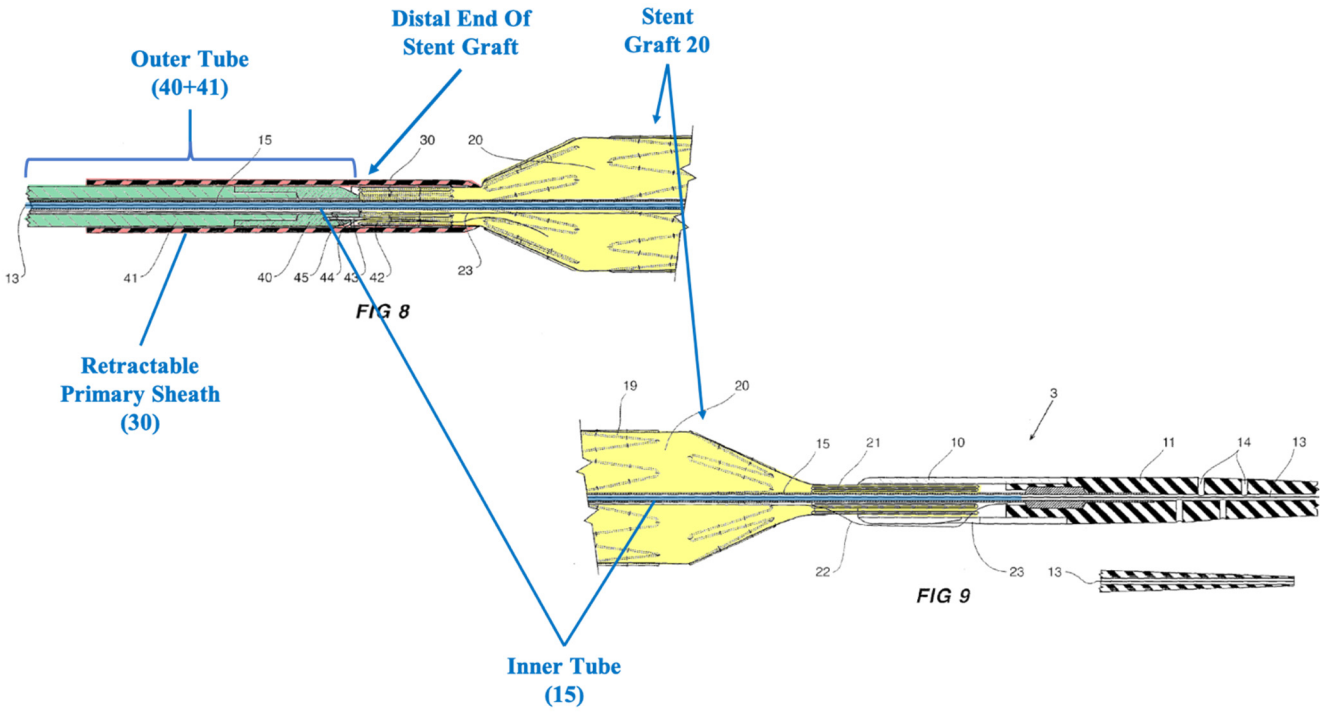
As shown below in Figure 8A, Hartley discloses in Embodiment #2 an outer tube (thick walled tube 160 (highlighted in green)) within the retractable primary sheath (30 (highlighted in red)).



(Ex. 1005 at 8:1-2, 13:34-14:1, 14:9-17). The distal tapered end 161 of outer tube (160) is disposed within the distal end (the end furthest from the heart) of the stent graft 171. (Ex. 1014 at ¶67).

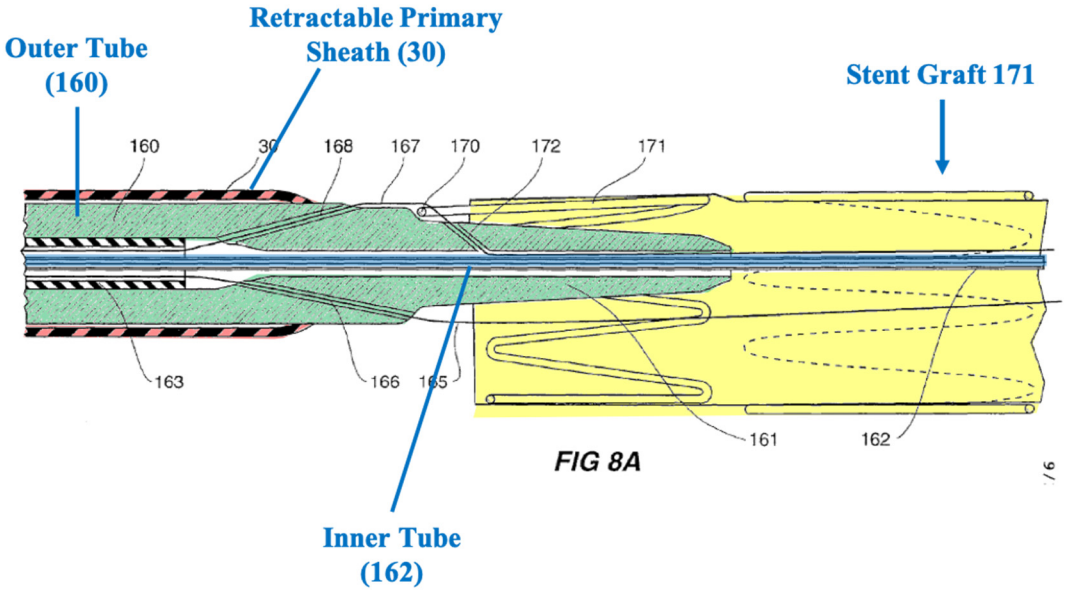
e. *"an inner tube within the outer tube,"*

As shown below in annotated Figures 8 and 9, Hartley discloses in Embodiment #1 an inner tube (thin walled tube 15 (highlighted in blue)) within the outer tube (40+41 (highlighted in green)).



(Ex. 1005 at 13:34-14:1 ("The thick walled tube is coaxial with and radially outside the thin walled tube 15 and the sheath 30 is coaxial with and radially outside the thick walled tube 41."); Ex. 1014 at ¶68).

As shown below in annotated Figure 8A, Hartley discloses in Embodiment #2 an inner tube (thin walled tube 162 (highlighted in blue)) within the outer tube (thick walled tube 160 (highlighted in green)).



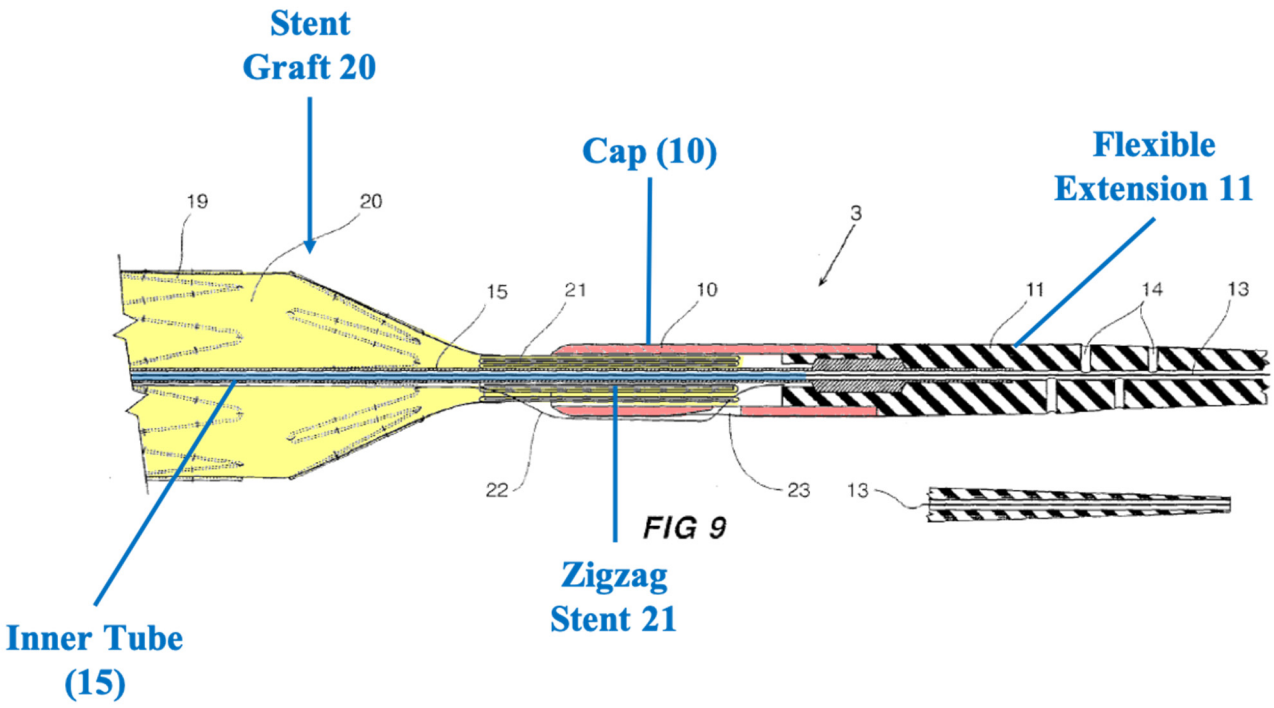
(Ex. 1005 at 13:34-14:1, 14:9-17; Ex. 1014 at ¶69).

f. ***"wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;"***

Hartley discloses in Embodiment #1 and Embodiment #2 that the inner tube (15 (Embodiment #1); 162 (Embodiment #2)) and outer tube (40+41 (Embodiment #1); 160 (Embodiment #2)) both move relative to the retractable sheath (30 (both embodiments)), and to each other. (Ex. 1005 at 8:1-2 ("The external sheath may be coaxial with and a sliding fit on the thick walled tube."), 15:31-32 ("By release of the pin vice 39 to allow small movements of the thin walled tubing…with respect to the thick walled tubing…."), 14:9-17, claims 11, 29, and 37, Figures 1-7; Ex. 1014 at ¶70).

g. ***"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,"***

As shown below in annotated Figure 9, Hartley discloses in Embodiment #1 a cap (cylindrical sleeve 10 (highlighted in red)) coupled to a distal end of the inner tube (15 (highlighted in blue)) via flexible extension 11.



(Ex. 1005 at 12:27–13:10 ("The proximal attachment region 3 shown in detail in FIG 9 includes a cylindrical sleeve 10 with a long tapered flexible extension 11 extending from its proximal end….A thin walled metal tube 15 is fastened to the extension 11…."), Figures 1-8; Ex. 1014 at ¶71). The cap (10 (highlighted in red)) is configured to retain at least a portion of a proximal portion of the stent graft

(zig-zag stent 21) in a radially compressed configuration, as shown above in annotated Figure 9. (Ex. 1005 at 13:16-22 ("[S]elf expanding zigzag stent 21 extend[s] from [the] proximal end [of stent graft 20] and in the compressed condition the zigzag stent 21 is retained in the cylindrical sleeve 10 of the proximal attachment region 3….."), 15:25-30 ("[T]he most proximal zigzag stent 21 is still retained within the proximal attachment device 10…."), 16:10-16, Figures 2-9; Ex. 1014 at ¶71).

As shown below in annotated Figure 8B, Hartley discloses in Embodiment #2 a cap (tube 175 (highlighted in red)).

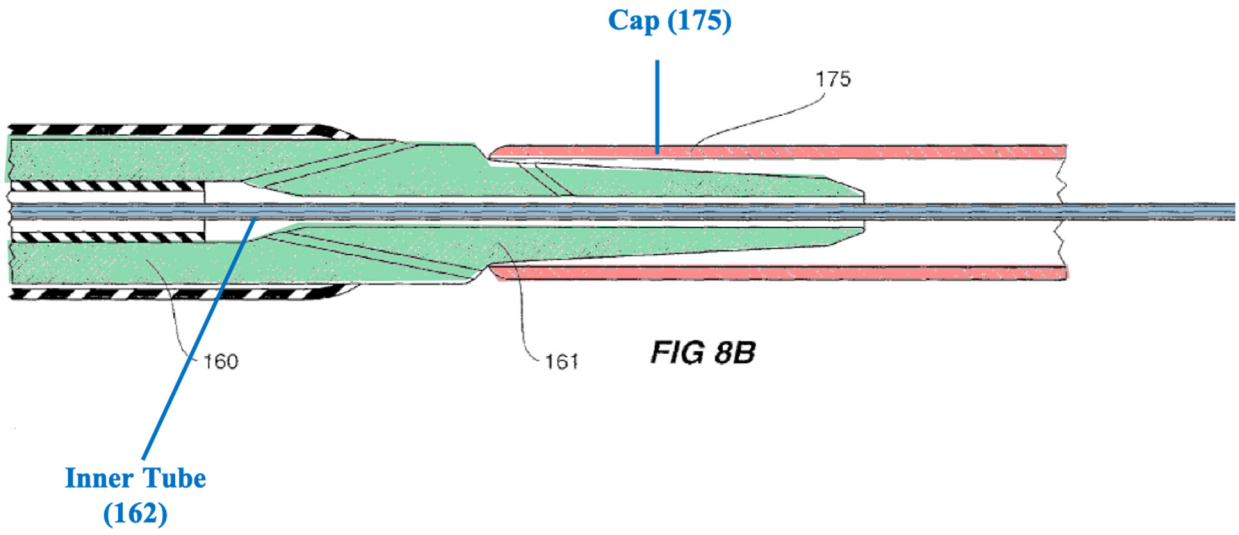


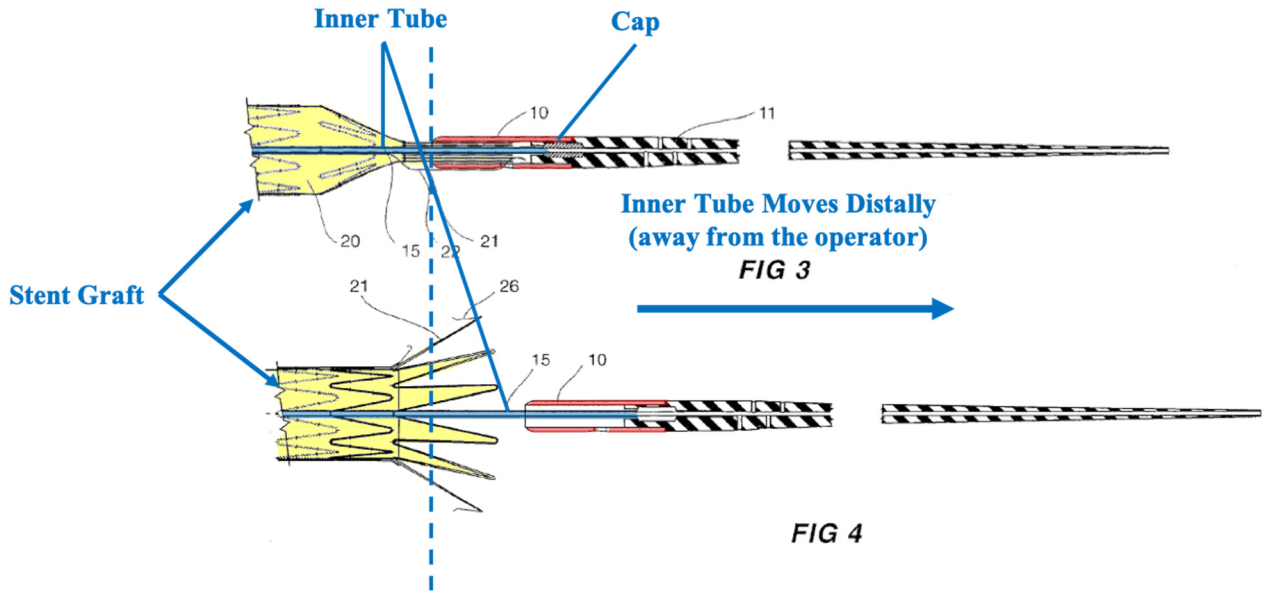
FIG 8B

(Ex. 1014 at ¶72). Cap (175) is analogous to cap (10) in Embodiment #1. Although not illustrated in Figure 8B, a PHOSITA would have recognized that cap (175) is coupled to a distal end of the inner tube (162 (highlighted in blue)) via flexible extension 11 (depicted in Figure 1). (*Id.*; Ex. 1005 at 12:27-13:10, 13:16-

22, 14:17-20, 15:25-30, 16:10-16, Figures 1-9). The cap (175 (highlighted in red)) is configured to retain at least a portion of a proximal portion of the stent graft in a radially compressed configuration, as shown above in the previous paragraph, in annotated Figure 9. (Ex. 1005 at 13:16-22, 14:9-20, 15:25-30, 16:10-16, Figures 2-9; Ex. 1014 at ¶72).

h. ***"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."***

Hartley discloses an "expansion control mechanism for controlling expansion of the prosthesis." (Ex. 1005 at 3:25-27, 5:1-4; *see also id.*, 5:18-21). As shown below in annotated Figures 3 and 4, Hartley discloses in Embodiment #1 and Embodiment #2 that a relative axial movement (from Figure 3 to Figure 4) between the outer tube (40+41 (Embodiment #1); 160 (Embodiment #2) (outer tube illustrated in Figures 8A and 8B)) and inner tube (15 (Embodiment #1); 162 (Embodiment #2) (inner tube illustrated in Figures 8A and 8B)) releases the proximal end of the stent graft (zigzag stent 21) from the cap (10 (Embodiment #1); 175 (Embodiment #2)) and from the radially compressed configuration.

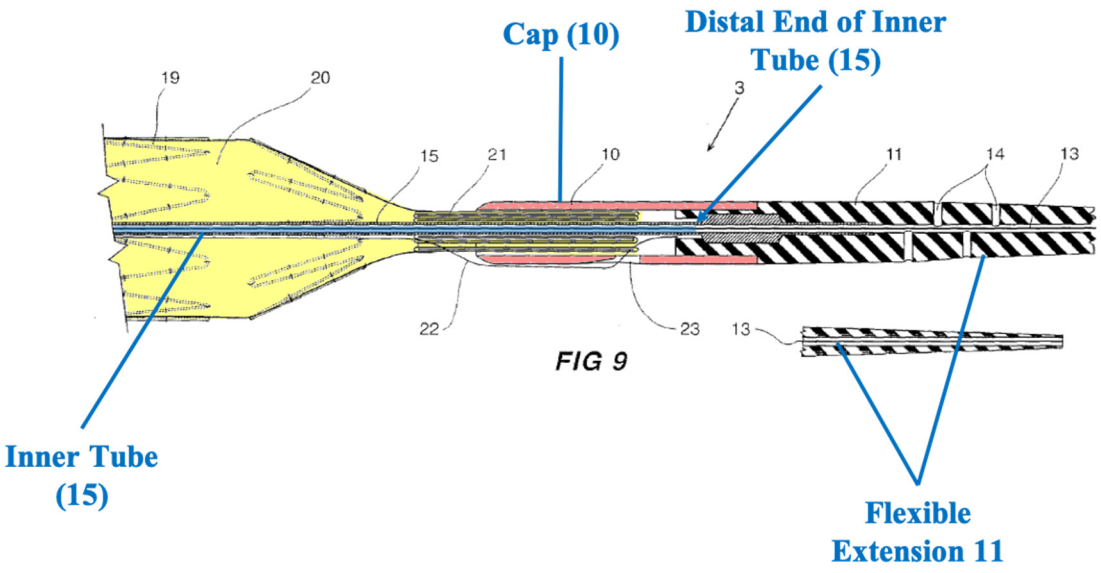


(Ex. 1005 at 15:31-16:2 ("[R]elease of the pin vice 39…allow[s] small movements of the thin walled tubing 15 with respect to the thick walled tubing 41…."), 16:10-14 ("[T]he thin walled tubing 15 can be pushed in a [distal] direction to move the [cap] 10 in a [distal] direction thereby releasing the zigzag stent 21 at the proximal end of the prosthesis from the [cap] 10."), 14:9-20, Figures 8A-B; Ex. 1014 at ¶73). Hartley discloses moving the inner tube relative to the outer tube by having the operator "push[]" the inner tube forward, "in a proximal direction," while holding the outer tube stationary. (Ex. 1005 at 16:10-14; *see also id.*, 15:7-14, 15:31-16:2; Ex. 1014 at ¶73).

2. Dependent Claim 2

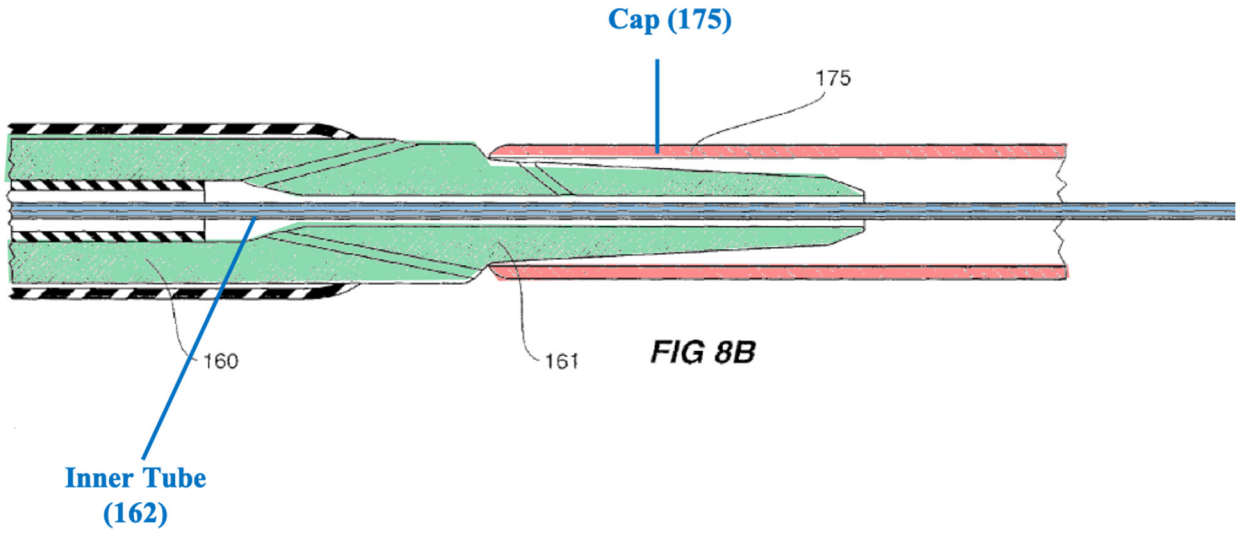
Claim 2 depends from claim 1 and further states "the cap is a shroud portion of a flexible tapered tip fixed to the distal end of the inner tube."

As shown below in annotated Figure 9, the cap (10 (highlighted in red)) in Embodiment #1 is a shroud portion of a flexible tapered tip (10 + tapered flexible extension 11) fixed to the distal end (the end furthest from the operator) of inner tube (15).



(Ex. 1005 at Figure 9, 12:27–13:2, 13:6-7, 13:16-22, 14:9-17; Ex. 1014 at ¶¶74-75; *see also* Section V.A.1.g., above).

As shown below in annotated Figure 8B, the cap (175 (highlighted in red)) in Embodiment #2 is also a shroud.

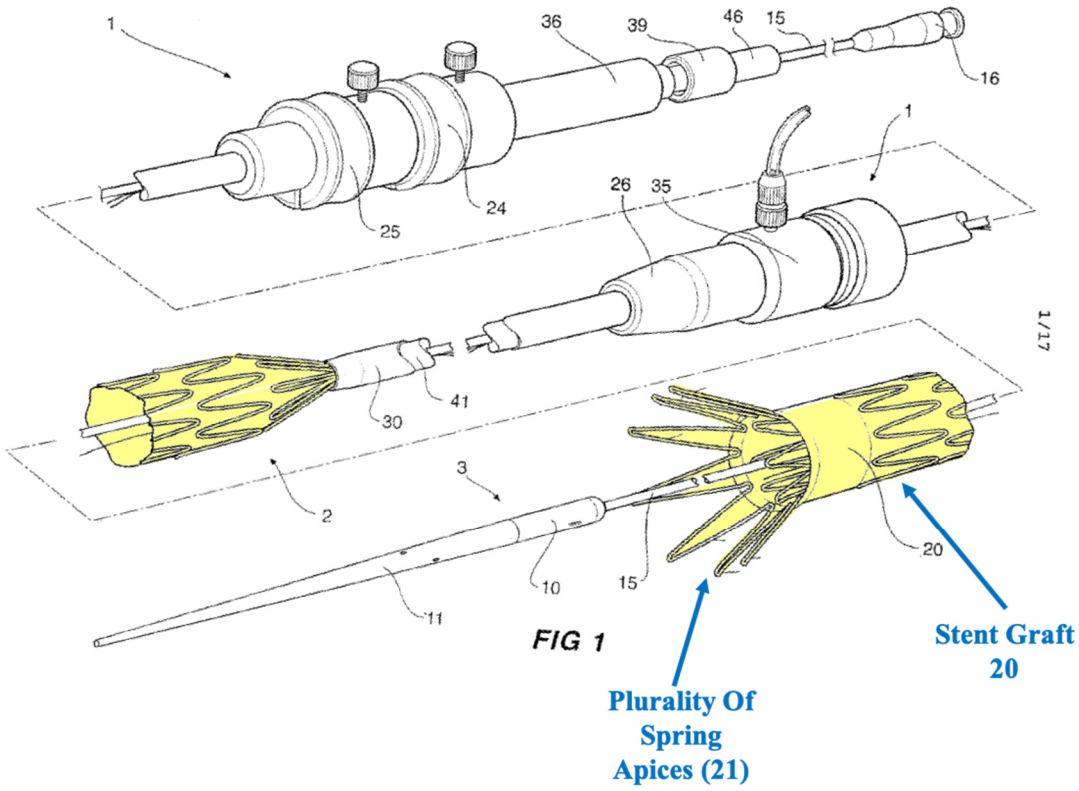


(Ex. 1014 at ¶76; Section V.A.1.g., above). Cap (175) in Embodiment #2 is analogous to cap (10) in Embodiment #1. (*Id.*). Although not illustrated in Figure 8B, a PHOSITA would have understood that cap (175) is a shroud portion of flexible tapered tip 11 (illustrated in Figure 1), and is fixed to the distal end (the end furthest from the operator) of inner tube (162), as shown above in the previous paragraph, in annotated Figure 9. (Ex. 1014 at ¶76; Ex. 1005 at 12:27–13:10, 13:16-22, 14:9-20, Figures 1-9, 8A-8B; *see also* Sections IV.A. and V.A.1.g., above).

3. Dependent Claim 4

Claim 4 depends from claim 1 and further states "further comprising 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."

As shown below in annotated Figure 1, Hartley discloses the stent graft 20 has a plurality of spring apices (zigzag stent 21) at its proximal end.



(Ex. 1014 at ¶78).

As shown below in annotated Figures 9 and 11, Hartley discloses in Embodiment #1 a proximal lock (including trigger wire 22 (highlighted in red)).

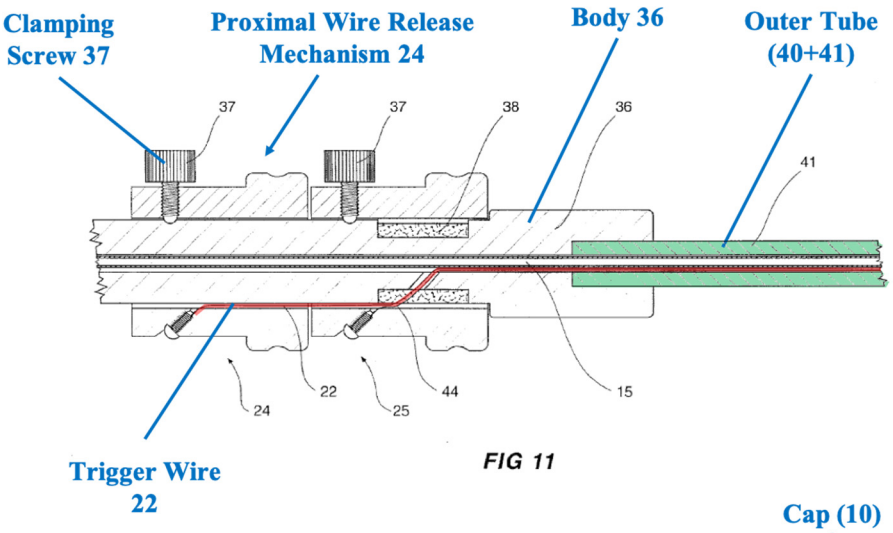


FIG 11

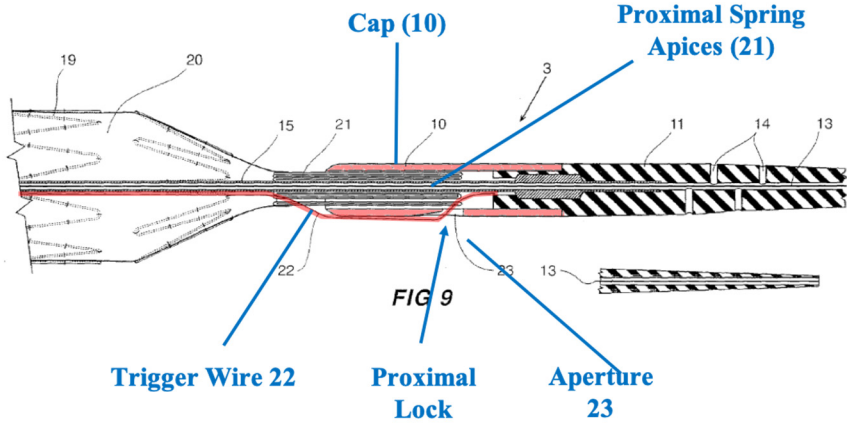
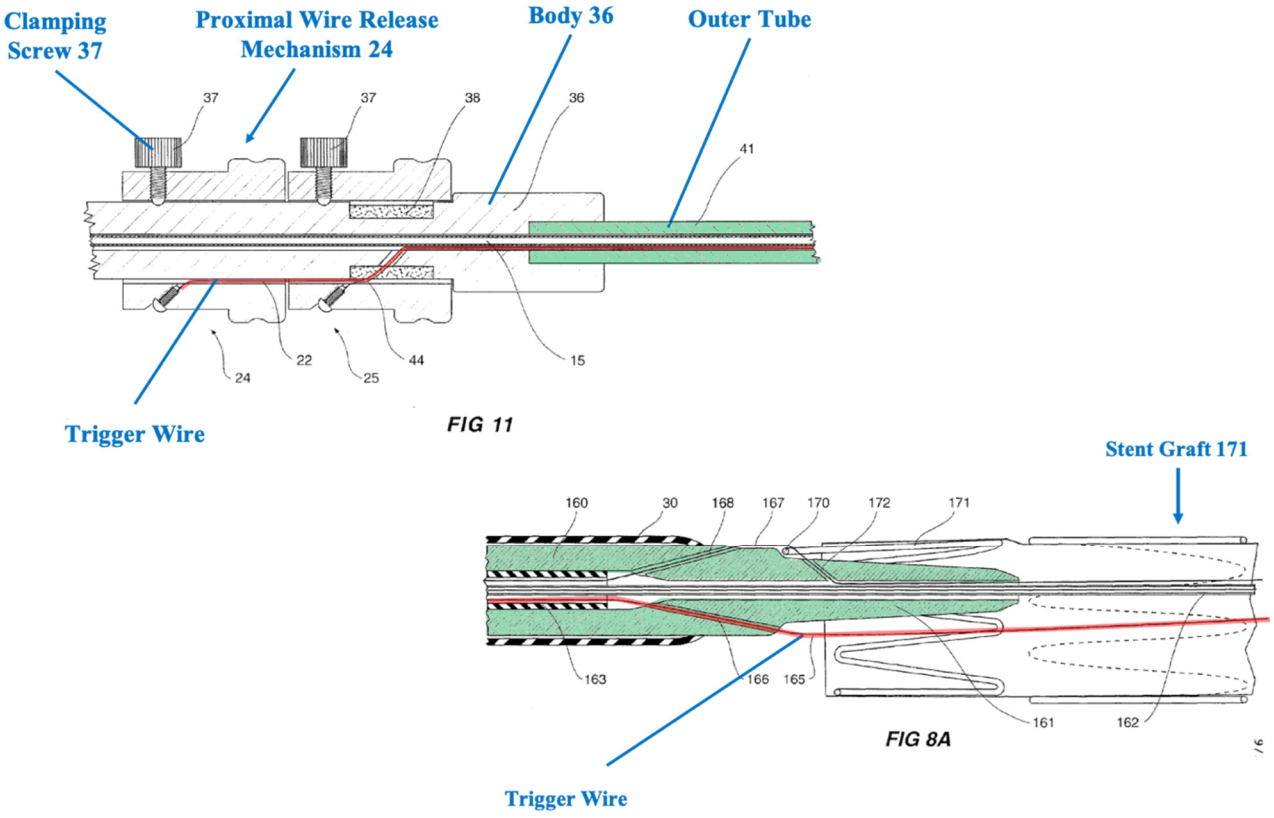


FIG 9

(Ex. 1014 at ¶79). As shown above in annotated Figure 11, the proximal lock (including 22) is attached to outer tube (40+41) via proximal wire release mechanism 24 and clamping screw 37, and via body 36. (Ex. 1005 at 14:27-15:4 ("[T]he release wire actuation section…has a body 36 into the end of which is mounted the thick walled tubing 41….Clamping screws 37 are provided on…the proximal wire release mechanism 24…to prevent inadvertent early release of either

end of the prosthesis."), 16:5-6 ("[T]he proximal trigger wire 22…[is] withdrawn by distal movement of the proximal wire release mechanism 24…."), Figure 3). As shown above in annotated Figure 9, the proximal lock (including 22) is latched onto the proximal spring apices (21) of stent graft 22, while the proximal spring apices (21) are compressed within cap (cylindrical sleeve 10). (*Id.*, 13:16-22 ("[A] trigger wire 22…extends through an aperture 23 in the side of the [cap] 10 and is received in one of the loops of the zigzag stent.")). The proximal lock (including 22) remains latched onto the proximal spring apices (21) until the proximal wire release mechanism 24 is withdrawn. (*Id.*, 14:27-15:4, 16:5-6; Ex. 1014 at ¶79).

As shown below in annotated Figures 8A and 11, Hartley discloses in Embodiment #2 a proximal lock (including trigger wire 165 (highlighted in red)).



(Ex. 1014 at ¶80). As shown above, the proximal lock (including 165) is attached to outer tube (160) via proximal wire release mechanism 24 and clamping screw 37, and via body 36. (Ex. 1005 at 14:27-15:4, 16:5-6, Figure 3). Although not illustrated in Figure 8A, a PHOSITA would have understood that the proximal lock (including 165) is latched onto proximal spring apices of the stent graft, while the proximal spring apices (21) are compressed within the cap (tube 175), as illustrated in the previous paragraph with respect to Figure 9 (and cap (10)). (*Id.*, 13:16-22, Figure 8B; Ex. 1014 at ¶80). The proximal lock (including 165) remains

latched onto the proximal spring apices (21) until the proximal wire release mechanism 24 is withdrawn. (Ex. 1005 at 14:27-15:4, 16:5-6; *see also id.*, 14:9-20; Ex. 1014 at ¶80).

4. Independent Claim 7

a. *"A controlled stent graft deployment delivery system, comprising:"*

Hartley discloses this preamble for the reasons in Section V.A.1.a. (Ex. 1014 at ¶81).

b. *"a retractable primary sheath;"*

Hartley discloses this limitation for the reasons in Section V.A.1.c. (Ex. 1014 at ¶82).

c. *"an outer tube within the retractable primary sheath;"*

Hartley discloses this limitation for the reasons in Section V.A.1.d. (Ex. 1014 at ¶83).

d. *"an inner tube within the outer tube,"*

Hartley discloses this limitation for the reasons in Section V.A.1.e. (Ex. 1014 at ¶84).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Hartley discloses this limitation for the reasons in Section V.A.1.f. (Ex. 1014 at ¶85).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Hartley discloses this limitation for the reasons in Sections V.A.1.g. and V.A.2. (Ex. 1014 at ¶86).

g. ***"and 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."***

Hartley discloses in Embodiment #1 a proximal lock (including trigger wire 22) fixed, or attached, to outer tube (40+41), for the reasons in Section V.A.3. (Ex. 1014 at ¶87). Likewise, Hartley discloses in Embodiment #2 a proximal lock (including trigger wire 165) fixed, or attached, to outer tube (160), for the reasons in Section V.A.3. (*Id.*). A PHOSITA would consider each of these proximal locks as at least a portion of a "retention mechanism." (*Id.*). Thus, Hartley discloses "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…wherein the retention mechanism comprises a proximal lock fixed to the outer tube," for the reasons in Section V.A.3. (*Id.*).

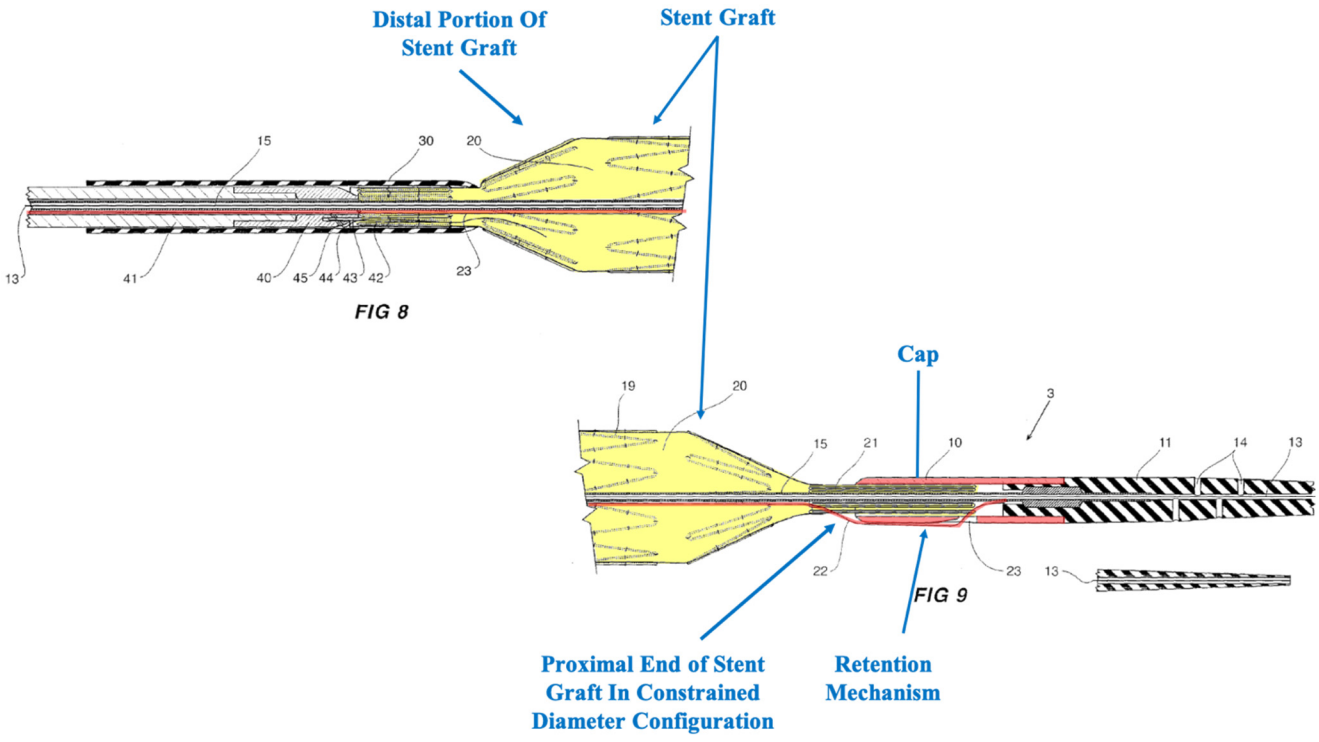
Hartley discloses that the retention mechanisms (including 22 (Embodiment #1); including 165 (Embodiment #2)) each still enable axial and radial movement of the stent graft 20. (Ex. 1005 at 15:25–16:2 ("By release of the pin vice 39 to allow small movements of the thin walled tubing 15 with respect to the thick walled tubing 41 the prosthesis 20 may now be lengthened or shortened or rotated or compressed to accurately place in the desired place within the body

lumen."); *see also id.*, 5:22-31 ("[A] control arrangement for controlling the length of the prosthesis during the manipulation in the patient….[T]he control arrangement and/or members can be individually controlled for rotating the relative ends of the prosthesis with respect to each other in the same or opposite directions."); Ex. 1014 at ¶88; *see also* Section IV.A., above).

5. Dependent Claim 8

Claim 8 depends from Claim 7 and further states "wherein the retention mechanism enables a partial deployment of a remaining distal portion of the stent-graft while maintaining the proximal end of the stent-graft in the constrained diameter configuration."

As illustrated below by annotated Figures 8 and 9, Hartley discloses in Embodiment #1 and Embodiment #2 the retention mechanism (trigger wire 22 (Embodiment #1); 165 (Embodiment #2) (illustrated in Figure 8A)) enables a partial deployment of a remaining distal portion of the stent graft while maintaining the proximal end of the stent graft in the constrained diameter configuration.



(Ex. 1005 at 15:25-16:2 ("[O]nce the introducer assembly is in a selected position the external sheath 30 is withdrawn to just proximal of the distal attachment device…so that the prosthesis…is now released so that it can expand radially except where the most proximal zigzag stent 21 is still retained within the proximal attachment device…and where its distal end 42 is retained within the external sheath 30."), Figure 3; Ex. 1014 at ¶90).

6. Independent Claim 12

a. *"A controlled stent-graft deployment delivery system, comprising:"*

Hartley discloses this preamble for the reasons in Section V.A.1.a. (Ex. 1014 at ¶91).

b. *"a retractable primary sheath;"*

Hartley discloses this limitation for the reasons in Section V.A.1.c. (Ex. 1014 at ¶92).

c. *"an outer tube within the retractable primary sheath;"*

Hartley discloses this limitation for the reasons in Section V.A.1.d. (Ex. 1014 at ¶93).

d. *"an inner tube within the outer tube,"*

Hartley discloses this limitation for the reasons in Section V.A.1.e. (Ex. 1014 at ¶94).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Hartley discloses this limitation for the reasons in Section V.A.1.f. (Ex. 1014 at ¶95).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Hartley discloses this limitation for the reasons in Sections V.A.1.g. and V.A.2. (Ex. 1014 at ¶96).

g. ***"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;"***

Hartley discloses this limitation for the reasons in Sections V.A.4.g. and V.A.3. (Ex. 1014 at ¶97).

h. ***"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."***

As shown below in annotated Figure 1, Hartley discloses in Embodiment #1 and Embodiment #2 a second retention mechanism in the form of a sleeve 30, which retains a distal end on the stent graft undeployed while a remaining portion of the stent graft is deployed.

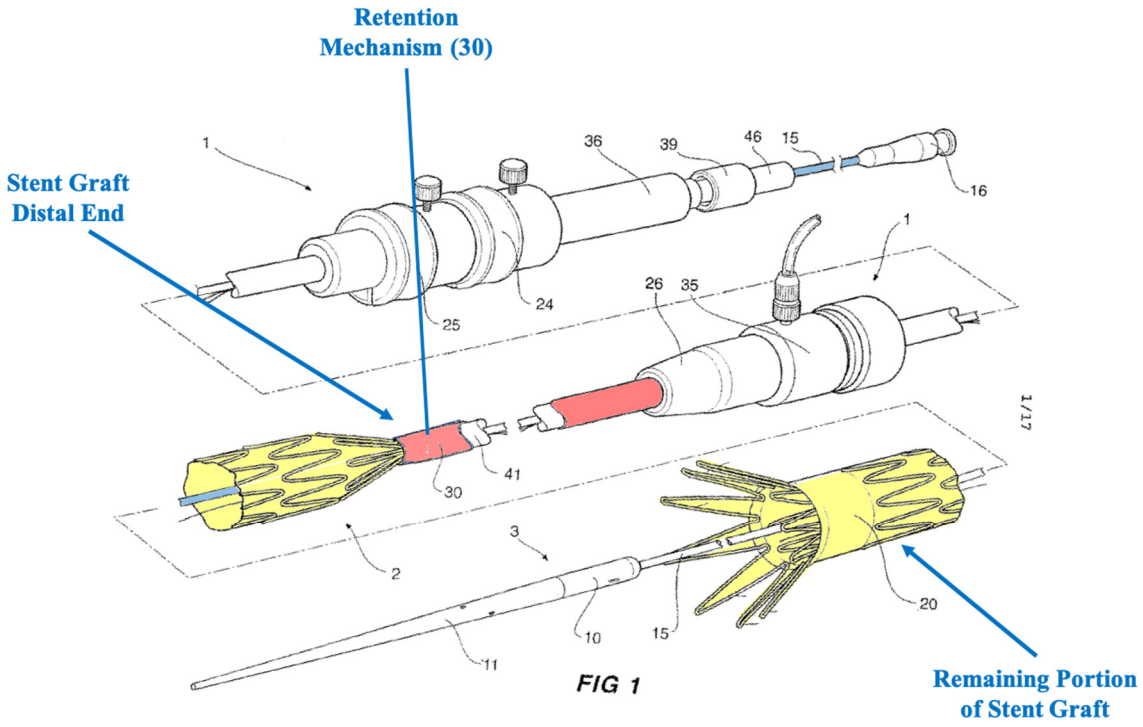


FIG 1

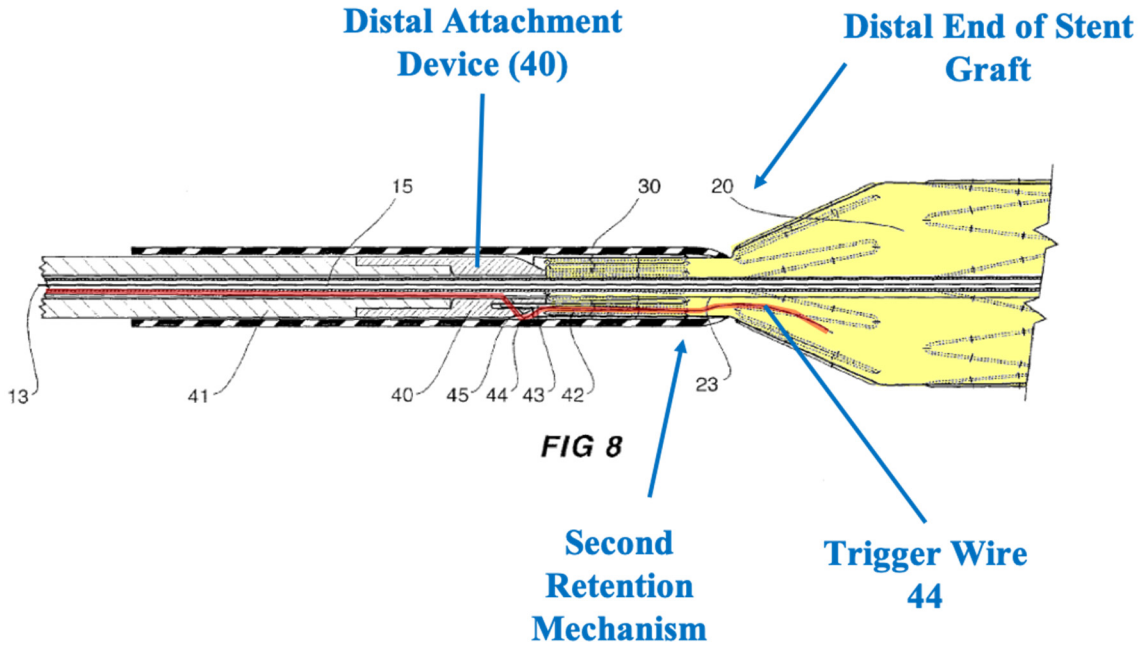
(Ex. 1014 at ¶98; Ex. 1005 at 15:19-21 ("The prosthesis 20 is…compressed by the external sleeve 30."), 15:25-30 ("[O]nce the introducer assembly is in a selected position the external sheath 30 is withdrawn to just proximal of the distal

attachment device 40 so that the prosthesis 20 is now released so that it can expand radially except where the most proximal zigzag stent 21 is still retained within the proximal attachment device 10 and where its distal end 42 is retained within the external sheath 30.")). Sleeve 30 is a "second retention mechanism for retaining a distal end of the stent-graft undeployed while a remaining portion of the stent-graft is deployed," for the reasons in Section III.D.2. (Ex. 1014 at ¶98).

Hartley also discloses in Embodiment #1 and Embodiment #2 a distal attachment device including a distal trigger wire, which further retains a distal end of the stent graft. (Ex. 1005 at 3:15-18 ("The prosthesis positioning mechanism can include a distal attachment region….[includ[ing] a distal attachment device."), 6:11-23 ("[A]n introducer [is] adapted for the introduction of a self expanding endovascular prosthesis into a lumen of a patient,…[comprising] a distal attachment device adapted to be attached to the distal end of the prosthesis…."), 8:23-27 ("[T]he insertion assembly includes…a distal attachment device adapted to retain the…distal end[] of the prosthesis…."), 12:22-26 ("[A]n endovascular arrangement…comprises generally an external manipulation section 1, [and] a distal attachment region 2…."), 15:19-21 ("The prosthesis 20 is retained at each of its ends by the proximal and distal retaining assemblies respectively…."), 16:17-20 ("The distal end of the prosthesis 42 is still retained by the distal attachment means 40 with the loop 43 retained therein. The external sheath 30 has been

withdrawn to distal of the distal attachment device 40 to allow the distal end of the attachment device to expand."), 7:4-8, 14:9-20, 15:1-4, Figure 8A; Ex. 1014 at ¶99; Section IV.A., above).

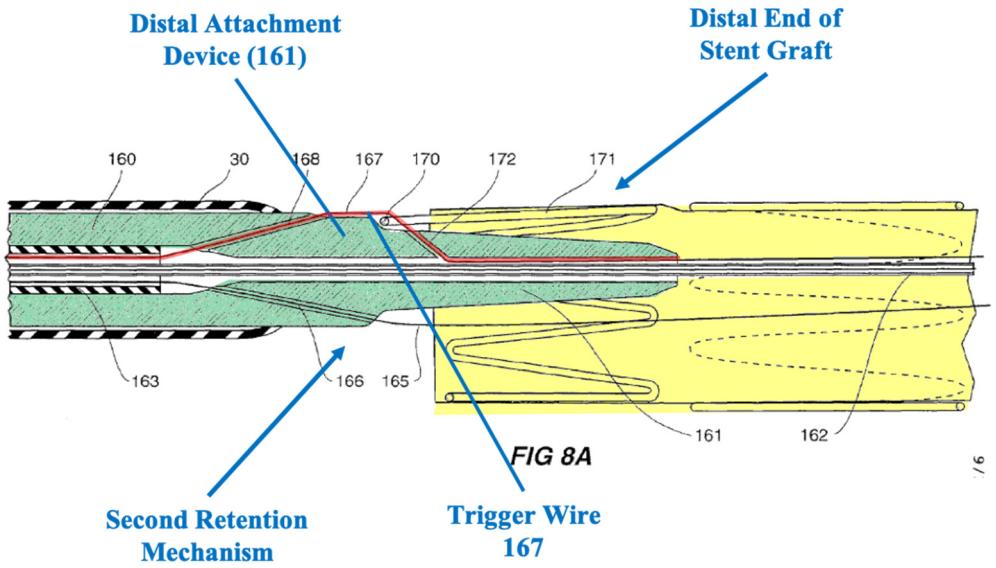
As shown below in annotated Figure 8, Hartley discloses in Embodiment #1 a distal retention mechanism for retaining a distal end on the stent graft undeployed while a remaining portion of the stent graft is deployed, the distal attachment mechanism including distal attachment device 40 and trigger wire 44 (highlighted in red).



(Ex. 1014 at ¶100; Ex. 1005 at 13:31-34 ("[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."), 14:1-8 ("The distal end 42 of the prosthesis 20 has a loop 43 through which a distal trigger wire 44 extends. The distal trigger wire extends through an aperture 45 on the distal attachment device into the annular region between the thin walled tube 15 and the thick walled tube 41….")).

As shown below in annotated Figure 8A, Hartley discloses in Embodiment #2 a distal attachment mechanism for retaining a distal end on the stent graft undeployed while a remaining portion of the stent graft is deployed, the distal attachment mechanism including distal attachment device (tapered end 161) and trigger wire 167 (highlighted in red).



(Ex. 1014 at ¶101; Ex. 1005 at 13:31-34, 14:1-20).

B. Ground 2: Claims 1-4 Are Obvious In View Of Hartley (Ex. 1005) In Combination With Lindenberg (Ex. 1007) And/Or Olson (Ex. 1004)

1. Independent Claim 1

a. *"A controlled stent-graft deployment delivery system, comprising:*

Hartley discloses this preamble for the reasons in Section V.A.1.a.

(Ex. 1014 at ¶102).

b. *"a stent-graft;"*

Hartley discloses this limitation for the reasons in Section V.A.1.b.

(Ex. 1014 at ¶103).

c. *"a retractable primary sheath containing said stent-graft in a first constrained diameter configuration;"*

Hartley discloses this limitation for the reasons in Section V.A.1.c.

(Ex. 1014 at ¶104).

d. *"an outer tube within the retractable primary sheath and within the stent-graft;"*

Hartley discloses this limitation for the reasons in Section V.A.1.d.

(Ex. 1014 at ¶105).

e. *"an inner tube within the outer tube,"*

Hartley discloses this limitation for the reasons in Section V.A.1.e.

(Ex. 1014 at ¶106).

f. ***"wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;"***

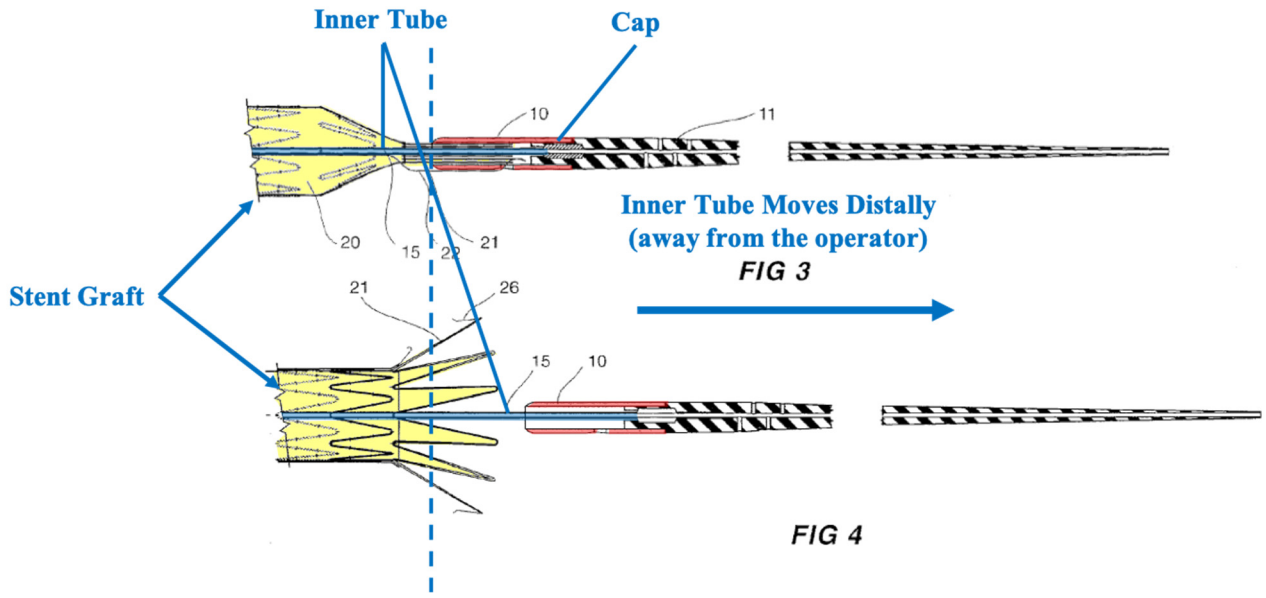
Hartley discloses this limitation for the reasons in Section V.A.1.f. (Ex. 1014 at ¶107).

g. ***"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,"***

Hartley discloses this limitation for the reasons in Sections V.A.1.g. and V.A.2. (Ex. 1014 at ¶108).

h. ***"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."***

Hartley discloses this limitation for the reasons in Section V.A.1.h. (Ex. 1014 at ¶109). As illustrated below in annotated Figures 3 and 4, Hartley discloses that a relative axial movement (from Figure 3 to Figure 4) between the outer tube (40+41 (Embodiment #1); 160 (Embodiment #2) (illustrated in Figure 8A)) and inner tube (15 (Embodiment #1); 162 (Embodiment #2) (illustrated in Figure 8A)) releases the proximal end of the stent graft (zigzag stent 21) from the cap (10 (Embodiment #1); 175 (Embodiment #2)) and from the radially compressed configuration.



(Ex. 1005 at 15:31-16:2, 16:10-14, 14:9-20, Figures 8A-B; Ex. 1014 at ¶109).

Hartley discloses that the inner tube is moved relative to the outer tube by "push[ing]" the inner tube forward "in a proximal direction," while holding the outer tube stationary. (Ex. 1005 at 16:10-14; *see also id.*, 15:7-14, 15:31-16:2; Ex. 1014 at ¶110). Thus, any relative axial movement between the outer tube and the inner tube is controlled directly by the operator, rather than a structure of the stent graft deployment delivery system, as described in the '632 patent. (*See, e.g.*, Ex. 1001 at 2:66-3:3 (describing "a threaded collar coupled to the inner tube and a mating threaded shaft coupled to the outer tube" that "enables the relative axial movement between the inner tube and the outer tube for controlled deployment of the stent-graft"), Figure 8). To 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. (Ex. 1014 at ¶110).

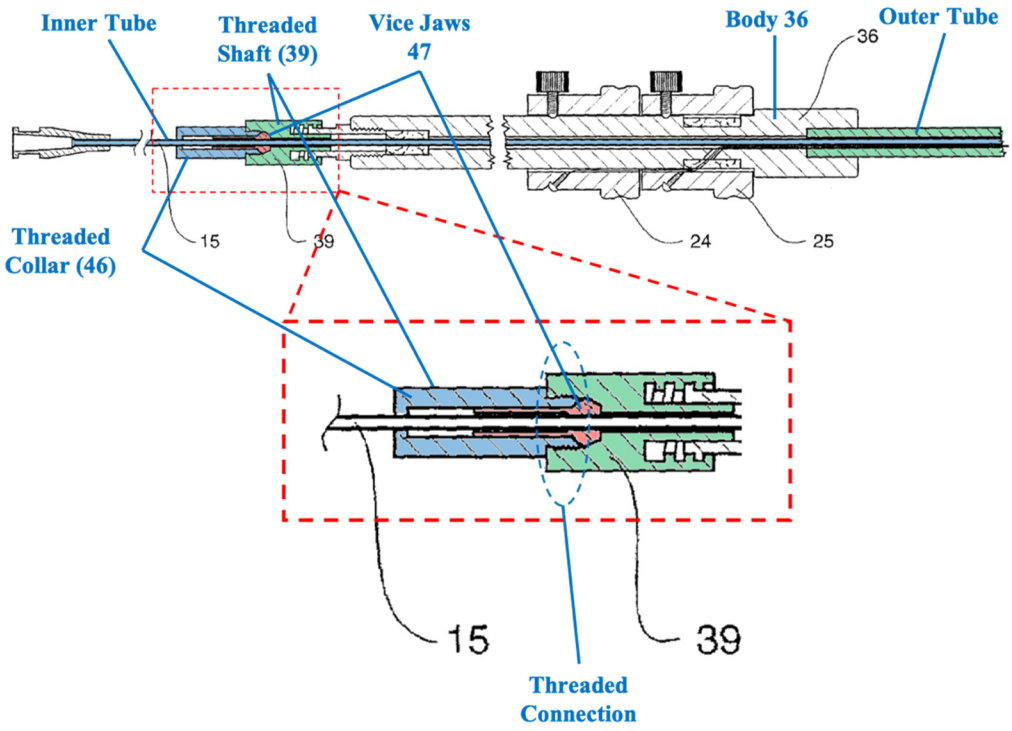
As explained above in Sections IV.B. and IV.C., Lindenberg and Olson each disclose prosthesis delivery systems including rotary control handle structures for providing controlled relative axial movement between an inner tube (applicator 3 (Lindenberg); shaft 34 (Olson)) and an outer tube (sleeve 2 (Lindenberg); tubular sheath 32 (Olson)). (Ex. 1007 at 4:64-67, 5:13-68, Figures 1-3; Ex. 1004 at 5:6-55, 7:13-8:8, Figures 2, 8-12). Lindenberg and Olson each teach that rotary control handle structures provide advantages over push/pull devices, as described in Hartley. (Ex. 1014 at ¶111). For example, Lindenberg discloses that rotary control

handle structures allow the prosthesis to be "precisely…held in position" during deployment, and "reliably maintain the endoprosthesis at the application point" until desired deployment. (Ex. 1007 at 3:30-40, 5:42-48). Olson discloses that rotary control handle structures are advantageous in order to overcome perceived problems with prior art delivery systems, where the prosthesis is "tightly compressed within the [delivery] catheter." (Ex. 1004 at 1:47-51). Olson also teaches that rotary control handle structures provide a "mechanical advantage," compared to push/pull systems, "helping the physician to overcome the large static frictional forces between the prosthesis and the surrounding sheath," as well as "any invagination of the prosthetic frame into the surrounding sheath material." (*Id.*, 7:65-8:4). Olson further teaches that rotary control handle structures provide the operator with the ability to "very gradually release[]" the end of the prosthesis, which a PHOSITA would perceive as potentially providing improved control over push/pull systems, as described in Hartley. (*Id.*, 8:4-8; Ex. 1014 at ¶111).

It would have been obvious to modify Hartley to include a rotary control handle structure, as described in Lindenberg and Olson, so that Hartley's inner tube (15 (Embodiment #1); 162 (Embodiment #2)) moves relative to the outer tube (40+41 (Embodiment #1); 160 (Embodiment #2)) by rotation, instead of by pushing and pulling. (Ex. 1014 at ¶112). In the 2002-2003 timeframe (and still today), rotation was one of a finite number of techniques used in the art to effect

relative movement between inner and outer tubes of a delivery device (the other being direct pushing/pulling). (*Id.*). As explained above in Section IV.B., for example, Lindenberg discloses using a rotary control handle mechanism as an alternative to using a simple push/pull device. (Ex. 1007 at 7:41-53). A PHOSITA would have been motivated to modify Hartley to include a rotary control handle structure, in order to provide the advantages described in the prior art, including "reliabl[e]" and "precise[]" deployment, (Ex. 1007 at 3:30-40, 5:42-48), and a "mechanical advantage" to "help[] the physician to overcome [any] large static frictional forces" between Hartley's stent graft and cap. (Ex. 1004 at 7:65-8:4; Ex. 1014 at ¶112). A PHOSITA would have expected that modifying Hartley to include a rotary control handle structure would provide greater control over the relative axial movement of Hartley's inner and outer tubes, for example by allowing a more controlled and more "gradual[] release[]" of the proximal end of Hartley's stent graft from the delivery system. (*Id.*, 8:4-8; Ex. 1014 at ¶112).

The proposed modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Hartley, to achieve predictable results. (Ex. 1014 at ¶113). As shown below in annotated Figure 2, for example, Hartley already discloses in Embodiment #1 and Embodiment #2 a rotary structure in the form of a threaded collar (screw cap 46 (highlighted in blue)) surrounding and coupled to the inner tube (15 (Embodiment #1); 162 (Embodiment #2)), and a mating threaded shaft (portion of pin vice 39 highlighted in green) coupled to the outer tube (40+41 (Embodiment #1); 160 (Embodiment #2)).

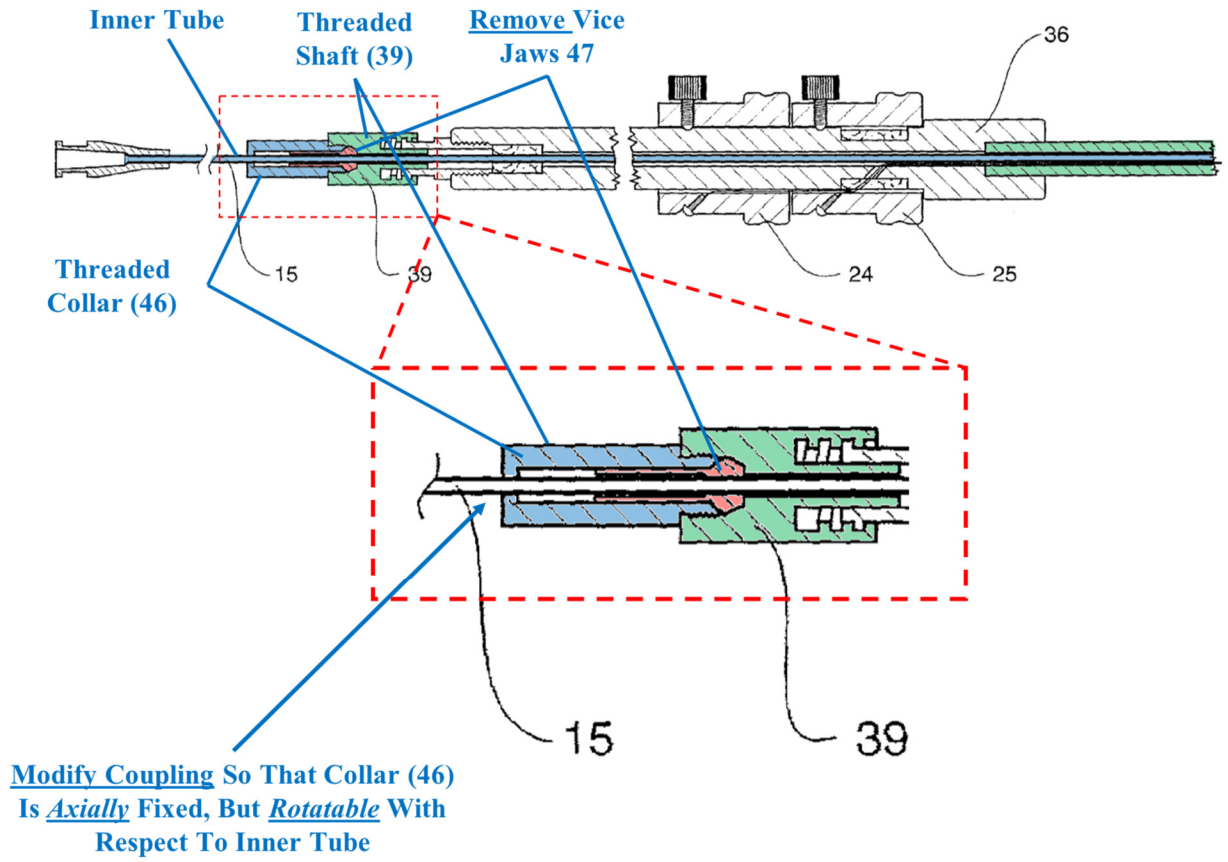


(Ex. 1005 at 15:7-13, 16:10-14, Figures 11-12; Ex. 1014 at ¶113). Hartley discloses that rotating the threaded collar (46) in one direction "clamps vice jaws 47 [(highlighted above in red)] against the [inner] tube," so that the inner and

outer tube move together, in unison. (*Id.*). Rotating the threaded collar (46) in the other direction, on the other hand, releases vice jaws 47 from the inner tube, allowing the operator to slide the inner tube axially relative to the outer tube, and relative to the threaded collar (46). (*Id.*). A PHOSITA would have recognized that Hartley's rotary structure could easily be modified so that rotating the collar (46) moves the inner tube relative to the outer tube, as described in Lindenberg. A PHOSITA would have recognized that this could be accomplished by making two simple modifications: (1) remove the vice jaws 47; and (2) modify the coupling between the threaded collar (46) and inner tube, so that the threaded collar (46) moves in unison with the inner tube. (Ex. 1014 at ¶114). With respect to the second modification, it would have been obvious to couple the threaded collar (46) to the inner tube using an intermediate ring structure, similar to ring 13 described in Lindenberg. (*See* Section IV.B., above). Consistent with Lindenberg, the ring 13 in the modified Hartley embodiments would be firmly *axially* connected to the inner tube, to allow the collar (46) to move in unison axially with the inner tube. (*See* Section IV.B., above; Ex. 1007 at 5:38-41 ("first handle 5 is freely rotatably inserted in a ring 13"), 5:64-68 ("ring 13…is firmly axially connected" to sleeve 2), Figure 3 (disclosing a simple mechanical "ring 13" coupling between rotatable handle 5 and sleeve 2, which allows rotatable handle 5 to be "freely rotatabl[e]," without rotating sleeve 2)). At the same time, the collar (46) in the

modified Hartley embodiments would be *rotatable* with respect to the ring 13 (and the inner tube), so that the collar (46) can be rotated without rotating the inner tube. (*Id.*). A PHOSITA would have recognized that the length of threading engagement in the rotary structure of the modified Hartley embodiments could be optimized, as necessary, to enable the desired axial travel distance between the inner and outer tubes (*e.g.*, increasing the length of the threading engagement to allow increased axial travel distance). (Ex. 1014 at ¶115). The above modifications would have involved simple mechanical structures and no more than routine skill in the art, and would have yielded the predictable result of controlled relative axial movement between Hartley's inner and outer tubes. (*Id.*); *KSR*, 550 U.S. at 416-17.

Annotated Figure 2, below, illustrates the proposed modifications to the Hartley embodiments.



(Ex. 1014 at ¶116). As modified, rotating the threaded collar (46) with respect to the threaded shaft (portion of pin vice 39 highlighted above in green) would result in a controlled relative axial movement between Hartley's inner tube (15 (Embodiment #1); 165 (Embodiment #2)) and outer tube (40+41 (Embodiment #1); 160 (Embodiment #2)), to release the proximal end of Hartley's stent graft from the cap and from the radially compressed configuration. (Ex. 1005 at 16:10-14; Ex. 1014 at ¶116).

2. Dependent Claim 2

Claim 2 depends from claim 1 and further states "the cap is a shroud portion of a flexible tapered tip fixed to the distal end of the inner tube." Claim 1 would have been obvious for the reasons in Section V.B.1. Hartley discloses the limitations of claim 2 for the reasons in Section V.A.2. (Ex. 1014 at ¶117).

3. Dependent Claim 3

Claim 3 depends from claim 1 and further states "wherein 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." Claim 1 would have been obvious for the reasons in Section V.B.1. (Ex. 1014 at ¶118).

As explained in Section V.B.1., modified Hartley Embodiments #1 and #2 each disclose a threaded collar coupled to the inner tube (15 (Embodiment #1); 162 (Embodiment #2)) and a mating threaded shaft coupled to the outer tube (40+41 (Embodiment #1); 165 (Embodiment #2)). The modifications "enable[s] the relative axial movement between the inner tube and the outer tube for controlled deployment of the stent-graft," for the reasons in Section V.B.1.h. (Ex. 1014 at ¶119).

4. Dependent Claim 4

Claim 4 depends from claim 1 and further states "further comprising 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." Claim 1 would have been obvious for the reasons in Section V.B.1. Hartley discloses the additional limitations of claim 4 for the reasons in Section V.A.3. (Ex. 1014 at ¶120).

VI. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Petitioners reserve the right to address any secondary considerations of nonobviousness that Patent Owner may assert.

VII. CONCLUSION

There is a reasonable likelihood that at least one of the challenged claims is unpatentable. Therefore, Petitioners respectfully request that the PTAB grant this petition for *inter partes* review.

Dated: November 12, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24(a)(1)(i). This brief contains 11,701 words as calculated by the "Word Count" feature of Microsoft Word, the word processing program used to create it.

The undersigned further certifies that this brief complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and typestyle requirements of 37 C.F.R. § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: November 12, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,264,632, as well as the accompanying Power of Attorney, and Exhibits 1001-1005, 1007, 1009, and 1014 have been served in their entirety on November 12, 2018, by Federal Express (Overnight Delivery) on:

MEDTRONIC VASCULAR, INC. IP Legal Department 3576 Unocal Place Santa Rosa, California 95403
Counsel of Record for Medtronic Vascular, Inc. at the U.S. Patent & Trademark Office with respect to U.S. Patent No. 7,264,632

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