

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Harrison M. Lazarus, et al.

U.S. Patent No.: 5,562,728

Issue Date: October 8, 1996

Appl. No.: 420,623

Filing Date: April 12, 1995

Title: ENDOVASCULAR GRAFTING APPARATUS, SYSTEM AND
METHOD AND DEVICES FOR USE THEREWITH

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PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 5,562,728 UNDER 35 U.S.C. §§ 311-319

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EXHIBIT LIST

- 1001** U.S. Patent No. 5,562,728 to Lazarus et al.
- 1002** Prosecution History of U.S. Patent No. 5,562,728
- 1003** Lawrence et al., *Percutaneous Endovascular Graft: Experimental Evaluation*, Radiology, Vol. 163:357:360 (May 1987)
- 1004** Charnsangavej et al., *Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents*, Radiology, Vol. 161:295-298 (November 1986)
- 1005** U.S. Patent No. 4,140,126 to Choudhury
- 1006** U.S. Patent No. 4,202,349 to Jones
- 1007** U.S. Patent No. 4,580,568 to Gianturco
- 1008** U.S. Patent No. 4,739,762 to Palmaz
- 1009** U.S. Patent No. 4,562,596 to Kornberg
- 1010** Uchida et al., *Modifications of Gianturco Expandable Wire Stents*, AJR, Vol. 150:1185-1187 (May 1988)
- 1011** Yoshioka et al., *Self-Expanding Endovascular Graft: An Experimental Study in Dogs*, AJR, Vol. 151:673-676 (October 1988)
- 1012** U.S. Patent No. 4,425,908 to Simon
- 1013** Wallace et al., *Inferior Vena Caval Stent Filter*, AJR, Vol. 147:1247-1250 (December 1986)
- 1014** U.S. Patent No. 4,793,359 to Sharrow
- 1015** U.S. Patent No. 2,104,880 to Lintner
- 1016** Dotter et al., *Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report*, Radiology, Vol. 147:259-260 (April 1983)
- 1017** U.S. Patent No. 3,952,747 to Kimmell, Jr.

- 1018** U.S. Patent No. 6,306,141 to Jervis
- 1019** Soviet Union Patent No. SU 1,217,402 to Volodos
- 1020** U.S. Patent No. 4,665,906 to Jervis
- 1021** U.S. Patent No. 4,800,882 to Gianturco
- 1022** U.S. Patent No. 4,503,568 to Madras
- 1023** U.S. Patent No. 4,740,207 to Kreamer
- 1024** U.S. Patent No. 4,041,931 to Elliott et al.
- 1025** U.S. Patent No. 4,693,237 to Hoffman et al.
- 1026** U.S. Patent No. 4,787,899 to Lazarus et al.
- 1027** U.S. Patent No. 4,688,553 to Metals
- 1028** Declaration of Gary L. Loomis
- 1029** Curriculum Vitae of Gary L. Loomis

Medtronic, Inc. and Medtronic Vascular, Inc. (together, “Petitioners”), petition for *inter partes* review (“IPR”) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-5, 9-18, 23, 27-31, and 33-35 of U.S. Patent No. 5,562,728 (the “’728 patent”, Ex. 1001), and assert that there is a reasonable likelihood that they will prevail with respect to the challenged claims. A supporting Declaration of Gary L. Loomis, Ex. 1028, is submitted herewith.

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

Petitioners are real parties-in-interest with respect to the instant petition.

The ’728 patent is asserted in actions captioned: (1) *LifePort Sciences LLC v. Medtronic, Inc., et al.*, Case No. 1:12-cv-1793 (D. Del.), filed December 28, 2012; and (2) *LifePort Sciences LLC v. W.L. Gore & Associates, Inc.*, Case No. 12-cv-1792 (D. Del.), filed December 28, 2012.

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this petition. Service of any documents via hand-delivery may be made at the postal mailing address of the respective lead or back-up counsel designated below:

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II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 19-2385 for the fee set in 37 C.F.R. § 42.15(a) for this Petition and further authorizes payment of any additional fees to be charged to that Account.

III. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioners certify that the '728 patent is available for IPR and that: (1) none of the Petitioners owns the '728 patent; (2) prior to the date this Petition was filed, neither Petitioners nor any real party-in-interest filed a civil action challenging the validity of a claim in the '728 patent; (3) this Petition has been filed less than one year after January 3, 2013, the date on which Petitioners were served with a complaint alleging infringement of the '728 patent; and (4) neither Petitioners, any real parties-in-interest, nor any privies of Petitioners, are estopped from challenging the claims on the grounds identified in this Petition.

IV. SUMMARY OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 1-5, 9-18, 23, 27-31, and 33-35 (“the IPR Claims”) of the '728 patent in view of the following references:

Patent/Pub. Title	Priority Date	Date of Issuance or Publication	Exhibit
Lawrence et al., <i>Percutaneous Endovascular Graft: Experimental Evaluation</i> (“Lawrence”)		May 1987	1003

Charnsangavej et al., <i>Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents</i> (“Charnsangavej”)		November 1986	1004
U.S. Patent No. 4,140,126 (“Choudhury”)	February 18, 1977	February 20, 1979	1005
U.S. Patent No. 4,202,349 (“Jones”)	April 24, 1978	May 13, 1980	1006
U.S. Patent No. 4,562,596 (“Kornberg”)	April 25, 1984	January 7, 1986	1009
U.S. Patent No. 4,793,359 (“Sharrow”)	April 24, 1987	December 27, 1988	1028
Dotter et al., <i>Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report, Radiology</i> (“Dotter”)		April 1983	1016

Petitioners asserts the following specific grounds of rejection under 35

U.S.C. §§ 102 and 103:

Ground	'728 Patent Claims	Grounds for Trial
1	23, 27	Anticipated by Lawrence
2	1, 4-5, 9-15, 18, 28-30, 33-35	Obvious over Lawrence in view of Charnsangavej
3	1, 4-5, 9-18, 28-30, 33-35	Obvious over Choudhury or Kornberg in view of Lawrence
4	1, 4-5, 9-18, 23, 27-30, 33-35	Obvious over Choudhury or Kornberg in view of Charnsangavej
5	9-10, 27, 33-34	Obvious over the above combinations in view of Jones and Sharrow
6	2-3, 31	Obvious over the above combinations in view of Dotter

V. SUMMARY OF THE '728 PATENT

A. Background on Intraluminal Devices to Treat Vascular Diseases

When the walls of an artery or other body lumen weaken, an excessive,

localized enlargement of the lumen known as an aneurysm can occur, which affects the lumen's ability to conduct fluids and may be life threatening if untreated. Since the 1950s, grafts placed during open surgery have been used to repair aneurysms. Ex. 1028 (Declaration of Gary L. Loomis) ¶ 5. However, these early surgical techniques were highly invasive and risky. *See, e.g.*, Ex. 1009 at 1:29-35. To lessen the risks, physicians needed to develop endovascular prostheses with an initial configuration small enough to be implanted without open surgery, but which could then be expanded to a larger configuration at the desired site to treat the defective artery. Ex. 1028 ¶ 6.

Prior to the mid-1980s, numerous devices were developed in this crowded field of art, including coil grafts formed from Nitinol alloys (Dotter, Ex. 1016; and Jervis, Ex. 1018); balloon-assisted, expandable grafts composed of a wire mesh (Palmaz, Ex. 1008); and stents made from a single piece of stainless steel wire bent into a “zig-zag” configuration (Gianturco, Ex. 1007). Ex. 1028 ¶¶ 10, 12, 15.

Without open surgery, however, surgeons could not suture or otherwise affix the expanded prosthesis to the lumen. Thus, the implanted device was susceptible to unwanted migration or drift from the desired treatment site of a damaged or deteriorated vessel. Ex. 1028 ¶ 7. This problem was widely recognized and well-known prior to the mid-1980s. *See, e.g.*, Ex. 1008 at 1:61-2:1 (noting that improperly secured grafts tended to “migrate away from the desired location within

the body passageway”); Ex. 1012 (U.S. Patent No. 4,425,908) at 2:27-50, 3:11-16, 7:3-7 (disclosing the use of hooks to prevent migration).

Because the aortal lining lacks any nerve endings, metal barbs or hooks were frequently employed to anchor medical devices to the lumen wall. *See* Ex. 1028 ¶ 8. For instance, prior art such as Choudhury taught a device for intraluminal repair of an aneurysm with hooks that the user mechanically engaged with the blood vessel wall. *See* Ex. 1026 (U.S. Patent No. 4,787,899) at 1:52-56. Use of hooks on other intraluminal devices, such as blood clot filters, was also widely known as a solution to prevent migration. *See* Ex. 1028 ¶ 19; *see, e.g.*, Ex. 1027 (U.S. Patent No. 4,668,553) at 3:54-58 & Fig. 10.

B. Summary of the '728 Patent and IPR Claims

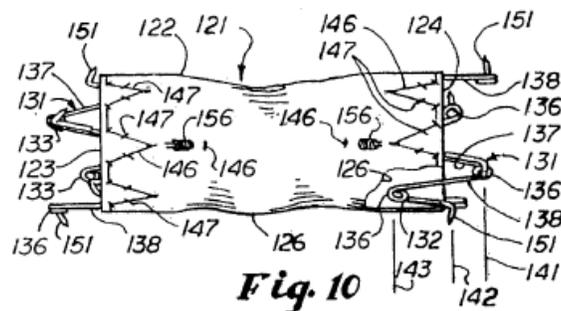
The '728 patent issued on October 8, 1996 from U.S. Application No. 420,623, filed April 12, 1995. *See* Ex. 1001 ('728 patent). The claims challenged in this petition claim priority to U.S. Application No. 07/166,093, which was filed on March 9, 1988. *See* Ex. 1002 ('728 patent prosecution history) at 121.

The '728 patent has not been the subject of any post-grant proceedings, either in the United States Patent and Trademark Office, or in district court.

The IPR Claims relate to an expandable, tubular endovascular graft that can assume two different configurations—one of reduced size for maneuvering the device to the desired site, and one of expanded size for engagement with the

damaged body vessel or lumen. Ex. 1028 ¶ 23. These claims generally recite an expandable graft with certain combinations of the following structural elements:

(a) a **spring arrangement** designed to urge the tubular member from the first conformation to the second, expanded conformation; (b) one or more **attachment systems** connected to the end(s) of the tubular member, that include a plurality of legs joined by a plurality of apices, and that can engage with the body lumen; (c) **hook-like elements** that further secure or anchor the graft to the lumen. Elements (a) through (c) are illustrated in Figure 10 of the '728 patent:



See also Ex. 1001 at 1:39-47. The specification describes the claimed “spring arrangement” or “expandable spring means” as serving to “yieldably urge the tubular member **122** from a first compressed or collapsed position to a second expanded position.” *Id.* at 8:24-27. This “spring means” is a single piece of wire shaped to form “vees **132**,” with helical coil springs **136** at the apices of the vees to allow for compression and expansion. *See id.* at 8:22-35; 9:36-50. The vees are equipped with “hook-like elements **151** [that] serve as attachment means at each end of the graft **121** and when implanted oppose migration of the graft.” *See id.* at

9:34-36. Figure 11, reproduced below, shows a closer view of the hook-like elements **151**, which are conventional hooks designed to become embedded in the lumen wall. Alternative arrangements for these hook-like elements include barb and arrowhead configurations, which are shown below in Figures 12 and 13:

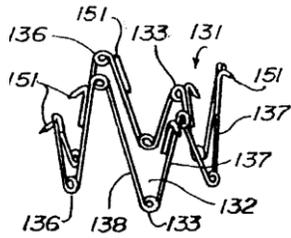


Fig. 11



Fig. 12

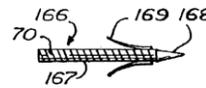


Fig. 13

C. Person of Ordinary Skill in the Art of the '728 Patent

By the mid-1980s, a person of ordinary skill in the art of the '728 patent would have been highly skilled, and typically would have possessed the following education and experience: a degree in mechanical or chemical engineering, or material science, and would have knowledge of the vascular system of mammals and 3-5 years of experience in intravascular device design and methods of making intravascular devices. Ex. 1028 ¶ 29.

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

The claims of the '728 patent should be given their “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b). This standard of claim construction can be broader than that generally employed by a federal district court when interpreting the scope of a claim. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). Several of the terms should be construed

pursuant to section 112(f) as means-plus-function (“MPF”) terms limited to the disclosed embodiments and their equivalents. Although Petitioners reserve the right to present different constructions in related litigation, Petitioners’ proposed broadest reasonable constructions for the MPF terms are set forth below. All other terms should be construed according to their plain and ordinary meaning.¹

MPF Claim Term	Proposed Construction	Support In Specification
“expandable yieldable spring means . . . for urging said tubular member from said first position of reduced size to a second expanded position” (claim 1)	<u>Function</u> : “urging the tubular member from a first position of reduced size to a second expanded position” <u>Structure</u> : “a circularly continuous spring that can be compressed radially to exert a radially outward force without permanent deformation”	8:22-56; Figs. 10-11
“attachment means . . . for attachment to the body vessel” (claim 1)	<u>Function</u> : “attaching to the vessel wall” <u>Structure</u> : “hooks or hook-like elements, including at least those shown in Figures 10-13”	8:57-65, 9:34-36, 10:23-55, 13:66-14:6; Figs. 10-13
“conforming means for engrafting a body vessel” (claim 35)	<u>Function</u> : “engrafting a body vessel” <u>Structure</u> : “a deformable tubular member”	8:5-22; Figs. 10-11
“attachment means . . . for engaging the body vessel” (claim 35)	<u>Function</u> : “engaging the body vessel” <u>Structure</u> : “a plurality of apices and vees that are self-expanding”	8:22-56; Figs. 10-11
“engaging means for securing said conforming means to a wall of the body vessel” (claim 35)	<u>Function</u> : “securing to a wall of the body vessel” <u>Structure</u> : “hooks or hook-like elements, including at least those shown in Figures 10-13”	8:57-65, 9:34-36, 10:23-55, 13:66-14:6; Figs. 10-13

¹ Even if the Board adopts a different claim construction, Petitioners believe that the prior art references nevertheless invalidate the ’728 claims.

VI. ANALYSIS OF GROUNDS FOR TRIAL

A. Introduction to the Unpatentability Arguments

The IPR claims recite an assembly of well-known structures combined in well-known ways to address well-known issues with intraluminal prosthesis implantation (i.e., the need to trigger a change from reduced to expanded size, and the need to prevent unwanted migration of the implanted device). Several years before the alleged priority date of the IPR claims, self-expanding stents (known as Gianturco stents, discussed in greater detail below) were used to treat damaged arteries by automatically “springing” into an expanded conformation from a compressed conformation upon removal from a catheter. After the Gianturco stents were disclosed, they were the subject of extensive further development and research. Through various modifications—including through the addition of well-known hooks and barbs, and by combining stents with flexible, bio-compatible material to form a graft—researchers developed and disclosed all of the elements of the IPR claims well before their alleged priority date of March 9, 1988.

B. Ground 1: Claims 23 and 27 Are Anticipated by Lawrence Under 35 U.S.C. § 102(a)

1. Summary of Lawrence

Lawrence was submitted for publication on November 10, 1986, and was published before May 1987. It therefore is prior art to the IPR claims under 35 U.S.C. § 102(a).

Lawrence teaches the “intravascular placement of a Dacron graft, using multiple Gianturco stents as a superstructure to anchor and support the graft.” *See* Ex. 1003 at 387. The stents mechanically urge this device into an expanded configuration upon placement at the desired site, and secure the endovascular graft at that site. Ex. 1028 ¶ 47.

The Gianturco stent used by Lawrence is taught by U.S. Patent No. 4,580,568 (“Gianturco”, Ex. 1007), issued on April 8, 1986. *See* Ex. 1003 at 357 (“Another use of the Gianturco stent is as a vehicle for the intravascular placement of other materials. We developed such a modification to allow intravascular placement of a Dacron graft, using multiple Gianturco stents as a superstructure by which to anchor and support the graft.”). The Gianturco stent is formed by bending a single piece of wire in a zig-zag configuration and joining the two ends. *See* Ex. 1007 at 2:48-55 & Fig. 1.

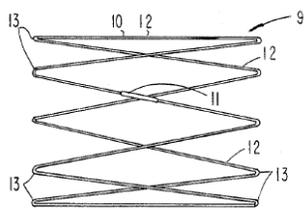


Fig.1

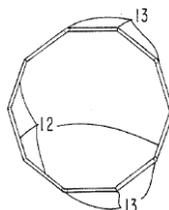
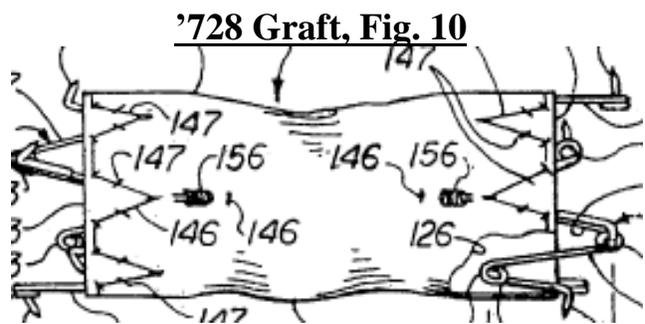
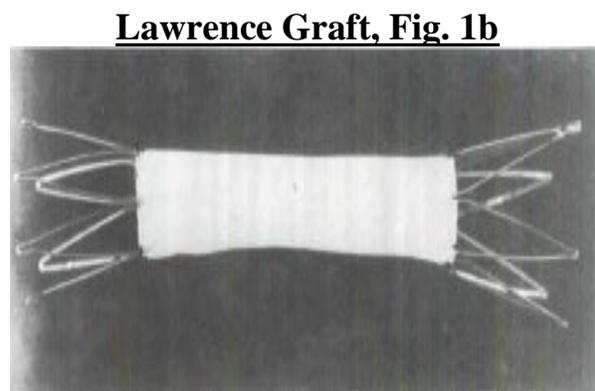


Fig.2

Thus, the final product has a circular shape when viewed along the central axis, *see id.* at Fig. 2, and has straight legs joined at apices to form “v”-shapes at the bends, visible when viewed perpendicular to the central axis, *see id.* at Fig. 1.

The shape and material of the Gianturco stent give it spring-like characteristics that allow the stent to be “resiliently expandable from the compressed first shape of FIG. 4 into a second shape illustrated in FIGS. 1, 2 and 6, wherein the straight sections 12 press against the walls of passageway to maintain the passageway open.” *Id.* at 2:59-68; *see* Ex. 1028 at ¶ 50.

Figure 1(b) of Lawrence shows the assembled device as a Dacron tube with Gianturco stents at both ends. *See* Ex. 1003 at 358 & Fig. 1(b). Like the graft of the IPR Claims, the Lawrence device was designed to “pass through a relatively small catheter and expand to fit the lumen of the vessel” when deployed, such that it then “act[s] in the same way as a surgically placed graft, providing a new conduit for blood flow and supporting the weakened vascular wall.” *Id.* at 359. When constructed according to Lawrence, the Gianturco stents also serve as springs to mechanically urge the “open[ing of] the Dacron tubing when the device was released from the catheter.” *Id.* at 357. The similarities between the graft of the '728 patent and that of Lawrence are exemplified by the comparison below:



Several of the authors of Lawrence had been working with the Gianturco stents for years, including those that were equipped with barbs. *See, e.g.*, Charnsangavej, identified as Reference (1) in Lawrence, at Fig. 1. However, Lawrence implanted the stent grafts into healthy aortas. *See* Ex. 1003 at 357. Thus, the experimental circumstances did not present a risk of migration and did not require barbs. *See* Ex. 1028 ¶¶ 51-56.

2. Lawrence Explicitly Discloses Each and Every Limitation of Claims 23 and 27 of the '728 Patent

Claim 23, unlike the other independent claims in the '728 patent, does not recite any structures for engaging or securing the prosthesis to the vessel wall (i.e., hooks). *See* Ex. 1028 ¶ 54. Instead, claim 23 covers three basic structures: (1) a tubular member; (2) a first attachment system positioned proximate the first end of the tube; and (3) a second attachment system proximate the second end of the tube. *See* Ex. 1001 at 15:60-16:7. The attachment systems are described as including only “a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement.” *Id.* at 15:63-16:7.

Lawrence teaches element (1) in the form of the “graft tubes . . . made from thin, woven Dacron sheets.” *Id.* at 357 & Fig. 1; Ex. 1028 ¶ 55. Lawrence teaches elements (2) and (3) in the form of two Gianturco stents, which are made of wire bent to form legs and apices, resulting in a circular arrangement. *See* Ex. 1003 at 357 & Fig. 1; Ex. 1007 at Figs. 1-2; Ex. 1028 ¶ 56. Lawrence also teaches the use

of the Gianturco stents to “anchor and support the graft.” Ex. 1003 at 357; *see* Ex. 1028 ¶ 47.

Lawrence discloses each and every element of claim 23 of the '728 patent, so claim 23 is unpatentable as anticipated under section 102(a). An element-by-element analysis of claim 23 is shown below:

'728 Patent: Claim 23	Lawrence (Ex. 1003)
23. A graft for intraluminal placement in a corporeal lumen, said graft comprising:	Non-limiting preamble. But, Lawrence discloses a graft for intraluminal placement in a corporeal lumen. P. 357, col. 2, ¶2 (“intravascular placement of a Dacron graft, using multiple Gianturco stents”); Fig. 2.
a tubular member having a first end and a second end;	Lawrence discloses a Dacron tube with a first end and a second end. P. 357, col. 2, ¶3; Fig. 1.
a first attachment system positioned proximate the first end of said tubular member,	Lawrence discloses a first attachment system in the form of a Gianturco stent, which is positioned proximate the first end of the tubular member (i.e., the Dacron stent. P. 357, col. 2, ¶3; Fig. 1.
said first attachment system including a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement;	The first Gianturco stent, which is used as the attachment system, includes a plurality of legs joined by a plurality of apices and the legs are configured in a circular arrangement. Fig. 1.
and a second attachment system positioned proximate the second end of said tubular member,	Lawrence also discloses a second attachment system in the form of another Gianturco stent that is positioned proximate the second end of said tubular member. P. 357, col. 2, ¶3; Fig. 1.
said second attachment system including a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement.	The second Gianturco stent, which is used as the second attachment system, also includes a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement. P. 357, col. 2, ¶3; Fig. 1.

Dependent claim 27 incorporates the limitations of claim 23 and only adds

the limitation of “a plurality of radiopaque markers secured to said tubular member.” Ex. 1001 at 16:16-17. Lawrence’s use of internal Gianturco stents, which are made of radiopaque stainless steel, discloses the limitation of radiopaque markers. *See* Ex. 1003 at 357 & Fig. 2 (showing a radiograph where the internal stents are visible); Ex. 1028 ¶ 59. Thus, Lawrence discloses each and every element of claim 27 of the ’728 patent, so claim 27 is unpatentable as anticipated under section 102(a).

’728 Patent: Claim 27	Lawrence (Ex. 1003)
<p>27. The graft of claim 23, further comprising a plurality of radiopaque markers secured to said tubular member.</p>	<p><i>See</i> above discussion of claim 23. Lawrence also discloses radiopaque markers in the form of internal stents constructed from radiopaque stainless steel that are secured to the lead and trail stents, and the tubular member. P. 357 & Fig. 2.</p>

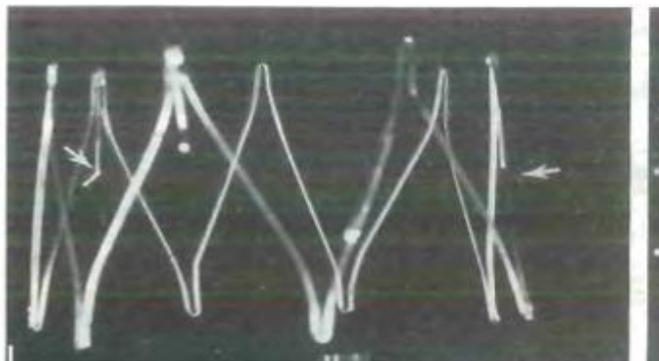
C. Ground 2: Claims 1, 4-5, 9-15, 18, 28-30, and 33-35 of the ’728 Patent Are Obvious Based on Lawrence in View of Charnsangavej

1. Summary of Charnsangavej

Charnsangavej was published before November 1986, and is therefore prior art to the IPR Claims under 35 U.S.C. § 102(b). Charnsangavej was **not** before the examiner during prosecution of the ’728 patent.

Charnsangavej explicitly shows the addition of barbs to Gianturco stents, particularly to prevent migration. *See* Ex. 1004 at 295 & Fig. 1. Charnsangavej uses the same Gianturco stents as Lawrence to expand a blood vessel and combat

abnormal narrowing of that vessel (stenosis), but does not include graft material. *See id.* at 295. When discussing the results, the authors—four of which (Drs. Charnsangavej, Wright, Gianturco, and Wallace) are also authors of Lawrence—acknowledge that, in two instances, the stents encountered early migration problems. *Id.* at 298. Charnsangavej addressed those migration problems by using barbed stents, as shown below by the arrows in Figure 1(a) from Charnsangavej:



2. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Lawrence with Charnsangavej

The combination of Lawrence and Charnsangavej was **not** before the examiner during prosecution of the '728 patent. As discussed above, Lawrence alone invalidates claims 23 and 27. Unlike claim 23, the remaining independent claims (1, 11, 28, and 35) all recite structures for engaging or securing the prosthesis to the vessel wall (i.e., hooks). These structures were well-known in the art prior to March 1988 to solve the problem of intraluminal device migration. *See* Ex. 1028 ¶¶ 18-19.

Charnsangavej identifies the problem of migration when intraluminal

medical devices are deployed in damaged human body lumens, and solves that problem by modifying the Gianturco stent with barbs. *See id.* at 295 (“To prevent migration, the stent was modified by attaching barbs (Fig. 1a), which allowed the stent to become affixed to the wall of the vessel as it was released from the catheter.”), 298. Charnsangavej also teaches positioning the barbs near the apices of the stent’s legs, as recited in claims 4, 14, and 32. *See id.* at Fig. 1. A person of ordinary skill would have been motivated to combine Charnsangavej and Lawrence to solve the problem of intraluminal device migration, especially because Lawrence itself cites to Charnsangavej. *See* Ex. 1003 at 360 (citing Charnsangavej as reference 1); Ex. 1028 ¶ 90.

Unlike in Charnsangavej, the experimental conditions of Lawrence did not present a risk of migration. *See* Ex. 1028 ¶¶ 51-56. Lawrence’s deployment of the devices in normal aortas allowed the internal stents to push against the vessel wall, resulting in additional force resisting migration. *See id.* ¶ 53.

Thus, a person of ordinary skill would have recognized that Lawrence did not have migration issues, so barbs were not needed. *See id.* Therefore, Lawrence does not teach away from the use of barbs on an intraluminal device *when that device is susceptible to unwanted migration*. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (holding that a reference that “does not criticize, discredit, or otherwise discourage” the solution does not teach away from that solution); Ex.

1028 ¶¶ 91-92, 98. If presented with a migration issue when using the teachings of Lawrence, such as in an aortal lumen affected by an aneurysm, a person of ordinary skill would have been motivated to combine its teachings with the barbs disclosed in Charnsangavej. *See id.* ¶ 90.

Indeed, two contemporaneous articles—Yoshioka and Uchida—show that a person of ordinary skill not only would have been motivated to combine the Lawrence device with the barbs of Charnsangavej, but also that several persons of ordinary skill in the art **did so combine** these teachings to address the tendency of an implanted intraluminal device to migrate. *See Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000) (“The fact of near-simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of ordinary skill in the art.” (internal quotations and citations omitted)).

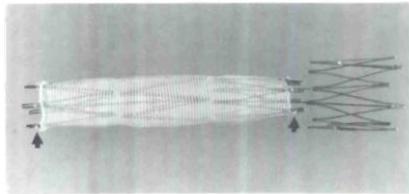
Yoshioka et al., *Self-Expanding Endovascular Graft: An Experimental Study in Dogs*, *AJR*, Vol. 151:673-676 (October 1988) (“Yoshioka”, Ex. 1011)² was initially submitted for publication on March 7, 1988—two days before the alleged priority date of the IPR claims—but was not published until October 1988.

Yoshioka shows that the authors of Lawrence did not teach away from the use of

² Other than Dr. Lawrence, all of Lawrence’s authors are also authors of Yoshioka—i.e., Drs. Charnsangavej, Wright, Gianturco, and Wallace.

barbs, because they subsequently used barbs to prevent migration of a stent-graft, reaffirming their use of barbs in Charnsangavej.³ See Ex. 1028 ¶ 96.

Yoshioka teaches a stent-graft constructed by placing nylon graft material over a framework of Gianturco stents. See Ex. 1011 at 673-74. Yoshioka uses a barbed stent on the leading edge of the graft to anchor the device, and support stents to expand the graft material to conform to the wall of the blood vessel. See *id.* at 673.



Id. at Fig. 1. The authors note that:

One of the seven grafts placed in this project migrated. In this case, the lead stent was not equipped with barbs that engage the vessel wall and prevent movement during neointimal encasement. None of the stent grafts that were equipped with barbs migrated. This is similar to results reported by [Charnsangavej] and **again emphasizes the need for barbs** on the anchoring stent.

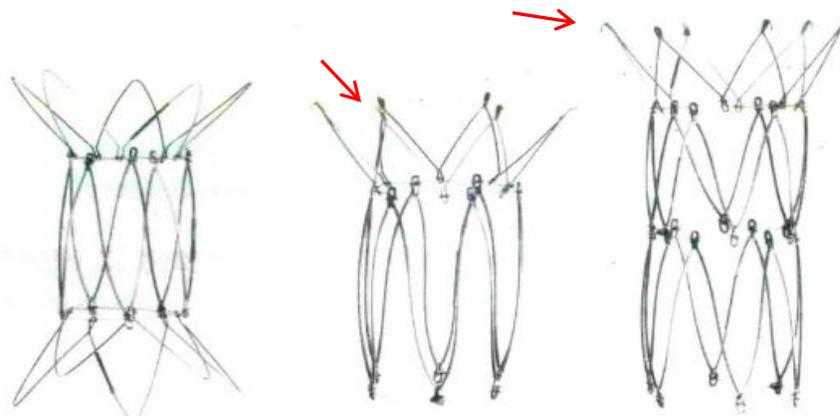
Id. at 675-76 (emphasis added). Yoshioka concludes that “anchoring stents should be equipped with barbs to help prevent migration.” *Id.* at 676.

The Lawrence authors’ use of barbs in Yoshioka confirms that Lawrence did

³ In another earlier article, three of the authors of Lawrence specifically noted the use of barbs to address migration problems in vena cava filters. See Wallace et al., *Inferior Vena Caval Stent Filter*, *AJR*, Vol. 147:1247-1250 (December 1986), Ex. 1013.

not teach away from the use of barbs. *See* Ex. 1028 ¶ 94. To the contrary, Yoshioka cited explicitly to Charnsangavej for the desirability of barbs, and cited to Lawrence but made no mention of Lawrence’s omission of barbs. *See* Ex. 1011 at 676. Yoshioka makes clear that, migration motivated the authors of Lawrence and Charnsangavej to attach barbs to the device. *See* Ex. 1028 ¶ 96.

Uchida et al., *Modifications of Gianturco Expandable Wire Stents*, *AJR*, Vol. 150:1185-1187 (May 1988) (“Uchida”, Ex. 1010), another contemporaneous article, was submitted and accepted after revision in 1987 (prior to the alleged priority date of the IPR claims) but not published until April 1988. Uchida shares no common authors with Lawrence, indicating that persons of ordinary skill— independent from the team in Lawrence—similarly used barbs with the Gianturco stent to assist in anchoring, and cited to Charnsangavej. *See* Ex. 1010 at 1185, 1187. Specifically, Uchida uses wire skirts equipped with “hooks and spikes . . . to ensure a fixed position of the stent in a major vessel,” as shown below:



Id. at Fig. 1 (arrows added). As a result of the experiment, the authors concluded

that the wire skirts “prevent stent dislodgment, particularly if they have spikes and hooks. Once such a stent is released, it is fixed in the vessel or ductal wall and cannot move in either direction.” *See id.* at 1187.

The contemporaneous Yoshioka and Uchida references are strong evidence that, before the alleged priority date of the IPR claims, a person having ordinary skill in the art routinely used barbs or hooks to prevent migration of a device implanted within a damaged body lumen, and would have combined the teachings of Lawrence and Charnsangavej. The use of hooks, barbs, and other similar anchoring devices does not result in any unexpected synergy—the addition of these well-known structures for securing medical devices functions exactly as one of skill in the art would have expected, to achieve expected results (i.e., better device anchoring). *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 4186 (2007).

Thus, a person of ordinary skill would have found it obvious to combine Lawrence and Charnsangavej to achieve all elements of claims 1, 4-5, 9-15, 18, 28-30, and 33-35 of the ’728 patent, so those claims are unpatentable as obvious under section 103.

’728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
1. An expandable intraluminal vascular graft for implanting in a body vessel comprising	Non-limiting preamble. But, Lawrence discloses a graft for intravascular implantation into a body vessel. P. 357, col. 2, ¶2 (“intravascular placement of a Dacron graft, using multiple Gianturco stents”); Fig. 2.

'728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends,	Lawrence discloses a deformable tubular member in the form of a Dacron tube that has proximal and distal ends and a wall extending between the proximal and distal ends. P. 357, col. 2, ¶3; Fig. 1.
the wall being formed of a flexible material capable of receiving tissue ingrowth,	Lawrence discloses that the Dacron wall was a flexible material that received tissue ingrowth. P. 358, col. 2-3.
said tubular member being capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position,	Lawrence discloses that the graft was capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position as exemplified by the graft being inserted into a 11-F sheath catheter and then introduced into the vasculature. P. 357, col. 3, ¶2; Fig. 1(c).
expandable yieldable spring means respectively secured to the proximal and distal ends of the tubular member,	Lawrence discloses expandable yieldable spring means in the form of Gianturco stents. P. 357, col. 2, ¶3. These stents were secured to both the proximal and distal ends of the tubular member. <i>Id.</i> ; Fig. 1(b).
said yieldable spring means urging said tubular member from said first position of reduced size to a second expanded position and	Lawrence discloses yieldable spring means that urge the tubular member from a first position of reduced size to a second expanded position in the form of the Gianturco stents connected to the Dacron graft. P. 357, col. 2, ¶3; Fig. 1.
attachment means secured to said expandable spring means for attachment to the body vessel.	Charnsangavej discloses the attachment of barbs to Gianturco stents for attachment to the body vessel when deployed. Charnsangavej, P. 295, col. 3, ¶3; P. 298, col. 1, ¶3; Fig. 1.
4. A graft as in claim 3, wherein the attachment means is in the form of hook elements secured to the spring means proximate the apices of the vees.	Charnsangavej discloses hook elements that are secured to the Gianturco stents (i.e. the spring means) proximate the apices of the vees. Charnsangavej, P. 295, col. 3, ¶3; Fig. 1.

'728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
<p>5. A graft as in claim 4, wherein the apices of the vees of each of the expandable spring means lie in first and second planes spaced along a longitudinal axis of the graft.</p>	<p>Lawrence discloses the use of expandable spring means in the form of the Gianturco stent, which has apices in two planes spaced along the longitudinal axis of the stent. P. 357, col. 2, ¶2; Fig. 1.</p> <p>Charnsangavej similarly discloses the use of the Gianturco stent. P. 295, col. 2, ¶2; Fig. 1.</p>
<p>9. A graft as in claim 1, further comprising radiopaque marker means secured to the wall of the tubular member, said marker means including first and second aligned radiopaque markers spaced apart longitudinally of the tubular member to permit ascertaining whether any twisting of the tubular member has occurred.</p>	<p>Lawrence discloses radiopaque marker means secured to the wall of the tubular member in the form of the stent itself. Fig. 2(a). There are multiple middle Gianturco stents that are attached to the Dacron graft. P. 357, col. 2, ¶3; Fig. 1. And, these stents are radiopaque and spaced longitudinally of the tubular member. Fig. 2. This permits ascertaining whether any twisting of the tubular member has occurred. Fig. 2.</p>
<p>10. A graft as in claim 9, wherein the first and second markers are positioned adjacent apices of the yieldable spring means.</p>	<p>Lawrence also discloses radiopaque markers in the form of stent struts and legs that are positioned adjacent apices of the yieldable spring means. Fig. 2.</p>
<p>11. A graft for emplacement by a balloon catheter, said graft comprising:</p>	<p>Non-limiting preamble. Deployment of an intraluminal device with a balloon catheter was well known to a person of ordinary skill in the art. <i>See, e.g.</i>, Palmaz, Ex. 1008.</p>
<p>a tubular member having a first end and a second end;</p>	<p>Lawrence discloses a Dacron tube that has proximal and distal ends. P. 357, col. 2, ¶3; Fig. 1.</p>
<p>a first attachment system connected to and positioned proximate the first end of said tubular member,</p>	<p>Lawrence discloses a first attachment system in the form of the Gianturco stent which is positioned proximate the first end of the Dacron tube. P. 357, col. 2, ¶3 (“The lead and trail stents acted as anchors for the</p>

’728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
	graft”); Fig. 1.
said first attachment system including a plurality of support members each having two legs joined to form an apex,	Lawrence discloses an attachment system in the form of the Gianturco stent which has a plurality of support members each having two legs to form an apex. P. 357, col. 2, ¶3; Fig. 1.
each leg being joined to the legs of adjacent support members to form a circular arrangement of the support members about a central axis	Lawrence discloses each leg of the attachment system (i.e. the Gianturco stent) being joined to the legs of adjacent support members to form a circular arrangement of the support members about a central axis. P. 357, col. 2, ¶3; Fig. 1.
and operable between a first collapsed position and a second expanded position; and	Lawrence discloses that the Gianturco stent is operable between a first collapsed position and a second expanded position. P. 357, col. 3, ¶2; Fig. 1(c).
first wall engaging members connected to an[d] [sic] positioned proximate the first end of said tubular member.	Charnsangavej discloses the attachment of wall engaging members (i.e. barbs) to Gianturco stents for attachment to the body vessel when deployed. Charnsangavej, P. 295, col. 3, ¶3; P. 298, col. 1, ¶3; Fig. 1. The combination of Lawrence with Charnsangavej thus results in first wall engaging members in the form of barbed Gianturco stents positioned proximate the first end of the tubular member (i.e., the Dacron tube). <i>See</i> Ex. 1028 ¶ 100.
12. A graft as in claim 11, wherein said first attachment system is self-expanding.	Lawrence discloses the Gianturco stent, which is self-expanding. P. 357, col. 2, ¶2; Fig. 1.
13. A graft as in claim 12, wherein each of the legs of the support members are formed of a spring material and are substantially straight.	Lawrence discloses the Gianturco stent, which has legs of the support members that are formed of a spring material and are substantially straight. P. 357, col. 2, ¶2; Fig. 1.
14. A graft as in claim 13, wherein each of said first wall	Charnsangavej discloses wall engaging members (i.e. barbs) that are secured to a

'728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
engaging members are secured to a respective on[e] [sic] leg of one of the support members.	respective one leg of one of the support members (i.e. the Gianturco stents). Charnsangavej, P. 295, col. 3, ¶3; Fig. 1.
15. A graft as in claim 14, wherein the support members are vee-shaped.	Lawrence discloses the Gianturco stent, which has vee-shaped support members. P. 357, col. 2, ¶2; Fig. 1.
18. A graft as in claim 14, wherein the legs extend away from the apex so that said first attachment system is sinusoidal in shape.	Lawrence discloses legs that extend away from the apex so that the first attachment system is sinusoidal in shape. Fig. 1(b).
28. An expandable intraluminal vascular graft comprising:	Non-limiting preamble. But, Lawrence discloses an intraluminal vascular graft. P. 357, col. 2, ¶2 (“intravascular placement of a Dacron graft, using multiple Gianturco stents”); Fig. 2.
a deformable tubular member having proximal and distal ends,	Lawrence discloses a deformable tubular member in the form of Dacron tubing that has proximal and distal ends. P. 357, col. 2, ¶3; Fig. 1.
said tubular member having a first reduced position and a second expanded position;	Lawrence discloses that its tubular member (i.e., the Dacron tubing) has a first reduced position and a second expanded position. P. 357, col. 3, ¶2; Fig. 1(c).
an expandable spring arrangement secured to the proximal and distal ends of the tubular member,	Lawrence discloses an expandable spring arrangement in the form of the Gianturco stents attached to the Dacron tubing. P. 357, col. 2, ¶3; Fig. 1.
said expandable spring arrangement capable of urging said tubular member from the first reduced position to the second expanded position; and	Lawrence also discloses that the Gianturco stents are capable of urging the tubular member from the first reduced position to the second expanded position. P. 357, col. 3, ¶2; Fig. 1(c).
an attachment system secured to said expandable spring arrangement for securing said tubular member to a wall of a	Charnsangavej discloses an attachment system secured to that expandable spring arrangement (i.e. the attachment of barbs to Gianturco stents) for securing that tubular

'728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
body vessel.	member to the wall of the body vessel when deployed. Charnsangavej, P. 295, col. 3, ¶3; P. 298, col. 1, ¶3; Fig. 1.
29. A graft as in claim 28, wherein said expandable spring arrangement is in the form of substantially vee-shaped spring portions having apices with legs extending from the apices.	Lawrence discloses an expandable spring arrangement in the form of Gianturco stents. P. 357, col. 2, ¶3; Fig. 1. The Gianturco stents are in the form of substantially vee-shaped spring portions having apices with legs extending from the apices. P. 357, col. 2, ¶3; Fig. 1.
30. A graft as in claim 29, wherein said attachment system comprises wall engaging members secured to the legs of said expandable spring arrangement.	Charnsangavej discloses wall engaging members (i.e. barbs) that are secured to the legs of the expandable spring arrangement (i.e. the Gianturco stents). Charnsangavej, P. 295, col. 3, ¶3; Fig. 1.
33. A graft as in claim 30, having a plurality of radiopaque markers secured to said tubular member, said markers including first and second aligned radiopaque markers spaced apart longitudinally of said tubular member.	Lawrence discloses a middle group of Gianturco stents that are secured to the tubular member (i.e. the Dacron graft). P. 357, col. 2, ¶3; Fig. 1. These stents are radiopaque and satisfy a plurality of radiopaque markers secured to the tubular member. Fig. 2. The markers include a first and second stent that are spaced apart longitudinally of said tubular member. Fig. 2.
34. A graft as in claim 33, wherein the first aligned radiopaque marker is positioned adjacent the proximal end of said tubular member and	Lawrence discloses that a first aligned radioactive marker in the form of a Gianturco stent is positioned adjacent the proximal end of the tubular member. Fig. 1 & 2.
the second aligned radiopaque marker is positioned adjacent the distal end of said tubular member.	Lawrence discloses that a second aligned radioactive marker in the form of a Gianturco stent is positioned adjacent the distal end of the tubular member. Fig. 1 & 2.
35. An expandable intraluminal vascular graft for implanting in a	Non-limiting preamble. But, Lawrence discloses an expandable intraluminal

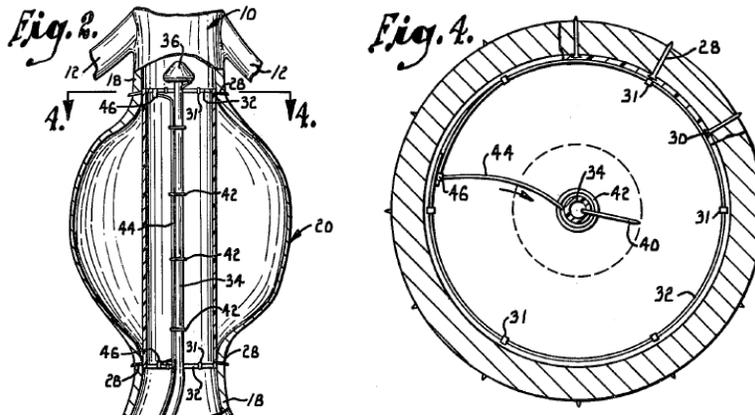
'728 Patent: Claims 1, 4-5, 9-15, 18, 28-30, & 33-35	Lawrence (Ex. 1003) in View of Charnsangavej (Ex. 1004)
body vessel having a wall, the graft comprising:	vascular graft for implanting in a body vessel having a wall. P. 357, col. 2, ¶2 (“intravascular placement of a Dacron graft, using multiple Gianturco stents”); Fig. 2.
conforming means for engrafting a body vessel, said conforming means having proximal and distal extremities; and	Lawrence discloses conforming means for engrafting a body vessel in the form of Dacron tubing. P. 357, col. 2, ¶3. The Dacron tube has proximal and distal extremities. Fig. 1.
attachment means secured to the proximal and distal extremities of said conforming means for engaging the body vessel, said attachment means being self-expanding and	Lawrence discloses attachment means secured to the proximal and distal extremities of the conforming means in the form of the lead and trail Gianturco stents, which are self-expanding stents and act as anchors for the graft, engaging the body vessel. P. 357, col. 2, ¶3; Fig. 1.
having engaging means for securing said conforming means to a wall of the body vessel.	Charnsangavej discloses the attachment means having engaging means (i.e. the attachment of barbs to Gianturco stents for securing to the body vessel when deployed. Charnsangavej, P. 295, col. 3, ¶3; P. 298, col. 1, ¶3; Fig. 1.

D. Ground 3: Claims 1, 4-5, 9-18, 28-30, and 33-35 of the '728 Patent Are Obvious Under § 103(a) Based on Choudhury or Kornberg, in View of Lawrence

1. Summary of Choudhury

Choudhury was filed on February 18, 1977, and issued on February 20, 1979. It is thus prior art to the IPR Claims under 35 U.S.C. § 102(b). Choudhury teaches an intraluminal graft for treating aneurysms. *See* Ex. 1005 at Abstract. The graft taught by Choudhury is an “elongated tube 24 which is moveable into a collapsed formation,” and which is made of a flexible material such as Dacron. *Id.*

at 2:23-28 & Fig. 2.



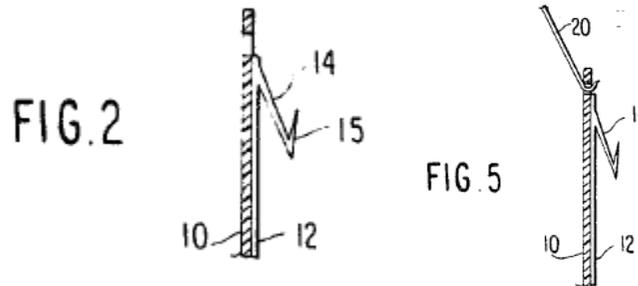
Anchor pins (28) are attached to each end of the tube (though not to any self-expanding spring means). *See id.* at 2:31-39. After positioning, the graft is mechanically expanded, causing the anchor pins to engage the vessel wall. *See id.* at 3:39:56 & Fig. 4.

2. Summary of the Kornberg Reference

Kornberg was filed on April 25, 1984, and issued on January 7, 1986. It is therefore prior art to the IPR claims under 35 U.S.C. § 102(b). Kornberg was **not** cited during prosecution of the '728 patent.

Kornberg teaches the use of an intraluminal graft to treat aortic aneurysms that “is specifically constructed for intraluminal insertion and comprising a flexible hollow, tubular material,” which was equipped with struts that had “angled hooks with barbs at their upper ends . . . thus allowing the graft to be securely attached to the inside of the aorta.” *See Ex. 1009 at Abstract; see also id.* at 1:6-8; 3:60-62. The hooks are engaged with the vessel wall by operation of a mechanical system.

Id. at 5:1-10 & Figs. 3, 4. Each hook (14) also has a barb (15) oriented in the opposite direction, so the hook and barb structure inhibits movement in either direction. *Id.* at 3:66-4:1 & Fig. 2.



3. A Person of Ordinary Skill in the Art Would Have Been Motivated to Combine Choudhury or Kornberg with Lawrence

Choudhury, Kornberg, and Lawrence are all directed to grafts for treating aortic aneurysms, and thus are all highly analogous art that address the same problems associated with deployment of an endovascular prosthesis. To the extent that the patentee is able to swear behind Lawrence, Charnsangavej (Ex. 1004) and Gianturco (Ex. 1007) similarly disclose the Gianturco stent from Lawrence for the purposes of these combinations.

As the '728 patent's prosecution history shows, the differences between Choudhury and the alleged invention of the '728 patent are minimal—the only allegedly distinguishing element is the inclusion of an expanding spring element in the IPR claims, which was well known in the field prior to March 1988. *See* Ex. 1028 ¶ 18. During prosecution, the examiner rejected issued claims 1, 28, and 35

as anticipated by Choudhury. *See* Ex. 1002 at 96. To overcome the rejection, the patentee argued that Choudhury's expansion ring (32) did not disclose the "expandable yieldable spring means" (claims 1 and 28) or "attachment means being self-expanding" (claim 35) limitations. *See id.* at 103-04. Relying on the patentee's argument, the examiner allowed claims 1, 28, and 35. *See id.* at 136. The examiner did not revisit Choudhury in combination with other references for claims 1, 28, and 35.

Similarly, the "expanding spring element" is the only limitation of the independent IPR claims that is arguably not present in Kornberg. *See* Ex. 1028 ¶¶ 112. Kornberg discloses the tubular member in the form of a graft material "capable of conforming to the interior contour of the wall portion of the artery into which it is inserted." Ex. 1009 at 2:58-62, 4:28-47 & Fig. 2. Kornberg also discloses the use of hooks and barbs attached to the support struts of the graft to inhibit movement. *See id.* at 3:66-4:1.

A person of ordinary skill in the art would have been motivated to combine the teaching of Lawrence to use a Gianturco stent to open the graft disclosed by Choudhury or Kornberg. *See* Ex. 1028 ¶¶ 113-16. Choudhury and Kornberg show that market and design pressures motivated persons of ordinary skill to explore different ways to open the graft: Choudhury used a wire and slip-ring system, *see* Ex. 1005 at 2:54-56, 3:39-42, while Kornberg used a lever system, *see* Ex. 1009 at

6:8-20. *See KSR*, 550 U.S. at 417-18. Another prior art embodiment, Palmaz, used a balloon catheter to expand the stent and graft. *See Ex. 1008* at 9:9-16.

Thus, combining the subsequently-introduced Gianturco stent with Choudhury or Kornberg to provide for a self-opening graft would have been obvious to a person of ordinary skill to try. *See id.*; *Ex. 1028 ¶¶ 113-17*. This combination would result in a predictable solution—namely that the Gianturco stent’s spring characteristics would serve to open the graft. *See KSR*, 550 U.S. at 416; *Ex. 1028 ¶ 117*. Indeed, the authors of Lawrence and Yoshioka used the Gianturco stent for this very purpose. *See Ex. 1003* at 357; *Ex. 1011* at 673.

All elements of the independent claims of the ’728 patent are disclosed by the obvious combination of Choudhury or Kornberg with the Gianturco stent of Lawrence. *See Ex. 1028 ¶ 119*. Thus, independent claims 1, 11, 28, and 35 of the ’728 patent are unpatentable as obvious under section 103.

The combination of Choudhury or Kornberg with the Gianturco stent of Lawrence also teaches each and every element of the dependent IPR claims. A number of dependent claims are drawn to features of the spring structure being self-expanding and comprising substantially straight legs joined to form “v”-shaped apices in a circular configuration. *See, e.g., Ex. 1001* at 14:25-35 (claims 2 and 3), 15:10-14 (claims 12 and 13), 16:31-34 (claim 29). The Gianturco stent used in Lawrence teaches all of these structural limitations. *See Ex. 1003* at 357 &

Fig. 1; Ex. 1007 at Figs. 1-2.

The Gianturco stent, by its construction, has apices in two planes and thus forms a “sinusoidal” shape. *See* Ex. 1028 ¶ 121; Ex. 1007 at Fig. 1. Therefore, the Gianturco stent used in Lawrence inherently discloses the limitations that the spring structure have apices that “lie in first and second planes spaced along a longitudinal axis of the graft” (claim 5), and be “sinusoidal in shape” (claim 18). *See* Ex. 1028 ¶ 121.

Claims 4, 14, and 30 further specify that the device include hooks attached either proximate the apices (claims 4 and 30) or to the legs of the spring structure (claim 14). A person of ordinary skill, when combining Choudhury or Kornberg with the Gianturco stent in Lawrence, would find it obvious to place the barbs or hooks on the legs of the Gianturco stent, near the apices. *See* Ex. 1028 ¶ 122. Indeed, in Kornberg, the hooks and barbs were placed on the leading edge of the support struts. *See* Ex. 1009 at 3:60-62. Furthermore, prior art attachments of barbs to the Gianturco stent in particular were proximate the apices. *See* Ex. 1004 at Fig. 1.

The combination of Choudhury or Kornberg with Lawrence, in light of the knowledge of the person of ordinary skill, would disclose all elements of claims 4-5, 12-15, and 29-31 of the '728 patent. Thus, those dependent claims are also unpatentable as obvious under section 103.

As discussed above, the internal stents of Lawrence disclose the radiopaque marker limitations. *See supra*, Section B.2. Kornberg further teaches using radiopaque material for the struts so that the device can be radiographically visualized. *See Ex. 1009 at 3:11-13.*

Claims 16 and 17 of the '728 patent are drawn to the angle of the hooks as between “about 55 degrees to about 80 degrees” (claim 16), or more specifically, “about 65 degrees” (claim 17). *See Ex. 1001 at 15:20-28.* Choudhury discloses anchor pins angled at 90 degrees. *See Ex. 1005 at 2:31-39 & Figs. 2, 4.* Kornberg teaches angling the hooks between 10 and 45 degrees. *See Ex. 1009 at 3:62-65.* Neither Choudhury nor Kornberg teach away from using angles between 45 and 90 degrees. *See Ex. 1028 ¶ 125.* Additional prior art teaches angling the hooks at an angle less than 90 degrees. *See Ex. 1017 (U.S. Patent No. 3,952,747) at 5:39-42 & Fig. 1; Ex. 1028 ¶ 124.* It would have been obvious to a person of ordinary skill to position the hooks or barbs at an angle between those disclosed by Choudhury and Kornberg to take advantage of the Gianturco stent’s physical properties. *See Ex. 1028 ¶ 125.* Thus, claims 16 and 17 of the '728 patent are unpatentable as obvious under section 103.

In sum, claims 1, 4-5, 9-18, 28-30, and 33-35 are unpatentable as obvious under section 103 over Kornberg or Choudhury in view of Lawrence.

<p>'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)</p>
<p>1. An expandable intraluminal vascular graft for implanting in a body vessel comprising</p>	<p>Non-limiting preamble. But, Choudhury teaches a graft for aneurysm repair. Abstract; 1:41-53. Similarly, Kornberg discloses an expandable intraluminal vascular graft for implanting in a body vessel. Abstract; 1:6-8.</p>
<p>a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends,</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26. Kornberg discloses a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends. 2:57-65; 6:54-59.</p>
<p>the wall being formed of a flexible material capable of receiving tissue ingrowth,</p>	<p>Choudhury discloses use of “a material such as Dacron which is known to be sufficiently biologically inert [sic] to permit safe insertion inside the human body.” 2:23-26. Choudhury also notes that the tube formed by the material is “moveable into a collapsed formation.” 2:26-31. Kornberg discloses the wall being formed of a material capable of receiving tissue ingrowth. 3:26-35.</p>
<p>said tubular member being capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position,</p>	<p>Choudhury discloses the graft being moveable into a collapsed position for insertion, and then expanded once the graft is positioned. 2:26-31, 3:39-46; Figs. 3-4. Kornberg discloses a tubular member that is capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position. Figs. 3-4, 8-9.</p>
<p>expandable yieldable spring means respectively secured to the proximal and distal ends of the tubular member,</p>	<p>Lawrence discloses expandable yieldable spring means in the form of Gianturco stents. P. 357, col. 2, ¶3. These stents were secured to both the proximal and distal ends of the tubular member. <i>Id.</i>; Fig. 1(b).</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)</p>
<p>said yieldable spring means urging said tubular member from said first position of reduced size to a second expanded position and</p>	<p>Lawrence discloses yieldable spring means that urge the tubular member from a first position of reduced size to a second expanded position in the form of the Gianturco stents that were connected to the Dacron graft. P. 357, col. 2, ¶3; Fig. 1.</p>
<p>attachment means secured to said expandable spring means for attachment to the body vessel.</p>	<p>Choudhury teaches the use of anchor pins designed to attach to the vessel wall and hold the graft in place. 3:44-46; Fig. 2. Kornberg discloses the use of barbs (14) attached to the elements (12) that provide support for the graft. 3:60-4:5; Figs. 1-2. In Lawrence, the elements that provide support are the Gianturco stents. Fig. 1. Thus, as the Loomis Declaration explains, it would have been obvious to one skilled in the art to combine the references and put barbs on the stent to aid attachment to the body vessel. Ex. 1028 ¶ 122.</p>
<p>4. A graft as in claim 3, wherein the attachment means is in the form of hook elements secured to the spring means proximate the apices of the vees.</p>	<p>Choudhury teaches the use of anchor pins designed to attach to the vessel wall and hold the graft in place. 3:44-46. The Loomis Declaration explains that a person of ordinary skilled in the art would have been motivated to include these hook elements proximate the apices of the vees of the attachment means of Lawrence. <i>See</i> Ex. 1028 ¶ 122. Similarly, Kornberg discloses hook elements secured to support means (which are analogous to the spring means in Lawrence) proximate the end of the support means. 3:60-4:5; Figs. 1-2. The Loomis Declaration explains that a person of ordinary skilled in the art would have been motivated to add hook elements near the vees of the spring means as this is at the proximal end of the graft. <i>See</i> Ex. 1028 ¶ 122.</p>

'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35	Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)
<p>5. A graft as in claim 4, wherein the apices of the vees of each of the expandable spring means lie in first and second planes spaced along a longitudinal axis of the graft.</p>	<p>Lawrence discloses the use of expandable spring means in the form of the Gianturco stent, which has apices in two planes spaced along the longitudinal axis of the stent. P. 357, col. 2, ¶2; Fig. 1.</p>
<p>9. A graft as in claim 1, further comprising radiopaque marker means secured to the wall of the tubular member, said marker means including first and second aligned radiopaque markers spaced apart longitudinally of the tubular member to permit ascertaining whether any twisting of the tubular member has occurred.</p>	<p>Lawrence discloses radiopaque marker means secured to the wall of the tubular member in the form of the stent itself. Fig. 2(a). There are multiple middle Gianturco stents that are attached to the Dacron graft. P. 357, col. 2, ¶3; Fig. 1. And, these stents are radiopaque and spaced longitudinally of the tubular member. Fig. 2. This permits ascertaining whether any twisting of the tubular member has occurred. Fig. 2.</p>
<p>10. A graft as in claim 9, wherein the first and second markers are positioned adjacent apices of the yieldable spring means.</p>	<p>Lawrence also discloses radiopaque markers in the form of stent struts and legs that are positioned adjacent apices of the yieldable spring means. Fig. 2.</p>
<p>11. A graft for emplacement by a balloon catheter, said graft comprising:</p>	<p>Non-limiting preamble. Deployment of an intraluminal device with a balloon catheter was well known to a person of ordinary skill in the art. <i>See, e.g.</i>, Palmaz, Ex. 1008; Loomis Decl.</p>
<p>a tubular member having a first end and a second end;</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26. Kornberg discloses a tubular member having a first end and a second end. 2:57-65; 6:54-59. Lawrence discloses a Dacron tube that has proximal and distal ends. P. 357, col. 2, ¶3; Fig. 1.</p>
<p>a first attachment system connected to and positioned proximate the first end of said</p>	<p>Kornberg teaches the use of flexible, resilient ring proximate the first end of the tubular member that springs open to contact the</p>

'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35	Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)
tubular member,	lumen wall. 4:6-15. Lawrence discloses a first attachment system in the form of the Gianturco stent which is positioned proximate the first end of the Dacron tube. P. 357, col. 2, ¶3 (“The lead and trail stents acted as anchors for the graft”); Fig. 1.
said first attachment system including a plurality of support members each having two legs joined to form an apex,	Lawrence discloses an attachment system in the form of the Gianturco stent which has a plurality of support members each having two legs to form an apex. P. 357, col. 2, ¶3; Fig. 1.
each leg being joined to the legs of adjacent support members to form a circular arrangement of the support members about a central axis	Lawrence discloses each leg of the attachment system (i.e. the Gianturco stent) being joined to the legs of adjacent support members to form a circular arrangement of the support members about a central axis. P. 357, col. 2, ¶3; Fig. 1.
and operable between a first collapsed position and a second expanded position; and	Choudhury discloses the graft being moveable into a collapsed position for insertion, and then expanded once the graft is positioned. 2:26-31, 3:39-46; Figs. 3-4. Kornberg discloses a tubular member that is capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position. Figs. 3-4, 8-9. Lawrence discloses that the Gianturco stent is operable between a first collapsed position and a second expanded position. P. 357, col. 3, ¶2; Fig. 1(c).
first wall engaging members connected to an[d] [sic] positioned proximate the first end of said tubular member.	Choudhury teaches the use of an attachment system in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4. Kornberg disclosed wall engaging members (14) connected to and positioned proximate the first end of the tubular member. 3:60-4:16;

'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35	Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)
	Fig. 1.
12. A graft as in claim 11, wherein said first attachment system is self-expanding.	Lawrence discloses the Gianturco stent, which is self-expanding. P. 357, col. 2, ¶2; Fig. 1.
13. A graft as in claim 12, wherein each of the legs of the support members are formed of a spring material and are substantially straight.	Lawrence discloses the Gianturco stent, which has legs of the support members that are formed of a spring material and are substantially straight. P. 357, col. 2, ¶2; Fig. 1.
14. A graft as in claim 13, wherein each of said first wall engaging members are secured to a respective on leg of one of the support members.	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4.</p> <p>Kornberg teaches the use of hooks and barbs as wall engaging members secured to the graft's support struts at the upper end of the struts. 3:60-62; Figs. 1-2.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have been motivated to place the anchor pins of Choudhury or the hooks of Kornberg on the legs of the support members of Lawrence for engagement with the vessel wall. <i>See</i> Ex. 1028 ¶ 122.</p>
15. A graft as in claim 14, wherein the support members are vee-shaped.	Lawrence discloses the Gianturco stent, as part of a graft, where those stents have vee-shaped support members. P. 357, col. 2, ¶2; Fig. 1.
16. A graft as in claim 15, wherein each of said first wall engaging members have tip portions extending at an angle from the central axis of about 55 degrees to about 80 degrees toward the second end of said tubular member.	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins angled at 90 degrees designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37.</p> <p>Kornberg discloses wall engaging members (14) that extend at an angle from the central axis of about 10 degrees to about 45 degrees.</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)</p>
	<p>3:62-65. The Loomis Declaration explains that a person of ordinary skilled in the art would have been motivated to angle wall engaging members at any angle between 10 and 90 degrees to anchor the graft, including at an angle from the central axis of about 55 degrees to about 80 degrees. <i>See</i> Ex. 1028 ¶ 125.</p>
<p>18. A graft as in claim 14, wherein the legs extend away from the apex so that said first attachment system is sinusoidal in shape.</p>	<p>Lawrence discloses legs in the Gianturco stent that extend away from the apex so that the first attachment system is sinusoidal in shape. Fig. 1(b).</p>
<p>28. An expandable intraluminal vascular graft comprising:</p>	<p>Non-limiting preamble. But, Choudhury teaches a graft for aneurysm repair. Abstract; 1:41-53. Similarly, Kornberg discloses a graft for intraluminal placement in a corporeal lumen. Abstract; 1:6-8.</p>
<p>a deformable tubular member having proximal and distal ends,</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26; Fig. 2. Kornberg discloses a deformable tubular member having proximal and distal ends. 2:57-65; 6:54-59.</p>
<p>said tubular member having a first reduced position and a second expanded position;</p>	<p>Choudhury discloses the graft being moveable into a collapsed position for insertion, and then expanded once the graft is positioned. 2:26-31, 3:39-46; Figs. 3-4. Kornberg discloses a tubular member that is capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position. Figs. 3-4, 8-9.</p>
<p>an expandable spring arrangement secured to the proximal and distal ends of the tubular member,</p>	<p>Lawrence discloses an expandable spring arrangement in the form of the Gianturco stents attached to the Dacron tubing. P. 357, col. 2, ¶3; Fig. 1.</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)</p>
<p>said expandable spring arrangement capable of urging said tubular member from the first reduced position to the second expanded position; and</p>	<p>Lawrence also discloses that the Gianturco stents are capable of urging the tubular member from the first reduced position to the second expanded position. P. 357, col. 3, ¶2; Fig. 1(c).</p>
<p>an attachment system secured to said expandable spring arrangement for securing said tubular member to a wall of a body vessel.</p>	<p>Choudhury teaches the use of anchor pins for securing a tubular member to a vessel wall. 2:31-37.</p> <p>Kornberg discloses the use of barbs (14) attached to the elements (12) that secure the tubular member of the graft to the wall. 3:60-4:5; Figs. 1-2.</p> <p>In Lawrence, the elements that provide support are the Gianturco stents. Fig. 1. The Loomis Declaration explains that a person of ordinary skilled in the art would have been motivated to combine the references and put barbs on the expandable spring arrangement of Lawrence to aid attachment to the body vessel. <i>See</i> Ex. 1028 ¶ 122.</p>
<p>29. A graft as in claim 28, wherein said expandable spring arrangement is in the form of substantially vee-shaped spring portions having apices with legs extending from the apices.</p>	<p>Lawrence discloses an expandable spring arrangement in the form of Gianturco stents. P. 357, col. 2, ¶3; Fig. 1. The Gianturco stents are in the form of substantially vee-shaped spring portions having apices with legs extending from the apices. P. 357, col. 2, ¶3; Fig. 1.</p>
<p>30. A graft as in claim 29, wherein said attachment system comprises wall engaging members secured to the legs of said expandable spring arrangement.</p>	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4.</p> <p>Kornberg discloses the use of wall engaging members of barbs (14) attached to the ends of the elements (12) that provide support for the graft. 3:60-4:5; Figs. 1-2.</p> <p>In Lawrence, the ends of the elements that provide support are the legs of the Gianturco stents. Fig. 1. The Loomis Declaration</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)</p>
	<p>explains that a person of ordinary skilled in the art would have been motivated to combine the references and put barbs on the legs of the stent to aid in attachment to the body vessel. <i>See</i> Ex. 1028 ¶ 122.</p>
<p>33. A graft as in claim 30, having a plurality of radiopaque markers secured to said tubular member, said markers including first and second aligned radiopaque markers spaced apart longitudinally of said tubular member.</p>	<p>Lawrence discloses a middle group of Gianturco stents that are secured to the tubular member (i.e. the Dacron graft). P. 357, col. 2, ¶3; Fig. 1. These stents are radiopaque and satisfy a plurality of radiopaque markers secured to the tubular member. Fig. 2. The markers include a first and second stent that are spaced apart longitudinally of said tubular member. Fig. 2.</p>
<p>34. A graft as in claim 33, wherein the first aligned radiopaque marker is positioned adjacent the proximal end of said tubular member and</p>	<p>Lawrence discloses that a first aligned radioactive marker in the form of a Gianturco stent is positioned adjacent the proximal end of the tubular member. Fig. 1 & 2.</p>
<p>the second aligned radiopaque marker is positioned adjacent the distal end of said tubular member.</p>	<p>Lawrence discloses that a second aligned radioactive marker in the form of a Gianturco stent is positioned adjacent the distal end of the tubular member. Fig. 1 & 2.</p>
<p>35. An expandable intraluminal vascular graft for implanting in a body vessel having a wall, the graft comprising:</p>	<p>Non-limiting preamble. But, Choudhury teaches an expandable graft for aneurysm repair. Abstract; 1:41-53. Kornberg discloses an expandable intraluminal vascular graft for implanting in a body vessel. Abstract; 1:6-8.</p>
<p>conforming means for engrafting a body vessel, said conforming means having proximal and distal extremities; and</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26; Fig. 2. Kornberg discloses conforming means (10) having proximal and distal extremities. 2:57-65; 6:54-59; Fig. 1.</p>
<p>attachment means secured to</p>	<p>Lawrence discloses attachment means</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 28-30, & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005), in View of Lawrence (Ex. 1003)</p>
<p>the proximal and distal extremities of said conforming means for engaging the body vessel, said attachment means being self-expanding and</p>	<p>secured to the proximal and distal extremities of the conforming means in the form of the lead and trail Gianturco stents, which are self-expanding stents and act as anchors for the graft, engaging the body vessel. P. 357, col. 2, ¶3; Fig. 1.</p>
<p>having engaging means for securing said conforming means to a wall of the body vessel.</p>	<p>Choudhury teaches the use of wall engaging means in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4.</p> <p>Kornberg discloses engaging means (14) for securing the conforming means (10) to a wall of the body vessel. 3:60-4:5; Figs. 1-2.</p> <p>The Loomis Declaration explains that a person of ordinary skilled in the art would have been motivated to add the Choudhury engaging means (in the form of anchoring pins) or the Kornberg engaging means (in the form of barbs) to the attachment means of Lawrence (i.e., the self-expanding Gianturco stents on either end of the conforming means). <i>See</i> Ex. 1028 ¶ 122.</p>

E. Ground 4: Claims 1, 4-5, 9-18, 23, 27-30, and 33-35 Are Obvious Under § 103(a) Over Kornberg or Choudhury in View of Charnsangavej

To the extent that the patent holder swears behind Lawrence or the Board finds Lawrence inapplicable, Charnsangavej can be substituted for Lawrence. The above discussion of Kornberg, Choudhury, and Lawrence are incorporated into this Ground. Like Lawrence, Charnsangavej teaches the use of the Gianturco stent, though to expand a narrowed, natural blood vessel rather than deploy a graft. *See*

Ex. 1004 at 295.

In light of Charnsangavej's use of the Gianturco stent to expand a compressed, natural blood vessel wall, the need for the expansion of a graft that had been compressed for insertion via a catheter would have motivated a person of ordinary skill to try the stent as a mode of expanding the graft material. *See* Ex. 1028 ¶ 128. Indeed, Lawrence and Yoshioka show that persons of ordinary skill **did** do so, and achieved the predictable result that the stent successfully expanded the graft. *See* Ex. 1003 at 357; Ex. 1011 at 675-76.

Charnsangavej also identifies the problem of migration, and advises the use of barbs to allow the device "to become affixed to the wall of the vessel" as it is deployed. *See* Ex. 1004 at 295, 298. Kornberg and Choudhury disclose grafts for performing intraluminal aneurysm repair, which likewise are equipped with either barbs or anchoring pins so as to anchor the device to the luminal wall but without a self-expanding mechanism. *See* Ex. 1009 at 1:6-8, 3:60-63; Ex. 1005 at 1:5-7, 2:21-39. These references are thus within the same field, addressing the same issue (repair of damaged body lumens) in the same way (utilizing an implanted endoprosthesis equipped with barbs or hooks to avoid unwanted migration of the device), so, a person of ordinary skill in the art would have been motivated to combine either Charnsangavej with either Kornberg or Choudhury. *See* Ex. 1028 ¶ 128. This is especially apparent in light of the contemporaneous research that

actually did use the barbs to prevent migration. *See id.* ¶ 129; Ex. 1011 at 675-76; Ex. 1010 at 1185-87.

For the foregoing reasons, and as discussed in greater detail below, the IPR claims are obvious under section 103 over these combinations.

'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35	Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)
<p>1. An expandable intraluminal vascular graft for implanting in a body vessel comprising</p>	<p>Non-limiting preamble. But, Choudhury teaches a graft for aneurysm repair. Abstract; 1:41-53.</p> <p>Kornberg discloses an expandable intraluminal vascular graft for implanting in a body vessel. Abstract; 1:6-8.</p>
<p>a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends,</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26.</p> <p>Kornberg discloses a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends. 2:57-65; 6:54-59.</p>
<p>the wall being formed of a flexible material capable of receiving tissue ingrowth,</p>	<p>Choudhury discloses use of “a material such as Dacron which is known to be sufficiently biologically inert [sic] to permit safe insertion inside the human body.” 2:23-26. Choudhury also notes that the tube formed by the material is “moveable into a collapsed formation.” 2:26-31.</p> <p>Kornberg discloses the wall being formed of a material capable of receiving tissue ingrowth. 3:26-35.</p>
<p>said tubular member being capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position,</p>	<p>Choudhury discloses the graft being moveable into a collapsed position for insertion, and then expanded once the graft is positioned. 2:26-31, 3:39-46; Figs. 3-4.</p> <p>Kornberg discloses a tubular member that is capable of assuming a first position of reduced size for insertion into the body vessel and a</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
	<p>second expanded position. Figs. 3-4, 8-9.</p>
<p>expandable yieldable spring means respectively secured to the proximal and distal ends of the tubular member,</p>	<p>Charnsangavej teaches use of the Gianturco stent, which is a self-expanding metallic spring. P. 295, col. 2, ¶ 2, 4. The Loomis Declaration explains that a person of ordinary skilled in the art would have been motivated to use the Gianturco stent in place of Choudhury's expansion ring (32) and Kornberg's mechanical expansion structure (16). <i>See</i> Ex. 1028 ¶ 130.</p>
<p>said yieldable spring means urging said tubular member from said first position of reduced size to a second expanded position and</p>	<p>Charnsangavej teaches the use of the Gianturco stent's self-expanding properties to "maintain patency" in a blood vessel. P. 295, col. 1, ¶ 1; P. 295, col. 2, ¶ 4.</p>
<p>attachment means secured to said expandable spring means for attachment to the body vessel.</p>	<p>Choudhury teaches the use of anchor pins designed to attach to the vessel wall and hold the graft in place. 3:44-46; Fig. 2. Kornberg discloses the use of barbs (14) attached to the elements (12) that provide support for the graft. 3:60-4:5; Figs. 1-2. Charnsangavej teaches barbs attached to the stent "which allowed the stent to become affixed to the wall of the vessel as it was released from the catheter." P. 295, col. 3, ¶ 3.</p>
<p>4. A graft as in claim 3, wherein the attachment means is in the form of hook elements secured to the spring means proximate the apices of the vees.</p>	<p>Choudhury teaches the use of hook elements in the form of anchor pins designed to attach to the vessel wall and hold the graft in place. 3:44-46. Similarly, Kornberg discloses hook elements secured to support means proximate the end of the support means. 3:60-4:5; Figs. 1-2. The Loomis Declaration explains that it would have been obvious to one having skill in the art to add hook elements near the vees of the spring means as this is at the proximal end of the graft. <i>See</i> Ex. 1028 ¶ 130.</p>

'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35	Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)
<p>5. A graft as in claim 4, wherein the apices of the vees of each of the expandable spring means lie in first and second planes spaced along a longitudinal axis of the graft.</p>	<p>Charnsangavej teaches use of the Gianturco stent, which has apices in first and second planes. Fig. 1.</p>
<p>9. A graft as in claim 1, further comprising radiopaque marker means secured to the wall of the tubular member, said marker means including first and second aligned radiopaque markers spaced apart longitudinally of the tubular member to permit ascertaining whether any twisting of the tubular member has occurred.</p>	<p>Charnsangavej teaches use of multiple Gianturco stents made of radiopaque stainless steel, which would permit ascertaining whether twisting has occurred. P. 295, col. 3, ¶ 3; Figs. 1-3.</p> <p>Additionally, Kornberg discusses the desirability of using struts made of radiopaque materials to permit ascertaining whether any twisting of the tubular member has occurred. 4:23-27.</p>
<p>10. A graft as in claim 9, wherein the first and second markers are positioned adjacent apices of the yieldable spring means.</p>	<p>Charnsangavej teaches use of multiple Gianturco stents made of radiopaque stainless steel, which would permit ascertaining whether twisting has occurred. P. 295, col. 3, ¶ 3; Figs. 1-3.</p>
<p>11. A graft for emplacement by a balloon catheter, said graft comprising:</p>	<p>Non-limiting preamble. Deployment of an intraluminal device with a balloon catheter was well known to a person of ordinary skill in the art. <i>See</i> Palmaz, Ex. 1008; Ex. 1028 ¶ 10.</p>
<p>a tubular member having a first end and a second end;</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26.</p> <p>Kornberg discloses a tubular member having a first end and a second end. 2:57-65; 6:54-59.</p>
<p>a first attachment system connected to and positioned proximate the first end of said tubular member,</p>	<p>Charnsangavej teaches use of the Gianturco stent, which attaches to the vessel wall. P. 295, col. 3, ¶ 3.</p> <p>Kornberg teaches the use of flexible, resilient ring proximate the first end of the tubular member that springs open to contact the</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
	<p>lumen wall. 4:6-15. The Loomis Declaration explains that a person of skill in the art would have known to place the attachment system of Charnsangavej proximate the first end of the tubular member of either Choudhury or Kornberg. <i>See Ex. 1028 ¶</i>.</p>
<p>said first attachment system including a plurality of support members each having two legs joined to form an apex,</p>	<p>Charnsangavej teaches use of the Gianturco stent, which is comprised of a plurality of support members with two legs joined to form an apex. P. 295, col. 3, ¶ 3; Fig. 1.</p>
<p>each leg being joined to the legs of adjacent support members to form a circular arrangement of the support members about a central axis</p>	<p>Charnsangavej teaches use of the Gianturco stent, which comprises support members joined to form a circular arrangement about a central axis. P. 295, col. 3, ¶ 3; Fig. 1.</p>
<p>and operable between a first collapsed position and a second expanded position; and</p>	<p>Choudhury discloses the graft being moveable into a collapsed position for insertion, and then expanded once the graft is positioned. 2:26-31, 3:39-46; Figs. 3-4. Kornberg discloses a tubular member that is capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position. Figs. 3-4, 8-9.</p>
<p>first wall engaging members connected to an[d] [sic] positioned proximate the first end of said tubular member.</p>	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4. Kornberg discloses wall engaging members (14) connected to and positioned proximate the first end of the tubular member. 3:60-4:16; Fig. 1.</p>
<p>12. A graft as in claim 11, wherein said first attachment system is self-expanding.</p>	<p>Charnsangavej teaches use of the “Gianturco expandable metallic stent” that self-expands upon release from a catheter. P. 295, col. 2, ¶ 2; Fig. 3.</p>

'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35	Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)
<p>13. A graft as in claim 12, wherein each of the legs of the support members are formed of a spring material and are substantially straight.</p>	<p>Charnsangavej discloses the use of the Gianturco stent, which has legs formed of stainless steel spring material and are substantially straight. P. 295, col. 2, ¶ 2; Fig. 1.</p>
<p>14. A graft as in claim 13, wherein each of said first wall engaging members are secured to a respective on leg of one of the support members.</p>	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4.</p> <p>Kornberg discloses wall engaging members (14) in the form of hooks with barbs at their upper ends. 3:60-4:16; Figs. 2, 5.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have known to place the engaging members of Choudhury or Kornberg on the legs of the support members of Lawrence for engagement with the vessel wall. <i>See Ex. 1028 ¶ 130.</i></p>
<p>15. A graft as in claim 14, wherein the support members are vee-shaped.</p>	<p>Charnsangavej teaches the use of the Gianturco stent, which has vee-shaped support members. P. 295, col. 2, ¶ 2; Fig. 1.</p>
<p>16. A graft as in claim 15, wherein each of said first wall engaging members have tip portions extending at an angle from the central axis of about 55 degrees to about 80 degrees toward the second end of said tubular member.</p>	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37.</p> <p>Kornberg discloses wall engaging members (14) that extend at an angle from the central axis of about 10 degrees to about 45 degrees. 3:62-65.</p> <p>The Loomis Declaration explains that it would have been obvious to one having skill in the art to angle wall engaging members at any angle between 10 and 90 degrees to anchor the graft. <i>See Ex. 1028 ¶ 124.</i></p>
<p>17. A graft as in claim 15, wherein each of said first wall</p>	<p>Choudhury teaches the use of an attachment system in the form of anchor pins designed to</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
<p>engaging members are attached to a leg of a support members and have tip portions extending at an angle from the central axis of about 65 degrees toward the second end of said tubular member.</p>	<p>attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37.</p> <p>Kornberg discloses wall engaging members (14) that extend at an angle from the central axis of about 10 degrees to about 45 degrees. 3:62-65.</p> <p>The Loomis Declaration explains that a person having ordinary skill in the art would have been motivated to angle wall engaging members at any angle between 10 and 90 degrees to anchor the graft. <i>See</i> Ex. 1028 ¶ 124.</p>
<p>18. A graft as in claim 14, wherein the legs extend away from the apex so that said first attachment system is sinusoidal in shape.</p>	<p>Charnsangavej teaches the use of the Gianturco stent, which has legs extending away from apices such that the attachment system is sinusoidal in shape. P. 295, col. 2, ¶ 2; Fig. 1.</p>
<p>23. A graft for intraluminal placement in a corporeal lumen, said graft comprising:</p>	<p>Non-limiting preamble. But, Choudhury teaches a graft for aneurysm repair. Abstract; 1:41-53.</p> <p>Also, Kornberg discloses a graft for intraluminal placement in a corporeal lumen. Abstract; 1:6-8.</p>
<p>a tubular member having a first end and a second end;</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26.</p> <p>Kornberg discloses a deformable tubular member having proximal and distal ends. 2:57-65; 6:54-59.</p>
<p>a first attachment system positioned proximate the first end of said tubular member,</p>	<p>Charnsangavej teaches use of the Gianturco stent as a first attachment system, which is comprised of support members with two legs joined to form an apex. P. 295, col. 3, ¶ 3; Fig. 1. The Loomis Declaration explains that a person of skill in the art would have recognized that when combined with the tubular member of Choudhury or Kornberg, the Gianturco stent</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
	<p>should be placed proximate the first end of the tubular member. Ex. 1028 ¶ 130.</p>
<p>said first attachment system including a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement;</p>	<p>The Gianturco stent of Charnsangavej, which is used as the first attachment system, includes a plurality of legs joined by a plurality of apices and the legs are configured in a circular arrangement. Fig. 1.</p>
<p>and a second attachment system positioned proximate the second end of said tubular member,</p>	<p>Choudhury teaches the desirability of attachment systems on both ends of the tubular graft. 2:26-39. Charnsangavej teaches use of the Gianturco stent as a first attachment system, which is comprised of support members with two legs joined to form an apex. P. 295, col. 3, ¶ 3; Fig. 1. The Loomis Declaration explains that a person of skill in the art would have recognized that when combined with the tubular member of Choudhury or Kornberg, a second Gianturco stent should be placed proximate the second end of the tubular member. Loomis Decl. ¶ 130.</p>
<p>said second attachment system including a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement.</p>	<p>The Gianturco stent of Charnsangavej, which is used as the second attachment system, also includes a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement. Fig. 1. Choudhury teaches the desirability of having attachment systems on both ends of the graft. 2:24-39.</p>
<p>27. The graft of claim 23, further comprising a plurality of radiopaque markers secured to said tubular member.</p>	<p>Charnsangavej teaches use of multiple Gianturco stents made of radiopaque stainless steel. P. 295, col. 3, ¶ 3; Figs. 1-3. Kornberg discusses the desirability of using struts (12) made of radiopaque materials. 4:23-27; Fig. 1.</p>
<p>28. An expandable intraluminal vascular graft</p>	<p>Non-limiting preamble. But, Choudhury teaches a graft for aneurysm repair. Abstract;</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
<p>comprising:</p>	<p>1:41-53. Kornberg similarly teaches a graft for aneurysm repair. 1:6-8.</p>
<p>a deformable tubular member having proximal and distal ends,</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26; Fig. 2. Kornberg discloses a deformable tubular member having proximal and distal ends. 2:57-65; 6:54-59.</p>
<p>said tubular member having a first reduced position and a second expanded position;</p>	<p>Choudhury discloses the graft being moveable into a collapsed position for insertion, and then expanded once the graft is positioned. 2:26-31, 3:39-46; Figs. 3-4. Kornberg discloses a tubular member that is capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position. Figs. 3-4, 8-9.</p>
<p>an expandable spring arrangement secured to the proximal and distal ends of the tubular member,</p>	<p>Charnsangavej teaches the use of the Gianturco expandable metallic stent, which is an expandable spring arrangement. P. 295, col. 2, ¶ 2.</p>
<p>said expandable spring arrangement capable of urging said tubular member from the first reduced position to the second expanded position; and</p>	<p>Charnsangavej teaches the use of the Gianturco expandable metallic stent, that is capable of collapsed and expanded positions, and thus is capable of urging a tubular member from the first reduced position to the second expanded position. P. 295, col. 2, ¶2; Fig. 1.</p>
<p>an attachment system secured to said expandable spring arrangement for securing said tubular member to a wall of a body vessel.</p>	<p>Choudhury teaches the use of an attachment system in the form of anchor pins designed to secure the tubular member to the vessel wall. 2:31-37. Kornberg discloses the use of barbs (14) attached to the elements (12) to secure the tubular member to the vessel wall. 3:60-4:5; Figs. 1-2. Charnsangavej teaches use of the Gianturco stent, which is a self-expanding metallic spring. The Loomis Declaration explains that a person</p>

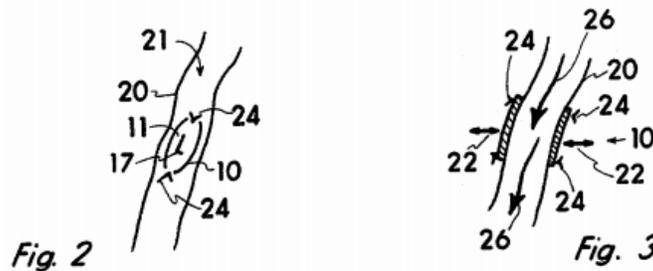
<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
	<p>of ordinary skill would have known to use the Gianturco stent in place of Choudhury's expansion ring (32) and Kornberg's mechanical expansion structure (16). <i>See</i> Ex. 1028 ¶ 130. Thus, the attachment systems of Choudhury and Kornberg are secured to the expandable spring arrangement of Charnsangavej.</p>
<p>29. A graft as in claim 28, wherein said expandable spring arrangement is in the form of substantially vee-shaped spring portions having apices with legs extending from the apices.</p>	<p>Charnsangavej teaches the use of the Gianturco stent as an expandable spring arrangement, which has vee-shaped spring portions with apices and legs. P. 295, col. 2, ¶ 2; Fig. 1.</p>
<p>30. A graft as in claim 29, wherein said attachment system comprises wall engaging members secured to the legs of said expandable spring arrangement.</p>	<p>Choudhury teaches the use of wall engaging members in the form of anchor pins designed to attach to the vessel wall and hold the graft in place that are secured to a plate integral with the graft. 2:31-37; Figs. 2, 4.</p> <p>Kornberg discloses the use wall engaging members in the form of barbs (14) attached to the ends of the elements (12) that provide support for the graft. 3:60-4:5; Figs. 1-2.</p> <p>Charnsangavej teaches the attachment of barbs to the legs of Gianturco stent (which in this combination, is the attachment system) to prevent migration. P. 295, col. 3, ¶ 3; Fig. 1.</p>
<p>33. A graft as in claim 30, having a plurality of radiopaque markers secured to said tubular member, said markers including first and second aligned radiopaque markers spaced apart longitudinally of said tubular member.</p>	<p>Charnsangavej teaches use of multiple Gianturco stents made of radiopaque stainless steel, which would permit ascertaining whether twisting has occurred. P. 295, col. 3, ¶ 3; Figs. 1-3.</p> <p>Kornberg discusses the desirability of using struts (12) made of radiopaque materials. 4:23-27; Fig. 1.</p>
<p>34. A graft as in claim 33, wherein the first aligned radiopaque marker is</p>	<p>Kornberg discusses the desirability of using struts (12) made of radiopaque materials, the tips of which are positioned adjacent the</p>

<p>'728 Patent: Claims 1, 4-5, 9-18, 23, 27-30 & 33-35</p>	<p>Kornberg (Ex. 1009) or Choudhury (Ex. 1005) in View of Charnsangavej (Ex. 1004)</p>
<p>positioned adjacent the proximal end of said tubular member and</p>	<p>proximal end of the tubular member. 4:23-27; Fig. 1.</p>
<p>the second aligned radiopaque marker is positioned adjacent the distal end of said tubular member.</p>	<p>Kornberg discusses the desirability of using struts (12) made of radiopaque materials, the tips of which are positioned adjacent the distal end of the tubular member. 4:23-27; Fig. 1.</p>
<p>35. An expandable intraluminal vascular graft for implanting in a body vessel having a wall, the graft comprising:</p>	<p>Non-limiting preamble. But, Choudhury teaches an expandable graft for aneurysm repair. Abstract; 1:41-53. Kornberg discloses an expandable intraluminal vascular graft for implanting in a body vessel. Abstract; 1:6-8.</p>
<p>conforming means for engrafting a body vessel, said conforming means having proximal and distal extremities; and</p>	<p>Choudhury discloses a graft constructed of material such as Dacron that “comprises an elongated tube 24.” 2:23-26; Fig. 2. Kornberg discloses conforming means (10) having proximal and distal extremities. 2:57-65; 6:54-59; Fig. 1.</p>
<p>attachment means secured to the proximal and distal extremities of said conforming means for engaging the body vessel, said attachment means being self-expanding and</p>	<p>Charnsangavej teaches use of the Gianturco stent and using the self-expanding characteristics of the stent to conform to the body vessel. P. 295, col. 2, ¶ 2; Fig. 1.</p>
<p>having engaging means for securing said conforming means to a wall of the body vessel.</p>	<p>Choudhury teaches the use of engaging means in the form of anchor pins designed to securing the conforming means (i.e., the tubular, flexible graft) to the vessel wall. 2:31-37; Figs. 2, 4. Kornberg discloses engaging means (14) for securing the conforming means (10) to a wall of the body vessel. 3:60-4:5; Figs. 1-2.</p>

F. Ground 5: Claims 9-10, 27, and 33-34 of the '728 Patent Are Invalid Under 35 U.S.C. § 103 as Obvious Over the Above References in View of Jones and Sharrow

1. Summary of the Jones Reference

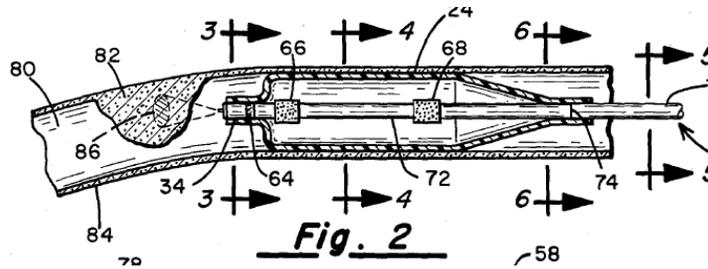
Jones was filed April 24, 1978 and issued May 13, 1980. Jones is therefore prior art to the IPR claims under 35 U.S.C. § 102(b). Jones teaches the use of at least two radiopaque markers (10) sutured to graft material, conveying the relative positions of the markers. *See* Ex. 1006 at 3:17-25 & Figs. 2-3.



This allows the markers to indicate whether the walls are expanding and contracting consistently with blood flowing through the vessel (the movement would be in the directions of arrows 22). *See id.*

2. Summary of the Sharrow Reference

Sharrow was filed on April 24, 1987 and issued on December 27, 1988. Sharrow discloses the use of two radiopaque markers (66, 68) on opposite ends of a balloon catheter to indicate its position and length. *See* Ex. 1014 at 3:68-4:8 & Fig. 2. The two markers at the ends of the device allow the user to determine the length of the balloon when in the artery, and can be used relative to the additional marker (64) on the device to ensure proper alignment and positioning. *See id.*



3. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Jones and Sharrow with the Combinations in Grounds 2-4

To the extent that the patent holder swears behind Lawrence or the Board determines that Lawrence or Kornberg does not disclose radiopaque markers, Jones and Sharrow serve as alternative references that teach the plurality of radiopaque markers recited in claims 9-10, 27, and 33-34 of the '728 patent.

Radiopaque markers were well-known in the art, and were regularly used on intraluminal devices. *See* Ex. 1028 ¶ 135. Prior art examples of radiopaque markers and materials can be found in U.S. Patent No. 4,503,568 to Madras (Ex. 1022); U.S. Patent No. 4,740,207 to Kreamer (Ex. 1023); U.S. Patent No. 4,041,931 to Elliott et al. (Ex. 1024); and U.S. Patent No. 4,693,237 to Hoffman et al. (Ex. 1025).

Claim 27 requires “a plurality of radiopaque markers secured to said tubular member.” Ex. 1001 at 16:16-17. Both Sharrow and Jones teach a plurality of radiopaque markers attached to a graft. *See* Ex. 1006 at 2:52-57, 3:5-8; Ex. 1014 at 3:68-4:8. It would have been obvious to a person of ordinary skill to combine the

radiopaque markers of these references with the device of claim 23 to aid in visualization of the device. Ex. 1028 ¶ 136.

Claims 9-10 and 33-34 recite two pairs of radiopaque markers. Jones teaches the use of two radiopaque markers and the measurement of their relative position to convey information about the graft beyond mere positioning. *See* Ex. 1006 at 1:67-2:25, 3:22-25. Sharrow also teaches the use of two radiopaque markers to verify the length of an intraluminal device in the lumen. *See* Ex. 1014 at 3:68-4:8 & Fig. 2. While each of Jones and Sharrow only teaches the use of one pair, it would have been obvious to a person of ordinary skill to use both the length-indicating pair of Sharrow and the width-indicating pair of Jones to convey both length and width. Ex. 1028 ¶¶ 137-139.

Claims 10 and 34 further require that the radiopaque markers be placed near the apices of the spring element (claim 10) or near the ends of the tubular graft material (claim 34). Sharrow teaches the placement of the radiopaque markers near the ends of the device—which would be near the apices—so that the markers serve as indicators of the device’s length. *See* Ex. 1014 at 3:68-4:8. It would have been obvious to place markers by the ends of the device. *See* Ex. 1028 ¶ 140.

Thus, claims 9-10, 27, and 33-34 are obvious under Section 103.

'728 Patent: Claims 9-10, 27, & 33-34	Combinations with Jones (Ex. 1006)
9. A graft as in claim 1, further comprising radiopaque	As discussed above, all elements of claim 1 are taught by Lawrence with Charnsangavej;

'728 Patent: Claims 9-10, 27, & 33-34	Combinations with Jones (Ex. 1006)
<p>marker means secured to the wall of the tubular member, said marker means including first and second aligned radiopaque markers spaced apart longitudinally of the tubular member to permit ascertaining whether any twisting of the tubular member has occurred.</p>	<p>Kornberg or Choudhury in view of Lawrence; or Kornberg or Choudhury in view of Charnsangavej.</p> <p>Jones teaches the use of at least two radiopaque markers attached to the tubular graft material. 3:5-11; Figs. 2-3. The markers are used to illustrate relative position of the two walls of the graft. 3:18-23.</p> <p>Sharrow teaches the use of two radiopaque markers attached to a balloon spaced longitudinally apart to convey length. 3:68-4:8 & Fig. 2.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have been motivated to use the additional markers disclosed in Jones and Sharrow spaced longitudinally apart to convey information regarding the relative positions and orientation of the graft material taught by the above prior art references. Ex. 1028 ¶¶ 137-39.</p>
<p>10. A graft as in claim 9, wherein the first and second markers are positioned adjacent apices of the yieldable spring means.</p>	<p><i>See</i> above discussion of claim 9.</p> <p>Sharrow teaches the placement of radiopaque markers on the proximal and distal ends of the device to convey length. 3:68-4:8; Fig. 2.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have known to place the radiopaque markers taught by Jones adjacent to apices of the spring means on each end of the graft, so as to provide for more precise positioning of the device <i>in vivo</i>. Ex. 1028 ¶¶ 140.</p>
<p>27. The graft of claim 23, further comprising a plurality of radiopaque markers secured to said tubular member.</p>	<p>As discussed above, either Lawrence; Lawrence with Charnsangavej; Kornberg or Choudhury in view of Lawrence; or Kornberg or Choudhury in view of Charnsangavej to disclose all elements of claim 23.</p> <p>The Loomis Declaration explains that a</p>

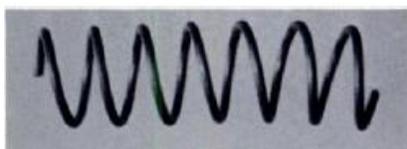
'728 Patent: Claims 9-10, 27, & 33-34	Combinations with Jones (Ex. 1006)
	<p>person of ordinary skill would have been motivated to use the additional markers disclosed in Jones and Sharrow spaced longitudinally apart to convey information regarding the relative positions and orientation of the graft material taught by the above prior art references. Ex. 1028 ¶ 136.</p>
<p>33. A graft as in claim 30, having a plurality of radiopaque markers secured to said tubular member, said markers including first and second aligned radiopaque markers spaced apart longitudinally of said tubular member.</p>	<p>As discussed above, all elements of claim 30 are taught by Lawrence with Charnsangavej; Kornberg or Choudhury in view of Lawrence; or Kornberg or Choudhury in view of Charnsangavej.</p> <p>Jones teaches the use of at least two radiopaque markers attached to the tubular graft material. 3:5-11; Figs. 2-3. The markers are used to illustrate relative position of the two walls of the graft. 3:18-23.</p> <p>Sharrow teaches the use of two radiopaque markers attached to a balloon spaced longitudinally apart to convey length. 3:68-4:8 & Fig. 2.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have known to use these additional markers taught by Jones spaced longitudinally apart to convey information regarding the relative positions and orientation of the graft material. Ex. 1028 ¶¶ 137-39.</p>
<p>34. A graft as in claim 33, wherein the first aligned radiopaque marker is positioned adjacent the proximal end of said tubular member and the second aligned radiopaque marker is positioned adjacent the distal end of said tubular member.</p>	<p><i>See</i> above discussion of claim 33.</p> <p>Sharrow teaches the placement of radiopaque markers on the proximal and distal ends of the device to convey length. 3:68-4:8; Fig. 2.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have known to place the radiopaque markers taught by Jones adjacent to the proximal and distal ends of the graft, so as to provide for more precise</p>

'728 Patent: Claims 9-10, 27, & 33-34	Combinations with Jones (Ex. 1006)
	positioning of the device <i>in vivo</i> . Ex. 1028 ¶ 140.

G. Ground 6: Claims 2-3 and 31 Are Invalid Under 35 U.S.C. § 103 as Obvious Over the Above References in View of Dotter

1. Summary of the Dotter Reference

Dotter was published in April 1983, and shows the use of a helical spring structure in medical devices. *See* Ex. 1016 at Fig. 1.



Dotter specifically notes that the use of “tubular coiled wire stent grafts was first described in a 1969 report from this laboratory.” *See id.* at 259.

2. A Person Having Ordinary Skill in the Art Would Have Been Motivated to Combine Dotter with the Combinations in Grounds 2-4

Coil or helical spring arrangements were well known to medical device designers in March 1988. *See, e.g.*, Ex. 1020 at 8:31-32. Prior art examples of helical coil springs include U.S. Patent No. 4,665,906 to Jervis (Ex. 1020) and U.S. Patent No. 4,800,882 to Gianturco (Ex. 1021). Helical coil springs were also long in use in everyday items, such as safety pins, to allow two legs joined at a vee to be resiliently compressed, and then to urge the legs apart upon removal of the compression force. *See* Ex. 1015 (U.S. Patent No. 2,104,880) at 2:27-34, 3:9-23 &

Figs. 1-2, 4; Ex. 1028 ¶ 145.

The '728 patent recites limitations of “a helical torsion spring” (claim 2), “coil spring means” (claim 3), or “a coil spring arrangement” (claim 31) at the apices of the vees. A person of ordinary skill would have been motivated to substitute a helical coil spring, as shown in Dotter or as used in a safety pin, with the teachings of the above combinations to achieve the helical coil spring at the apices. *See* Ex. 1028 ¶ 146.

'728 Patent: Claims 2-3, and 31	Combinations with Dotter (Ex. 1016)
<p>2. A graft as in claim 1 wherein said expandable spring means is in the form of substantially vee-shaped spring portions having apices and legs extending from the apices, the spring means having a helical torsion spring at each apex yieldably urging said legs in a direction to open the vee-shaped spring portions.</p>	<p>As discussed above, all elements of claim 1 are taught by Lawrence with Charnsangavej; Kornberg or Choudhury in view of Lawrence; or Kornberg or Choudhury in view of Charnsangavej.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have known to use the helical coil spring structure taught by Dotter at the apices of the vees to aid in the resiliently compressible character of the expandable spring means. Ex. 1028 ¶ 146.</p>
<p>3. A graft as in claim 1, wherein said expandable spring means includes a plurality of interconnected vees with each vee having an apex and</p>	<p><i>See</i> above discussion of claim 2.</p> <p>The combinations discussed above would also yield an expandable spring means including a plurality of interconnected vees and apices in the form of a Gianturco stent.</p>
<p>with coil spring means formed at each apex serving to expand the vees in an outward direction along the plane of each of the vees.</p>	<p>The Loomis Declaration explains that a person of ordinary skill would have known to use the helical coil spring structure taught by Dotter at the apices of the vees to aid in the resiliently compressible character of the expandable spring means. Ex. 1028 ¶ 146.</p>

'728 Patent: Claims 2-3, and 31	Combinations with Dotter (Ex. 1016)
<p>31. A graft as in claim 30, wherein each of the apices of said expandable spring arrangement comprise a coil spring arrangement.</p>	<p>As discussed above, all elements of claim 30 are taught by Lawrence with Charnsangavej; Kornberg or Choudhury in view of Lawrence; or Kornberg or Choudhury in view of Charnsangavej.</p> <p>The Loomis Declaration explains that a person of ordinary skill would have known to use the helical coil spring structure taught by Dotter at the apices of the vees to aid in the resiliently compressible character of the expandable spring means. Ex. 1028 ¶ 146.</p>

VII. CONCLUSION

For the foregoing reasons, *inter partes* review of the IPR Claims is respectfully requested, followed by the rejection of the IPR Claims on each of the bases detailed in this Petition.

Respectfully Submitted,

December 20, 2013
Date

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§ 42.6(e) - CERTIFICATION OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105 on the Patent Owner of a copy of this Petition for *Inter Partes* Review and supporting materials at the corresponding address of record for the '728 patent:

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The undersigned further certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105 to the Patent Owner of a copy of this Petition for *Inter Partes* Review and supporting materials at the address of counsel in Case No. 1:12-cv-1793, filed December 28, 2012, in the United States District Court for the District of Delaware:

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