Paper 10

Entered: June 25, 2014

# UNITED STATES PATENT AND TRADEMARK OFFICE

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#### BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC., Petitioner,

v.

LIFEPORT SCIENCES LLC, Patent Owner.

Case IPR2014-00284 Patent 5,562,728

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Before LORA M. GREEN, SCOTT E. KAMHOLZ, and BARBARA A. BENOIT, *Administrative Patent Judges*.

BENOIT, Administrative Patent Judge.

DECISION Institution of *Inter Partes* Review 37 C.F.R. § 42.108

#### I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Petitioner") filed a corrected petition (Paper 7, "Pet.") requesting an *inter partes* review of claims 1-5, 9-18, 23, 27-31, and 33-35 of U.S. Patent No. 5,562,728 (Ex. 1001, "the '728 patent"). Patent Owner, Lifeport Sciences LLC, filed a preliminary response (Paper 9, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

THRESHOLD—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the petition and the preliminary response, we determine that the information presented in the petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claims 1-3, 9-18, 23, 27-31, and 33-35 of the '728 patent, but not with respect to claims 4 and 5. Accordingly, pursuant to 35 U.S.C. § 314, we authorize an *inter partes* review to be instituted as to claims 1-3, 9-18, 23, 27-31, and 33-35 of the '728 patent.

#### A. Related Matters

Petitioner indicates that the '728 patent was asserted in *LifePort Sciences LLC v. Medtronic, Inc.*, Case No. 1:12-cv-1793 (D. Del.) and

LifePort Sciences LLC v. W.L. Gore & Associates, Inc., Case No. 1:12-cv-1792 (D. Del.). Pet. 1; see also Paper 5 (Patent Owner's Mandatory Notice).

#### B. The '728 Patent

The '728 patent, titled "Endovascular Grafting Apparatus, System and Method and Devices for Use Therewith," issued October 8, 1996, from an application filed on April 12, 1995. The '728 patent relates to an expandable, tubular endovascular graft that can assume two different configurations—a reduced position for insertion into the body and a second, expanded position for use when attached to a wall of a body vessel. *See* Ex. 1001, 9:37-50, 14:16-20, 15:5-7, 16:20-22. The graft may be used, for example, to strengthen the vessel of a patient in which an aneurysm has occurred. *See, e.g., id.* at 11:7-15, 13:3-9.

Figure 10 of the '728 patent is set forth below:

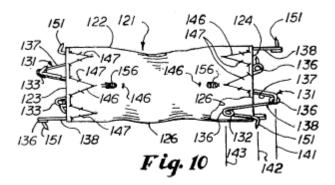


Figure 10 illustrates a side elevational view of a graft for implanting into a body vessel. Ex. 1001, 2:25-26, 8:5-7. Graft 121 consists of deformable tubular member 122 with wall 126 extending between two ends 123, 124. *Id.* at 8:7-11. Expandable spring means 131 is provided on each end 123, 124 and serves to urge tubular member 122 from a compressed or collapsed

position to an expanded position. *Id.* at 8:22-27. Expandable spring means 131 consists of interconnected vees 132, with apices 133 of the vees 132 formed with helical coil springs 136 between legs 137, 138 of each vee. *Id.* at 8:27-29. Helical coil springs 136 of expandable spring means 131 yieldably urge legs 137, 138 of each of the vees 132 "outwardly at a direction at right angles to the plane in which each of the vees lie." *Id.* at 8:27-32. Expandable spring means 131 is secured to ends 123, 124 of tubular member 122 by suture material 146. *Id.* at 8:43-56. Hook-like elements 151 are provided on some apices of some vees of spring means 131 for attachment to the body vessel. *Id.* at 8:57-67.

#### C. Illustrative Claims

Independent claims 1, 11, 23, 28, and 35 relate to an expandable intraluminal vascular graft (independent claims 1, 28, and 35), a graft for emplacement by a balloon catheter (independent claim 11), and a graft for intraluminal placement in a corporeal lumen (claim 23). Claims 1 and 23, reproduced below, are illustrative of the claimed subject matter:

1. An expandable intraluminal vascular graft for implanting in a body vessel comprising a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends, the wall being formed of a flexible material capable of receiving tissue ingrowth, said tubular member being capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position, expandable yieldable spring means respectively secured to the proximal and distal ends of the tubular member, said yieldable spring means urging said tubular member from said first position of reduced size to a

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second expanded position and attachment means secured to said expandable spring means for attachment to the body vessel.

*Id.* at 14:11-24.

23. A graft for intraluminal placement in a corporeal lumen, said graft comprising:

a tubular member having a first end and a second end;

a first attachment system positioned proximate the first end of said tubular member, said first attachment system including a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement; and

a second attachment system positioned proximate the second end of said tubular member, said second attachment system including a plurality of legs joined by a plurality of apices, the legs being configured in a circular arrangement.

*Id.* at 15:60-16:7.

# D. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds:

Reference(s)	Basis	Claims Challenged
Lawrence <sup>1</sup>	§ 102(a)	23 and 27
Lawrence and Charnsangavej <sup>2</sup>	§ 103(a)	1, 4, 5, 9-15, 18, 28- 30, and 33-35
Choudhury <sup>3</sup> or Kornberg <sup>4</sup> , and Lawrence	§ 103(a)	1, 4, 5, 9-18, 28-30, and 33-35
Kornberg or Choudhury, and Charnsangavej	§ 103(a)	1, 4, 5, 9-18, 23, 27- 30, and 33-35
Jones <sup>5</sup> and Sharrow <sup>6</sup> in combination with (i) Lawrence and Charnsangavej, (ii) Choudhury or Kornberg, and Lawrence, or (iii) Kornberg or Choudhury, and Charnsangavej	§ 103(a)	9, 10, 27, 33, and 34

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<sup>&</sup>lt;sup>1</sup> DAVID D. LAWRENCE ET AL., *Percutaneous Endovascular Graft: Experimental Evaluation*, RADIOLOGY, Vol. 163, No. 2, pp. 357-60, published May 1987 (Ex. 1003) ("Lawrence").

<sup>&</sup>lt;sup>2</sup> CHUSILP CHARNSANGAVEJ ET AL., Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents, RADIOLOGY, Vol. 161, No. 2, pp. 295-98, published November 1986 (Ex. 1004) ("Charnsangavej").

<sup>&</sup>lt;sup>3</sup> U.S. Patent No. 4,140,126, issued Feb. 20, 1979 (Ex. 1005) ("Choudhury").

<sup>&</sup>lt;sup>4</sup> U.S. Patent No. 4,562,596, issued Jan. 7, 1986 (Ex. 1009) ("Kornberg").

<sup>&</sup>lt;sup>5</sup> U.S. Patent No. 4,202,349, issued May 13, 1980 (Ex. 1006) ("Jones").

<sup>&</sup>lt;sup>6</sup> U.S. Patent No. 4,793,359, issued Dec. 27, 1988 (Ex. 1014) ("Sharrow").

Reference(s)	Basis	Claims Challenged
Dotter <sup>7</sup> in combination with  (i) Lawrence and Charnsangavej,  (ii) Choudhury or Kornberg, and  Lawrence, or (iii) Kornberg or  Choudhury, and Charnsangavej	§ 103(a)	2, 3, and 31

# II. ANALYSIS A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Under the broadest reasonable construction standard, claim terms are presumed to be given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). An inventor may rebut that presumption by providing a definition of the term in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). We construe the terms below in accordance with these principles.

<sup>&</sup>lt;sup>7</sup> CHARLES T. DOTTER ET AL., *Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report*, RADIOLOGY, Vol. 147, pp. 259-60, published Apr. 1983 (Ex. 1016) ("Dotter").

With the exception of certain claim terms that Petitioner asserts should be construed under 35 U.S.C. § 112,  $\P$  6, Petitioner proposes all other terms should be given their ordinary and customary meaning. Pet. 9-10. We address terms that recite "means" in the challenged claims, and we identify the structure in the specification corresponding to the terms that should be construed as means-plus-function limitations. No other terms in the challenged claims require express construction for this decision.

"expandable yieldable spring means" (claim 1)

Independent claim 1 recites "expandable yieldable spring means respectively secured to the proximal and distal ends of the tubular member, said yieldable spring means urging said tubular member from said first position of reduced size to a second expanded position." Petitioner asserts "expandable yieldable spring means" should be construed under 35 U.S.C. § 112, ¶ 6 for performing the function of "urging the tubular member from a first position of reduced size to a second expanded position." Pet. 9. Petitioner, however, does not provide persuasive argument or evidence to support its assertion. *See id.; see also* Ex. 1028 ¶ 42 (Petitioner's declarant indicating he agrees with Petitioner's construction but does not further support this position with facts or analysis).

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<sup>&</sup>lt;sup>8</sup> Section 4(c) of the *Leahy-Smith America Invents Act*, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), re-designated 35 U.S.C. § 112, ¶ 6, as 35 U.S.C. § 112(f). Because the '728 patent has a filing date before September 16, 2012 (effective date of AIA), we use the citation "§ 112, ¶ 6."

Section 112, ¶ 6 permits an element in a claim for a combination to be expressed as a means for performing a specified function without the recital of structure in support thereof, but with the provision that "such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

The use of the word "means" creates a rebuttable presumption that the inventor intended to invoke § 112, ¶ 6. *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703-04 (Fed. Cir. 1998). The presumption may be overcome when a claim recites a sufficient structure to perform the recited function. *Id.* at 704. Nor will claim language invoke a § 112, ¶ 6 construction if persons of ordinary skill in the art reading the specification understand the term to be the name for a structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function. *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996) ("Many devices take their names from the functions they perform.").

Although the term "expandable yieldable spring means" uses the word "means" to identify what performs the function "urging the tubular member from a first position of reduced size to a second expanded position," the word "spring" modifies "means." A dictionary definition shows that the noun "spring" has a reasonably well-understood meaning as a name for structure. A person ordinarily skilled in the art would understand the term "spring" to mean an elastic device, such as a coil of wire, that regains its

original shape after being compressed or extended. \*\* Cf. Greenberg\*, 91 F.3d at 1583 (holding § 112, ¶ 6 did not apply to the claim limitation "detent mechanism" because dictionary definitions established "detent" denotes a type of device with a generally understood meaning). This understanding of the term "spring" is consistent with the written description of the '728 patent, which indicates "[t]he spring means 131 is formed of . . . apices 133 of the vees 132 being formed with helical *coil springs* 136 to yieldably urge the legs 137 and 138 of each of the vees 132." Ex. 1001, 8:27-30 (emphasis added).

Moreover, the "spring means" is further qualified as "expandable" and "yieldable." The surrounding claim language requires that the "expandable yieldable spring means" is "respectively secured to the proximal and distal ends of the tubular member," a structural limitation for how the spring means is secured to the tubular member, which is urged from a position of reduced size to an expanded position, according to the claim.

On this record, we disagree with Petitioner's proposed construction of "expandable yieldable spring means" under  $\S 112$ ,  $\P 6$ , because the claim language connotes sufficient structure for the "expandable yieldable spring means" to urge a tubular member from a position of reduced size to an expanded position, as required by the claim. We find, therefore, that the

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<sup>&</sup>lt;sup>9</sup> See AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1744 (3d ed. 1992) (defining the noun spring as "an elastic device, such as a coil of wire, that regains its original shape after being compressed or extended").

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term "expandable yieldable spring means" as used here imparts sufficient structure such that the presumption of applying § 112, ¶ 6 is overcome.

"attachment means . . . for attachment to the body vessel" (claim 1)

Independent claim 1 also recites "attachment means secured to said expandable spring means for attachment to the body vessel." Construing a term under § 112, ¶ 6 requires first defining the particular function of the limitation and then identifying, in the specification, the corresponding structure that performs the claimed function. *Golight, Inc. v. Wal-Mart Stores Inc.*, 355 F.3d 1327, 1333-34 (Fed. Cir. 2004).

Petitioner asserts that the attachment means should be construed under  $\S 112$ ,  $\P 6$ , with the attachment means performing the function of "attaching to the vessel wall" and being limited to the structure "hooks or hook-like elements, including at least those shown in Figures 10-13)." Pet. 9 (citing Ex. 1001, 8:57-65, 9:34-36, 10:23-55, 13:66 – 14:6, figs. 10-13).

On this record, we agree with Petitioner that the attachment means should be construed under § 112, ¶ 6 because: (1) the limitation uses the word "means," (2) the term in the limitation is modified by functional language ("for attachment to the body vessel"), and (3) the term is not modified by sufficient structure recited in the claim for performing the claimed function. *See Flo Healthcare Solutions, LLC v. Kappos*, 697 F.3d 1367, 1373 (Fed. Cir. 2012). Securing the attachment means to the expandable spring means, as required in claim 1, does not connote sufficient structure for performing the function of "attachment to the body vessel" because the claim language only specifies that the attachment means is

secured to the expandable spring means, but does not provide any structure by which it could attach to the wall of the body vessel.

We also agree with Petitioner, on this record, that the corresponding structure in the specification for performing the function of attachment to the body vessel is a hook or a hook-like element. For example, the written description indicates "hook-like elements 151 serve as attachment means at each end of the graft 121" and "hook-like elements 151 should [be] sufficient for the hook to penetrate into the vessel wall, but not through the vessel wall." Ex. 1001, 9:34-36, 8:63-65. The abstract of the '728 patent indicates that "[h]ooks are secured to the proximal and distal ends of the tubular member and face in a direction outwardly." Ex. 1001, Abstract.

"conforming means" (claim 35)

Independent claim 35 recites "conforming means for engrafting a body vessel, said conforming means having proximal and distal extremities." Petitioner asserts the conforming means should be construed under § 112, ¶ 6 with the conforming means performing the function of "engrafting a body vessel" and being limited to the structure "a deformable tubular member." Pet. 9-10 (citing Ex. 1001, 8:5-22, figs. 10-11).

On this record, we agree that the conforming means should be construed under § 112, ¶ 6 because: (1) the limitation uses the word "means," (2) the term in the limitation is modified by functional language ("for engrafting a body vessel"), and (3) the term is not modified by sufficient structure recited in the claim for performing the claimed function. *See Flo Healthcare*, 697 F.3d at 1373. Although claim 35 recites the

conforming means as "having proximal and distal extremities," that structure is insufficient to perform the function of "engrafting a body vessel."

We also agree, on this record, that the corresponding structure in the specification for performing the function of for engrafting a body vessel is a deformable tubular member. The '728 patent does not use the term "conforming means" other than in the claims. The written description, however, indicates "an expandable intraluminal vascular graft 121 . . . for implanting in a body vessel . . . consists of a deformable tubular member 122 . . . with first and second ends 123 and 124." Ex. 1001, 8:5-9.

"engaging means for securing said conforming means to a wall of the body vessel" (claim 35)

Independent claim 35 further recites "attachment means being self-expanding and having engaging means for securing said conforming means to a wall of the body vessel." Petitioner contends that the engaging means should be construed under § 112, ¶ 6 with the engaging means performing the function of "securing to a wall of the body vessel" and being limited to the structure "hooks or hook-like elements, including at least those shown in Figures 10-13." Pet. 10 (citing Ex. 1001, 8:57-65, 9:34-36, 10:23-55, 13:66-14:6, figs. 10-13).

On this record, we agree that the engaging means should be construed under  $\S 112$ ,  $\P 6$  because: (1) the limitation uses the word "means," (2) the term in the limitation is modified by functional language ("for securing said conforming means to a wall of the body vessel"), and (3) the term is not

modified by sufficient structure recited in the claim for performing the claimed function. *See Flo Healthcare*, 697 F.3d at 1373.

Although the claim indicates that the "attachment means . . . [has] engaging means," the engaging means being part of the attachment means is not sufficient structure to secure a particular structure—a deformable tubular member (i.e., conforming means, as discussed previously)—to a wall of the body vessel. Thus, the engaging means has insufficient structure to perform "securing said conforming means to a wall of the body vessel," which is the function of the engaging means.

As discussed previously, the specification describes hooks or hook-like elements as being used to secure the tubular member to the wall of the body vessel. Thus, on this record, we agree with Petitioner's proposed structure corresponding to the engaging means is hooks or hook-like elements, including at least those shown in Figures 10-13.

"attachment means . . . for engaging the body vessel" (claim 35)

Independent claim 35 recites "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 having engaging means for securing said conforming means to a wall of the body vessel." Petitioner asserts that the attachment means recited in claim 35 should be construed under § 112, ¶ 6, with the attachment means performing the function of "engaging the body vessel" and being limited to a structure of "a plurality of apices and vees that are self-expanding." Pet. 10 (citing Ex. 1001, 8:22-56; figs. 10-11).

On this record, we agree with Petitioner that the attachment means should be construed under § 112, ¶ 6 because: (1) the limitation uses the word "means," (2) the term in the limitation is modified by functional language ("for engaging the body vessel"), and (3) the term is not modified by sufficient structure recited in the claim for performing the claimed function. *See Flo Healthcare*, 697 F.3d at 1373.

The claim requires that the attachment means is "self-expanding," has an engaging means for securing said conforming means to a wall of the body vessel, and is secured to the extremities of the conforming means. Those limitations, however, are insufficient for imparting structure to perform the function of engaging the body vessel. As discussed previously, the conforming means requires the structure of a deformable tubular member and the engaging means requires the structure of hooks or hook-like elements. Having an engaging means for securing a deformable tubular member to the wall of the body vessel (i.e., having hooks or hook-like elements) is not sufficient structure to perform the function of engaging the body vessel, which is the function of the attachment means. Nor does the characteristic of being self-expanding or being secured to the extremities of the deformable tubular member (i.e., the conforming means) recite sufficient structure for engaging the body vessel.

The '728 patent provides an embodiment of an expandable spring attachment means provided on each end of a deformable tubular member. Figure 11 of the '728 patent is set forth below:

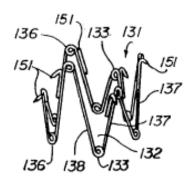


Fig.11

Figure 11 illustrates a "spring attachment means." Ex. 1001, 2:26-27. The written description of the '728 patent indicates that expandable spring attachment means 131 is provided on each end of deformable tubular member 122 (as shown in Figure 10, depicted previously). *Id.* at 8:22-24. Expandable spring attachment means 131 consists of interconnected vees 132, with apices 133 of the vees 132 formed with helical coil springs 136 between legs 137, 138 of each vee. *Id.* at 8:27-29. The tubular member 122 is a component of a graft implanted in a body vessel. *See id.* at 8:5-11.

We agree with Petitioner, on this record and for purposes of institution, that the corresponding structure in the specification for an attachment means performing the function of "engaging the body vessel" is a plurality of apices and vees. The written description describes a spring attachment means as expandable and having interconnected apices and vees. *See id.* at 8:22-30; figs. 10-11.

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"coil spring means" (claim 3)

Claim 3, which depends from claim 1, additionally recites "said expandable spring means includes a plurality of interconnected vees with each vee having an apex and 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." Petitioner does not address expressly this term. Presumably, because Petitioner does not propose that this term be construed under § 112, ¶ 6, Petitioner implicitly proposes this term be given its ordinary and customary meaning. *See generally* Pet. 9-10.

We determine, on the present record, that "coil spring means" imparts sufficient structure to avoid applying § 112, ¶ 6. First, "means" is qualified to be a "coil spring means" and, as noted previously, a person ordinarily skilled in the art would understand the term "spring" to mean an elastic device, such as a coil of wire, that regains its original shape after being compressed or extended. Moreover, the claim requires the "coil spring means" to be "formed at each apex." Thus, we find that claim 3 recites sufficient structure for "coil spring means" to perform the function: "to expand the vees in an outward direction along the plane of each of the vees."

"radiopaque marker means" (claim 9)

Claim 9, which depends from independent claim 1, recites "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." Petitioner does not

address expressly this term. Presumably, because Petitioner does not propose that this term be construed under § 112, ¶ 6, Petitioner implicitly proposes that "radiopaque marker means" be given its ordinary and customary meaning in light of the specification. *See generally* Pet. 9-10.

On this record, we find that the claim language connotes sufficient structure ("radiopaque marker means secured to the wall of the tubular member" and "first and second aligned radiopaque markers spaced apart longitudinally of the tubular member") to perform the function "to permit ascertaining whether any twisting of the tubular member has occurred." Thus, we find that the term "radiopaque marker means" reasonably imparts sufficient structure so that the presumption, based on the recitation of the word "means," of applying § 112, ¶ 6 is overcome.

# B. Asserted Grounds of Obviousness Challenging Claims 4 and 5

Claims 4 and 5 depend, directly or indirectly, from claim 3, which, in turn, depends from independent claim 1. Petitioner asserts claims 1, 4, and 5—but not claim 3—would have been obvious over various combinations of references—Lawrence and Charnsangavej; or Choudhury or Kornberg, and Lawrence; or Kornberg or Choudhury, and Charnsangavej. *See* Pet. 4, 16, 22-23, 27, 33-35, 41, 43-44. Claim 3 recites, among other limitations, "coil spring means formed at each apex serving to expand the vees in an outward direction along the plane of each of the vees."

## Additional Limitations Recited in Claim 3

Patent Owner contends that we should deny institution as to claims 4 and 5 for all grounds asserted against those claims because the additional limitations recited in claim 3, from which claims 4 and 5 directly or indirectly depend, are not addressed in any of the grounds asserted against claims 4 and 5. Prelim. Resp. 2-7.

We agree. Petitioner contends that the asserted combinations of references teach every limitation of the claims challenged in the various grounds of obviousness asserted against claims 1, 4, and 5. *See*, *e.g.*, Pet. 22 ("[A] person of ordinary skill would have found it obvious to combine Lawrence and Charnsangavej to achieve all elements of claims 1, 4-5 . . . of the '728 patent"); 31 ("The combination of Choudhury or Kornberg with the Gianturco stent of Lawrence also teaches each and every element of the dependent IPR claims"); 41 (discussing Kornberg or Choudhury, and Charnsangavej, Petitioner contends "Charnsangavej can be substituted for Lawrence"). Petitioner also asserts that Lawrence's Gianturco stent teaches "all of the [self-expanding spring structure with a circular configuration] structural limitations" recited in "a number of dependent claims," including claim 3. *See id.* at 31-32.

Petitioner, however, does not address all the limitations of claims 4 and 5 in the grounds asserted against those claims. By virtue of the dependency of claims 4 and 5 on claim 3, the additional limitation recited in claim 3 also is a limitation in claims 4 and 5. The petition does not address, in any of the grounds asserted against claims 4 and 5, the additional

limitation recited in claim 3. Specifically, Petitioner does not address "said expandable spring means includes a plurality of interconnected vees with each vee having an apex and 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," as recited in claim 3, in the claim charts or substantive arguments set forth in the grounds asserted against claims 4 and 5. *See id.* at 16-52; *see especially id.* at 22-23, 33-35, 43-44 (claim charts, pinpointing no disclosure that satisfies the claim 3 limitation relating to the expandable spring means including coil spring means, among other structures).

Although the Petitioner asserts that the additional limitation in claim 3 is found in Dotter (Pet. 58), that reference is not asserted against claims 4 and 5. *See generally* Pet. 16-52 (discussing grounds asserted against claims 4 and 5). Evidence must be presented for each asserted ground. *See* 35 U.S.C. § 312(a)(3) (requiring the petition identify "evidence that *supports the grounds* for the challenge to each claim") (emphasis added); 37 C.F.R. § 42.108 (only permitting institution of an *inter partes* review "for a ground of unpatentability [when] the Board decides that the petition *supporting the ground* would demonstrate that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable") (emphasis added). Further, each limitation in a challenged claim must be addressed. 37 C.F.R. § 42.104(b)(4) (requiring the petition to "specify where each element of the claim is found in the prior art patents or printed publications relied upon").

On this record, the information presented in the petition is insufficient to establish a reasonable likelihood that claims 4 and 5 are obvious in view of the references asserted against claims 4 and 5—(i) Lawrence and Charnsangavej; (ii) Choudhury or Kornberg, and Lawrence; or (iii) Kornberg or Choudhury, and Charnsangavej. We, therefore, do not institute *inter partes* review of claims 4 and 5 for any ground asserted against those claims.

The Requirements of 35 U.S.C.  $\S$  312(a)(3)

Patent Owner also contends that, because the limitations additionally recited by claim 3 are not addressed in the grounds asserted against claims 4 and 5, the petition itself fails to comply with the requirements of 35 U.S.C. § 312(a)(3) and cannot be considered. Pet. 2-4.

We find Patent Owner's argument unpersuasive. Patent Owner is correct that, among other requirements, a petition must identify "in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. § 312(a)(3).

The petition identifies claims 1-5, 9-18, 23, 27-31, and 33-35 as the claims challenged, asserts multiple grounds of unpatentability against specific claims based on particular patents and printed publications, provides the patents and printed publications asserted as prior art as exhibits to the petition, provides detailed claim charts and explanations for each ground, and provides a declaration from Gary L. Loomis, Ph.D., in support of the arguments presented in the petition.

Thus, in the present circumstances, we find that the petition meets the requirements of 35 U.S.C. § 312(a)(3) and can be considered. *See* 35 U.S.C. § 312(a) (indicating a petition can be considered only if the requirement of § 312(a)(3) is met).

## C. Anticipation by Lawrence

Petitioner contends that Lawrence anticipates, under § 102(a), independent claim 23 and its dependent claim 27. Pet. 11-15. Petitioner provides explanations and claim charts specifying where limitations of the challenged claims purportedly are disclosed in Lawrence. *Id.* Petitioner also relies on the declaration of Gary L. Loomis, Ph.D. (Ex. 1028). We determine that Petitioner has demonstrated a reasonable likelihood that claims 23 and 27 are anticipated by Lawrence.

#### Lawrence

Lawrence describes "intravascular placement of a Dacron graft, using multiple Gianturco stents as a superstructure by which to anchor and support the graft" to treat aneurysms. Ex. 1003 at 357. "The endovascular graph consist[s] of multiple [Gianturco] stents in tandem connection to each other by metallic struts." *Id.* Lawrence's Figures 1(a) and 1(b) are set forth below:

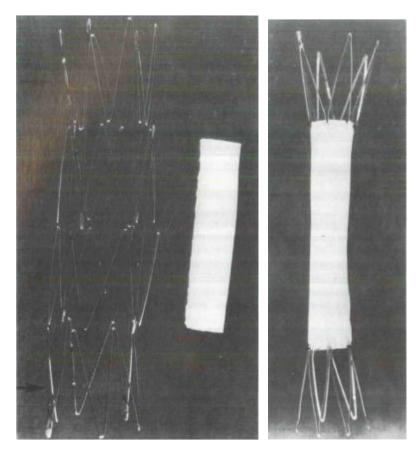


Figure 1(a)

Figure 1(b)

Figure 1(a) shows "components of the endovascular graft"—the Gianturco stents and Dacron tubing. *Id.* at 358. Figure 1(b) shows an endovascular graft with Gianturco stents and a Dacron graft around internal Gianturco stents. *Id.* at 357. The first and last Gianturco stents "acted as anchors for the graft, while the internal stents served to open the Dacron tubing when the device was released from the catheter." *Id.* at 357.

# Analysis

Petitioner contends Lawrence's description of a graft made from Dacron tubing discloses "a tubular member having a first end and a second end," as recited in claim 23. Pet. 14. According to Petitioner, Lawrence's first and last Gianturco stents anchor the graft, and each stent includes apices and legs configured in a circular arrangement, which collectively disclose the first attachment system and the second attachment system, as recited in claim 23. *Id.* at 15.

Upon consideration of the information in the petition, we conclude that there is a reasonable likelihood that Lawrence discloses all limitations of claim 23 for purposes of institution. We determine, based on the record presently before us, that Petitioner has established a reasonable likelihood that it would prevail in demonstrating that claim 23 is anticipated by Lawrence.

We also have considered Petitioner's contentions regarding anticipation by Lawrence of dependent claim 27, which additionally recites "a plurality of radiopaque markers secured to said tubular member." According to Petitioner, Lawrence's Gianturco stents internal to the Dacron tubing are made from radiopaque stainless steel and so disclose the recited radiopaque markers. Pet. 15 (citing Ex. 1003 at 357, Fig. 2 (showing a radiograph where the internal stents are visible); Ex. 1028 ¶ 59). We conclude, on this record, that there is a reasonable likelihood that Lawrence discloses the recited radiopaque markers for purposes of institution and has established a reasonable likelihood that it would prevail in showing that claim 27 is anticipated by Lawrence.

Accordingly, we institute *inter partes* review of claims 23 and 27 for anticipation by Lawrence.

#### D. Obviousness over Lawrence and Charnsangavej

Petitioner contends that claims 1, 9-15, 18, 28-30, and 33-35 would have been obvious over Lawrence and Charnsangavej. See Pet. 16-27. Petitioner provides explanations and claim charts specifying where limitations of the challenged claims purportedly are taught in Lawrence and Charnsangavej, reasons why one skilled in the art would have combined the references, and testimony of Dr. Loomis to explain how the combination of Lawrence and Charnsangavej would have rendered obvious claims 1, 9-15, 18, 28-30, and 33-35. We determine that Petitioner has demonstrated a reasonable likelihood that claims 1, 9-15, 18, 28-30, and 33-35 would have been obvious over Lawrence and Charnsangavej.

## Charnsangavej

Charnsangavej describes animal experiments and clinical applications of Gianturco expandable metallic stents "constructed of a stainless steel wire bent in a zigzag pattern to form a cylinder." Ex. 1004 at 295. The stent can be compressed and introduced to the animal or person through a catheter. *Id.* "As the stent is released from the catheter, it expands to its original diameter." *Id.* Charnsangavej teaches attaching barbs to the Gianturco stent, which "allowed the stent to become affixed to the wall of the vessel as it was released from the catheter," to prevent migration of the stent. *Id.* 

<sup>&</sup>lt;sup>10</sup> Petitioner also contends that claims 4 and 5 would have been obvious over Kornberg and Charnsangavej. Those claims are addressed in Section II.B.

# **Analysis**

Petitioner relies on Lawrence for many limitations, but relies on Charnsangavej's use of barbs for limitations related to engaging or securing the graft to the vessel wall. Pet. 16-27. Regarding independent claim 1, Petitioner contends Lawrence teaches the recited limitations, except for the "attachment means secured to said expandable spring means for attachment to the body vessel" for which Charnsangavej is cited. Pet. 22-23. Specifically, Petitioner relies on Charnsangavej's teaching "the attachment of barbs to Gianturco stents for attachment to the body vessel when deployed." Pet. 23.

Petitioner, relying on Dr. Loomis' testimony, also provides reasons why one skilled in the art would have combined the references. Pet. 17-22. Petitioner contends that a person of ordinary skill would have had reason "to combine Charnsangavej and Lawrence to solve the problem of intraluminal device migration, especially because Lawrence itself cites to Charnsangavej." Pet. 17 (citing Ex. 1003 at 360 (Lawrence citing Charnsangavej as a reference); Ex. 1004 at 298 ("To prevent such migration, . . . use of a barbed stent [is] recommended for fixation of the stent to the caval wall"); Ex. 1028 ¶ 90); see also Ex. 1004 at 295 ("To prevent migration, the stent was modified by attaching barbs").

Petitioner acknowledges that Lawrence indicates that the Gianturco stents used in the described experiments did not include barbs. Pet. 17-18; *see also* Ex. 1003 at 357 ("Each stent had six bends and no side barbs."). According to Petitioner, however, Lawrence does not criticize, discredit, or

otherwise discourage the use of barbs and so does not teach away from their use. Pet. 18 (citing *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)).

Petitioner, supported by Dr. Loomis' testimony, contends that a person of ordinary skill in the art would have recognized that Lawrence's experimental conditions did not need barbs because risk of migration was not an issue, but, if presented with migration issues when using the teachings of Lawrence, a person of ordinary skill in the art would have combined Charnsangavej's barbs with Lawrence's graft made from Dacron tubing and Gianturco stents. Pet. 17-18 (citing Ex. 1028 ¶¶ 51-56).

On this record and for purposes of institution, we are satisfied that Petitioner's articulated reasoning is supported by sufficient rational underpinnings. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (an apparent reason to combine known elements in the fashion claimed by the patent at issue should be made explicit). We are persuaded, based on the record presently before us, that Petitioner has established a reasonable likelihood that it would prevail in showing that claim 1 would have been obvious over Lawrence and Charnsangavej.

We also have considered Petitioner's arguments and evidence concerning obviousness over Lawrence and Charnsangavej of claims 9-15, 18, 28-30, and 33-35. We are persuaded that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 9-15, 18, 28-30, and 33-35 would have been obvious over Lawrence and Charnsangavej.

Accordingly, we institute *inter partes* review of claims 1, 9-15, 18, 28-30, and 33-35 for obviousness over Lawrence and Charnsangavej.

#### E. Obviousness over Kornberg and Charnsangavej

Petitioner contends that claims 1, 9-18, 23, 27-30, and 33-35 would have been obvious over Kornberg and Charnsangavej. See Pet. 41-52. Petitioner provides explanations and claim charts specifying where limitations of the challenged claims purportedly are taught in Kornberg and Charnsangavej, reasons why one skilled in the art would have combined the references, and testimony of Dr. Loomis to explain how the combination of Kornberg and Charnsangavej would have rendered obvious claims 1, 9-18, 23, 27-30, and 33-35.

We determine that Petitioner has demonstrated a reasonable likelihood that claims 1, 9-18, 23, 27-30, and 33-35 would have been obvious over Kornberg and Charnsangavej.

# Kornberg

Kornberg describes an "aortic graft that is specifically constructed for intraluminal insertion." Ex. 1009, Abstract. The graft is a flexible, hollow, tubular material having parallel struts, which have angled hooks with barbs to allow the graft to be securely attached to the inside of the aorta. *Id.* Kornberg also describes a tubular device for inserting the graft. *Id.* Kornberg's Figure 1 is set forth below:

<sup>&</sup>lt;sup>11</sup> Petitioner also contends that claims 4 and 5 would have been obvious over Kornberg and Charnsangavej. These claims are addressed in Section II.B.

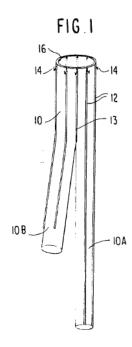


Figure 1 shows graft 10 that is a generally cylindrical, hollow, sleeve with longitudinal, supporting struts 12 and circumferential row of hooks 14. Ex. 1009, 2:23-26, 52-53, 62-66. Graft 10 has two legs 10A and 10B and may be fabricated from Dacron. *Id.* at 2:66-68, 3:26-28.

Flexible ring 16 is located at the circular opening at the top of the graph. *Id.* at 3:24-25, 4:6-7. "The ring 16 may be fabricated of flexible, resilient plastic or rubber which is in the compressed, or partially open state prior to positioning in the damaged artery." *Id.* at 4:9-12. "Once in place, the ring will spring open and snug up against the walls of the artery . . . ." *Id.* at 4:12-14.

Kornberg also describes that during insertion, short leg 10B is folded against longer leg 10A. *Id.* at 5:61-68. "At the appropriate point when

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blood flow begins to enter the graft, the shorter leg 10B floats free in the blood stream and may be directed to the proper position." *Id.* at 5:68-6:3.

#### **Analysis**

Petitioner contends that Kornberg's graft discloses the tubular member recited in independent claims 1, 11, 23, and 28 and discloses the conforming means recited in independent claim 35. *See* Pet. 43, 45, 48, 49, 51; *see id.* at 30 (asserting that "the 'expanding spring element' is the only limitation of the [challenged] claims that is arguably not present in Kornberg"); *see also id.* at 41 (indicating Petitioner's analysis of Kornberg and Lawrence are applicable to the asserted ground of obviousness over Kornberg and Charnsangavej). Petitioner relies on Charnsangavej's use of a self-expanding Gianturco stent for the expandable spring recited in independent claims 1 and 28; for the attachment system including a plurality of two legs joined at an apex or by apices recited in independent claims 11 and 23; and for the self-expanding attachment means recited in claim 35. *See id.* at 43-46, 48-51.

According to Petitioner, a person having ordinary skill in the art would have thought it obvious to combine Kornberg's use of a graft to expand a graft that had been compressed for insertion using a catheter with Charnsangavej's self-expanding Gianturco stent as a way to expand graft material. Pet. 42 (citing Ex. 1028 ¶ 128). As Dr. Loomis explains, a person having ordinary skill in the art would have known that the self-expanding spring characteristics of Charnsangavej's Gianturco stent "would readily address the challenges of deploying a graft via a catheter." Ex. 1028 ¶ 128.

Petitioner also asserts a person of ordinary skill in the art would have combined Charnsangavej's Gianturco stent with Kornberg's graft because "persons of ordinary skill *did* do so, and achieved the predictable result that the stent successfully expanded the graft," as evidenced by contemporaneous research. Pet. 42 (citing Ex. 1011<sup>12</sup> at 675-76).

On this record, and for purposes of institution, we are satisfied that Petitioner's articulated reasoning is supported by sufficient rational underpinnings. *See KSR*, 550 U.S. at 418 (an apparent reason to combine known elements in the fashion claimed should be made explicit). For those reasons, we determine that Petitioner has demonstrated a reasonable likelihood that independent claims 1, 11, 23, 28, and 35 are unpatentable over Kornberg and Charnsangavej.

We also have considered Petitioner's arguments and evidence concerning obviousness over Kornberg and Charnsangavej of dependent claims 9, 10, 12-18, 27, 29-30, 33, and 34. For example, claim 9, which depends from independent claim 1, additionally recites "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." For the reasons discussed previously in Section II.A, we determined that radiopaque marker means

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<sup>&</sup>lt;sup>12</sup> TETSUYAYOSHIOKA ET AL., *Self-Expanding Endovascular Graft: An Experimental Study in Dogs*, AMERICAN JOURNAL OF ROENTGENOLOGY, Vol.151, pp. 673-676 (October 1988) (paper received Mar. 7, 1988; accepted after revision May 4, 1988) ("Yoshioka").

does not invoke § 112, ¶ 6 and so is not limited to the corresponding structures disclosed by the written description of the '728 patent. Petitioner relies on Kornberg's description that the struts may be made of radiopaque materials for the additional limitation recited in claim 9. Pet. 45 (citing Ex. 1009, 4:23-27). Specifically, Kornberg states that the struts "may be formed of any biologically acceptable material, such as surgical steel or even plastic of sufficient rigidity and preferably radiologically opaque to permit visualization during the positioning of the graft in the patient." Ex. 1009, 4:23-27.

We are persuaded that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 9, 10, 12-18, 27, 29-30, 33, and 34 would have been obvious over Kornberg and Charnsangavej.

# F. Obviousness over Dotter and Various References

Petitioner contends that dependent claims 2, 3, and 31 would have been obvious over Dotter in combination with various references—(i) Lawrence with Charnsangavej; (ii) Kornberg or Choudhury, and Lawrence; or (iii) Kornberg or Choudhury, and Charnsangavej—and Dotter. Pet. 56-58.

Claim 2, depends directly from independent claim 1, and additionally recites "said expandable spring means is in the form of substantially veeshaped 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." Claim 3, which also depends directly from independent claim 1, additionally recites

"said expandable spring means includes a plurality of interconnected vees with each vee having an apex and 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." Claim 31, which depends directly from dependent claim 30 and indirectly from claim 29 and independent claim 28, additionally recites "each of the apices of said expandable spring arrangement comprise a coil spring arrangement."

Petitioner augments its prior arguments regarding independent claim 1 and dependent claim 30 with explanations and claim charts specifying where the additional limitations of claims 2, 3, and 31 are taught in the combinations with Dotter. Pet. 58.

#### Dotter

Dotter describes "a method . . . for . . . catheter placement of expandable nitinol coil stents," noting "placement of tubular coiled wire stent grafts was first described in a 1969 report." Ex. 1016 at 259. Dotter's Figure 1 is set forth below:

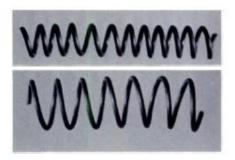


Figure 1 shows a nitinol coil wire stent in two configurations. *Id.* The top configuration shows the nitinol coil wire stent compacted for transcatheter placement, whereas the bottom configuration shows the same nitinol coil

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wire stent after it reverts to the initial, uncompacted configuration. Ex. 1016 at 259.

## **Analysis**

Petitioner asserts Dotter's coil spring discloses the "helical torsion spring" recited in claim 2, the "coil spring means" recited in claim 3, and "a coil spring arrangement" recited in claim 31. Pet. 57-58. Petitioner asserts the combination of Dotter with the references asserted against the claims from which claims 2, 3, and 31, respectively, depend disclose the additional limitations recited in claims 2, 3, and 31. *Id*.

Petitioner, relying on the testimony of Dr. Loomis, contends that a person of ordinary skill would have combined Dotter with the combinations discussed above "to achieve the helical coil spring at the apices" to render obvious claims 2, 3, and 31. Pet. 57 (citing Ex. 1028 ¶ 146). Specifically, Petitioner notes, again relying on Dr. Loomis, that helical torsion springs, such as a safety pin, are used widely in everyday life to allow the legs to be resiliently compressed and then urge the legs apart when the compression force is removed. *Id.* (citing Ex. 1028 ¶ 145). Dr. Loomis concludes a person of ordinary skill would have had reason to combine Dotter with the other asserted references "to aid in the resiliently compressible character of the expandable spring means" recited in claims 2, 3, and 31. Pet. 58 (citing Ex. 1028 ¶ 146).

We determined that there is a reasonable likelihood that Petitioner would prevail in showing claims 1 and 30 would have been obvious over Lawrence and Charnsangavej and also would have been obvious over

Kornberg and Charnsangavej. We are persuaded that, for purposes of institution, Dotter discloses a helical spring means. Also, on this record and for purposes of institution, we are satisfied that Petitioner's articulated reason to combine the references to arrive at the claimed invention is supported by sufficient rational underpinnings. *See KSR*, 550 U.S. at 418 (an apparent reason to combine known elements in the fashion claimed should be made explicit).

We thus determine that the information presented in the petition establishes a reasonable likelihood that claims 2, 3, and 31 would have been obvious over Lawrence, Charnsangavej, and Dotter, and also would have been obvious over Kornberg, Charnsangavej, and Dotter. We, therefore, institute *inter partes* review of claims 2, 3, and 31 for those asserted grounds of unpatentability.

#### G. Other Asserted Grounds of Unpatentability

Having reviewed the other grounds of unpatentability asserted by Petitioner, we exercise our discretion and determine that these grounds are redundant to the grounds of unpatentability on which we institute *inter* partes review for the same claims. See 37 C.F.R. § 42.108(a).

#### III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the petition establishes that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1-3, 9-18, 23, 27-31, and 33-35 of the '728 patent are unpatentable. The Board, however, has not made a

final determination with respect to the patentability of these claims. We further determine that there is not a reasonable likelihood that Petitioner would prevail in showing that claims 4 and 5 of the '728 patent are unpatentable.

#### IV. ORDER

For the foregoing reasons, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review is hereby instituted as to claims 1-3, 9-18, 23, 27-31, and 33-35 of the '728 patent based on the following grounds of unpatentability:

- A. Claims 23 and 27 as anticipated under 35 U.S.C. § 102 by Lawrence;
- B. Claims 1, 9-15, 18, 28-30, and 33-35 for obviousness under 35 U.S.C. § 103 over Lawrence and Charnsangavej;
- C. Claims 1, 9-18, 23, 27-30, and 33-35 as unpatentable for obviousness under 35 U.S.C. § 103 over Kornberg and Charnsangavej;
- D. Claims 2, 3, and 31 for obviousness under 35 U.S.C. § 103 over Lawrence, Charnsangavej, and Dotter; and
- E. Claims 2, 3, and 31 for obviousness under 35 U.S.C. § 103 over Kornberg, Charnsangavej, and Dotter;

FURTHER ORDERED that no other grounds of unpatentability are authorized for the *inter partes* review as to claims 1-3, 9-18, 23, 27-31, and 33-35 of the '728 patent; and

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

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