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Paper 15
Entered: March 25, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and MEDTRONIC VASCULAR, INC.
Petitioner

v.

ENDOTACH LLC
Patent Owner

Case IPR2014-00100
Patent 5,593,417

Before JACQUELINE WRIGHT BONILLA, MICHAEL J. FITZPATRICK, and HYUN J. JUNG, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Petitioner Medtronic, Inc. and Medtronic Vascular, Inc. ("Medtronic") filed a corrected Petition (Paper 5, "Pet.") to institute an *inter partes* review of claims 1, 2, 9, 10, and 13 of U.S. Patent No. 5,593,417 (Ex. 1001, "the '417 patent"), pursuant to 35 U.S.C. § 311. Patent Owner Endotach LLC ("Endotach") did not file a Preliminary Response. 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:

> 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.

For the reasons set forth below, we conclude that Medtronic has shown that, under 35 U.S.C. § 314(a), there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We institute an *inter partes* review of claims 1, 2, 9, 10, and 13 of the '417 patent.

B. Related Matters

Medtronic indicates that Endotach asserted the '417 patent against it in *Endotach LLC v. Medtronic, Inc. and Medtronic Vascular, Inc.*, No. 5:13-cv-03292-EJD (N.D. Cal.). Pet. 1. In its Mandatory Notices, Endotach identifies two other cases that may affect or be affected by this proceeding: *Endotach LLC v. Cook Medical Inc.*, No. 1:13-cv-1135 (S.D. Ind.) and *Endotach LLC v. W.L. Gore & Associates, Inc.*, No. 3:12-cv-00308 (N.D. Fla.). Paper 10, 2-3.

C. The '417 Patent (Ex. 1001)

The '417 patent relates to an intraluminal medical device, such as an endovascular graft or stent. Ex. 1001, 3:45-48. The patent discusses U.S. Pat. No. 5,122,154 (Ex. 1008, "Rhodes '154"), also relating to an intraluminal graft. Ex. 1001, 2:64-3:27. The '417 patent states the present graft device "is constructed in accordance with the teachings of my aforementioned patent [Rhodes '154], except for the means for fixedly holding it in place within the vessel, duct, or lumen," i.e., the "anchoring means." *Id*. at 5:10-17.

Figures 2, 3, 7, and 8 of the '417 patent are reproduced below.

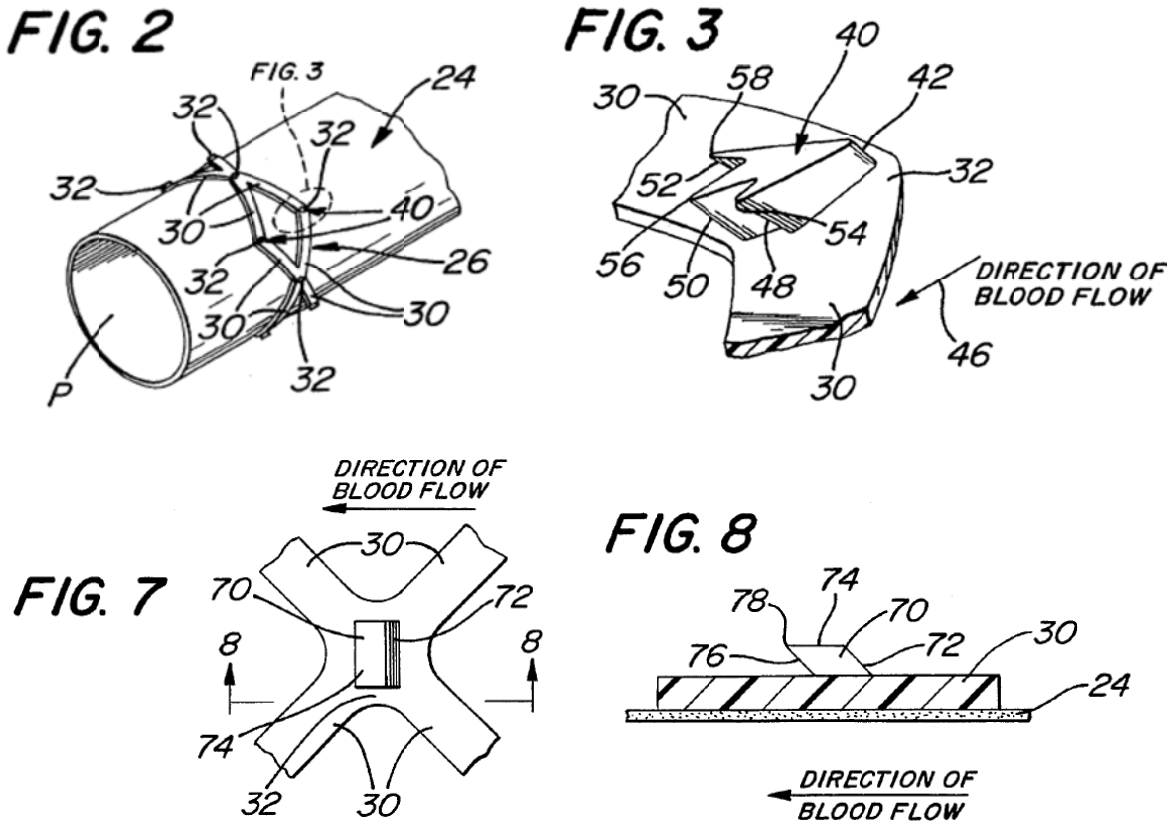


Figure 2 depicts a portion of an endovascular bypass graft. *Id*. at 4:47-52. Figure 3 depicts an enlarged view of the portion in Figure 2 designated as "FIG. 3" with broken lines. *Id*. at 4:53-55. Figure 7 depicts another embodiment of a graft. *Id*.

at 4:65-67. Figure 8 depicts an enlarged sectional view taken along line 8-8 of Figure 7. *Id*. at 5:1-2.

In Figure 2, the graft comprises tubular member 24 having a plurality of expandable, ring-like, stent members 26. *Id*. at 5:54-59. Each stent member 26 comprises a plurality of links 30, where each link is joined to another link by joint 32. *Id*. at 6:21-32. "In order to help hold or secure the graft in position in the artery (or lumen or duct) once the graft has been expanded," the graft includes anchoring means comprising projections 40. *Id*. at 7:9-13. Figure 3 shows details of an embodiment of "arrow head" projections 40 on joint 32. *Id*. at 7:60-63. Each projection "includes a leading edge 42 defining the 'tip' of the 'arrow-head,'" where "leading edge 42 extends upward at an acute angle to the exterior surface of the stent and terminates at the top surface 44 of the projection." *Id*. at 7:63-67; *see also* Fig. 4. The projections also include trailing edges 48, 50, and 52, each of which "inclines upward in the direction of the blood flow to terminate at the top surface 44." *Id*. at 8:2-6.

In another embodiment, shown in Figures 7 and 8, projections 70 are "wedge" shaped. *Id*. at 8:54-56. Leading surface 72 defines "the 'front face' of the 'wedge,'" and "extends upward at an acute angle to the exterior surface of the stent and terminates at the top surface 74." *Id*. at 8:56-58. The projections also include "trailing surface 76 which inclines upward in the direction of the blood flow to terminate at the top surface 74 in a penetration edge 78," and "are preferentially oriented at an acute angle to the direction of blood flow." *Id*. at 8:58-67.

D. Illustrative Claim

Claim 1, the only challenged independent claim, is reproduced below.

> 1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface, said device comprising a tubular member and anchoring means,
>
> said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member,
>
> said *anchoring means* being located adjacent said outer periphery of said tubular member and *comprising plural projections* arranged for engagement with the interior surface of the vessel, duct, or lumen,
>
> each of said projections having *a leading portion located in the upstream direction of the fluid flow* and *a trailing portion located in the downstream direction thereof, said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first direction*,
>
> whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.

Id. at 9:23-45 (paragraph indentation and emphasis added).

E. Prior Art Relied Upon

Medtronic relies upon the following prior art references:

Lazarus, U.S. Pat. No. 5,104,399, issued Apr. 14, 1992 ("Lazarus") (Ex. 1005);

Kornberg, U.S. Pat. No. 4,562,596, issued Jan. 7, 1986 ("Kornberg") (Ex.1006);

Marin, U.S. Pat. No. 5,397,355, issued Mar. 14, 1995 ("Marin") (Ex. 1007); and

Rhodes, U.S. Pat. No. 5,122,154, issued Jun. 16, 1992 ("Rhodes '154") (Ex. 1008).

F. Alleged Grounds of Unpatentability

Medtronic contends that the challenged claims of the '417 patent are unpatentable under 35 U.S.C. § 102 and § 103 based on the following grounds. Pet. 8.

Reference(s)	Basis	Claims Challenged
Lazarus	§ 102	1, 2, 9, 10, and 13
Kornberg	§ 102	1, 2, 9, 10, and 13
Marin	§ 102	1, 2, 9, 10, and 13
Rhodes '154 and Lazarus	§ 103	1, 2, 9, 10, and 13
Rhodes '154 and Kornberg	§ 103	1, 2, 9, 10, and 13
Rhodes '154 and Marin	§ 103	1, 2, 9, 10, and 13

II. ANALYSIS

A. Claim Construction

Consistent with the statute and legislative history of the America Invents Act, the Board interprets claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). There is a "heavy presumption" that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

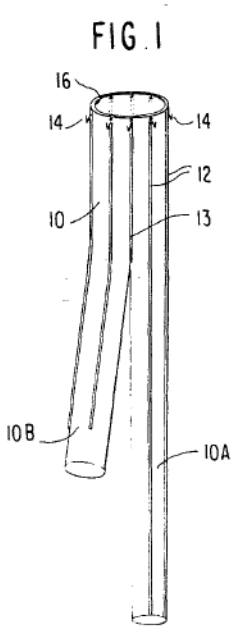
Medtronic offers express constructions for the terms "projection," "leading portion," and "trailing portion," recited in claim 1, as well as "stent" recited in claims 9, 10, and 13. Pet. 9-12. Those terms carry their ordinary and customary meaning and do not need further construction at this stage of the proceeding.

B. Anticipation by Kornberg

Medtronic argues that Kornberg anticipates claims 1, 2, 9, 10, and 13. Pet. 8, 19-22.

1. Kornberg (Ex. 1006)

Kornberg describes a tubular graft comprising "a plurality of struts or stays equipped with hooks for rapid and secure attachment within the desired location of the damaged artery." Ex. 1006, 2:15-19. Figures 1 and 2 of Kornberg are reproduced below.



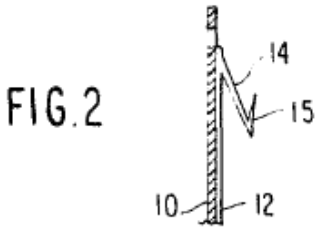


Figure 1 depicts an aortic bifurcation graft equipped with a circumferential row of hooks 14 and a plurality of longitudinal struts 12. *Id*. at 2:23-27. Figure 2 depicts an enlarged view of the upper end of a single strut 12 with hook 14. *Id*. at 2:28-29.

Kornberg states that graft 10 "must have support along its length, so that the blood flow does not dislodge it," but the graft "is sufficiently flexible to be capable of conforming to the interior contour of the wall portion of the artery into which it is inserted." *Id*. at 2:56-62. Graft 10 "is a generally cylindrical, hollow, bifurcated sleeve with longitudinal supporting and reinforcing members called struts 12

running along the major axis of the cylindrical sleeve." *Id*. at 2:62-65. For instance, as shown in Figure 1, struts 12 run along the length of legs (10A and 10B) of graft 10 and "assure proper orientation of the graft within the artery." *Id*. at 2:62-68; 4:17-20. As described in Kornberg, "the number of circumferential located strengthening struts or ribs 12 attached or formed in the wall of the graft may vary from a minimum of four up to twelve or more, preferably eight." *Id*. at 3:1-5. Graft 10 also includes flexible ring 16 at the upper end of the graft. *Id*. at 4:6-9.

Hooks 14 are located at the upper end of each strut 12, and a "row of hooks 14 forms a ring around the outer circumference of graft 10 and are oriented downwardly at an angle of about 10º-45º C. with respect to the vertical." *Id*. at 3:60-65; *see also* 4:28-30 (stating that hook 14 is at an angle of about 30º in Figure 2). As described in Kornberg, "[e]ach hook 14 has a barb 15 located at the lower end of the hook so as to inhibit upward movement which might tend to dislodge the graft after it is positioned and attached to the aorta wall." *Id*. at 3:66-4:1.

2. Analysis

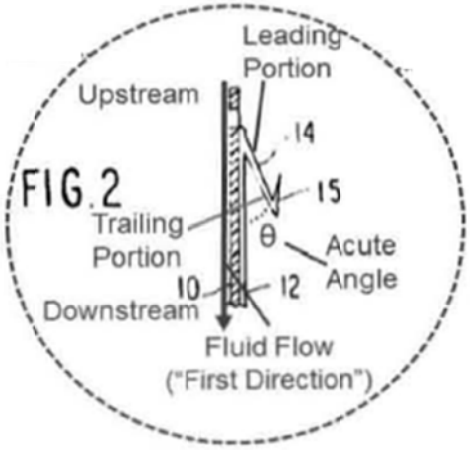
Medtronic contends that Kornberg discloses each and every element of claim 1, referring to annotated versions of Figures 1, 2, and 9 in Kornberg and disclosures in the reference, as well as a claim chart and a Declaration by Travis Rowe. Pet. 19-22, Appx. A2, pp. 5-9; Ex. 1003 ¶¶ 22-26. For example, Medtronic points to disclosure in Kornberg as corresponding to certain elements in claim 1 as follows:

Element in claim 1	Disclosure in Kornberg
"intraluminal medical device"	Graft 10
"tubular member"	Struts 12 and ring 16

Element in claim 1	Disclosure in Kornberg
"anchoring means" comprising "plural projections"	Hooks 14

Pet. 20, Appx. A2, pp. 5-7.

In relation to the "leading portion" and "trailing portion" of the projections recited in claim 1, Medtronic provides annotated figures from Kornberg, including annotated Figure 2, reproduced below.



Pet. 20. Annotated Figure 2 depicts Figure 2 of Kornberg (shown previously), with added designations including "Leading Portion," "Upstream," "Trailing Portion," "Acute Angle," "Downstream," and an arrow indicating "Fluid Flow ('First Direction')." *Id*.

Medtronic contends that hooks 14 are located adjacent to the outer periphery of the tubular member (struts 12 and ring 16) in Kornberg's graft 10. *Id*. According to Medtronic, each hook 14 includes a "leading portion," as designated in annotated Figure 2, located in the upstream direction of fluid flow, as recited in claim 1. *Id*. Medtronic further contends that each hook includes a "trailing portion," as also designated in annotated Figure 2, located in the downstream

direction of fluid flow, which includes a portion that is oriented to extend at an acute angle to the fluid flow, as also recited in claim 1. *Id*. at 20-21.

In relation to the last "whereupon" clause in claim 1, Medtronic also contends, relying on the Rowe Declaration, that

> force applied to the manually-anchored tubular member ("struts 12 and ring 16") of Kornberg by fluid flowing through the interior passageway thereof inherently produces on each of the projections ("hooks 14") a force component that causes at least one surface of the trailing portion to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure the device ("graft 10") in place.

Id. at 21 (citing Ex. 1003 ¶¶ 22-26). Medtronic also points us to Kornberg's Abstract, which describes "struts having angled hooks with barbs at their upper ends, the upper ends of the struts extending beyond the upper end of the tubular material, thus allowing the graft to be securely attached to the inside of the aorta." Ex. 1006, Abstract; Pet. Appx. A2, pp. 7-8.

Based on the record before us, Medtronic reasonably identifies where Kornberg describes, expressly or inherently, every element of claim 1. Pet. 19-21, Appx. A2, pp. 5-8. We are persuaded that Medtronic has demonstrated that there is a reasonable likelihood that it would prevail on the ground that claim 1 is anticipated by Kornberg.

In addition, Medtronic reasonably identifies where Kornberg describes the elements of dependent claims 2, 9, 10, and 13. Pet. 21-22, Appx. A2, pp. 8-9. In relation to claim 2, Medtronic contends that, in Kornberg, "at least one surface of the trailing portion is inclined upward in the first direction ('fluid flow direction') when the device ('graft 10') is placed in a vessel, duct, or lumen," as depicted in annotated Figure 2 above. Pet. 21, Appx. A2, p. 8.

In relation to claims 9 and 10, Medtronic contends that Kornberg describes a graft comprising a tubular member (struts 12 and ring 16) that is an expandable stent, i.e., "longitudinal supporting and reinforcing members called struts 12 running along the major axis of the cylindrical sleeve," where ring 16 "[f]unction[s] to keep the graft fully expanded." Pet. 21-22, Appx. A2, p. 8; Ex. 1006, 2:62-65, 6:35-37. Medtronic further points to where Kornberg describes ring 16 in a "compressed, or partially open state prior to positioning in the damaged artery," and that "[o]nce in place, the ring will spring open and snug up against the walls of the artery covering the punctures in the arterial wall made by the hooks 14." Pet. Appx. A2, pp. 8-9; Ex. 1006, 4:6-15. In relation to claim 13, Medtronic contends that Kornberg describes an endovascular graft (graft 10) that comprises a graft sleeve ("cylindrical, hollow, bifurcated sleeve") that is coupled to the expandable stent (struts 12 and ring 16, as discussed above), where blood flow applies pressure to projections (hooks 14). Pet. 22, Appx. A2, p. 9; Ex. 1006, 2:62-65.

We are persuaded that Medtronic has demonstrated that there is a reasonable likelihood that it would prevail on the ground that dependent claims 2, 9, 10, and 13 are anticipated by Kornberg.

C. Obviousness over Rhodes '154 and Kornberg

Medtronic contends that claims 1, 2, 9, 10, and 13 would have been obvious over Rhodes '154 and Kornberg. Pet. 8, 27-29. We discuss Kornberg above.

1. Rhodes '154 (Ex. 1008)

Rhodes '154 describes an endovascular graft. Figure 1 in Rhodes '154 (Ex. 1008) and Figure 1 in the '417 patent (Ex. 1001) are reproduced below.

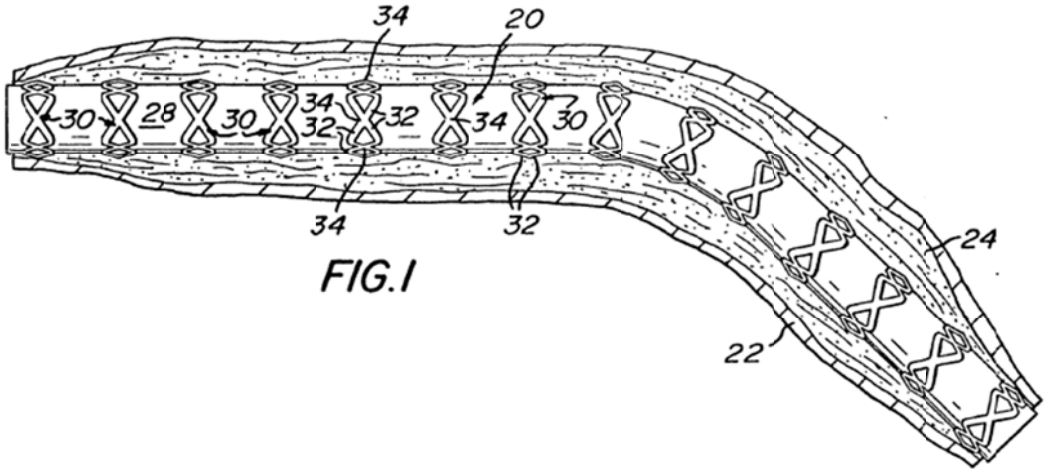


FIG.1

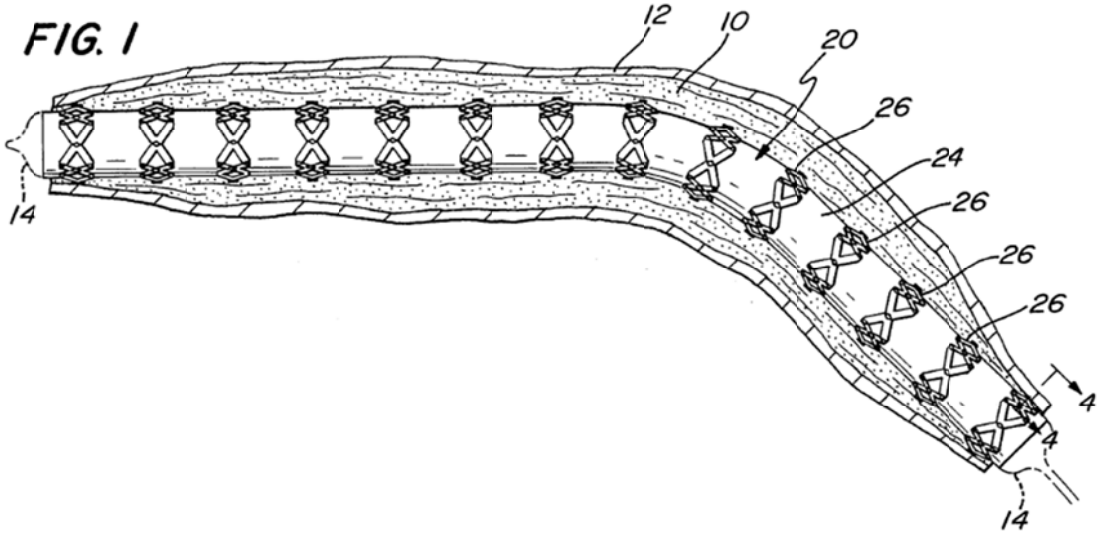


FIG. 1

Figure 1 in Rhodes ’154 (top) and Figure 1 in the ’417 patent (bottom) both depict a sectional view of an artery with an expandable intraluminal vascular bypass graft. Ex. 1008, 4:58-62; Ex. 1001, 4:46-50.

As stated in the ’417 patent, Rhodes ’154 describes a graft comprising an expandable sleeve (a tubular member) having expandable plural stents, where “[e]ach stent is a generally ring-like member formed a plurality of interconnected movable links and is mounted about the periphery of a surface, e.g., inner or outer, of the sleeve at selected points along the sleeve to form respective spaced first

sleeve sections." Ex. 1001, 2:64-3:20; Ex. 1008, 5:62-66. In addition, as stated in the '417 patent, the graft in Rhodes '154 "makes use of some anchoring means, e.g., small dome shaped projections, for aiding in the securement of the graft in place within the vessel, duct, or lumen," although the anchoring means are "amenable to improvement insofar as graft retention is concerned." Ex. 1001, 3:21-26; *see also* Ex. 1008, 7:18-24 (describing a "plurality of protuberances 50 projecting slightly outward from the outer surface of the graft . . . [that] help impact the graft into the arterial wall to maintain a fixed position therein . . . [and] are preferably located at the joints 34").

2. Analysis

Medtronic contends that Rhodes '154 discloses all elements of the challenged claims except "the specific orientation of the intraluminal medical device's projections – that the projections be oriented to extend at an acute angle to the direction of fluid flow," citing Rhodes '154, the '417 patent and its prosecution history, and the Rowe Declaration. Pet. 27-28, Appx. A5, pp. 19-24; *see also* Ex. 1002, 48-49; Ex. 1003 ¶¶ 22, 23, 28. Medtronic relies on Kornberg as disclosing a relevant device "comprising projections ('hooks 14') where the trailing portion ('downstream portions') of each projection ('hooks 14') has at least one surface that is preferentially oriented to extend at an acute angle to the fluid flow direction." Pet. 28, Appx. A5, pp. 20-21. Regarding dependent claim 2, Medtronic contends that Kornberg discloses at least one surface of the trailing portion of each projection (hook 14) as being inclined upward in the first direction (fluid flow direction). *Id*. at Pet. Appx. A5, pp. 22-23. Regarding dependent claims 9, 10, and 13, Medtronic reasonably points to where Rhodes '154 and Kornberg each disclose the recited elements. *Id*. at Pet. Appx. A5, pp. 23-24.

Medtronic further contends that a person of ordinary skill in the art would have had reason to use the projections (hooks 14) of Kornberg with the device of Rhodes '154 (in place of Rhodes '154's projections) "to provide an intraluminal medical device with improved anchoring capabilities for securing the device in place within a vessel, duct, or lumen," and "to prevent migration of the intraluminal medical device," citing a Declaration by Atul Gupta in support. *Id*. at 28-29 (citing Ex. 1004 ¶¶ 30-33).

Rhodes '154 discloses the use of projections (protuberances 50), located at on the outer periphery of a tubular member at stent joints in a relevant device, where those protuberances act as "small pressure points" to help a graft "maintain a fixed position" in an artery wall. Ex. 1008, 7:18-26; Figures 8 and 9. Kornberg describes attaching a graft to the inside wall of an aorta using hooks 14, which "inhibit upward movement which might tend to dislodge the graft," as discussed above. Ex. 1006, 3:60-4:1. Based on the record before us, we are persuaded that Medtronic reasonably contends that a person of ordinary skill in the art would have had reason to use the hooks disclosed in Kornberg in place of protuberances 50 in the device of Rhodes '154.

Medtronic has demonstrated that there is a reasonable likelihood that it would prevail on the ground that claims 1, 2, 9, 10, and 13 of the '417 patent would have been obvious over Rhodes '154 and Kornberg.

D. Remaining Ground of Unpatentability

In addition to the grounds of unpatentability discussed above, Medtronic also alleges other grounds with respect to the challenged claims. Upon review of those grounds, we conclude that they are redundant in light of the grounds on the basis of which we institute *inter partes* review of the same claims. We do not

authorize an *inter partes* review on those redundant grounds. *See* 37 C.F.R. § 42.108(a).

III. CONCLUSION

For the foregoing reasons, we are persuaded that Medtronic has demonstrated that there is a reasonable likelihood that it would prevail on the grounds that Kornberg anticipates, and Rhodes '154 and Kornberg rendered obvious, claims 1, 2, 9, 10, and 13 of the '417 patent. The Board has not made a final determination on the patentability of the challenged claims.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is *granted* with respect to the alleged ground, under 35 U.S.C. § 102, that Kornberg anticipates claims 1, 2, 9, 10, and 13 of the '417 patent;

FURTHER ORDERED that the Petition is *granted* with respect to the alleged ground, under 35 U.S.C. § 103, that claims 1, 2, 9, 10, and 13 of the '417 patent would have been obvious over Rhodes '154 and Kornberg;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '417 patent is hereby instituted commencing on the entry date of this Order, and 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;

FURTHER ORDERED that the other grounds presented in Medtronic's Petition are *denied*, and no ground other than that specifically granted above is authorized for the *inter partes* review as to claims 1, 2, 9, 10, and 13; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 11:00 AM Eastern Time on April 17, 2014. The parties are

directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,765-66, for guidance in preparing for the initial conference call, and should be prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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