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Paper 46
Entered: March 24, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

MARITAL DEDUCTION TRUST and 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*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Petitioner Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") 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"). 35 U.S.C. § 311. Patent Owner, the Marital Deduction Trust, and its exclusive licensee Endotach LLC ("Patent Owner")[1] did not file a Preliminary Response. We determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1, 2, 9, 10, and 13 of the '417 patent as unpatentable. Paper 15 ("Dec. to Inst."), 2, 15. Pursuant to 35 U.S.C. § 314, we instituted this proceeding on March 25, 2014, to review whether Kornberg[2] anticipates claims 1, 2, 9, 10, and 13 of the '417 patent under 35 U.S.C. § 102, and also whether those claims would have been obvious over Rhodes '154[3] and Kornberg under 35 U.S.C. § 103. Dec. to Inst. 15.

After institution of trial, Patent Owner filed a Patent Owner Response. Paper 27 ("PO Resp."). Petitioner subsequently filed a Reply to the Response. Paper 35 ("Reply"). An oral hearing was held on November 20, 2014. A transcript of the hearing has been entered into the record. Paper 44 ("Tr.").

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[1] Patent Owner indicates that the Marital Deduction Trust, created under the Valentine J. Rhodes Revocable Trust, is the owner of the '417 patent, while Endotach LLC is the exclusive licensee of all substantial interests of the patent. Paper 10, 2; Paper 20, 2.

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

[3] Rhodes, U.S. Pat. No. 5,122,154, issued June 16, 1992 ("Rhodes '154") (Ex. 1008).

We have statutory authority under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Petitioner has shown by a preponderance of the evidence that claims 1, 2, 9, 10, and 13 of the '417 patent are unpatentable.

B. Related Matters

Petitioner indicates that Patent Owner has asserted the '417 patent against it in *Endotach LLC v. Medtronic, Inc.*, No. 5:13-cv-03292-EJD (N.D. Cal.). Pet. 1. In its Mandatory Notices, Patent Owner 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; Paper 20, 2–3.

On April 25, 2014, after we instituted a trial in the current case, Petitioner filed another Petition in Case IPR2014-00695, involving the same parties and same claims of the '417 patent at issue in this proceeding. IPR2014-00695, Paper 1 ("Second Petition"). Petitioner also filed a Motion for Joinder requesting "that the Second Petition be joined with IPR2014-00100." IPR2014-00695, Paper 2, 2. The Second Petition reasserted two grounds of unpatentability previously asserted in this proceeding, as well as three new grounds relying on two additional references. Second Petition 10–11, 13–32. In a Decision dated September 25, 2014, we denied Petitioner's Motion for Joinder, as well as Petitioner's Second Petition. IPR2014-00695, Paper 18, majority op. at 9.

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.

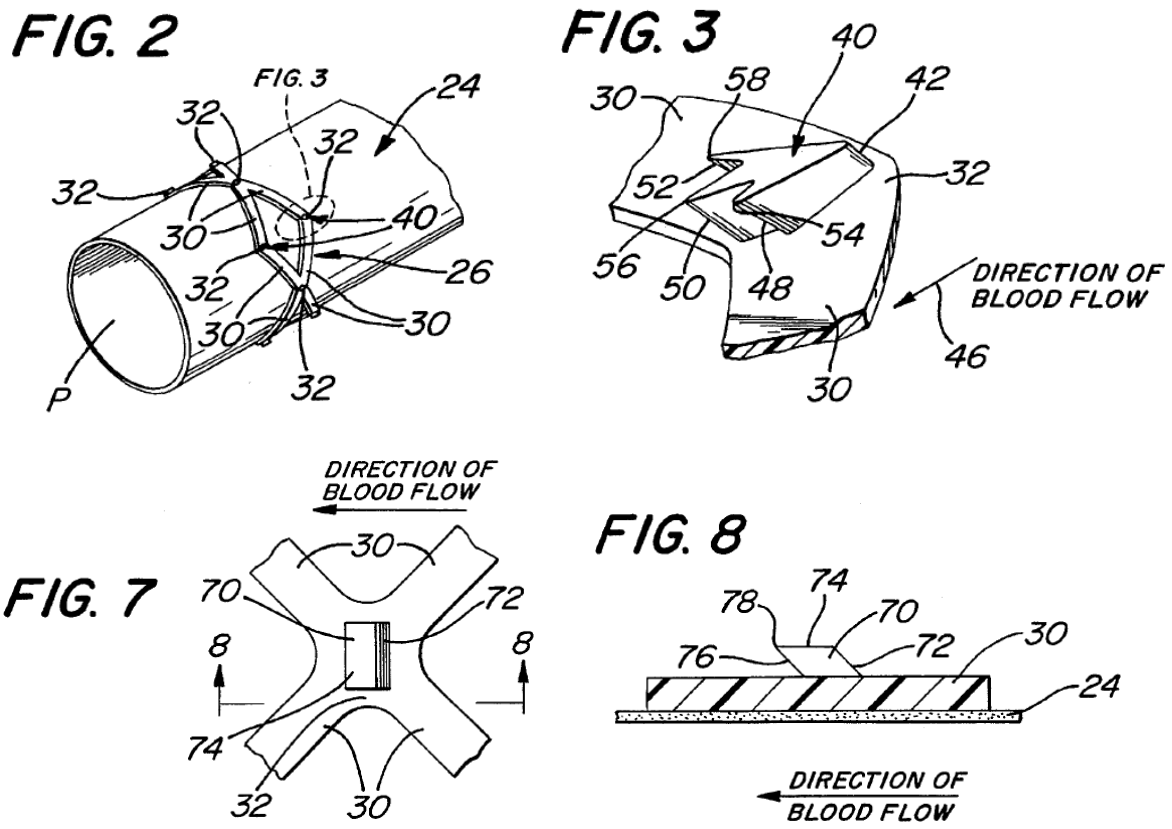


Figure 2 depicts a portion of an endovascular bypass graft. *Id*. at 4:47–52. Figure 3 depicts an enlarged view of the portion in Figure 2 designated as "FIG. 3" with broken lines. *Id*. at 4:53–55. Figure 7 depicts another embodiment of a graft. *Id*. at 4:65–67. Figure 8 depicts an enlarged sectional 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 added).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, "[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Tech., LLC*, No. 2014-1301, 2015 WL 448667, at *5–*8 (Fed. Cir. Feb. 4, 2015) ("Congress implicitly adopted the broadest reasonable interpretation standard in enacting the AIA," and "the standard was properly adopted by PTO regulation"). 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); *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may rebut this presumption, however, by acting as his own lexicographer, 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). In the absence

of such a definition, limitations are not to be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

1. "Projection," "Leading Portion," "Trailing Portion," and "Stent"

Petitioner offers 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. Upon review of the Specification of the '417 patent and the challenged claims, we construe "projection" to mean a structure that extends outward from a surface, such as a surface of a stent. Additional claim language indicates that the projection comprises a leading portion and a trailing portion, where the projection is capable of engaging with an interior surface of a vessel, duct, or lumen in a living being. Ex. 1001, 3:21–24, 7:9–59, claim 1. The "leading portion" of a projection is located in an upstream direction of fluid flow, while the "trailing portion" is located in the downstream direction of fluid flow. *Id*. at claim 1; Pet. 10–11. For example, as shown in Figure 8 of the Specification, leading surface 72 corresponds to a leading portion (oriented upstream from the direction of blood flow), while trailing surface 76 corresponds to a trailing portion (oriented downstream from the direction of blood flow). In addition, we construe "stent" to mean any structure that provides structural support, such as for a blood vessel, duct, or lumen. Ex. 1001, 2:12–14, 3:45–48; Pet. 11.

2. "At Least One Surface"

Patent Owner contends that the phrase "at least one surface" in relation to the "trailing portion" in claim 1 refers to "a portion, part or surface of the trailing portion of a projection which is oriented at an acute angle to the fluid flow," as recited in claim 1. PO Resp. 25–26. We note that claim 1 recites in relevant part that the trailing portion includes "at least one surface preferentially oriented to extend at an acute angle to the first direction." In view of the Specification, we

interpret this limitation as proposed by Patent Owner, i.e., as referring to a structural limitation indicating direction. *Id*.; Tr. 37–38. Petitioner does not disagree with this construction.

3. "Engagement With" and "Engaging"

Patent Owner contends that "engagement with" and "engaging," as recited in claim 1, require no construction, and the plain and ordinary meaning applies. PO Resp. 26. We generally agree but clarify that those terms mean contacting in some fashion. *See, e.g.*, Transcript of Deposition of James Silver, Ph.D., Ex. 1014, 22:13–20 (Dr. Silver testifying that "engage would mean that the device was in contact with the vessel wall"); Order on Claim Construction (S.D. Ind. 2013), Ex. 2013, 34.

4. "Tightly Engage"

Patent Owner contends that "tightly engage" means more than "engage" in that it describes the degree of connection between the projections and interior surface of the vessel, duct, or lumen. PO Resp. 26. Patent Owner notes that claim 1 recites that a "force from the fluid flowing through" the tubular member produces a force "to cause" a surface of the trailing portion "to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place." *Id*. at 27; Ex. 1001, claim 1.

Referring to this claim language, Patent Owner contends that being "fixedly secure" occurs as a result of forces from blood flow only, but not other forces, such as manual force exerted by a physician, or force from a balloon or stent itself. *Id*. at 30. Patent Owner also contends, citing certain portions of the Specification, that a surface of the trailing portion tightly contacts or penetrates, i.e., tightly engages, only the interior surface of the vessel wall, i.e., "the intima (inner) layer, but not into the medial (middle) or adventitial (outer) layers." *Id*. at 27–29 (citing

Ex. 1001, 8:28–30, 3:53–57).

We agree with Patent Owner that "tightly engage" means more than simply "engage." The Specification of the '417 patent does not define "tightly" per se. Rather, it states that a force of fluid, e.g., blood flow, causes projections "to tightly engage, e.g., burrow slightly into, the interior of the wall of the vessel, duct, or lumen to thereby fixedly secure the device in place." Ex. 1001, 4:13–25, 34–39, 7:17–32. The Specification also states that projections "tightly engage (and not necessarily penetrate) the interior of the wall of the vessel, duct, or lumen to fixedly secure the device in place against migration." *Id*. at 9:1–17. It also indicates that projections can "penetrate or burrow slightly into the artery wall." *Id*. at 8:19–23, 42–45. Thus, the Specification clarifies that "tightly engage" encompasses burrowing slightly into, penetrating, or not necessarily penetrating, a blood vessel wall.

In relation to a particular embodiment, shown in Figure 4, the Specification states that "[i]f some penetration is deemed desirable the height of the projections is selected so that their penetrating points do not penetrate too deeply into the artery wall," i.e., "the height of the projections is selected so that they do not penetrate into the adventicial or medial layers of the artery wall, but can penetrate its intima." *Id*. at 8:22–31. Notwithstanding that discussion, we do not read the Specification as a whole to require that "tightly engage" precludes projections penetrating adventicial or medial layers of an artery wall. Instead, the Specification states that an object of the invention is to provide anchoring means that do "not pose a significant risk of perforating the tissue of the vessel, duct, or lumen." *Id*. at 3:53–58.

Thus, we construe "tightly engage" in claim 1 to mean that trailing portions of the recited projections are structurally capable of contacting, burrowing into, or

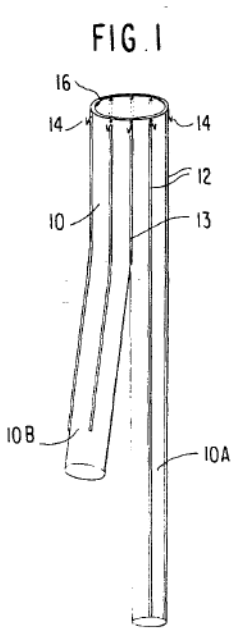
penetrating into an interior surface of a vessel, duct, or lumen in a manner that fixedly secures the device in place, without posing "a significant risk of perforating the vessel, duct, or lumen" altogether. *Id*. The projections and their trailing portions must be structurally capable of allowing a fluid flow force, e.g., blood flow, through the tubular member to help cause and maintain the tight engagement of the projections, and keep the device securely in place, even if other forces, such as manual force by a physician, are also involved in deploying the device initially. *See, e.g.*, Ex. 1001, 7:9–33 (stating that "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 "plural protuberances or projections 40"), 3:35–37, 8:11–45 (stating that "flow of fluid, e.g., blood, through the device 20 will tend to force the projections 40 into good engagement" and "penetration may not be necessary for good resistance to migration of the device"); Declaration of James Silver, Ph.D., Ex. 2002 ¶ 45.

B. Anticipation by Kornberg

Petitioner argues that Kornberg anticipates claims 1, 2, 9, 10, and 13 of the '417 patent. 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.



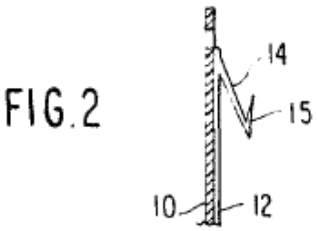


Figure 1 depicts an aortic bifurcation graft equipped with a circumferential row of hooks 14 and a plurality of longitudinal struts 12. *Id*. at 2:23–27. Figure 2 depicts an enlarged view of the upper end of a single strut 12 with hook 14 having barb 15. *Id*. at 2:28–29.

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 id.* at 4:28–30 (stating that hook 14 is at an angle of about 30º in Figure 2). Hook lengths are "typically 2 to 8 mm." *Id*. at 4:40–42; Ex. 2002 ¶ 68. 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." Ex. 1006, 3:66–4:1.

Kornberg also describes, referring to Figure 9, that "downward flow of blood holds the distal graft limbs 10A and 10B in place so that no mechanical attachment is necessary distally," and that the "flow mechanism of the blood keeps the graft open." *Id*. at 6:20–30. In relation to Figure 10, Kornberg describes that the "aortic wall at the neck of the aneurysm 56 is pierced by the multiple radially placed hooks 14. These puncture wounds are then excluded from the blood flow by the snug fit provided by the flexible ring 16 at the top of the graft." *Id*. at 6:40–47. Kornberg also contemplates that one could make its graft without ring 16. *Id*. at 4:6–16.

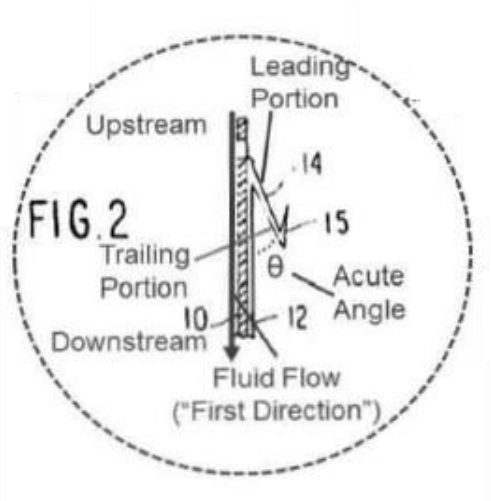
2. Analysis—Claim 1

Petitioner 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, 5–9; Declaration of Travis Rowe, Ex. 1003 ¶¶ 22–26. For example, Petitioner 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
"anchoring means" comprising "plural projections"	Hooks 14

Pet. 20, Appx. A2, 5–7.

In relation to the "leading portion" and "trailing portion" of the projections recited in claim 1, Petitioner 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*.

Petitioner 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 Petitioner, 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*. Petitioner 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, Petitioner 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). Petitioner 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, 7–8.

Patent Owner responds, relying on a Declaration by Dr. James Silver (Ex. 2002). PO Resp. 1. First, Patent Owner contends that Kornberg discloses that its graft projections fully engage upon completion of the device's deployment, and therefore, Kornberg fails to disclose that fluid flow forces cause projections to engage after deployment. *Id*. at 1, 13. Patent Owner contends that, when using Kornberg's device, "blood flow forces would either have no effect on the amount of securement provided by the anchors or force the anchors to further penetrate the vessel such that there would be an increased risk of damage to the vessel wall, or . . . the anchor itself." *Id*. at 13–14 (citing Ex. 2012; Ex. 2023, 76:5–81:25; Ex. 2021, 52:9–14, 132:16–25; Ex. 2002 ¶¶ 44, 47). Patent Owner also refers to

the prosecution history of the '417 patent, arguing that inventor Dr. Rhodes addressed "the need for the fluid force to help secure the graft in place versus previous stent graft attachment methods." PO Resp. 15–17.

Along these lines, Patent Owner contends that "[w]hile forces from the fluid flow acting on the graft 10 may inherently exist and keep the graft 10 open, Kornberg does not teach or suggest that such fluid flow forces are what causes the at least one surface of the trailing portion of the hooks 14 to tightly engage the vessel wall." *Id*. at 35 (citing Ex. 2023, 80:1–7; Ex. 2002 ¶ 73). According to Patent Owner, Kornberg's device is "fixedly secured in place against migration" by manual force exerted by a physician, such that trailing portions of hooks 14 fully penetrate a vessel wall during deployment, and thereafter, the hooks "would not experience any further gain in fixation against migration resistance as a result of the blood flow forces." PO Resp. 35–36 (citing Ex. 2023, 80:14–25, 81:8–25; Ex. 2002 ¶¶ 74, 76, 77).

Petitioner establishes by a preponderance of the evidence that Kornberg's graft device includes a "tubular member," and that hooks 14 in Kornberg's graft device correspond to an "anchoring means" comprising "projections" that each have a "leading portion," located in the upstream direction of fluid flow, as well as a "trailing portion," located in the downstream direction of fluid flow, as recited in claim 1. Pet. 20 (including annotated Figure 2 from Kornberg). Petitioner also establishes sufficiently that Kornberg's projections (hooks 14 with barbs 15) have trailing portions with a surface "oriented to extend at an acute angle to the first direction," as recited in claim 1. Pet. 20–21 (including annotated Figure 2 from Kornberg), Appx. A2, 6–7.

Patent Owner does not contend otherwise. Nor does Patent Owner dispute that Kornberg's hooks and barbs are structurally capable of penetrating into an

interior surface of a vessel in a manner that fixedly secures graft 10 in place. PO Resp. 31–39; Pet. Appx. A2, 7–8 (citing Ex. 1001, Abstract, 3:60–62 (stating that "proximal attachment of the graft 10 to the inside wall of the aorta is accomplished by the hooks 14 which are located at the upper end of each strut 12")). Rather, Patent Owner relies on the last "whereupon" in claim 1 as providing additional structural limitations, including that the projections are structurally capable of having blood flow force "cause" a relevant surface of hooks 14 to "tightly engage" a blood vessel and "fixedly secure" the device in place. PO Resp. 34–36.

In this regard, Kornberg describes that "downward flow of blood holds the distal graft limbs 10A and 10B in place so that no mechanical attachment is necessary distally," and that the "flow mechanism of the blood keeps the graft open." Ex. 1006, 6:20–30; Reply 9–10. Because hooks 14 with barbs 15 are part of graft 10 in Kornberg's device, we are persuaded by Petitioner's position that blood flow through the interior passageway of Kornberg's device "inherently produces" a force that helps cause hooks 14, including their trailing portion surfaces, to engage and maintain engagement in the vessel, which fixedly secures the device ("graft 10") in place. Pet. 21; Reply 9–10.

Based on descriptions in Kornberg that blood flow keeps graft 10 open (Ex. 1006, 6:23–30), we are not persuaded that blood flow forces would have "no effect on the amount of securement provided by" hooks 14 located on the graft, as Patent Owner contends. PO Resp. 13, 36. Kornberg's descriptions necessarily imply that, absent forces from blood flow, the graft would not stay open, and therefore, hooks 14 would disengage from the vessel. Thus, a preponderance of the evidence establishes that Kornberg inherently describes projections (hooks 14 with barbs 15), including surfaces of trailing portions of the hooks, that are capable of being forced by blood fluid flow to cause engagement with the interior of the vessel to

"fixedly secure" the device in place, even if manual forces by a physician put the device and hooks in place initially.

We note that evidence submitted by Patent Owner further supports this finding. Patent Owner points us to the Malina article (Ex. 2012), discussing "the importance of using hooks and barbs to properly anchor the graft into the wall to prevent migration after deployment." PO Resp. 17. Patent Owner quotes that article as stating that the "angle between the stent and its hooks and barbs is important" for the action of the hooks and barbs engaging "the aortic wall when the stent-graft is pulled distally by the bloodstream." *Id*. (citing Ex. 2012, 6). Thus, Patent Owner's own evidence indicates that it is the presence and angles of hooks and barbs, exactly as depicted in Kornberg, that allow blood flow to cause and maintain tight engagement of projections in the vessel and keep the device securely in place.

Second, Patent Owner argues, in relation to the last "whereupon" clause in claim 1, that Kornberg's hooks 14 do not "tightly engage" a blood vessel because Kornberg's hooks pierce blood vessels, and Kornberg uses ring 16 to cover resulting punctures in the vessel wall. PO Resp. 36–39; Ex. 1006, 4:6–16. Thus, according to Patent Owner, Kornberg does not describe projections that do not pose a significant risk of perforating the vessel, as required in the last whereupon clause in claim 1.

Patent Owner acknowledges, as Petitioner contends, that Kornberg discloses a range of hook angles (10°–45°) and hook lengths (2–8 mm), and that certain lower angles and smaller lengths within those ranges would result in hooks being less than the thickness of an aorta vessel wall. PO Resp. 37 (citing Ex. 1006, 3:62–65, 4:40–42; 2002 ¶ 68 (stating that the height of Kornberg's anchors (hooks 14 with barbs 15) "will be from about 0.35 to 5.66 mm, and because the aortic wall is

typically only about 2 mm thick, the anchors will penetrate the aorta in the majority of cases"); Reply 7–9. Patent Owner argues, however, that because Kornberg does not describe a specific combination of hook angle and hook length, it does not describe a combination that "would necessarily result in a hook not perforating through the artery wall." PO Resp. 37–38. Patent Owner further contends that Kornberg lacks "sufficient specificity," as discussed in *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999–1000 (Fed. Cir. 2006), because Kornberg does not disclose or point to any particular embodiment as desirable, but instead emphasizes perforation, as shown in Figure 10 and addressed by ring 16. PO Resp. 38–39.

Atofina explains that a reference's description of a broad genus range (e.g., broad temperature range) does not anticipate necessarily every species within that range. *Atofina*, 441 F.3d at 999. Here, however, Kornberg discloses relatively narrow ranges of hook angles (10°–45°) and lengths (2–8 mm), as noted above, and specifically describes an angle of about 30º in the embodiment shown in Figure 2. Ex. 1006, 4:28–29. As Petitioner points out, any hook having a 10º angle (at any described length) and any hook being 2 mm length (at any described angle, including 30º shown in Figure 2) would not penetrate an aorta wall, which is about 2 mm thick. Reply 7–9; *see also* Ex. 2002 ¶ 68. Moreover, Kornberg expressly describes that its graft could be made without ring 16, indicating that Kornberg contemplates that ring 16 (used to cover "punctures in the aorta") may be unnecessary in certain embodiments. Reply 9; Ex. 1006, 4:6–16.

In addition, Kornberg clarifies that it is the presence of hooks with barbs, at the disclosed locations and angles, as shown in Figures 2 and 5, for example, that "inhibit[s] upward movement which might tend to dislodge the graft after it is positioned and attached to the aorta wall." Ex. 1006, 3:60–4:1. In this context,

although Kornberg describes and depicts hooks that pierce the aorta wall, the reference also discloses hooks that necessarily do not pierce the aorta wall in that it describes smaller angles and lengths for hooks 14, as well as ring 16 being optional. *Id*. at 3:60–4:46 (describing hook 14 angles and lengths, and attaching the graft to "the aorta wall").

The evidence before us does not persuade us that a "considerable difference" exists between possible (unrecited) ranges of angles and lengths for the projections recited in claim 1 and for Kornberg's hooks 14. *Atofina*, 441 F.3d at 993. In addition, evidence of record does not persuade us that Kornberg's graft and its hooks would have operated differently in terms of securing the device in place, depending on angle or length of hooks 14 within the ranges described in Kornberg. *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc*., 701 F.3d 698, 705–6 (Fed. Cir. 2012) (addressing whether something "worked differently at different points within the prior art range"); Ex 1014, 22:13–20 (testimony by Dr. Silver stating that "tightly engaged meant that it was very securely attached to the vessel wall, and then even more unlikely to move").

Similarly, we are not persuaded, based on the record before us, that an ordinary artisan would have failed to recognize that Kornberg's 2 mm length hooks, at any angle in the described range, such as 30º, or Kornberg's 10º angle hooks, at any length in the described range, would have been acceptable choices for use in graft 10 placed in the aorta, or that such hooks would have not pierced the aorta wall. *OSRAM Sylvania*, 701 F.3d at 705–6 (considering whether an ordinary artisan would not have recognized a specific value "as an acceptable value for the range provided in the prior art"); Ex. 1014, 119:11–121:12.

Thus, Kornberg describes a device comprising a tubular member and anchoring means comprising projections meeting the limitations required in

claim 1, including those provided by the last "whereupon" clause in the claim. Based on the record before us, we conclude that Petitioner has established by a preponderance of the evidence that Kornberg describes, expressly or inherently, every limitation in claim 1, and therefore, anticipates that claim, of the '417 patent.

3. Analysis—Claims 2, 9, 10, and 13

Petitioner contends that Kornberg describes all elements of dependent claims 2, 9, 10, and 13. Pet. 21–22, Appx. A2, 8–9. In relation to claim 2, Petitioner 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, 8.

In relation to claims 9 and 10, Petitioner 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, 8; Ex. 1006, 2:62–65, 6:35–37. Petitioner 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, 8–9; Ex. 1006, 4:6–15.

In relation to claim 13, Petitioner 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, 9; Ex. 1006, 2:62–65.

Patent Owner does not dispute that Kornberg describes the components recited in claims 2, 9, 10, and 13, but instead relies on contentions discussed above in relation to claim 1. PO Resp. 31–39. For the same reasons discussed above regarding claim 1, and in view of Petitioner's contentions and cited evidence regarding challenged dependent claims, we find that Kornberg describes the devices recited in claims 2, 9, 10, and 13.

Based on the record before us, we conclude that Petitioner has established by a preponderance of the evidence that Kornberg describes, expressly or inherently, every limitation in claims 2, 9, 10, and 13, and therefore, anticipates those claims, of the '417 patent.

C. Obviousness over Rhodes '154 and Kornberg

Petitioner contends that claims 1, 2, 9, 10, and 13 would have been obvious over Rhodes '154 and Kornberg. Pet. 8, 27–29.

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.

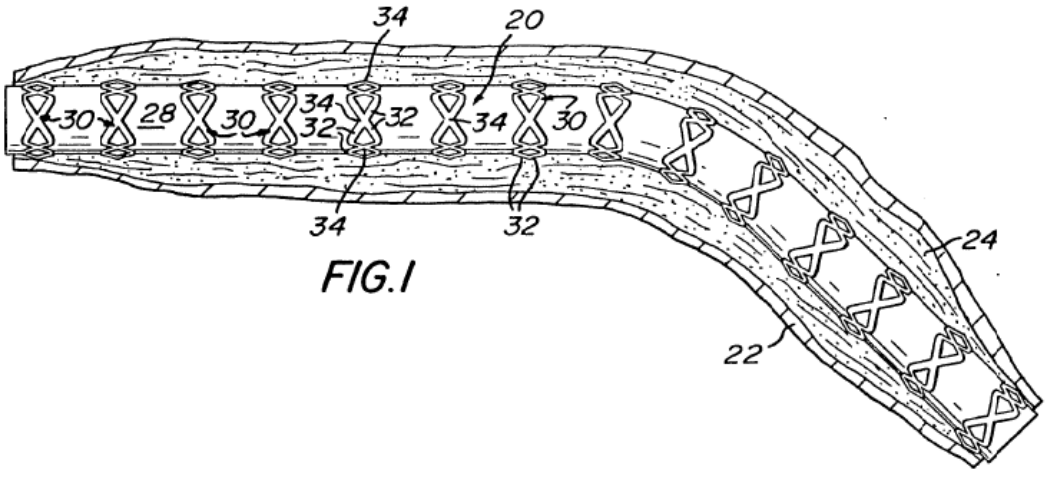


FIG.1

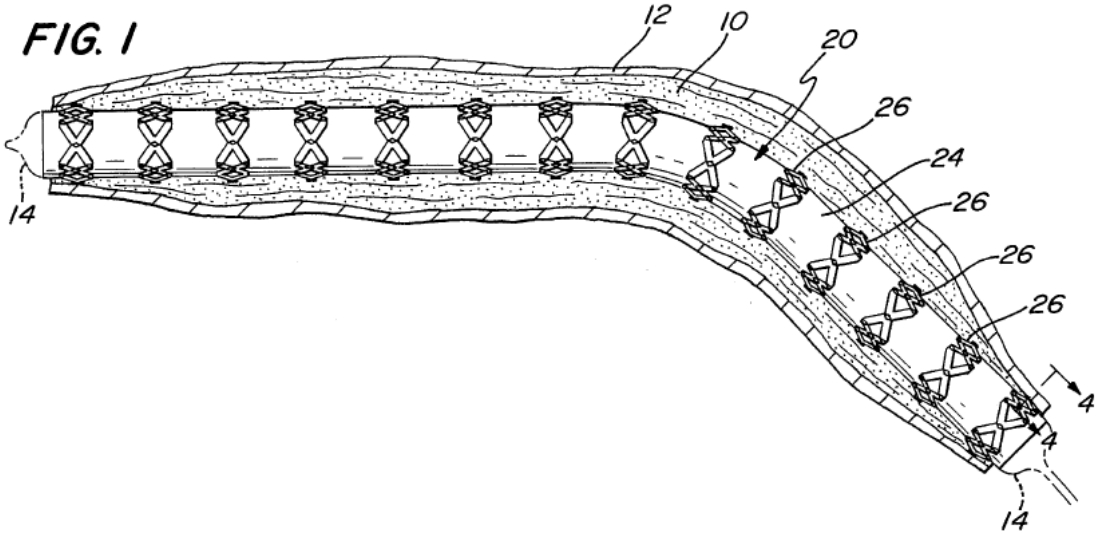


Figure 1 in Rhodes ’154 (top) and Figure 1 in the ’417 patent (bottom) both depict a sectional view of an artery with an expandable intraluminal vascular bypass graft. Ex. 1008, 4:58–62; Ex. 1001, 4:46–50.

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 [with] 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

Petitioner 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, 19–24; *see also* Ex. 1002, 48–49; Ex. 1003 ¶¶ 22, 23, 28. Petitioner 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, 20–21. Regarding dependent claim 2, Petitioner 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, 22–23. Regarding dependent claims 9, 10, and 13, Petitioner points to where Rhodes '154 and Kornberg each disclose the recited elements. *Id*. at Pet. Appx. A5, 23–24.

Petitioner 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 protuberances) "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).

Patent Owner responds that both Kornberg and Rhodes '154 fail to teach or suggest the limitations provided by the last "whereupon" clause in claim 1, discussed above regarding the anticipation ground based on Kornberg. PO

Resp. 39–42. Patent Owner contends, for example, that the small dome protuberances in Rhodes '154's device act as pressure points on the vessel wall, but do not penetrate the interior surface of the vessel wall, and therefore do not come into contact with the vessel as a result of fluid flow forces. *Id*. at 40–42. Patent Owner also contends that one would have had no reason to use the projections of Kornberg in Rhodes '154's device. *Id*. at 42–46.

As discussed above, Petitioner establishes by a preponderance of the evidence that Kornberg alone describes, expressly or inherently, every limitation recited in the challenged claims. Generally speaking, and we find applicable here, "anticipation is the 'epitome of obviousness.'" *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1363–64 (Fed. Cir. 2008) (quoting *In re Kalm*, 378 F.2d 959, 962 (CCPA 1967)); *Jones v. Hardy*, 727 F.2d 1524, 1529 (Fed. Cir. 1984) (noting that "though anticipation is the epitome of obviousness, [they] are separate and distinct concepts").

In addition, both Rhodes '154 and Kornberg disclose blood vessel grafts comprising tubular members and anchoring means comprising projections. In relation to its projections used "to help hold or secure the graft in position in the artery," Rhodes '154 teaches a plurality of protuberances that "act as small pressure points that help impact the graft into the arterial wall to maintain a fixed position therein." Ex. 1008, 7:18–26; Figures 8 and 9. Kornberg similarly describes attaching a graft to the inside wall of an aorta using projections, i.e., hooks 14 that "inhibit upward movement which might tend to dislodge the graft." Ex. 1006, 3:60–4:1. As discussed above, Kornberg's hooks meet the limitations provided by the last "whereupon" clause in claim 1.

Rhodes '154 teaches advantages of using its particular flexible and "expandable intraluminal vascular bypass graft," such as the ability to use it "over

long distances, for long segment occlusions in the vascular tree." Ex. 1008, 3:47–68. Kornberg teaches advantages of using its particular hooks with barbs "for rapid and secure attachment within the desired location of the damaged artery." Ex. 1006, 2:15–19.

Considering the similarities of the devices taught in Rhodes '154 and Kornberg, and the advantages taught in each reference about different components, we are not persuaded that one would have had no reason to use the projections of Kornberg in Rhodes '154's device, as Patent Owner contends. PO Resp. 42–46. Moreover, it is not the case that the only evidence of a motivation to combine the teachings of Kornberg and Rhodes '154 comes from Mr. Gupta's Declaration submitted by Petitioner, as Patent Owner contends. *Id*. at 43. The two references themselves, both relating to blood vessel grafts, provide reasons why one would have read those references together. The references themselves also indicate that an ordinary artisan would have had a reasonable expectation of success in replacing the protuberances in Rhodes '154's device with the barbed hooks taught in Kornberg, involving the substitution of a similar component for another in a similar device to yield a result one would have predicted from reading the references, i.e., greater anchoring ability. *See also* Ex. 1004 ¶¶ 32–33 (discussing the two references); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (stating that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results").

In its Response, Patent Owner relies on the Declaration by Dr. Silver, who testifies that "it is not at all clear" that an ordinary artisan "would feel a need" to combine an aortic stent, designed to be secured in place by friction i.e., passive fixation, with "active fixation components," i.e., hooks with barbs that penetrate the vessel. PO Resp. 45–46 (citing Ex. 2002 ¶ 79). In addition, Patent Owner

asserts that knowledge about "hook fracture" would have taught away from the combination (*id*. at 46–47, Ex. 2002 ¶ 86), and Petitioner's obviousness contentions are "tainted by impermissible hindsight" (*id*. at 47–49). Patent Owner further contends that replacing Rhodes '154's protuberances with Kornberg's hooks 14 would render Rhodes '154's device "unsatisfactory for its intended purpose and change its principle of operation." *Id*. at 49–51 (citing Ex. 2002 ¶¶ 90–91). According to Patent Owner, doing so would transform Rhodes '154's device from a passive-fixation device to an active-fixation device (involving punctures and risk of blood loss, requiring the need for ring 16), and "would complicate deployment of the modified device" and require "[s]ubstantial modification of the tubular device." *Id*. at 49–50.

As discussed above, Kornberg discloses the benefits of using hooks 16, and, in that context, teaches hooks with angles and lengths that would not have punctured an aorta wall during use, and consistently teaches use of its graft without ring 16. Moreover, Rhodes '154 teaches protuberances acting "as small pressure points," providing further suggestion to use hooks 16 having smaller lengths and angles, as described in Kornberg. Evidence cited by Patent Owner does not persuade us that replacing Rhodes '154's protuberances with Kornberg's hooks 14 would have complicated deployment above and beyond the deployment already disclosed in Kornberg, or require substantial modification of Rhodes '154's tubular device, rather than a relatively straightforward substitution. Dr. Silver's conclusory statements in this regard (Ex. 2002 ¶¶ 90–91) do not overcome teachings in the references themselves.

Asserted Secondary Considerations

Patent Owner also cites to secondary considerations of non-obviousness. PO Resp. 51–56. In relation to a long felt but unmet need, for example, Patent Owner

contends that "[n]one of the literature at that time of the filing" of the '417 patent recognized problems and solutions identified in the patent, i.e., "securement against the downstream migration that an intraluminal device experiences when deployed within a blood vessel," while "not posing a significant risk of perforating or significantly damaging the wall of the blood vessel and surrounding organs." *Id*. at 52–54. As discussed above, however, both Rhodes '154 and Kornberg proposed solutions to the issue of device migration, i.e., anchoring means comprising projections (protuberances in Rhodes '154, and hooks with barbs in Kornberg), and disclosed projections that would not have perforated aorta vessel walls or damaged surrounding organs.

Moreover, post-filing references cited by Patent Owner, such as the Malina article (Ex. 2012), indicate that "angle between the stent and its hooks and barbs is important" in engaging the hooks and barbs to "the aortic wall when the stent-graft is pulled distally by the bloodstream." Ex. 2012, 6; PO Resp. 17–18; Ex. 2002 ¶ 100. As noted above, Kornberg discloses hooks with barbs having relevant angles, and that the hooks prevent migration. Ex. 1006, 3:60–4:1 (describing the use of hook 14 "oriented downwardly at an angle of about 10º–45°" and having barb 15 "so as to inhibit upward movement which might tend to dislodge the graft after it is positioned"). The Cook '132 patent (U.S. Pat. No. 7,081,132 B2; Ex. 2018), also cited by Patent Owner, similarly describes a "series of staggered barbs" to prevent migration, where the barbs have ranges of angles and lengths mirroring those taught in Kornberg, i.e., "length is about 5 mm, the typical range being 3–8 mm," and an angle "being about 20–50°, e.g. 35°." Ex. 2018, 4:53–5:10, 5:55–6:10; PO Resp. 20–21, 54; Ex. 2002 ¶ 101.

Patent Owner also points us to the Sisken '289 patent (U.S. Pat. No. 7,572,289 B2; Ex. 2019) as describing "barb 12 having an angle of 10° or less

(more preferably 5° or less)," which "can provide superior anchoring characteristics over typical angled barbs that are configured to more readily penetrate tissue upon contact." Ex. 2019, 5:9–21; PO Resp. 21–22, 54. Notably, however, the '417 patent does not provide teachings regarding specific angles, and the challenged claims do not recite particular lengths or angles in relation to the claimed projections.

Patent Owner also asserts commercial success of various endovascular devices, but does not provide evidence indicating that any of those sold devices meet all limitations of the challenged claims. PO Resp. 55 (citing Ex. 2002 ¶¶ 104–105). Likewise, no evidence of record indicates that a nexus exists between the sales of the mentioned devices and novel or non-obvious aspects of the subject matter recited in the challenged claims. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (stating that "[w]here the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention"); *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). In addition, Patent Owner's one sentence statement indicating that the '417 patent has been licensed fails to indicate sufficient objective indicia of non-obviousness given the strong evidence of obviousness in view of the cited references themselves. PO Resp. 55–56 (citing Ex. 2002 ¶ 106 (testimony by Dr. Silver providing a similar single sentence); Ex. 2028 (mentioning resolution of a litigation in a short press release)).

Based on the record before us, Petitioner has established by a preponderance of the evidence that claims 1, 2, 9, 10, and 13 of the '417 patent would have been obvious over Rhodes '154 and Kornberg.

III. CONCLUSION

For the foregoing reasons, Petitioner has demonstrated by a preponderance of the evidence that Kornberg anticipates claims 1, 2, 9, 10, and 13 of the '417 patent under 35 U.S.C. § 102, and also that claims 1, 2, 9, 10, and 13 would have been obvious over Rhodes '154 and Kornberg under 35 U.S.C. § 103.

IV. ORDER

Accordingly, it is

ORDERED that claims 1, 2, 9, 10, and 13 of the '417 patent are held unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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