

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TRIVASCULAR, INC.,
Petitioner,

v.

SHAUN L.W. SAMUELS,
Patent Owner.

Case IPR2013-00493
Patent 6,007,575

Before TONI R. SCHEINER, RICHARD E. RICE, and
SCOTT E. KAMHOLZ, *Administrative Patent Judges.*

RICE, *Administrative Patent Judge.*

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

I. INTRODUCTION

A. Background

Petitioner TriVascular, Inc. (“TriVascular”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–24 of U.S. Patent No. 6,007,575 (Ex. 1001, “the ’575 Patent”). We instituted trial for claims 1, 2, and 4–24: claims 1, 2, 6–15, and 18–24 as obvious over Samuels ’851¹ and Todd;² and claims 1, 4–6, 9–11, 13, 14, 16, 17, and 19–21 as obvious over Lazarus³ and Todd. Decision to Institute (Paper 10, “Dec.”) 26.

Patent Owner Shaun L.W. Samuels (“Dr. Samuels”) filed a Request for Rehearing (Paper 13, “Req. Reh’g”). We denied the Request. Decision on Request for Rehearing (Paper 15).

Dr. Samuels filed a Patent Owner Response (Paper 19, “Resp.”) and a contingent Motion to Amend (Paper 21). TriVascular filed a Reply (Paper 28, “Reply”) and an Opposition to the Motion to Amend (Paper 27). Dr. Samuels filed a Reply to the Opposition (Paper 29).

In his Response (Paper 19), Dr. Samuels relied upon his own declaration (Ex. 2002) and the declaration of Timothy W.I. Clark, M.D. (Ex. 2003). In its Reply (Paper 28), TriVascular relied upon deposition testimony of Dr. Samuels (Ex. 1020) and Dr. Clark (Ex. 1021).

¹ US 5,423,851 (Ex. 1002).

² US 5,423,745 (Ex. 1008).

³ US 5,693,088 (Ex. 1004).

Oral argument was conducted on September 3, 2014. A transcript is entered as Paper 44 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

TriVascular has not proved that claims 1, 2, and 4–24 are unpatentable.

We dismiss as moot Dr. Samuels’s Motion to Amend.

B. The ’575 Patent

The ’575 Patent relates to an inflatable intraluminal stent that can be affixed to the interior surface of a tubular structure within the human body as a means of treating conditions such as stenosis. Ex. 1001, 2:28–31. The device features an inflatable cuff with a “friction-enhancing” outer surface. *Id.* at 2:35–36. Figure 1 of the ’575 Patent is reproduced below:

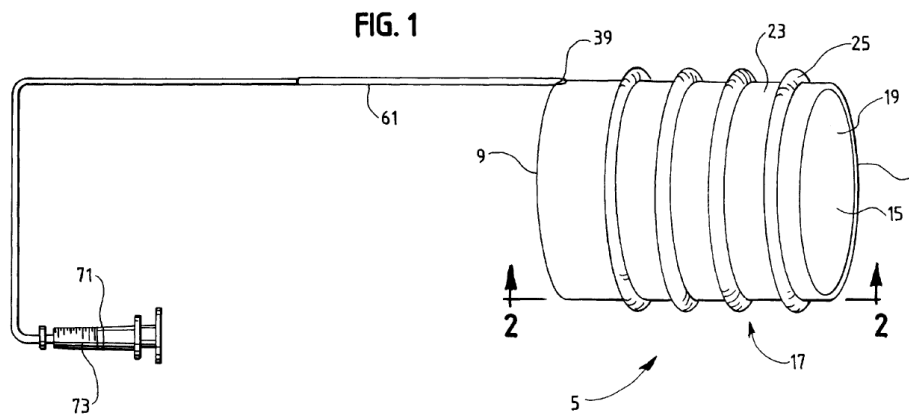


Figure 1 is a perspective view of “an embodiment of the inflatable intraluminal stent of the present invention.” *Id.* at 2:62–63, 3:24–25. As illustrated in Figure 1, stent 5 includes lumen 15, which is defined by inflatable cuff 17 having inner surface 19 and outer surface 23. *Id.* at 3:26–

31. Outer surface 23 includes “a number of inflatable ridges 25 disposed about its circumference.” *Id.* at 3:32–33.

Claim 1 is illustrative of the claimed subject matter and is reproduced below.

1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:

a) an inflatable and deflatable cuff of generally hollow cylindrical continuation having a collapsible lumen, an inner surface, an inlet, an outlet and a friction enhancing outer surface, said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff, said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;

b) means for injecting an inflation material into said cuff to inflate it; and

c) a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.

Id. at 6:47–67.

II. DISCUSSION

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). Claim terms are 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). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. “Friction-enhancing outer surface”

We determined, for purposes of instituting *inter partes* review, that the broadest reasonable interpretation consistent with the Specification of a “friction-enhancing outer surface” is an outer surface with features that increase its capability to engage or grip another surface. Dec. 8 (citing Ex. 1001, 2:35–37, 3:64–67). We maintain this interpretation because neither party has contested it, and we discern no evidence in the full record compelling a different interpretation.

2. “Circumferential ridge disposed about the inflatable cuff”

We determined, for purposes of instituting *inter partes* review, that the broadest reasonable interpretation consistent with the Specification of a “circumferential ridge disposed about the inflatable cuff” is a raised strip

disposed circumferentially about the outer surface of the inflatable cuff. *Id.* at 9 (citing Ex. 1001, 3:32–33, 54, Figs. 1, 2; Ex. 1014 (WEBSTER’S NINTH NEW COLLEGIATE DICTIONARY (1986)), 1014 (“ridge”)). We maintain this interpretation because neither party has contested it, and we discern no evidence in the full record compelling a different interpretation.

3. “*Means for*” terms

Petitioner proposes claim constructions for each of the following “means for” terms, which Petitioner contends are means-plus-function limitations governed by 35 U.S.C. § 112 ¶ 6: “means for injecting an inflation material into said cuff to inflate it,” recited in claim 1; “means for inflating the cuff with inflation material in fluid communication with said inflation port,” recited in claim 14; “means for inflating the plurality of cuffs with inflation material,” recited in claim 23; and “means for securing an intraluminal medical device to the inner surfaces of the cuffs,” recited in claim 24.⁴ Pet. 7–9. Dr. Samuels does not contest the applicability of § 112 ¶ 6 to these limitations, and does not contest the proposed constructions. We determine that express construction of these limitations is not required for this decision.

4. “*When said cuff is in a fully inflated condition*”
and “*when the cuff is fully inflated*”

Petitioner argues that the claim terms “when said cuff is in a *fully inflated* condition,” in claim 1 (emphasis added), and “when the cuff is *fully*

⁴ We note that claim 20 recites similarly “means for securing an intraluminal medical device to the inner surface of the cuff.”

inflated,” in claim 14 (emphasis added), each mean “when the cuff is inflated to the extent that the cuff is affixed to the lumen of the tubular structure but not inflated to the extent that it penetrates the tubular structure.” Pet. 11 (emphasis added). We determine that express construction of these claim terms is not required for this decision.

5. “*Inflatable protrusions*”

Each of the independent claims recites “said friction-enhancing outer surface featuring *inflatable protrusion(s)* including at least one circumferential ridge disposed about the inflatable cuff” (emphasis added). Petitioner did not propose a claim construction for “inflatable protrusions” in the Petition.

Dr. Samuels contends that “inflatable protrusions” are protrusions that contain fluid and are themselves inflatable. Resp. 5–8. In support of that claim construction, Dr. Samuels argues that ridges 25, as described in the Specification, are protrusions that “are themselves in fluid communication with the inflatable chamber 27 of cuff 17.” *Id.* at 5–6 (citing Ex. 1001, 3:54–56, Fig. 2).

TriVascular argues that “inflatable protrusions can be ‘solid’ structures such as barbs or[,] in the case of [] some of the prior art examples, solid circumferential ridges.” Reply 10 (citing Clark. Dep., Ex. 1021, 135:6–16 (discussing Samuels ’851 (Ex. 1002))). TriVascular’s proposed claim construction, however, does not accord with the plain meaning of “inflatable” as used in the Specification, i.e., expandable by being filled with fluid. *See, e.g.*, Ex. 1001, Abstr. 3–4, 3:55 (“inflatable chamber”), 1:30 (“inflatable balloon”), 2:33, 38, 3:30 (“inflatable cuff”), 3:33–34 (“inflatable

ridges”). Under the plain meaning of “inflatable” as used in the Specification, solid ridges are not “inflatable,” because they are not capable of being filled with fluid. *See* Resp. 5–8; *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989) (holding that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification).

Further, under TriVascular’s proposed claim construction, there is no meaningful difference between “protrusions” disposed on an inflatable cuff and “inflatable protrusions” disposed on an inflatable cuff. *See* Tr. 10:7–14. TriVascular’s proposed claim construction, therefore, fails to give any meaning to “inflatable” in “inflatable protrusions,” and by not giving effect to all words of the claim, runs afoul of a cardinal rule of claim construction. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“[C]laims are interpreted with an eye toward giving effect to all terms in the claim,” so that physical structures and characteristics described specifically in a claim are not rendered “merely superfluous.”).

TriVascular relies on the prosecution history of the ’575 Patent. *See* Reply 5–7. TriVascular views the prosecution history through the lens of its contention that Samuels ’851,⁵ which was applied as anticipatory prior art by the Examiner,⁶ discloses “inflatable protrusions” in the form of solid barbs 18. *See id.* Based on the premise that the only “inflatable protrusions”

⁵ We provide an overview of Samuels ’851 in section II.B.1 *infra*.

⁶ *See* Non-Final Act., mailed Nov. 16, 1998, Ex. 1012, 70–75.

disclosed in Samuels '851 are solid barbs, TriVascular argues that Dr. Samuels, by not traversing the Examiner's rejection over Samuels '851 but instead amending the claims, acted inconsistently with his claim construction in this proceeding. Reply 6–7 (citing Am't, dated Mar. 16, 1999, Ex. 1012, 81–89). TriVascular, however, has not persuaded us that the premise of its argument is correct. Indeed, the argument is inconsistent with TriVascular's assertion in this proceeding, discussed below, that the recesses of Samuels '851 (not just the solid barbs) constitute “inflatable protrusions.” *See, e.g.*, Pet. 27 (Claim Chart I, element 1a-3), 40–41 (Claim Chart II, element 1a-3, incorporating information from Chart I); Tr. 13:22–15:6.

Finally, TriVascular contends that Dr. Samuels's proposed construction of “inflatable protrusions” is inconsistent with dependent claims 2 and 15, which incorporate the “inflatable protrusions” limitation of claims 1 and 14, respectively, and recite additionally “wherein the friction enhancing outer surface is a coarse surface.” Reply 7–9. TriVascular relies on the embodiment illustrated in Figure 3 of the '575 Patent, which has an outer surface “made coarse by a combination of raised portions 31 and lowered portions 33.” *Id.* at 8 (citing Ex. 1001, 3:60–67, Fig. 3). In essence, TriVascular argues that the coarse surface described in the Specification is solid and, therefore, “inflatable protrusions” must encompass solid protrusions in order for claims 2 and 15 to encompass the embodiment illustrated in Figure 3. *Id.* at 7–9. TriVascular's analysis is unpersuasive because it fails to explain how claims 1, 2, 14, and 15 would encompass the embodiment illustrated in Figure 3, even if “inflatable protrusions” were

construed to encompass solid protrusions. For example, even under TriVascular's proposed construction, the embodiment illustrated in Figure 3 would not satisfy the claim requirement for "at least one circumferential ridge." We are not persuaded of any inconsistency in the scope of claims 1, 2, 14, and 15 under Dr. Samuels's proposed claim construction.

Accordingly, applying the standard of broadest reasonable interpretation consistent with the Specification, we determine that "inflatable protrusions" are protrusions that are themselves inflatable, i.e., expandable by being filled with fluid.

B. Obviousness Analysis

To prevail in its challenges to the patentability of claims 1, 2, and 4–24, TriVascular must prove a proposition of unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *KSR*, 550 U.S. at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching

directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420.

We analyze the instituted grounds of unpatentability in accordance with the above-stated principles.

*1. Asserted Obviousness of Claims 1, 2, 6–15,
and 18–24 over Samuels ’851 and Todd*

We instituted a review based on TriVascular’s contention that the combination of Samuels ’851 and Todd renders obvious claims 1, 2, 6–15, and 18–24 under 35 U.S.C. § 103(a). Upon consideration of the parties’ arguments and evidence, we determine that TriVascular has not demonstrated that those claims would have been obvious over Samuels ’851 and Todd, for the reasons explained below.

a. Overview of Samuels ’851

Samuels ’851 discloses inflatable balloon cuff 10, which can be used to affix a medical device within a tubular structure of the body. Ex. 1002, 2:35–37. Figures 1 and 2 of Samuels ’851, which are reproduced below, illustrate cuff 10 before and after inflation, respectively:

FIG. 1

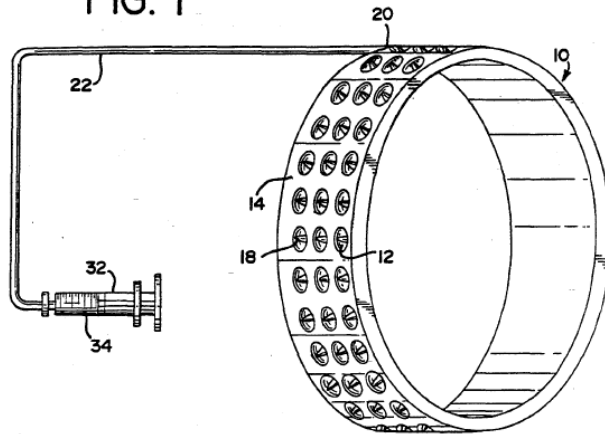
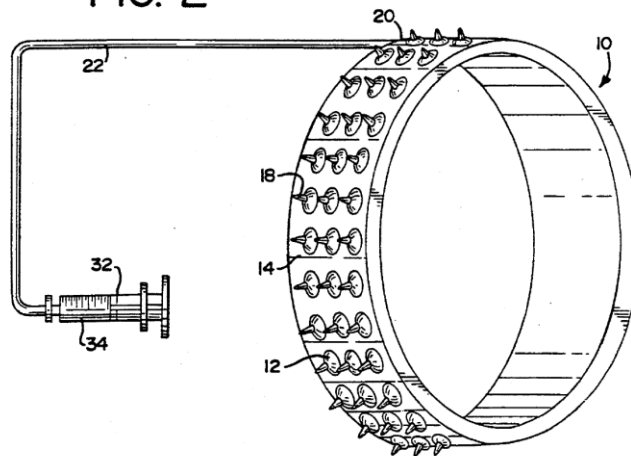


FIG. 2



Id., Figs. 1 & 2.

Figures 1 and 2 are pre- and post-deployment perspective views of cuff 10, respectively.

As illustrated in Figure 1, cuff 10 includes a plurality of reinforced recesses 12, each of which is bonded to individual barb 18 such that, before inflation, individual barbs 18 lie beneath outer surface 14 of cuff 10. *Id.* at 2:40–42, 59–61. “When the cuff 10 is fully inflated,” as illustrated in

Figure 2, “the recesses 12 pop out to allow the barbs 18 to engage the wall of a tubular structure within the body.” *Id.* at 2:62–64.

b. Overview of Todd

Todd is directed to balloon catheters that are “designed for secure placement and sealing within body passageways.” Ex. 1008, 3:67–4:2. In a preferred embodiment, “[g]ripping means project[] from the outer surface of the balloon for securely gripping the walls of the body passageway to secure the catheter in place.” *Id.* at 6:50–52. In this regard, Todd discloses:

A seal within the body passageway is also formed. This important gripping aspect of the present invention may comprise at least one irregularity in the outer surface of the balloon.

Id. at 6:52–56. The gripping means disclosed in Todd comprise “a plurality of protuberances that project outwardly from the outer surface of balloon 26.” *Id.* at 6:57–59. As defined expressly in Todd, “[t]he term ‘protuberance’ refers to a projection from the outer surface of a balloon that assists in the retention of that balloon in a body passageway of a patient.” *Id.* at 6:62–65. “The protuberances are soft enough to grip the walls of the body passageway without damaging the tissues.” *Id.* at 6:65–67. Figures 7 and 8 of Todd illustrate various configurations of protuberances. *Id.* at 6:6–7:2. Figure 7 is reproduced below.

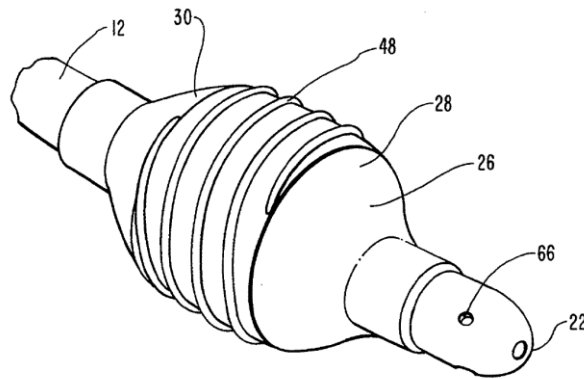


FIG. 7

Id., Fig. 7.

Figure 7 is a perspective view of inflatable balloon 26 illustrating “protuberances in the form of an outwardly projecting spiral ridge 48 wound about the exterior surface of balloon 26.” *Id.* at 7:35–37. “When inflated, the spiral ridge 48 contacts and tightly grips the walls of a body passageway in which it is inserted.” *Id.* at 7:37–39.

Figure 8 is reproduced below.

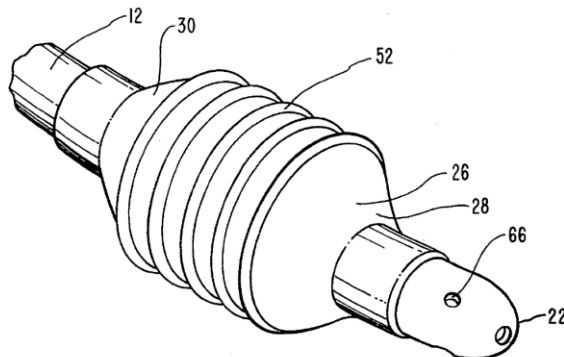


FIG. 8

Id., Fig. 8.

Figure 8 is a perspective view of inflatable balloon 26 illustrating “protuberances . . . in the form of outwardly projecting annular rings 52 wound about the exterior surface of balloon 26.” *Id.* at 7:41–43.

TriVascular contends that Todd discloses friction-enhancing, inflatable balloon protuberances, including “inflatable ridges.” Pet. 22 (citing Ex. 1008, Figs. 5–9), 41 & 51 (claim chart) (quoting Ex. 1008, 7:35–39, citing Ex. 1008, Fig. 7). At oral argument, TriVascular clarified its analysis of Todd’s disclosure, and asserted that the protuberances disclosed in Todd are hollow, and themselves inflatable. Tr. 6:5–12:20. TriVascular cited in support of its position the statement in column 7 of Todd that: “*When inflated, the spiral ridge 48 contacts and tightly grips the walls of a body passageway in which it is inserted.*” *Id.* at 6–7; Ex. 1008, 7:37–39 (emphasis added); *see* Pet. 40–41 (Claim Chart II, element 1a-3, quoting Ex. 1008, 7:35–39). TriVascular, however, has not provided a declaration, or any other evidence, to establish that a person of ordinary skill in the art would understand Todd to disclose protuberances that are hollow, and themselves inflatable.

Dr. Samuels does not agree that Todd discloses “inflatable protrusions.” Resp. 12. Dr. Samuels asserts that “the region between the inner and outer surfaces of balloon 26 of Todd is solid . . . and any provided roughened surfaces or protuberances are also solid.” *Id.* (citing Ex. 1008, Figs. 4 & 8; Ex. 2004).

On the record before us, TriVascular has failed to show that Todd discloses “inflatable protrusions,” i.e., protrusions that are expandable by being filled with fluid. *See* section II.A.5 *supra*. The protuberances

disclosed in Todd project outwardly “from the outer surface” of inflatable balloon 26. *See* Ex. 1008, 6:58–59, 62–63. As such, the protuberances are disposed on the exterior surface of the inflatable balloon, and are not in fluid communication with the balloon’s inner chamber 32. *See* Resp. 12; Ex. 1008, 7:15–16, Figs. 2, 4 & 5 (describing knobs 40 as solid structures on the outer surface of the balloon), 7:32–34, Fig. 6 (describing “cross-hatched pattern 44 projecting outwardly from the exterior surface of balloon 26”), 7:35–39, Fig. 7 (describing “outwardly projecting spiral ridge 48 wound about the exterior surface of balloon 26”), 7:40–46, Fig. 8 (describing “outwardly projecting annular rings 52 wound about the exterior surface of balloon 26”). Todd discloses expansion means in fluid communication with inner chamber 32 for inflating balloon 26 (*id.* at 7:53–60), but does not disclose expansion means for inflating the protuberances, either separately or in conjunction with inflation of the balloon. Todd discloses, simply, that “when balloon 26 is inflated, the gripping means [i.e., the protuberances] on the exterior of the balloon contact and grip the walls of the body passageway.” *Id.* at 8:14–16.

Trivascular has not persuaded us, moreover, that a person of ordinary skill in the art would have understood Todd’s statement “[w]hen inflated, the spiral ridge 48 contacts and tightly grips the walls of a body passageway in which it is inserted” (*id.* at 7:37–39 (emphasis added)), to teach or suggest that spiral ridge 48 is expandable by being filled with fluid. *See* Tr. 6–7. Other than that isolated statement, there is no suggestion, indication, or hint in Todd that any of the disclosed protuberances is hollow such that it can be filled with fluid and inflated. To the contrary, as discussed above, Todd

discloses that all of the protuberances, including spiral ridge 48, are formed on the exterior surface of the balloon. In light of that disclosure, a person of ordinary skill in the art would understand that spiral ridge 48 is not in fluid communication with the inner chamber of the balloon and, therefore, cannot be filled with fluid via the expansion means used to inflate the balloon.

TriVascular has failed to explain why, in the context of Todd's whole disclosure, the statement "[w]hen inflated, the spiral ridge 48 . . ." (Ex. 1008, 7:37–39) would not have been understood by a person of ordinary skill in the art as, simply, a specific example of the broader (and repeated) disclosure in Todd that "when balloon 26 is inflated, the gripping means on the exterior of the balloon contact and grip the walls of the body passageway" (*id.* at 8:14–16). *See also id.* at 4:19–21 ("When the balloon is inflated, the gripping means come into contact with the walls of the body passageway."), 6:48–52 ("Once . . . the balloon is inflated, the catheter is held in place by gripping means projecting from the outer surface of the balloon for securely gripping the walls of the body passageway . . .").

c. Analysis of Claims 1, 2, 6–15, and 18–24

TriVascular contends that it would have been "an obvious modification to take the friction-enhancing features of [Todd] and modify Samuels '851 while maintaining its basic intent and purpose." Pet. 22. TriVascular asserts that a common purpose of the "inflatable protrusions and barbs" of Samuels '851 and the "ridges" of Todd is "to firmly secure the stent in one position in the lumen of the tubular structure." Reply 12. Therefore, substitution of Todd's ridges for the barbs of Samuels '851,

TriVascular argues, “would have been an obvious modification carried out with predictable success.” *Id.*

Dr. Samuels counters that “no proper apparent reason has been presented by [Tri-Vascular] for the proposed combination.” Resp. 14. Dr. Samuels also argues that Tri-Vascular “has not explained how the combination would have inflatable circumferential ridges,” and that “Todd lacks any inflatable circumferential ridges.” *Id.* at 16.

For the reasons discussed below, we determine that TriVascular has not shown that the combination of Samuels ’851 and Todd satisfies the requirement of independent claims 1, 14, and 23 for “inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff.”

In its Petition, TriVascular contends that recesses 12 of Samuels ’851 satisfy the requirement of independent claims 1, 14, and 23 for “inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff.” *See, e.g.*, Pet. 27 (Claim Chart I, element 1a-3), 40–41 (Claim Chart II, element 1a-3, incorporating information from Chart I); Tr. 13:22–15:6. TriVascular has not explained sufficiently, however, why a person of ordinary skill in the art would have known to include the recesses of Samuels ’851 in the proposed combination of Samuels ’851 and Todd. As discussed above, recesses 12 of Samuels ’851 function to project barbs 18 into surrounding tissue when inflatable balloon cuff 10 is filled fully with fluid. *See* section II.B.1.a *supra*. In its Reply, TriVascular asserts that the “inflatable protrusions and barbs” of Samuels ’851 serve the same purpose as the “ridges” of Todd, but proposes, without elaboration, to

substitute just the barbs of Samuels '851 with the ridges of Todd. *See* Reply 12. At oral argument, TriVascular was unable to explain why anyone would use the recesses of Samuels '851 in the proposed combination of Samuels '851 and Todd. *See* Tr. 12:21–17:15.

We determine that Trivascular has not provided a sufficient rationale to support substituting the ridges of Todd for just the barbs of Samuels '851. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

TriVascular also contends that it would have been obvious to eliminate *both* the recesses and barbs of Samuels '851, and to substitute “a circumferential ridge, similar to the one that is in Todd.” *See* Tr. 15:24–17:15. TriVascular asserts three reasons why combining the references in that fashion would satisfy the requirement for “inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff”: (1) the ridges are “inflatable” in the combination simply because they are riding on an inflatable cuff; (2) the ridges in Todd are themselves inflatable; and (3) use of ridges that are themselves inflatable would have been obvious, as they would take up less volume and be easier to insert in blood vessels than ridges that are not themselves inflatable. *See id.* at 17:16–18:14. None of those reasons is persuasive. The first reason is not persuasive because it does not satisfy the requirement for “inflatable protrusions,” i.e., protrusions that are expandable by being filled with fluid. *See* section II.A.5 *supra*. The second reason is not persuasive because we do

not agree that Todd discloses ridges that are themselves inflatable. *See* section II.B.1.b *supra*.

Lastly, the third reason is not persuasive because TriVascular has not established that a person of ordinary skill in the art would have known to use, on an inflatable cuff, circumferential ridges that are themselves inflatable. The evidence is to the contrary. *See, e.g.*, Ex. 2002 (Samuels Decl.) ¶ 4.c (“No one else in the medical field, to the best of my knowledge, ever proposed or suggested an inflatable ridge-based sealing arrangement prior to my invention, ever.”); Ex. 1020 (Samuels Dep.), 138:20–140:7 (affirming testimony in ¶ 4.c of Samuels Decl.), 187:11–14 (testifying that inflatable ridges were not known in the medical field); Ex. 2003 (Clark Decl.) ¶ 8 (“[B]eing able to reduce the overall diameter by just deflating the fluid chamber and, correspondingly, the ridges is an intriguing concept, one which was not known, to the best of my knowledge, in the medical field prior to Samuels ’575.”); Ex. 1021 (Clark Dep.), 82:19–21 (“I’m not aware of any inflatable protrusions to support an endograft prior to Samuels [’575].”).

Upon consideration of the parties’ arguments and evidence, we determine that Petitioner has not demonstrated that independent claims 1, 14, and 23, and their dependent claims 2, 6–13, 15, 18–22, and 24, are unpatentable for obviousness over Samuels ’851 and Todd.

*2. Asserted Obviousness of Claims 1, 4–6, 9–11,
13, 14, 16, 17, and 19–21 over Lazarus and Todd*

We instituted a review based on TriVascular’s contention that the combination of Lazarus and Todd renders obvious claims 1, 4–6, 9–11, 13,

14, 16, 17, and 19–21 under 35 U.S.C. § 103(a). Upon consideration of the parties' arguments and evidence, we determine that TriVascular has not demonstrated that those claims would have been obvious over Lazarus and Todd, for the reasons explained below.

a. Overview of Lazarus

Lazarus relates to grafts that can be positioned intraluminally for repair of vascular defects such as aneurysms. Ex. 1004, 11–14. Figures 3 and 4 of Lazarus are reproduced below:

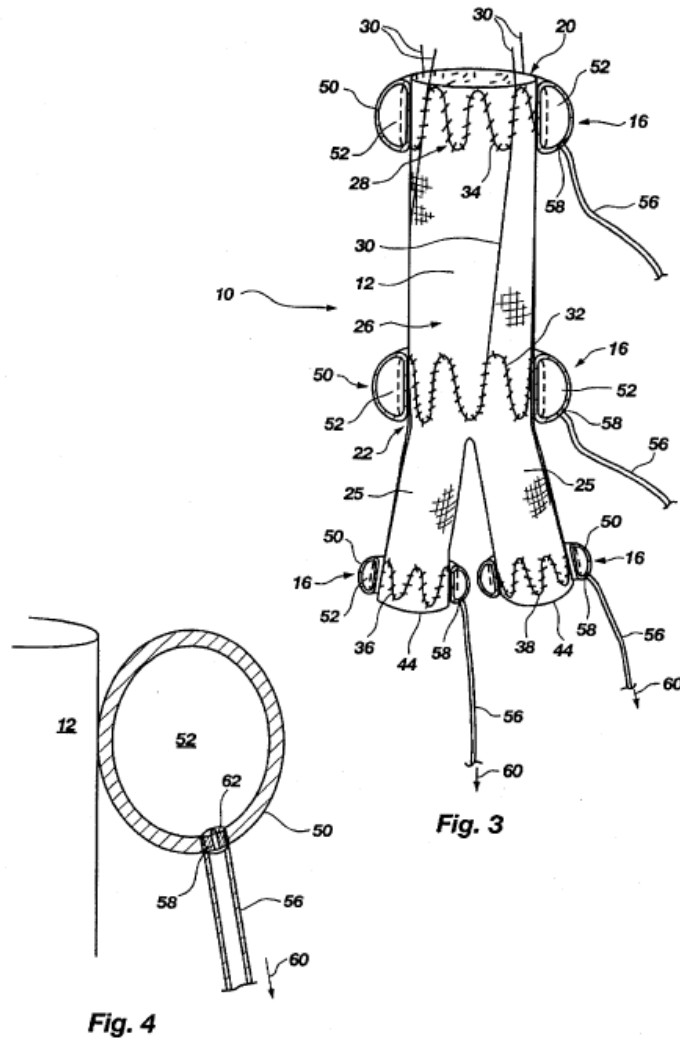


Figure 3 depicts intraluminal vascular graft 10, including attachment means 16 in the form of inflatable toroidal collars 50. *Id.* at 10:20–22, 15:15–18. Figure 4 is an enlarged view of a section of the inflatable collar illustrating inflation conduit 56 and closeable valve 58. *Id.* at 10:23, 15:15–18. Lazarus teaches that the intraluminal graft can be deployed within a vessel of the body to form a tight seal between the inflatable collar and the vessel wall, without use of potentially-damaging hooks or barbs. *Id.*, Abstr., 1:57–63, 15:24–28.

*b. Analysis of Claims 1, 4–6, 9–11,
13, 14, 16, 17, and 19–21*

TriVascular relies upon Lazarus for all limitations of independent claims 1 and 14, except “inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff,” for which TriVascular relies on Todd. Pet. 22–23, 40–41 (Claim Chart II, element 1a-3). As a reason to combine Lazarus and Todd, TriVascular asserts:

A POSA looking to make an intraluminal device for treating aneurysms would look to Lazarus '088 and modify it with the teachings of [Todd] to arrive at the Samuels '575 recited claims. A review of the claim charts provides a clear blueprint for such obvious modification.

Id. at 23. TriVascular further asserts that “[i]t would have been an obvious modification to use [Todd’s] circumferential ridges to facilitate the seal” between the intraluminal graft of Lazarus and a vessel of the body. Reply 15.

Dr. Samuels disagrees and argues that TriVascular has not provided an apparent reason to modify Lazarus. Resp. 22. Dr. Samuels also argues

that TriVascular has not explained how the combination of Lazarus and Todd would have inflatable circumferential ridges, and that TriVascular relies improperly on Todd “to meet the limitations of inflatable protrusion(s) including at least one circumferential ridge.” *Id.* at 24.

We agree with Dr. Samuels that Trivascular has failed to establish that the combination of Lazarus and Todd includes the claim limitation “inflatable protrusions.” As discussed previously, Trivascular has failed to persuade us that Todd discloses “inflatable protrusions.” *See* section II.B.1.b *supra*. Moreover, forming the non-inflatable protuberances disclosed in Todd on the inflatable collar of Lazarus would not satisfy the requirement for “inflatable protrusions” because the protuberances would not be expandable by being filled with fluid, or be themselves inflatable. *See* section II.A.5 *supra*. TriVascular has not established, furthermore, that a person of ordinary skill in the art would have known to use, on an inflatable collar, protrusions that are themselves inflatable. *See* Ex. 2002 ¶ 4.c; Ex. 1020, 138:20–140:7, 187:11–14; Ex. 2003 ¶ 8; Ex. 1021, 82:19–21.

Upon consideration of the parties’ arguments and evidence, we determine that TriVascular has not demonstrated that independent claims 1 and 14, and their dependent claims 4–6, 9–11, 13, 16, 17, and 19–21, are unpatentable as obvious over Lazarus and Todd.

III. CONCLUSION

TriVascular has not proved, by a preponderance of the evidence, that claims 1, 2, and 4–24 of the ’575 Patent are unpatentable. TriVascular has

not proved that claims 1, 2, 6–15, and 18–24 would have been obvious over Samuels '851 and Todd, or that claims 1, 4–6, 9–11, 13, 14, 16, 17, and 19–21 would have been obvious over Lazarus and Todd. Accordingly, Dr. Samuels's Motion to Amend, which is contingent on claims 1, 14, and 23 being found unpatentable, is moot.

IV. ORDER

For the reasons given, it is
ORDERED that claims 1, 2, and 4–24 of U.S. Patent No. 6,007,575 are not determined to be unpatentable; and
FURTHER ORDERED that Dr. Samuels's Motion to Amend is *dismissed* as moot.

This is a final decision. 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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Patent 6,007,575

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