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Attorneys for Defendant
TRIVASCULAR, INC.

12 **UNITED STATES DISTRICT COURT**
13 **NORTHERN DISTRICT OF CALIFORNIA**
14 **SAN FRANCISCO DIVISION**

15 DR. SHAUN L.W. SAMUELS,
16 Plaintiff,
17 vs.
18 TRIVASCULAR, INC.,
19 Defendant.

Case No. CV-13-2261-EMC

**JOINT STATUS REPORT ON THE
PATENT TRIAL AND APPEAL
BOARD'S DECISION ON THE *INTER
PARTES* PETITION**

20 TRIVASCULAR, INC.,
21 Counter-Claimant,
22 vs.
23 DR. SHAUN L. W. SAMUELS,
24 Counter-Defendant.

1 Pursuant to Paragraphs 2 and 5 of the Court's Order Granting Joint Stipulation to Stay Case
 2 Pending *Inter Partes* Review (Dkt. No. 32), Plaintiff Dr. Shaun L.W. Samuels ("Dr. Samuels") and
 3 Defendant TriVascular, Inc. ("TriVascular") submit a status report as follows:

4 1. On February 4, 2014, the Patent Trial and Appeals Board ("PTAB") issued a decision
 5 instituting *inter partes* review of U.S. Patent 6,007,575 ("the '575 patent"), the only patent-in-suit in
 6 this case. The decision is attached hereto as Exhibit A.

7 2. The PTAB further issued a Scheduling Order for the *inter partes* review, summarized
 8 below and attached hereto as Exhibit B.

EVENT	DUE DATE
Patent owner's response to the petition	April 4, 2014
Patent owner's motion to amend the patent	April 4, 2014
Petitioner's reply to patent owner response to petition	June 4, 2014
Petitioner's opposition to motion to amend	June 4, 2014
Patent owner's reply to petitioner opposition to motion to amend	July 8, 2014
Petitioner's motion for observation regarding cross-examination of reply witness	July 29, 2014
Motion to exclude evidence	July 29, 2014
Request for oral argument	July 29, 2014
Patent owner's response to observation	August 12, 2014
Opposition to motion to exclude	August 12, 2014
Reply to opposition to motion to exclude	August 19, 2014
Oral argument (if requested)	September 3, 2014

1 3. In accordance with Paragraph 3 of the Court’s Order Granting Joint Stipulation to
2 Stay Case Pending *Inter Partes* Review (Dkt. No. 32), since the PTAB has instituted *inter partes*
3 review of the ’575 patent, “the case shall be further stayed until the PTAB issues a final written
4 decision.”

5 DATED: February 13, 2014

6 /s/ James D. Petruzzi

7 James D. Petruzzi
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TRIVASCULAR, INC.

ATTESTATION OF CONCURRENCE IN FILING

I, Marc H. Cohen, am the ECF User whose identification and password are being used to file this Joint Stipulation. In compliance with Local Rule 5-1(i)(3), I hereby attest that James D. Petruzzi of Mason & Petruzzi has concurred in this filing.

DATED: February 13, 2014

/s/ Marc H. Cohen

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 13, 2014 that a copy of the foregoing document is being electronically filed with the Clerk of the United States District Court for the Northern District of California by using the CM/ECF system, which will send notice of such filing to all counsel of record.

DATED: February 13, 2014

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TriVascular, Inc.

IT IS SO ORDERED that the CMC is reset from 3/13/14 to 9/25/14 at 9:00 a.m. An updated joint CMC statement shall be filed by 9/18/14.

Edward M. Chen
U.S. District Judge

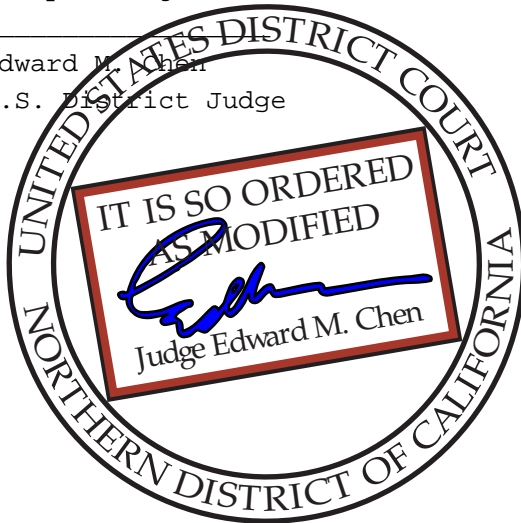


EXHIBIT A

Trials@uspto.gov
571-272-7822

Paper 10
Entered: February 4, 2014

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 RICHARD E. RICE, SCOTT E. KAMHOLZ, and
ADAM V. FLOYD, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

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

Case IPR2013-00493
Patent 6,007,575

I. INTRODUCTION

TriVascular, Inc. (“Petitioner”) filed a petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1-24 of U.S. Patent No. 6,007,575 (Ex. 1001, “the ’575 patent”). In response, Shaun L.W. Samuels (“Patent Owner”) filed a patent owner preliminary response (Paper 9, “Prelim. Resp.”).¹ We have jurisdiction under 35 U.S.C. § 314.

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

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

Upon consideration of the petition and the preliminary response, we determine that the information presented in the petition establishes that there is a reasonable likelihood that Petitioner would prevail in challenging claims 1, 2, and 4-24 as unpatentable on at least one ground of patentability. Accordingly, pursuant to 35 U.S.C. § 314, we institute an *inter partes* review for claims 1, 2, and 4-24 of the ’575 patent. However, we determine that the information presented in the petition does not establish that there is a reasonable likelihood that Petitioner

¹ We note that Patent Owner’s sole exhibit, as currently filed, is not numbered in the range 2001-2999, as required by 37 C.F.R. § 42.63(c). In particular, Patent Owner’s exhibit is filed as Exhibit 1015, rather than Exhibit 2001. Patent Owner will be required, within five business days of this decision, to re-file the exhibit using the correct numbering.

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would prevail in challenging claim 3 as unpatentable. Accordingly, we do not institute an *inter partes* review for claim 3.

A. Related Proceedings

Petitioner represents that the '575 patent is involved in co-pending litigation styled *Dr. Shaun L.W. Samuels v. Trivascular, Inc.*, Case No. 3:13-cv-02261 (EMC), filed in the United States District Court for the Northern District of California. Pet. 2.

B. The '575 Patent

The '575 patent, titled “Inflatable Intraluminal Stent and Method for Affixing Same within the Human Body,” issued on December 28, 1999, based on Application No. 08/870,745, filed June 6, 1997.

The patent describes prior art stent designs that utilize “anchoring pins, surgical staple-like clips or exposed barbs to secure the stent to the tube walls via penetration of the walls.” Ex. 1001, 1:52-54. The patent further explains that “[d]amage to the tubular wall may occur when [such a] device is being positioned within the tube” and that “repositioning of such stents cannot be accomplished without damaging the tube walls.” *Id.* at 1:54-58.

It is an objective of the invention of the '575 patent “to provide a stent, and a method of placing it, that allows for repositioning of the stent within a tubular structure of the body.” *Id.* at 1:64-67. It is also an objective of the invention of the patent “to provide a stent, and a method of placing it, that allows for the stent to be affixed to the tubular structure inner walls in a manner that prevents both damage to the walls and migration of the stent after it has been affixed.” *Id.* at 1:67-2:4.

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Figure 1 of the '575 patent is reproduced below:

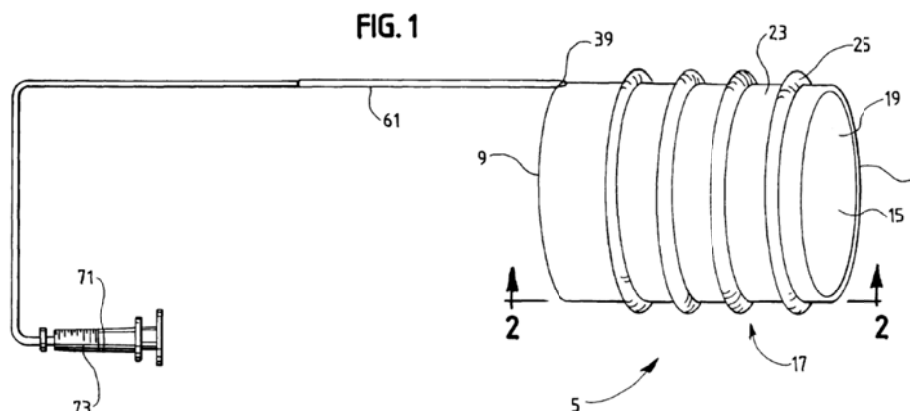


Figure 1 is a perspective view of “an embodiment of the inflatable intraluminal stent of the present invention.” *Id.* at 2:62-63, 3:24-25. As illustrated in Figure 1, stent 5 includes lumen 15, which is defined by inflatable cuff 17 having inner surface 19 and outer surface 23. *Id.* at 3:26-31. Outer surface 23 includes “a number of inflatable ridges 25 disposed about its circumference.” *Id.* at 3:32-33. As depicted in Figure 1, each of ridges 25 is a raised strip disposed about the circumference of the cuff. “[C]uff 17 is inflated by way of an inflation syringe 71 with an inflation material 73, [which] . . . hardens over time to permanently affix stent 5 within the tubular structure of the [human] body via circumferential ridges 25.” *Id.* at 4:33-43.

The patent states that “[a] unique feature of the present invention is its capability of being optimally positioned within a tubular structure in the body ([e.g.], a blood vessel) without causing damage to the surrounding tissue.” *Id.* at 4:66-5:2. In order to position the stent optimally, the stent is first inflated such that “[the] ridges [] affix the stent to the tubular walls without penetration.” *Id.* at 5:2-4. Next, “the position of the stent is examined fluoroscopically to determine

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if it is optimal.” *Id.* at 5:4-5. If the position needs to be changed, “[the] stent [] may be deflated, repositioned and then reinflated.” *Id.* at 5:6-7. The patent states that “[i]t is important to note that the tissue of the vessel walls is not damaged by exposure to [the] ridges [] of the stent.” *Id.* at 5:7-8.

C. Exemplary Claim

Claims 1, 14 and 23 are independent. Claims 2-13, directly or indirectly, depend from claim 1, and claims 15-22 and 24, directly or indirectly, depend from claim 14. Claim 1 is illustrative of the invention of the ’575 patent 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.

D. Prior Art Relied Upon

The Petitioner relies on the following prior art references:

Samuels ’851	US 5,423,851	June 13, 1995	Ex. 1002
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Rogers	US 5,534,024	July 9, 1996	Ex. 1003
Lazarus	US 5,693,088	Dec. 2, 1997	Ex. 1004
Rhodes	US 5,665,117	Sept. 9, 1997	Ex. 1005
Lane	US 5,494,029	Feb. 27, 1996	Ex. 1006
Miller, Jr.	US 3,991,767	Nov. 16, 1976	Ex. 1007
Todd	US 5,423,745	June 13, 1995	Ex. 1008
Sisson	US 4,586,505	May 6, 1986	Ex. 1009
Pigott	US 5,156,620	Oct. 20, 1992	Ex. 1010
Holman	US 5,871,537	Feb. 16, 1999	Ex. 1011

E. The Alleged Grounds of Unpatentability

The Petitioner challenges claims 1-24 of the '575 patent based on the alleged grounds of unpatentability set forth in the table below:

Reference(s)	Basis	Challenged Claims
Samuels '851	§ 102(b) and § 103(a)	1, 2, 6-15, and 18-24
Rogers	§ 102(e) and § 103(a)	1-6, 11, 14-17, and 21
Samuels '851 and Rogers	§ 103(a)	1-24
Samuels '851 and Lazarus	§ 103(a)	1, 2, and 4-24
Samuels '851 and Rhodes	§ 103(a)	1, 2, 4-16, and 18-24
Samuels '851 and Lane, Miller, Todd, or Sisson	§ 103(a)	1, 2, 6-15, and 18-24
Lazarus and Miller, Todd, or Sisson	§ 103(a)	1, 4-6, 9-11, 13, 14, 16, 17, and 19-21
Holman, Pigott, and Lane	§ 103(a)	1, 2, 4-8, 11, 13-18, and 21

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of

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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). The broadest reasonable construction of a means-plus-function limitation “is that statutorily mandated in [paragraph 6 of 35 U.S.C. § 112].” *In re Donaldson Co.*, 16 F.3d 1189, 1194-95 (Fed. Cir. 1994). Also, 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. *See In re Translogic Technology, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. “Means for” terms

Petitioner proposes claim constructions for each of the following “means for” terms, which Petitioner contends are means-plus-function limitations: “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 24.² Pet. 7-9. However, Patent Owner, in the preliminary response, does not propose competing claim constructions for, or rely on, any of these “means for” terms. *See* Prelim. Resp. 2, 19-33 (claim charts). We determine that these terms do not need to be construed at this time because they are not material to our decision.

² We note that claim 20 similarly recites “means for securing an intraluminal medical device to the inner surface of the cuff.”

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2. *“Friction-enhancing outer surface”*

Petitioner contends that:

“friction-enhancing outer surface” means the surface features of the outer surface of an inflatable cuff, such as inflatable ridges, nubs, bumps and indentations, such that when the inflatable cuff is deployed, such surface features engage or secure the inflated stent to the interior wall of a tubular structure without penetrating it or harming or damaging the tissue of the walls of the tubular structure.

Pet. 9. Patent Owner does not propose a competing claim construction in the preliminary response. Prelim. Resp. 2.

We do not agree with Petitioner’s proposed claim construction because it unjustifiably reads limitations into the claim language from an embodiment appearing in the specification of the ’575 patent. *See Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (“[A] particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.”) For purposes of this decision, we interpret “friction-enhancing outer surface” to mean surface features of an outer surface that increase the capability of the outer surface to engage or grip another surface. *See, e.g.*, Ex. 1001, 2:35-37 (“a friction-enhancing face that engages the interior surface of the tubular structure”); 3:64-67 (“surface features [that] allow the inflated stent to grip the interior walls of a tubular structure with a force that is sufficient to prevent its migration”).

3. *“Circumferential ridge disposed about the inflatable cuff”*

Petitioner contends that “circumferential ridge disposed about the inflatable cuff” means “an elevated part of the outer surface disposed about the inflatable

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cuff.” Pet. 10. Patent Owner responds that Petitioner’s proposed construction improperly ignores the term “circumferential.” Prelim. Resp. 3. Patent Owner contends that “the broadest reasonable interpretation . . . is ‘an elevated part of the outer surface extending circumferentially about the inflatable cuff.’” *Id.* We disagree with both parties’ proposed claim constructions.

As discussed above, the ’575 patent describes a “circumferential ridge” as a ridge, i.e., a raised strip, “disposed about [the] circumference” of outer surface 23 of inflatable cuff 17. Ex. 1001, 3:32-33, 54; Figs. 1 and 2. As this description accords with the ordinary and customary meaning of the word “ridge” as “a raised strip (as of plowed ground),”³ we interpret a “circumferential ridge disposed about the inflatable cuff” to mean a “raised strip disposed circumferentially about the outer surface of the inflatable cuff.”

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

Petitioner contends that the terms “when said cuff is in a *fully inflated* condition,” in claim 1 (emphasis added), and “when the cuff is *fully inflated*,” in claim 14 (emphasis added), each means “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). Patent Owner disagrees and argues these claim terms refer to “how much expansion of the cuff will occur when the maximum amount of fluid that the cuff can receive is placed therein.” Prelim. Resp. 3. However, these terms do not need to be construed at this time because they are not material to our decision.

³ Ex. 1014 (WEBSTER’S NINTH NEW COLLEGIATE DICTIONARY (1986)), 1014.

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5. Other Terms

All other terms in claims 1-24 are given their ordinary and customary meaning as would be understood by one with ordinary skill in the art and need not be construed explicitly at this time.

*B. Claims 1, 2, 6-15, and 18-24—Obviousness
over Samuels '851 and Todd*

As noted above, Petitioner alleges, *inter alia*, that claims 1, 2, 6-15, and 18-24 of the '575 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Samuels '851 and Todd. In light of the arguments and supporting evidence submitted by the parties, Petitioner has established a reasonable likelihood that claims 1, 2, 6-15, and 18-24 are unpatentable over Samuels '851 and Todd for the reasons explained below.

1. Samuels '851

Samuels '851 discloses inflatable balloon cuff 10, which can be used to affix a medical device within the tubular structures of the body. Ex. 1002, 2:35-37.

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Figures 1 and 2 of Samuels '851, which are reproduced below, illustrate the inflatable balloon cuff 10 before and after inflation, respectively:

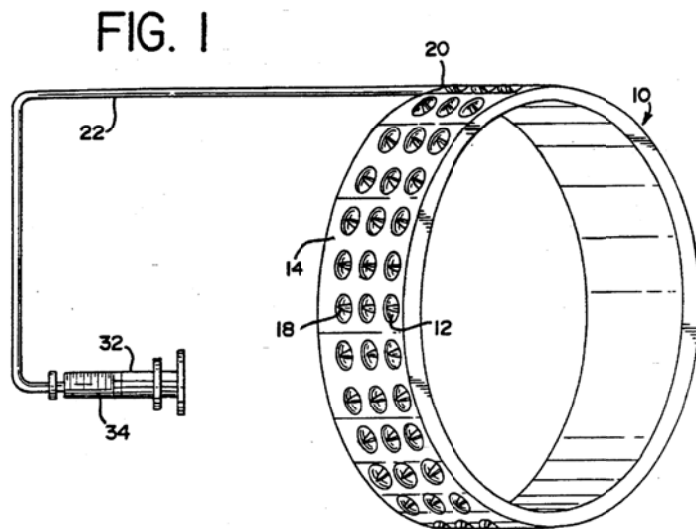


Figure 1 is a pre-deployment perspective view of an apparatus

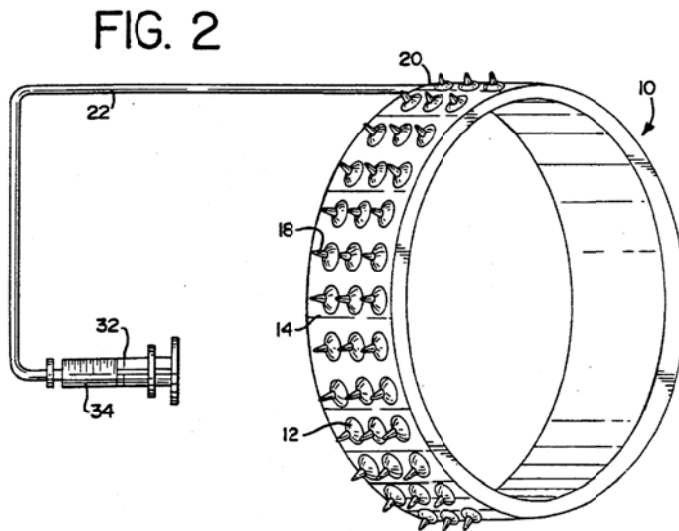


Figure 2 is a post-deployment perspective view of an apparatus.

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 Patent 6,007,575

As illustrated in Figure 1, inflatable 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 inflatable 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.

Figure 3 of Samuels ’851 is reproduced below:

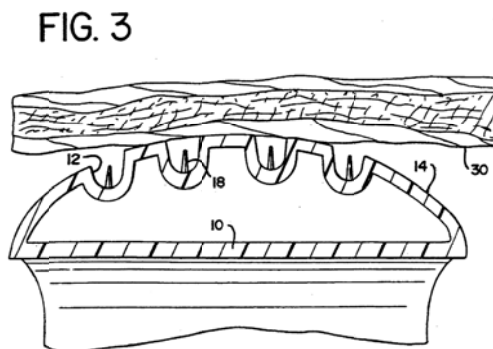


Figure 3 is a sectional view of a partially-inflated cuff.

Figure 3 is a sectional view of inflatable cuff 10 as deployed in a tubular structure of the human body when the cuff is inflated only partially; as shown in Figure 3, outer surface 14 of cuff 10 engages the tubular structure’s wall, but barbs 18 remain inside recesses 12. *Id.* at 3:57-60. It is disclosed that, as partially inflated, “the outer surface **14** holds the cuff **10** in place against the wall **30** so that it can be determined whether the positioning of . . . the cuff **10** is optimal.” *Id.* at 3:67-4:2. It is further disclosed that, “if the position is not optimal, then the cuff **10** can be deflated and moved to the optimal position without harming or damaging the surrounding tissue.” *Id.* at 4:6-9. “If the position is found to be optimal, then

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the cuff **10** is fully inflated so that the barbs **18** rigidly engage with the wall **30** to permanently hold the medical device in place.” *Id.* at 4:3-6. Inflation syringe 32 is connected by tubing 22 to duck bill valve 20, which is integral with side of cuff 10 and is comprised of opposing leaflets 21. *Id.* at 2:65-68; Figs. 1, 2, 5, and 6.

“Tubing **22** is inserted into the valve **20** to separate the opposing leaflets **21** of the valve **20** when the cuff **10** is to be inflated or deflated.” *Id.* at 3:2-5. “After the cuff **10** has been fully inflated, the tubing **22** is removed and the opposing leaflets **21** close to seal the inflated cuff **10**. *Id.* at 3:5-7.

2. Todd

Todd discloses “[g]ripping means for securely gripping the walls of a body passageway in order to secure [a] catheter in place within the passageway.” Ex. 1008, 4:16-18. Todd’s preferred embodiment comprises “a plurality of protuberances that project outwardly from the outer surface of [a] balloon.” *Id.* at 6:59-60. Todd describes the protuberances as “soft enough to grip the walls of the body passageway without damaging the tissues.” *Id.* at 6:66-68. Figures 5-8 of Todd illustrate various configurations of protuberances. *Id.* at 6:68-7:2.

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Figure 8 of Todd is reproduced below:

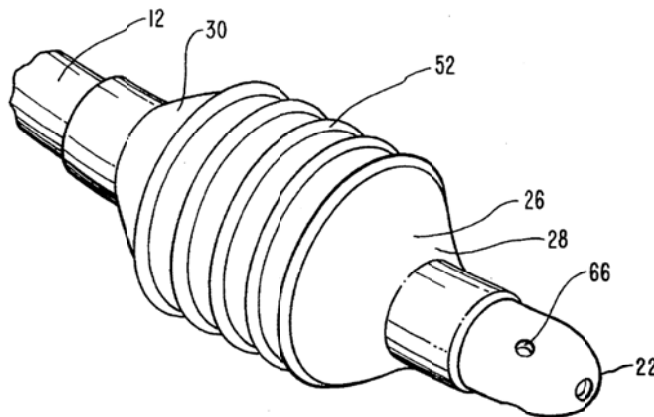


FIG. 8

Figure 8 is a perspective view of a catheter balloon.

Figure 8 illustrates “protuberances . . . in the form of outwardly projecting annular rings **52** wound about the exterior surface of balloon **26**.” *Id.* at 7:41-43.

3. *Obviousness Analysis*

Petitioner relies upon Samuels ’851 for all limitations of claim 1 except the friction-enhancing outer surface, and upon the “inflatable balloon protuberances” of Todd for this feature. Pet. 22. Petitioner contends that “[Todd] provides friction enhancing surfaces for preventing migration” and that, “[g]iven the basic structure of Samuels ’851, it would be an obvious modification to take the friction-enhancing features of [Todd] and modify Samuels ’851 while maintaining its basic intent and purpose.” *Id.* Petitioner further contends that “the teachings of these references when combined not only provide various non-penetrating aspects of creating friction-enhancing surfaces but disclose . . . inflatable ridges

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circumferentially positioned about the devices.” *Id.*

Patent Owner responds that “removing the barbs in Samuels ’851 would destroy the objective of the reference,” that “[n]one of the cited secondary references teaches removing barbs,” and that “Petitioner’s suggested modification goes totally against the basic teaching of Samuels [’851] and is thus not an obvious step to take.” Prelim. Resp. 12. Additionally, Patent Owner argues that Samuels ’851 “focuses on using barbs” and “stresses how important barbs are in order to avoid the catastrophic results of migration of the device to an undesired location.” *Id.* at 23, chart (citing Ex. 1002, 1:48-55; 2:5-6, 60-64; 3:51-56; claim 1(d)). Patent Owner also argues that “[n]o apparent reason to modify Samuels ’851 is given” and that “Petitioner has not explained how the combination would have inflatable circumferential ridges.” *Id.* at 12. Patent Owner also asserts that Samuels ’851 teaches away from the subject matter of claim 1. *See, e.g., id.* at 8.

Upon consideration of the parties’ arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1, 2, 6-15, and 18-24 are unpatentable for obviousness over Samuels ’851 and Todd.

We understand Petitioner to contend that it would have been obvious to a person of ordinary skill in the art to substitute Todd’s protuberances (such as outwardly projecting annular rings 52 of Figure 8) for the barbs of Samuels ’851, because the protuberances and the barbs are each friction-enhancing features used for attachment to a vessel. Pet. 22; *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (“when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the

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combination must do more than yield a predictable result”) (citing *United States v. Adams*, 383 U.S. 39, 50-51 (1966)).

We do not agree with Patent Owner’s contention that Petitioner has failed to explain how the combination of Samuels ’851 and Todd would have inflatable circumferential ridges. *See id.* at 12. As discussed above, Petitioner relies, for example, on Todd’s Figure 8, which depicts protuberances in the form of outwardly projecting annular rings 52 wound about the exterior surface of balloon 26. Pet. 22. This disclosure meets the requirement of claim 1 for “at least one circumferential ridge disposed about the inflatable cuff,” as construed above.

Furthermore, on the present record, we do not agree with Patent Owner’s argument that Samuels ’851 teaches away. *See, e.g.*, Prelim. Resp. 8. Patent Owner’s preliminary response does not explain sufficiently how Samuels ’851 criticizes, discredits, or otherwise discourages a friction-enhancing outer surface, including an inflatable circumferential ridge disposed about the cuff, that engages a tubular structure within the human body without penetration to prevent migration of the cuff to an undesired location when the cuff is inflated, as recited in claim 1. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (in order to “teach away,” a reference must “criticize, discredit, or otherwise discourage the solution claimed.”).

Similarly, on the present record, Patent Owner has not established that removing the barbs in Samuels ’851 would destroy the objective of the reference or go against its basic teaching. *See* Prelim. Resp. 12. For example, Patent Owner has not shown that substituting Todd’s protuberances for the barbs of Samuels ’851 necessarily would have increased the potential for migration of the device to

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an undesired location.

We have considered all of Patent Owner's arguments, but we are persuaded, on the present record, that Petitioner has provided adequate articulated reasoning with rational underpinning to support a legal conclusion of obviousness. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

For the foregoing reasons, Petitioner has established a reasonable likelihood that it would prevail in showing that claim 1 is unpatentable as obvious over Samuels '851 and Todd. In addition, the claim charts and supporting evidence presented by Petitioner that explain how these prior art references allegedly teach the claimed subject matter recited in claims 2, 6-15, and 18-24 have merit. Therefore, Petitioner also has established a reasonable likelihood that it would prevail in showing that claims 2, 6-15, and 18-24 are unpatentable under 35 U.S.C. § 103(a) over Samuels '851 and Todd.

*C. Claims 1, 4-6, 9-11, 13, 14, 16, 17, and 19-21—
Obviousness over Lazarus and Todd*

Petitioner also alleges, *inter alia*, that claims 1, 4-6, 9-11, 13, 14, 16, 17, and 19-21 are unpatentable under 35 U.S.C. § 103(a) as obvious over Lazarus and Todd. *E.g.*, Pet. 4. In light of the arguments and supporting evidence submitted by the parties, Petitioner has established a reasonable likelihood that claims 1, 4-6, 9-11, 13, 14, 16, 17, and 19-21 are unpatentable over Lazarus and Todd, for the reasons explained below.

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1. *Lazarus*

Lazarus discloses an intraluminal vascular graft “to be deployable within a vessel for incorporation therein without use of hooks or barbs.” Ex. 1004, Abstract. Lazarus explains that “hooks or barbs may damage the vessel, particularly where the vessel is weakened already by an aneurysm or other disease condition.” *Id.* at 1:56-59. As disclosed, the graft comprises a biocompatible tube and a “non-puncturing attachment means.” *Id.* at 2:51-52. “[T]he attachment means is formed from material which is, or is otherwise treated to be, porous and/or textured to promote the attachment or ingrowth of tissue into the attachment means thereby incorporating at least a portion of the intraluminal vascular graft into the vessel.” *Id.* at 5:35-39. “The attachment means may also be treated, such as by coating or infusion, with a substance or material which promotes attachment of the vessel to the graft.” *Id.* at 6:6-8. For example, “the attachment means may be a toroidal collar having an internal inflatable space which facilitates expansion of the intraluminal vascular graft to contact the inner surface of the vessel.” *Id.* at 6:39-42.

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Figures 3 and 4 of Lazarus are reproduced below:

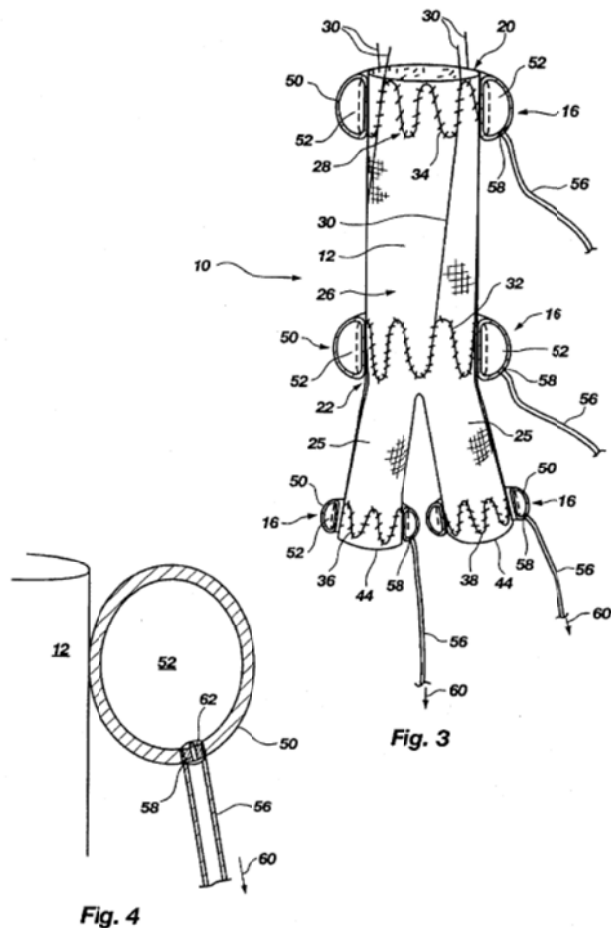


Figure 3 is a view in elevation of the intraluminal vascular graft, and
 Figure 4 is an enlarged view of a section of a toroidal collar.

Figure 3 depicts two attachment means 16, each in the form of toroidal inflatable collar 50, disposed about the circumference of tubular body 12. *Id.* at 14:20-23. Figure 4 depicts inflation conduit 56 attached via closeable valve 58 to toroidal collar 50. *Id.* at 15:15-18. Lazarus discloses that, after a fluid is pumped through inflation conduit 56 to inflate sufficiently toroidal collar 50, “[t]he inflation conduit 56 may then be removed from the valve 58, such as by pulling or

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gently turning the inflation conduit **56** to dislodge it from the valve **58**.” *Id.* at 15:28-31. Lazarus further discloses that, “[u]pon removal of the inflation conduit **56**, the valve automatically closes sealing the fluid within the internal space **52** of the toroidal collar **50**.” *Id.* at 15:31-33.

2. *Obviousness Analysis*

Petitioner relies upon Lazarus for all limitations of claim 1 except the friction-enhancing outer surface. Pet. 22-23. Petitioner argues that Lazarus discloses an inflatable intraluminal graft without barbs or hooks and that Todd discloses inflatable protuberances that prevent migration. *Id.* at 23. Petitioner reasons that

[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.

Patent Owner argues that Petitioner has not explained how the combination of Lazarus and Todd “would have corresponding inflatable circumferential ridges.” Prelim. Resp. 14. We disagree with this argument. We are persuaded that providing the outwardly projecting annular rings 52 illustrated in Todd’s Figure 8 on the toroidal attachment means 16 of Lazarus would satisfy the requirement of claim 1 for a friction-enhancing outer surface featuring inflatable protrusion(s) that engage the interior of the tubular structure of the human body, 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, including at least one circumferential ridge disposed about the inflatable cuff.

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Patent Owner further argues:

Even if one were to add spiral ridge 48 [of Todd's Figure 7] to the arrangement in Lazarus '088, the result would be a disaster as a spiral ridge would not stop fluid flow exterior to the tubular body 12 of intraluminal graft 10[,] and therefore[,] would destroy the objective in Lazarus '088 of creating a seal between tubular body 12 and the inner surface of the vessel wall, as stated in column 13, lines 1-7.

Id. at 15. As such, Patent Owner focuses on Todd's Figure 7 and fails to address Figure 8, upon which Petitioner also relies. Accordingly, on the record before us, Patent Owner's argument is not persuasive.

Patent Owner also argues that "[n]o explanation of an apparent reason to modify Lazarus '088 is given" and, similarly, that "no explanation is provided as to what apparent reason exists to modify Lazarus '088 and what modifications the Petitioner envisions." Prelim. Resp. 14, 15. However, we understand Petitioner to contend that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Lazarus and Todd, because Lazarus teaches the use of materials that enhance attachment to a vessel without barbs or other penetrating devices, and Todd similarly teaches the use of protuberances (such as outwardly projecting annular rings 52 of Figure 8) that grip the walls of a vessel without damaging the tissue. Pet. 22-23. We are persuaded, on the present record, that Petitioner has provided adequate articulated reasoning with rational underpinning to support combining the teachings of Lazarus and Todd. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 417 ("[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious.") (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

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For the foregoing reasons, Petitioner has established a reasonable likelihood that it would prevail in showing that claim 1 is unpatentable as obvious over Lazarus and Todd. In addition, the claim charts and supporting evidence presented by Petitioner that explain how these prior art references allegedly teach the claimed subject matter recited in claims 4-6, 9-11, 13, 14, 16, 17, and 19-21 have merit. Therefore, Petitioner also has established a reasonable likelihood that it would prevail in showing that claims 4-6, 9-11, 13, 14, 16, 17, and 19-21 are unpatentable under 35 U.S.C. § 103(a) over Lazarus and Todd.

*D. Claims 1, 2, 6-15, and 18-24—Anticipation
or Obviousness over Samuels '851*

Petitioner contends that claims 1, 2, 6-15, and 18-24 are anticipated under 35 U.S.C. § 102(b) by, or obvious under 35 U.S.C. § 103(a) over, Samuels '851. After considering the arguments and supporting evidence submitted by the parties, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing that any of claims 1, 2, 6-15, and 18-24 are unpatentable over Samuels '851.

Petitioner contends that Samuels '851 discloses inflatable cuff 10 having a plurality of reinforced recesses 12 radially arrayed around its outer surface and that, when cuff 10 is inflated fully, recesses 12 pop out and are dome-shaped. *E.g.*, Pet. 27, claim chart, at 1a-2 and 1a-3 (citing to Ex. 1002, 2:40-42, 57-59, 62-63, Fig. 3). Petitioner has not persuaded us that Samuels '851 discloses or suggests “at least one circumferential ridge disposed about the inflatable cuff,” as construed above, because the recesses 12 do not form a raised strip. Accordingly, we are not

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persuaded that Samuels '851 anticipates, or renders obvious, claims 1, 2, 6-15, and 18-24 of the '575 patent.

*E. Claims 1-6, 11, 14-17, and 21—Anticipation
or Obviousness over Rogers*

Petitioner contends that claims 1-6, 11, 14-17, and 21 are anticipated under 35 U.S.C. § 102(b) by, or obvious under 35 U.S.C. § 103(a) over, Rogers. After considering the arguments and supporting evidence submitted by the parties, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing that any of claims 1-6, 11, 14-17, and 21 are unpatentable over Rogers.

Petitioner contends that Rogers discloses an intraluminal stenting graft including collapsible tube 12 having outer layer 18 that is joined to inner layer 20 to form a plurality of cylinders 30 that extend longitudinally. *E.g.*, Pet. 27, claim chart, at 1a-2 and 1a-3 (citing to Ex. 1003, 2:33-37; Fig. 1). Petitioner has not persuaded us that Rogers discloses or suggests “at least one circumferential ridge disposed about the inflatable cuff,” as construed above, because there are no strips circumferentially disposed about the outer surface of the inflatable cuff. Accordingly, we are not persuaded that Rogers anticipates, or renders obvious, claims 1-6, 11, 14-17, and 21 of the '575 patent.

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*F. Claims 1-24—Obviousness
over Samuels '851 and Rogers*

For the reasons discussed above in sections II.D and II.E, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing that any of claims 1-24 are unpatentable under 35 U.S.C. § 103(a) over Samuels '851 and Rogers.

*G. Claims 1, 2 and 4-24—Obviousness
over Samuels '851 and Lazarus*

As discussed in section II.D, Petitioner has not persuaded us that Samuels '851 discloses or suggests “at least one circumferential ridge disposed about the inflatable cuff,” as construed above. Petitioner does not contend that Lazarus remedies that deficiency in Samuels '851. *See* Pet. 40-41, 50-51, 57, claim chart, at 1a-3, 14b-1, 23b-1. Accordingly, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing that any of claims 1, 2, and 4-24 are unpatentable under 35 U.S.C. § 103(a) over Samuels '851 and Lazarus.

*H. Claims 1, 2, 4-16, and 18-24—Obviousness
over Samuels '851 and Rhodes*

As discussed in section II.D, Petitioner has not persuaded us that Samuels '851 discloses or suggests “at least one circumferential ridge disposed about the inflatable cuff,” as construed above. Petitioner does not contend that Rhodes remedies that deficiency in Samuels '851. *See* Pet. 40, 50-51, 57, claim chart, at 1a-3, 14b-1, 23b-1. Accordingly, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing that any of claims 1, 2, 4-16,

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and 18-24 are unpatentable under 35 U.S.C. § 103(a) over Samuels '851 and Rhodes.

I. Remaining Grounds of Unpatentability

Petitioner also contends that the following claims are unpatentable under 35 U.S.C. § 103(a): 1) claims 1, 2, 6-15, and 18-24 over Samuels '851 and Lane, Miller, or Sisson; 2) claims 1, 4-6, 9-11, 13, 14, 16, 17, and 19-21 over Lazarus and Miller or Sisson; and 3) claims 1, 2, 4-8, 11, 13-18, and 21 over Holman, Pigott, and Lane. Petitioner relies upon Lane, Miller, and Sisson as disclosing friction-enhancing surfaces similar to those disclosed in Todd. Pet. 22-23. Further, the claims Petitioner asserts to be unpatentable over the combination of Holman, Pigott, and Lane are a subset of the two groups of claims asserted to be unpatentable over the combinations of 1) Samuels '851 and Todd and 2) Lazarus and Todd, respectively. Petitioner has not shown that either of those combinations has any deficiency, or potential deficiency, that might be remedied by the combination of Holman, Pigott, and Lane. Accordingly, the remaining grounds of unpatentability are redundant to the grounds of unpatentability on which we initiate an *inter partes* review. Therefore, we do not authorize an *inter partes* review on the remaining grounds of unpatentability asserted by Petitioner against claims 1, 2, and 4-24 of the '575 Patent. *See* 37 C.F.R. § 42.108(a).

III. CONCLUSION

For the forgoing reasons, we determine that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1, 2, and 4-24 of the '575

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patent are unpatentable. However, we have not made a final determination on the patentability of any challenged claim.

IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 1, 2, and 4-24 of the '575 patent on the following grounds of unpatentability:

1. Claims 1, 2, 6-15, and 18-24 as unpatentable under 35 U.S.C. § 103(a) as obvious over Samuels '851 and Todd; and
2. Claims 1, 4-6, 9-11, 13, 14, 16, 17, and 19-21 as unpatentable under 35 U.S.C. § 103(a) as obvious over Lazarus and Todd;

FURTHER ORDERED that no other grounds of unpatentability are authorized for the *inter partes* review as to claims 1-24 of the '575 patent;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial on the grounds of unpatentability authorized above; the trial commences on the entry date of this decision;

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2:00 PM Eastern Time on February 18, 2014; the parties are directed to the Office Trial Practice Guide (Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012)) for guidance in preparing for the conference call, and should be prepared to discuss any proposed change to the Scheduling Order concurrently entered herewith and any motion the parties intend to file; and

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FURTHER ORDERED that Patent Owner shall re-file, within five business days of the date of this decision, Exhibit 1015 correctly numbered per 37 C.F.R. § 42.63(c).

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ELD

EXHIBIT B

Trials@uspto.gov
571-272-7822

Paper 11
Entered: February 4, 2014

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 RICHARD E. RICE, SCOTT E. KAMHOLZ, and
ADAM V. FLOYD, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

SCHEDULING ORDER

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A. INITIAL CONFERENCE CALL

The initial conference call is scheduled for 2:00 PM Eastern Time on February 18, 2014.

B. DUE DATES

This order sets due dates for the parties to take action after institution of the proceeding. The parties may stipulate to different dates for DUE DATES 1 through 3 (earlier or later, but no later than DUE DATE 4). A notice of the stipulation, specifically identifying the changed due dates, must be promptly filed. The parties may not stipulate to an extension of DUE DATES 4-7.

In stipulating to different times, the parties should consider the effect of the stipulation on times to object to evidence (37 C.F.R. § 42.64(b)(1)), to supplement evidence (37 C.F.R. § 42.64(b)(2)), to conduct cross-examination (37 C.F.R. § 42.53(d)(2)), and to draft papers depending on the evidence and cross-examination testimony (*see* section C, below).

The parties are reminded that the Testimony Guidelines appended to the Office Trial Practice Guide, 77 Fed.Reg. 48,756, 48,772 (Aug. 14, 2012) (Appendix D), apply to this proceeding. The Board may impose an appropriate sanction for failure to adhere to the Testimony Guidelines. 37 C.F.R. § 42.12. For example, reasonable expenses and attorneys' fees incurred by any party may be levied on a person who impedes, delays, or frustrates the fair examination of a witness.

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1. DUE DATE 1

The patent owner may file—

- a. A response to the petition (37 C.F.R. § 42.120), and
- b. A motion to amend the patent (37 C.F.R. § 42.121).

The patent owner must file any such response or motion to amend by DUE DATE 1. If the patent owner elects not to file anything, the patent owner must arrange a conference call with the parties and the Board. The patent owner is cautioned that any arguments for patentability not raised in the response will be deemed waived.

2. DUE DATE 2

The petitioner must file any reply to the patent owner's response and opposition to the motion to amend by DUE DATE 2.

3. DUE DATE 3

The patent owner must file any reply to the petitioner's opposition to patent owner's motion to amend by DUE DATE 3.

4. DUE DATE 4

a. The petitioner must file any motion for an observation on the cross-examination testimony of a reply witness (*see* section C, below) by DUE DATE 4.

b. Each party must file any motion to exclude evidence (37 C.F.R. § 42.64(c)) and any request for oral argument (37 C.F.R. § 42.70(a)) by DUE DATE 4.

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5. DUE DATE 5

a. The patent owner must file any reply to a petitioner observation on cross-examination testimony by DUE DATE 5.

b. Each party must file any opposition to a motion to exclude evidence by DUE DATE 5.

6. DUE DATE 6

Each party must file any reply for a motion to exclude evidence by DUE DATE 6.

7. DUE DATE 7

The oral argument (if requested by either party) is set for DUE DATE 7.

C. CROSS-EXAMINATION

Except as the parties might otherwise agree, for each due date—

1. Cross-examination begins after any supplemental evidence is due.
37 C.F.R. § 42.53(d)(2).

2. Cross-examination ends no later than a week before the filing date for any paper in which the cross-examination testimony is expected to be used. *Id.*

D. MOTION FOR OBSERVATION ON CROSS-EXAMINATION

A motion for observation on cross-examination provides the petitioner with a mechanism to draw the Board's attention to relevant cross-examination testimony of a reply witness, since no further substantive paper is permitted after the reply. *See* Office Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012). The observation must be a concise statement of the relevance of precisely

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identified testimony to a precisely identified argument or portion of an exhibit. Each observation should not exceed a single, short paragraph. The patent owner may respond to the observation. Any response must be equally concise and specific.

DUE DATE APPENDIX

DUE DATE 1.....April 4, 2014
Patent owner’s response to the petition
Patent owner’s motion to amend the patent

DUE DATE 2..... June 4, 2014
Petitioner’s reply to patent owner response to petition
Petitioner’s opposition to motion to amend

DUE DATE 3..... July 8, 2014
Patent owner’s reply to petitioner opposition to motion to amend

DUE DATE 4..... July 29, 2014
Petitioner’s motion for observation regarding
cross-examination of reply witness

Motion to exclude evidence
Request for oral argument

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DUE DATE 5..... August 12, 2014

Patent owner's response to observation

Opposition to motion to exclude

DUE DATE 6..... August 19, 2014

Reply to opposition to motion to exclude

DUE DATE 7..... September 3, 2014

Oral argument (if requested)

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