Paper No. 29
Filed: October 24, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION
Petitioner

v.
BOSTON SCIENTIFIC SCIMED, INC.
Patent Owner

Case IPR2017-01295
Patent No. 8,709,062

PETITIONER'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 28 U.S.C. § 1295(a)(4)(A); 35 U.S.C. §§ 141(c), 142, and 319; 37 C.F.R. §§ 90.2(a) and 90.3; and Rule 4(a) of the Federal Rules of Appellate Procedure, Petitioner Edwards Lifesciences Corporation ("Edwards") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Patent Trial and Appeal Board's ("Board") Final Written Decision (Paper 28) entered on October 12, 2018 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Edwards related thereto and included therein, including those within the Decision on Institution of *Inter Partes* Review (Paper 9) entered October 25, 2017.

For the limited purpose of providing the information requested in 37 C.F.R. § 90.2(a)(3)(ii), Edwards identifies that the issues on appeal include, but are not limited to: whether the Board erred in determining that Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 8, 16, and 22 of U.S. Patent No. 8,709,062 would have been obvious under 35 U.S.C. § 103; any finding or determinations supporting or relating to these issues; and all other procedural and substantive issues decided adversely to Edwards in any order, decision, ruling, or opinion by the Board in this proceeding.

Edwards is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, with the Director of the United States Patent

and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Date: October 24, 2018

Respectfully submitted,

By: */s/ A. James Isbester*
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CERTIFICATE OF SERVICE

I hereby certify that the original of this Notice of Appeal was filed via U.S.P.S. Priority Mail Express on October 24, 2018 with the Director of the United States Patent and Trademark Office at the address below:

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To the U.S. Court of Appeals for the Federal Circuit:
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Respectfully,

Dated: October 24, 2018

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ATTACHMENT A

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571-272-7822

Paper No. 28
Entered: October 12, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORTATION,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-01295
Patent 8,709,062 B2

Before JAMES A. TARTAL, ROBERT L. KINDER, and AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Edwards Lifesciences Corporation ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–26 ("the challenged claims") of U.S. Patent No. 8,709,062 B2 (Ex. 1001, "the '062 patent"). Paper 2 ("Pet."). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We instituted an *inter partes* review of challenged claims 1–7, 9–15, 17–21, and 23–26 on one ground of unpatentability, pursuant to 35 U.S.C. § 314. Paper 9, 33–34 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 15, "PO Resp.") to the Petition. Before the due date for Petitioner's Reply, however, the U.S. Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *See* Paper 17. Pursuant to *SAS Institute*, a decision to institute an *inter partes* review under 35 U.S.C. § 314 may not institute trial on fewer than all claims challenged in the petition. *SAS Institute*, 138 S. Ct. at 1355–56, 1358. In this proceeding, however, we had denied institution with respect to challenged claims 8, 16, and 22, on two grounds of unpatentability. *See* Dec. on Inst. 9–21. Accordingly, we modified our Decision on Institution to include review of challenged claims 8, 16, and 22, and all grounds presented in the Petition. Paper 17, 2.

Pursuant to Patent Owner's request, we allowed Patent Owner to incorporate into its Patent Owner Response (Paper 15) the arguments presented in its Preliminary Response (Paper 8). Paper 18, 3–4. Additionally, we modified the due date for Petitioner's Reply and authorized Petitioner to respond to both the Decision on Institution and Patent Owner's

Preliminary Response, in its Reply. *Id.* at 4. Consistent with our Order, Petitioner filed a Reply to the Patent Owner Response (Paper 20, "Reply").

An oral hearing was held on August 7, 2018, and a transcript of the hearing is included in the record. Paper 27 ("Tr.").

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has shown by a preponderance of the evidence that challenged claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent are unpatentable, but has not met its burden with respect to claims 8, 16, and 22.

B. Related Proceedings

The parties represent that the '062 patent is at issue in *Boston Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp.*, No. 8:16-cv-00730 (C.D. Cal.). Pet. 101; Paper 4, 2.

C. The '062 Patent

The '062 patent, titled "Stent Delivery System Having Stent Securement Apparatus," issued April 29, 2014, from U.S. Patent Application No. 13/619,231, which was filed September 14, 2012. Ex. 1001, (45), (54), (21), (22).

Figure 1 of the '062 patent is reproduced below.

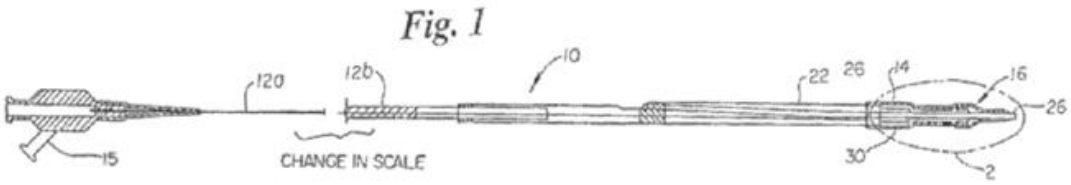


Figure 1 depicts an isometric view of a balloon catheter. Ex. 1001, 5:53–65. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 16, to which stent 18 is fixed. *Id.* at 8:15–18, 26–27 (stent not shown in Figure 1).

In use, catheter 12 is advanced through a patient's vasculature to a desired location and, once reached, balloon 14 and stent 18 are expanded. *Id.* at 8:49–55. After expansion, the balloon is deflated and the catheter and balloon are withdrawn, while the stent remains in place to maintain the vessel in an expanded state. *Id.* at 8:55–57.

Figure 4 of the '062 patent is reproduced below.

Fig. 4

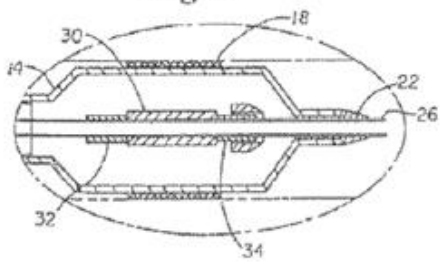


Figure 4 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 6:3–6.

As shown in Figure 4, "mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent to support and hold the stent and secure it during crimping and the delivery procedure." *Id.* at 9:28–32. In Figure 4, mounting body 30 is a cylindrical sleeve carried on inner lumen 26 of the catheter. *Id.* at 9:35–37. However, the '062 patent also discloses alternate mounting bodies including, for example, a spiral cut mounting body (*id.* at Fig. 5), a cylindrical body comprising separate, adjacent rings 30a (*id.* at Fig. 6), a two-piece interlocked body 30a, 30b (*id.* at Fig. 7), a body comprising a plurality of separate, spaced bodies 30a, 30b, 30c (*id.* at Fig. 9), a rigid coil mounting body (*id.* at Fig. 10), or an enlargeable and collapsible mounting body (*id.* at Figs. 11–12, 17–21). *See id.* at 9:66–11:17.

D. Illustrative Claim

Challenged claims 1, 13, 21, and 26 are independent. Claim 1 is illustrative, and is reproduced below.

> 1. A medical device, comprising:
> an elongate shaft including a first tubular member and a second tubular member;
> a balloon coupled to the shaft;
> a first member coupled to the first tubular member and positioned within the balloon, the first member including a distal stop with a tapered distal portion;
> wherein the distal stop includes a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft;
> a second member coupled to the first tubular member and positioned within the balloon, the second member having a distal end disposed proximal of the distal stop; and
> a medical implant coupled to the shaft and positioned adjacent to the balloon.

Ex. 1001, 25:30–44.

E. Applied References

Petitioner relies upon the following references, and the Declaration of Thomas Trotta ("the Trotta Declaration," Ex. 1003). Pet. 20–21; *see also* Ex. 1026 (correction to the Trotta Declaration).

Reference	Patent No.	Relevant Dates	Exhibit No.
Sugiyama	US 4,994,032	Filed Nov. 29, 1988 Issued Feb. 19, 1991	Ex. 1009
Fischell '507	US 4,768,507	Filed Aug. 31, 1987 Issued Sept. 6, 1988	Ex. 1010
Fischell '274	US 5,639,274	Filed June 2, 1995 Issued June 17, 1997	Ex. 1013
Burton	US 5,026,377	Filed Aug. 17, 1990 Issued June 25, 1991	Ex. 1014

Reference	Patent No.	Relevant Dates	Exhibit No.
Jendersee	US 5,836,965	Filed June 7, 1995 Issued Nov. 17, 1998	Ex. 1016
Rupp	US 5,653,691	Filed Apr. 25, 1996 Issued Aug. 5, 1997	Ex. 1023

Patent Owner relies upon the Declaration of Dr. Ronald J. Solar, Ph.D. ("the Solar Declaration," Ex. 2004).

Additionally, the parties rely upon the January 17, 2018, deposition of Mr. Trotta (Ex. 2008), and the April 4, 2018, deposition of Dr. Solar (Ex. 1027 (annotations made during deposition); Ex. 1028 (transcript)).

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–26 of the '062 patent based on the following grounds. Pet. 20–21, 46, 78; *see also* Dec. 6, n.1.

References	Basis	Claims Challenged
"Fischell '274 in View of Burton, in Further View of Knowledge of a POSITA [person of ordinary skill in the art] and/or Sugiyama"	§ 103(a)	1–26
"Sugiyama '032 in View of Fischell '507, and in Further View of Jendersee"	§ 103(a)	1–26
"Rupp in View of the Knowledge of a POSITA and/or Sugiyama '032 and in Further View of Jendersee"	§ 103(a)	1–7, 9–15, 17–21, and 23–26

II. DISCUSSION

A. Claim Construction

"The Board construes claims of an expired patent in accordance with *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)." *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279 (Fed. Cir. 2017). Accordingly, the "words of a claim 'are generally given their ordinary and customary meaning'" as understood by a POSITA at the time of the invention. *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "In determining the meaning of the disputed claim limitation[s], we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotation marks omitted).

The parties agree that the '062 patent has expired and, at least for this proceeding, agree that each claim term should receive its plain and ordinary meaning. Pet. 18–20; Prelim. Resp. 6; *see generally* PO Resp. (not directly addressing claim construction); Tr. 8:9–12 (claim 7), 29:11–12 (same), 30:23–25 (same).

Upon review of the record before us, we determine that we need not construe expressly any claim limitation. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Principles of Law

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 said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378

(Fed. Cir. 2015). To prevail, Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17.

Petitioner relies upon the Trotta Declaration and contends that a POSITA would have "an undergraduate degree in science in mechanical, manufacturing, or material science engineering, as well as at least five years' experience in designing minimally invasive catheter-based interventions," or "an undergraduate degree in a different subject matter . . . [and] five to ten years of experience in the industry in designing minimally invasive catheter-based interventions." Pet. 18 (citing Ex. 1003 ¶ 80).

Patent Owner does not provide an assessment of the relevant skill level. *See generally* PO Resp. However, Dr. Solar, Patent Owner's declarant, "generally agree[s]" with the definition offered by Mr. Trotta. *See* Ex. 2004 ¶ 23; Ex. 1028, 23:12–15 ("essentially concur[ring]").

Based on our review of the '062 patent, the types of problems and solutions described in the '062 patent and applied prior art, and the testimony of Mr. Trotta and Dr. Solar, we adopt Petitioner's identification of the credentials of a POSITA.

Patent Owner argues that the Board should afford Mr. Trotta's testimony little or no weight "because he lacks experience in the relevant technologies." PO Resp. 12–15. According to Patent Owner, Mr. Trotta

"has no actual experience in stent crimping" and "the first time [he] worked on any stent securement issue was in 1997," after the '062 patent was filed. *Id.* at 12, 13 n.2.

We disagree with Patent Owner because, as just discussed, the relevant level of skill in the art does not require experience with stent crimping or stent securement. Indeed, the challenged claims of the '062 patent do not include any limitations directed to stent crimping or stent securement. Ex. 1001, 25:30–28:32; *see also* Ex. 1028, 32:3–6 (Dr. Solar testifying that claim 1 does not recite "secure"), 49:20–23 (Dr. Solar testifying that claim 1 does not recite "crimping"); *see also infra* Section II.F.2.a.vi. Moreover, Dr. Solar testified that he considers Mr. Trotta to have been a POSITA in 1996. Ex. 1028, 23:16–25. Further, Patent Owner has not cited any persuasive authority for the proposition that a witness being offered as an expert must also have acquired the knowledge and skill set of a POSITA as of the critical date. As such, Patent Owner has not persuaded us that Mr. Trotta's testimony should be discounted.

D. Obviousness over the Combined Teachings of "Fischell '274 in View of Burton, in Further View of Knowledge of a POSITA and/or Sugiyama"

Petitioner contends that claims 1–26 of the '062 patent are unpatentable under 35 U.S.C. § 103(a), over the combined teachings of Fischell '274, Burton, Sugiyama, and the knowledge of a POSITA. Pet. 21–46; Reply 20–26. For reasons that follow, we determine Petitioner has not demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Fischell '274 (Ex. 1013)

Fischell '274 is a U.S. Patent titled "Integrated Catheter System for Balloon Angioplasty and Stent Delivery." Ex. 1013, [54]. Figure 2A of Fischell '274 is reproduced below.

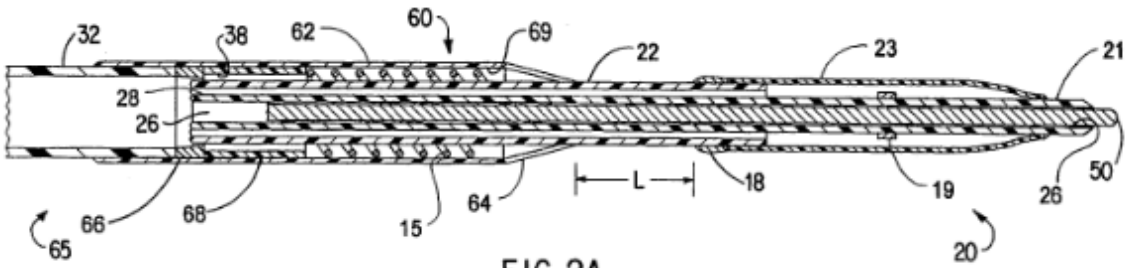


FIG. 2A

Figure 2A depicts a longitudinal cross-section of preferred integrated catheter system 60, which includes balloon angioplasty catheter 20 with inflatable balloon 23, and stent catheter 65 with stent 15 retained in containment cavity 69. *Id.* at 3:29–30, 4:50–57; *see also id.* at Fig. 1 (depicting a "simplified form of the integrated catheter system").

Integrated catheter system 60 is used as follows: (1) system 60 is advanced through an artery until balloon 23 lies within an arterial stenosis (*id.* at Fig. 7A); (2) balloon 23 is inflated and stent catheter 65 passes therethrough (*id.* at Fig. 7B); (3) balloon 23 is deflated (*id.* at Fig. 7C); (4) stent 15 is positioned over balloon 23 (*id.* at Fig. 7D); (5) balloon 23 is inflated minimally, which causes stent 15 to be retained on balloon 23, and the stent catheter is pulled back (*id.* at Fig. 7E); (6) stent 15 deploys, either through self-expansion (*id.* at Fig. 7E') or through inflation of the balloon to high pressure (*id.* at Fig. 7F); and (7) balloon 23 is deflated and retracted from the artery (*id.* at Fig. 7G). *See also id.* at 6:3–50.

2. Overview of Burton (Ex. 1014)

Burton is a U.S. Patent titled "Stent Placement Instrument and Method." Ex. 1014, [54]. Figures 1 and 3 of Burton are reproduced below.

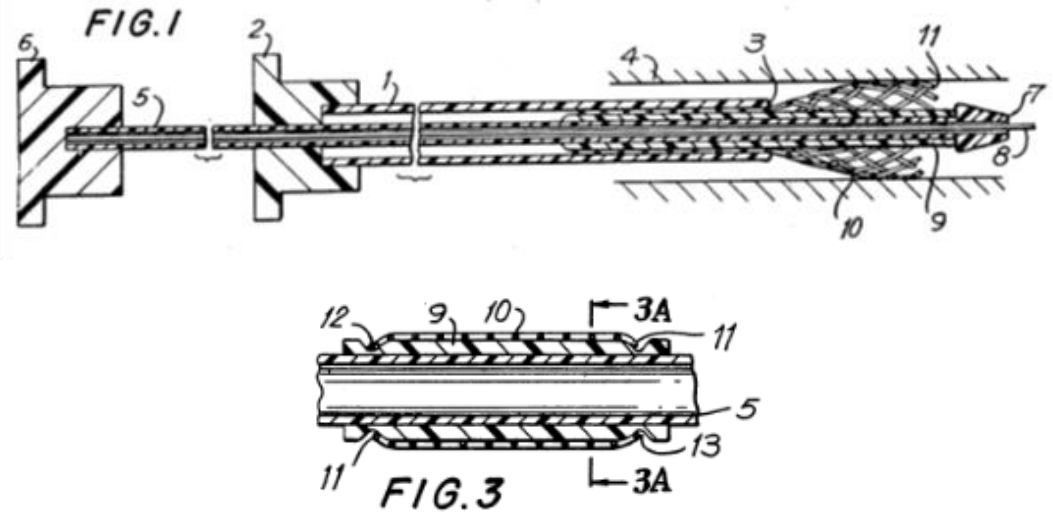


Figure 1 depicts an instrument for holding and deploying self-expanding stent 10, wherein the instrument includes grip member 9, one embodiment of which is depicted in greater detail in Figure 3. *Id.* at Abstract, 5:11–12, 5:15–16. Burton explains that grip member 9 engages stent 10 with a high-friction surface material (*id.* at Figs. 3–3A), with a coating of releasable adhesive (*id.* at Fig. 4), and/or with a surface material that takes a set and deforms due to compression of the stent against the settable material (*id.* at Fig. 5). *See, e.g.*, *id.* at 3:29–4:22, 5:46–64.

3. Overview of Sugiyama (Ex. 1009)

Sugiyama is a U.S. Patent titled "Balloon Catheter." Ex. 1009, [54]. Sugiyama's Figure 1 is reproduced below.

FIG.1

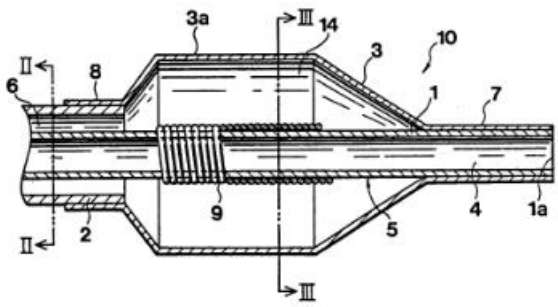


Figure 1 depicts an enlarged sectional view of the distal end of a balloon catheter. *Id.* at 2:47–48. As reflected in Figure 1, "reinforcement 9 is wound about a predetermined portion of the outer surface of the inner tube 1 which is enclosed within the balloon 3 . . . . [Accordingly], the inner tube is rendered more resistant against buckling." *Id.* at 4:58–65. Sugiyama specifies that reinforcement 9 may "have turns [thereof] so wound that they be in intimate contact with each other" or "may alternatively be so wound that its turns are thick for example in intimate contact with each other in both end parts and thin or sparse in the intermediate part of the coil spring." *Id.* at 7:53–63, Figs. 12–13.

Sugiyama also discloses that the ends of balloon 3 may be secured to inner and outer tubes 1, 2 with adhesive. *Id.* at 4:13–17.

4. Analysis of Applied Art

Petitioner contends that the combined teachings of Fischell '274, Burton, Sugiyama, and the knowledge of a POSITA render obvious claims 1–26 of the '062 patent. Pet. 21–46; Reply 20–26. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 8–21; *see also* Paper 18, 3–4. Patent Owner argues, *inter alia*, that a POSITA would not have modified Fischell '274 to arrive at the claimed invention. Prelim. Resp. 18.

After considering the parties' arguments and evidence, we determine Petitioner has not demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

a. Independent Claim 1

Petitioner contends that Fischell '274 discloses a medical device substantially as claimed including a catheter having balloon 23 and first distal stop member 7, wherein stent 15 is positioned adjacent the balloon. Pet. 21–22, 27–30. Petitioner states that Fischell '274 "lacks any under-balloon securement mechanism" akin to the claimed "second member . . . positioned within the balloon," but, nonetheless, "teaches that the balloon itself had some ability to retain the stent . . . [by] inflating the balloon to a low pressure [to] temporarily hold the stent in place." *Id.* at 22 (citing Ex. 1013, 6:34–38). Thus, Petitioner contends that the Fischell '274 stent delivery system "could be improved by increasing the balloon's ability to retain the stent," including by "adding securement structures under the balloon," such as Burton's "soft, elastomeric grip member." Pet. 22–23, 25–26. According to Petitioner, this "would allow the stent to be securely carried on the balloon during delivery," and "would ensure stent securement, simplify delivery system operation, and decrease the overall profile of the delivery catheter." *Id.* at 25–26 (citing Ex. 1003 ¶¶ 108–111), 28–29.

Petitioner relies upon Mr. Trotta's testimony that Burton's "soft, elastomeric mounting body . . . would be particularly suited to secure the balloon-expandable stent of Fischell '274 over the balloon without requiring an external sheath or other profile-increasing structure," which would improve the profile and trackability of the catheter. Ex. 1003 ¶ 110. Mr. Trotta also testified that Burton's grip member would be placed under

the balloon of Fischell '274 and would overlie or be positioned adjacent the radiopaque markers. *Id.* ¶¶ 111–112.

Patent Owner argues that a POSITA would not have modified Fischell '274 as proposed. Prelim. Resp. 18. According to Patent Owner, Fischell '274 concerns balloon-delivered stents, while Burton concerns self-expandable stents. *Id.* at 19–20. Due to these differences, Patent Owner alleges that Burton's grip member 9 "would be rendered ineffective if used under the balloon of Fischell '274, because the operation of the grip member requires direct contact between the stent and the grip member." *Id.* at 20 (citation omitted). "[P]lacing the grip member under the balloon as in Fischell '274 prevents the direct contact." *Id.*

In the Reply, Petitioner responds that a POSITA would have modified the prior art as proposed in order to eliminate the catheter's sheath and allow direct stenting, which reduces the time, cost, and complexity of surgery. Reply 22–23. Petitioner argues that although Burton's grip member "uses direct contact" to secure Burton's stent, it "would also be suitable for securing a balloon-expandable stent," as taught by Fischell '274, because placing the grip member under the balloon would avoid problems associated with over-crimping. *Id.* at 24 (citing Ex. 1003 ¶ 55). According to Petitioner, the grip member's "material composition would allow it to deform and support a stent and balloon compressed over it." *Id.* at 25 (citing Ex. 1003 ¶¶ 109–112). Also, Petitioner argues that by "providing an enlarged diameter from the catheter shaft, Burton's grip member would serve to better secure a balloon-expandable stent on to the balloon." *Id.* at 25 (citing Ex. 1003 ¶¶ 55, 109–111; Ex. 1014 at 3:25–28).

We are not persuaded by Petitioner's contentions. The proposed modification to Fischell '274 places Burton's grip member 9 underneath Fischell 274's balloon 23 and stent 15, to "ensure stent securement." Pet 25 (citing Ex. 1003 ¶¶ 108–109), 28–29. However, Burton explains that grip member 9 retains the stent through *physical contact,* for example, through a high-friction, adhesive, or settable contact surface between the grip member and the stent. *See, e.g.*, Ex. 1014, 5:46–64, 3:29–33 (disclosing a "friction contact surface . . . that will take a set"), 3:48–56 ("[A]n important characteristic of the grip member is that it should be capable of gripping or holding a stent . . . [e.g.,] a surface which offers high resistance to sliding motion."), 3:62–65 (disclosing a "releasable adhesive"). Neither Petitioner nor Mr. Trotta explains sufficiently how the grip member would retain the Fischell '274 stent, when balloon 23 is located between the grip member and the stent, precluding the physical contact relied upon by Burton. *See* Pet. 25–26; Ex. 1003 ¶¶ 107–111.

We recognize Petitioner's argument, made in its Reply and at the oral hearing, that Burton's grip member may include material that is deformable, which would secure the stent even with a balloon located between the stent and the grip member. Reply 25 (citing Ex. 1003 ¶¶ 109–112); Tr. 16:19–19:10. However, neither the Petition nor the Trotta Declaration discusses deformation at all; this argument was made for the first time in the Reply and, thus, is improper. *Compare* Pet. 21–46, *and* Ex. 1003 ¶¶ 109–112, *with* Reply 25; *see also* 37 C.F.R. § 42.23(b).

Additionally, Burton explains that deformable materials that "take a set" are inherently high-friction materials. *See, e.g.*, Ex. 1014, 4:13–16 ("When the core itself is made from a material that will take a set, such a

material being inherently of high friction, the larger diameter may not be necessary."), 4:16–21, 6:56–64. Neither Petitioner nor Mr. Trotta addresses this disclosure, or explains how Burton's grip member would secure the stent without contact between the high-friction, settable, deformable material and the stent to be secured. *See, e.g.*, Pet. 21–46; Ex. 1003 ¶¶ 107–111.

For example, Mr. Trotta testifies that the proposed modification would secure the stent without requiring an external sheath, which would improve trackability and profile. Ex. 1003 ¶ 110. Although this may be a beneficial result, if the modification were achieved, this testimony does not explain *how* the grip member would secure the stent in the absence of physical contact with high-friction, settable material or adhesive material. Likewise, Mr. Trotta's opinion regarding the location of Burton's grip member, when used with the stent of Fischell '237, fails to cure this deficiency. *Id.* ¶¶ 111–112 (located underneath the balloon and either overlying or adjacent radiopaque markers).[1] *See In re Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004); *see also* 37 C.F.R. § 42.65(a).

Additionally, we are unpersuaded by Petitioner's Reply argument that, by "providing an enlarged diameter from the catheter shaft, Burton's grip

[1] Petitioner's argument that placing Burton's grip member under the balloon would help avoid problems associated with over-crimping is also insufficiently supported. Reply 24 (citing Ex. 1003 ¶ 55). Mr. Trotta opined that, generally speaking, mounting a balloon-expandable stent on a catheter without a sheath "presented a difficult compromise in how tightly to crimp the stent," because over-crimping could damage the stent, but under-crimping might cause the stent to fall off. Ex. 1003 ¶ 55. This testimony, however, does not relate to the proposed combination, and does not explain how placing Burton's grip member underneath the Fischell '274 balloon would either retain the stent or avoid over-crimping. *See id.* ¶¶ 55, 109–112.

member would serve to better secure a balloon-expandable stent on to the balloon and catheter shaft." Reply 25 (citing Ex. 1003 ¶¶ 55, 109–111; Ex. 1014 at 3:25–28); Tr. 16:19–19:10. The Trotta Declaration states that the grip member "would have a larger diameter than the radiopaque markers" of Fischell '274. Ex. 1003 ¶ 112. This testimony, however, does not explain sufficiently how a diameter larger than certain markers "improve[s] securement for a balloon-expandable stent." Pet. 25. Petitioner's analogy to a golf club shaft, provided in the Reply, is new, speculative, and unsupported attorney argument, which cannot take the place of evidence. *Id.* at 25 n.8 (speculating that "a synthetic grip for a golf club shaft helps a player to have a secure grip by providing an increased diameter and a softer composition than the shaft, and its diameter and firmness can be adjusted to best fit an individual player's hands"); *cf. In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

Petitioner has not demonstrated sufficiently that, in the proposed combination, Burton's grip member would secure the Fischell '274 stent, in the absence of physical contact between the stent and the grip member. As such, Petitioner has not demonstrated that a skilled artisan would have made such a modification, whether to ensure stent securement, simplify delivery system operation, or decrease the catheter profile, as Petitioner contends.

b. Independent Claims 13, 21, and 26

Independent claims 13, 21, and 26 include limitations concerning a "proximal member," for which Petitioner relies on the combined teachings of Fischell '274 and Burton, as discussed above regarding claim 1. Pet. 36, 41, 45. For the same reasons discussed above regarding claim 1, we

determine that Petitioner has not met its burden to demonstrate, by a preponderance of the evidence, that the combined teachings of Fischell '274, Burton, Sugiyama, and the knowledge of a POSITA render obvious independent claims 13, 21, or 26.

c. Dependent Claims 2–12, 14–20, and 22–25

Claims 2–12 depend directly or indirectly from claim 1; claims 14–20 depend directly or indirectly from claim 13; and claims 22–25 depend directly from claim 21. For the same reasons discussed above regarding claims 1, 13, and 21, we determine that Petitioner has not met its burden to demonstrate, by a preponderance of the evidence, that the combined teachings of Fischell '274, Burton, Sugiyama, and the knowledge of a POSITA render obvious these claims.

E. Obviousness over the Combined Teachings of "Sugiyama '032 in View of Fischell '507, and in Further View of Jendersee"

Petitioner contends that claims 1–26 of the '062 patent are unpatentable under 35 U.S.C. § 103(a), over the combined teachings of Sugiyama, Fischell '507, and Jendersee. Pet. 46–78. For reasons that follow, we determine Petitioner has not demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Fischell '507 (Ex. 1010)

Fischell '507 is a U.S. Patent titled "Intravascular Stent and Percutaneous Insertion Catheter System for the Dilation of an Arterial Stenosis and the Prevention of Arterial Restenosis." Ex. 1010, [54]. Figure 3 of Fischell '507 is reproduced below.

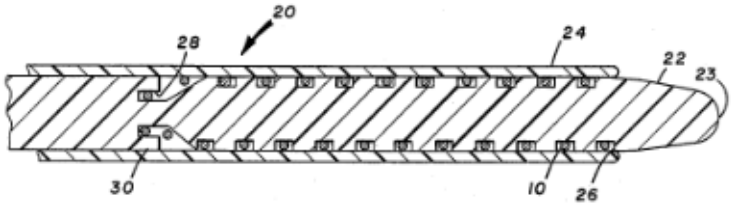


FIG. 3

Figure 3 depicts a cross-sectional view of the distal end of a catheter for inserting an intravascular stent. *Id.* at 3:11–12. As shown in Figure 3, catheter 20 includes inner core 22 and outer cylinder 24. *Id.* at 3:47–49. Inner core 22 includes spiral grooves 26 and back groove 28, into which stent 10 is placed, such that flange 30 retains the proximal end of stent 10 within back groove 28. *Id.* at 3:49–51, 3:66–4:27 (explaining that pliers hold distal portion of stent 10 into distal-most groove 26; the center of stent 10 is forced into spiral grooves 26 extending along the length of core 22 by pulling and twisting with pliers; the most proximal turn of stent 10 is forced into groove 28 with needle-nose pliers; and outer cylinder 24 is moved to cover the entire stent 10).

2. Overview of Jendersee (Ex. 1016)

Jendersee is a U.S. Patent titled "Stent Delivery and Deployment Method." Ex. 1016, [54]. Figure 3 of Jendersee is reproduced below.

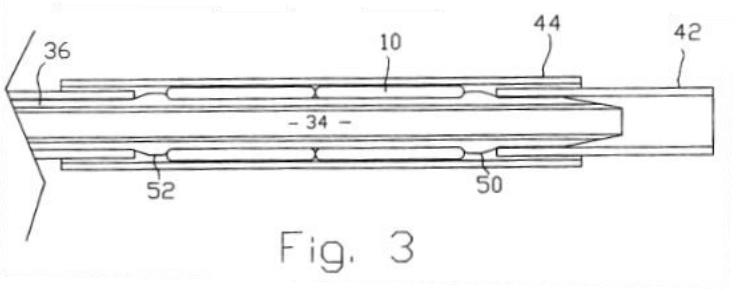


Fig. 3

Figure 3 depicts a longitudinal cross-sectional view of stent 10 and balloon 36, positioned with interior and exterior sheaths 42, 44, during a

process of encapsulation. *Id.* at 4:62–64. Jendersee explains that by encapsulating the stent with the catheter's balloon, the "balloon may expand part way around the stent and adhere thereto," such that a "smoother transition" is provided between the catheter and the ends of the stent. *Id.* at 3:21–31; *see also id.* at 6:41–53 (explaining that the encapsulation process includes steps of compressing stent segment 10 on balloon 36; placing sheaths 42, 44 over the catheter; partially expanding balloon 36; elevating the temperature such that balloon 36 expands partially outwardly around stent 10; and cooling the assembly to set the shape of balloon 36 and adhere it to stent 10).

Jendersee's Figure 8 is reproduced below.

FIGURE 8

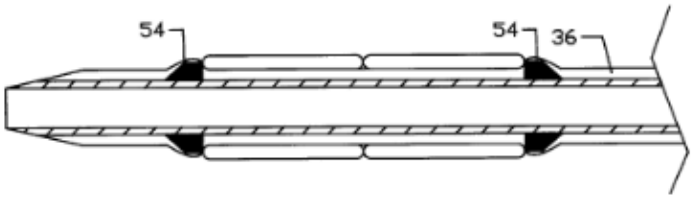


Figure 8 depicts a longitudinal cross sectional view of the stent assembly with "conventional retainers 54" located within the balloon to secure the stent to the balloon and to create a smooth transition across the assembly. *Id.* at 5:9–11, 7:36–40, 7:46–52.

3. Analysis of Applied Art

Petitioner contends that the combined teachings of Sugiyama, Fischell '507, and Jendersee render obvious claims 1–26 of the '062 patent. Pet. 46–78. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 22–26; *see also* Paper 18, 3–4. Patent Owner argues, *inter alia*, that a POSITA would not have modified Sugiyama to arrive at the claimed invention. Prelim. Resp. 22.

After considering the parties' arguments and evidence, we determine Petitioner has not demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

a. Independent Claim 1

Petitioner contends that Sugiyama discloses a medical device substantially as claimed, including a catheter having first and second tubular members 1, 2, and balloon 3, with coil-shaped reinforcement 9 positioned within the balloon. Pet. 46–49, 56–59. Although Sugiyama does not disclose a stent, Petitioner contends that it would have been obvious "to adapt Sugiyama's catheter for use as a stent delivery system because its balloon catheter is a vascular dilatation catheter . . . capable of exerting sufficient force to perform direct stenting." *Id.* at 49–50.

According to Petitioner, the "spiral coil shape [of Sugiyama's reinforcement 9] would make it particularly suitable for securely holding and delivering a spiral-shaped stent such as that taught by Fischell '507." *Id.* at 49–50, 52. Petitioner contends that Fischell '507 discloses a catheter for delivering coil spring stent 10, wherein the catheter includes spiral grooves 26 into which the stent is placed. *Id.* at 51, 59. According to Petitioner, "the gaps between the turns of [Sugiyama's] spiral reinforcement 9 would create a structure similar to the spiral grooves of Fischell '507, thereby providing a mounting body located on the catheter shaft to help secure the stent during delivery." *Id.* at 52 (citing Ex. 1003 ¶¶ 128–130). Petitioner also contends that by "modifying the Fischell '507 stent to be balloon-expandable, it would be unnecessary to use the outer sheath cylinder 24, thereby reducing the overall profile of the delivery system and

improving the flexibility and trackability of the delivery catheter." *Id.* at 52–53 (citing Ex. 1003 ¶ 131).

Patent Owner argues that a POSITA would not have used Sugiyama's balloon catheter with the Fischell '507 stent. Prelim. Resp. 22. According to Patent Owner, Sugiyama does not concern stent delivery, and Fischell '507 does not concern balloon-expandable stents. *Id.* Thus, Patent Owner contends that Petitioner "ignores the fundamental differences between a stent in Fischell '507 and a catheter shaft in Sugiyama." *Id.* at 22–23. Moreover, Patent Owner argues that "the self-expanding stent in Fischell '507 would be ineffective if used with a balloon catheter delivery system because the structures holding the self-expanding stent in Fischell '507 require direct contact with the stent." *Id.* at 23. According to Patent Owner, Fischell '507 discloses groove 28 and flange 30, into which the self-expanding stent is loaded, by manipulation of the stent with various sets of pliers. *Id.* Patent Owner argues that, "if a balloon were added to the catheter of Fischell '507, the balloon would be destroyed upon loading of the stent" into the groove and flange. *Id.* at 23–24.

In the Reply, Petitioner does not respond to Patent Owner's arguments. *See generally* Reply.

Petitioner proposes that the Fischell '507 self-expanding stent 10 be placed over Sugiyama's balloon 3 and spiral reinforcement 9, to "secure the stent during delivery" and to reduce the profile of the assembly. Pet. 52–53; Ex. 1003 ¶ 130. We agree with Patent Owner, however, that Petitioner has not demonstrated sufficiently that a POSITA would have found this obvious, in light of the fundamental differences between the references. Prelim. Resp. 22–24. Petitioner provides insufficient reasoning as to why a POSITA

would have added the Fischell '507 self-expanding stent to the outside of Sugiyama's balloon catheter. As discussed above, the Fischell '507 stent is *not* balloon expandable and Sugiyama does not describe its catheter as being used for deploying stents. As such, Petitioner's proposed combination appears to be premised on impermissible hindsight, rather than a rational basis to combine the references.

Additionally, Fischell '507 explains that stent 10 is secured to the catheter by forcing the entire length of stent 10 into grooves 26, 28 along the length of catheter core 22, and by forcing the end of the most proximal coil into flange 30 to prevent the stent "from springing radially outward." *See, e.g.*, Ex. 1010, 3:47–55, 3:67–4:27 (using pliers to secure the stent). Petitioner does not propose including the grooves and flange of the Fischell '507 catheter core into the combination. Additionally, neither Petitioner nor Mr. Trotta explains sufficiently how the Fischell '507 stent would be secured to Sugiyama's catheter, in the absence of such a groove and flange structure, when Sugiyama's balloon 3 is located between Sugiyama's spiral reinforcement 9 and the Fischell '507 stent, precluding the kind of force-fit relied upon in Fischell '507. *See* Pet. 52–53; Ex. 1003 ¶¶ 129–131. We agree with Patent Owner that the coil-shaped stent disclosed by Fischell '507 seemingly "would be ineffective" if used with Sugiyama's balloon catheter "because the structures holding the self-expanding stent in Fischell '507 require direct contact with the stent. If such structures are placed under the balloon, they lose direct contact with the stent." Prelim. Resp. 23–24.

As such, we are not persuaded that Petitioner presents sufficient reasoning to demonstrate that a POSITA would have combined Sugiyama

and Fischell '507 to help secure the stent during delivery, as Petitioner contends.

b. Independent Claims 13, 21, and 26

Independent claims 13, 21, and 26 include limitations concerning a "cardiovascular implant" or an "implantable endoprosthesis," for which Petitioner relies on the combined teachings of Sugiyama and Fischell '507, as discussed above regarding claim 1. *Id.* at 65–66, 71–72, 78. For the same reasons discussed above regarding claim 1, we determine that Petitioner has not met its burden to demonstrate, by a preponderance of the evidence, that the combined teachings of Sugiyama, Fischell '507, and Jendersee render obvious independent claims 13, 21, or 26.

c. Dependent Claims 2–12, 14–20, and 22–25

Claims 2–12 depend directly or indirectly from claim 1; claims 14–20 depend directly or indirectly from claim 13; and claims 22–25 depend directly from claim 21. For the same reasons discussed above regarding claims 1, 13, and 21, we determine that Petitioner has not met its burden to demonstrate, by a preponderance of the evidence, that the combined teachings of Sugiyama, Fischell '507, and Jendersee render obvious these claims.

F. Obviousness over the Combined Teachings of "Rupp in View of the Knowledge of a POSITA and/or Sugiyama '032 and in Further View of Jendersee"

Petitioner contends that claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent are unpatentable under 35 U.S.C. § 103(a), over the combined teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA. Pet. 78–100; Reply 3–20. For reasons that follow, we determine Petitioner

has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Rupp (Ex. 1023)

Rupp is a U.S. Patent titled "Thickened Inner Lumen for Uniform Stent Expansion and Method of Making." Ex. 1023, [54]. Rupp's Figure 1 is reproduced below.

Fig. 1

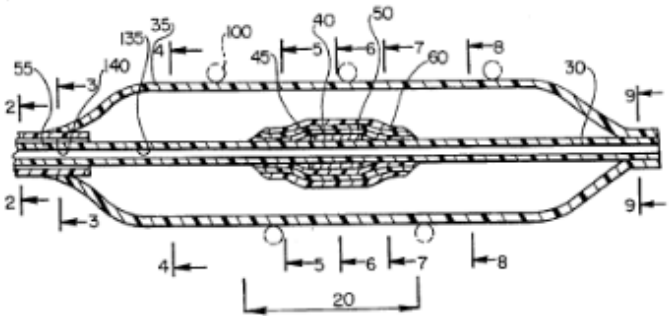


Figure 1 depicts a longitudinal cross-section of a stent deployment device that has multiple built-up layers. *Id.* at 2:63–65. As shown in Figure 1, Rupp discloses a catheter having inner lumen tubing 30, inflation lumen tubing 55, and balloon 35, wherein stent 100 is crimped upon balloon 35. *Id.* at 5:12–26, 5:38–40. Rupp discloses that built up section 20 (comprising layers 40, 50, and 60) is affixed to inner lumen tubing 30 and is centered underneath stent 100. *Id.* at 5:5–7, 5:41–45. Rupp explains that built-up section 20 ensures uniform expansion of the balloon and avoids pin-hole leaks. *Id.* at 4:56–67, 5:38–45.

2. Analysis of Applied Art

Petitioner contends that the combined teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSTIA render obvious claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent. Pet. 78–100; Reply 3–20. Patent Owner disputes Petitioner's contentions. PO Resp. 15–25. Patent Owner

argues, *inter alia*, that Petitioner provides only a conclusory rationale for modifying the prior art and that a POSITA would not have combined the prior art as proposed. *Id.* at 15, 18.

After considering the parties' arguments and evidence, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

a. Independent Claim 1

i. "A medical device comprising[] an elongate shaft including a first tubular member and a second tubular member"

Petitioner contends that Rupp discloses a "medical device" (i.e., a stent delivery catheter) substantially as claimed, including a "first tubular member" (i.e., inner lumen tubing 30) and a "second tubular member" (i.e., inflation lumen tubing 55). Pet. 82–83 (citing Ex. 1023, Abstract, 5:13–20, Fig. 1). Patent Owner does not dispute Petitioner's contentions. PO Resp. 15–25.

We are persuaded by Petitioner's contentions. Rupp discloses a "typical catheter," used for stent deployment, which includes "inner lumen tubing 30" and "inflation lumen tubing 55." Ex. 1023, 2:40–43, 5:12–20. As shown in Figure 1, inflation lumen tubing 55 is coaxial with inner lumen tubing 30, and the two lumens form an elongate shaft. *Id.* at Fig. 1.

ii. *"a balloon coupled to the shaft"*

Petitioner contends that Rupp discloses a "balloon coupled to the shaft" (i.e., balloon 35). Pet. 83 (citing Ex. 1023, 5:22–26). Patent Owner does not dispute Petitioner's contention. PO Resp. 15–25.

We are persuaded by Petitioner's contention. Rupp discloses that "distal end of the balloon 35 may be sealed to the distal end of the inner

lumen tubing 30 [and] proximal end of the balloon 35 may be sealed to the distal end of the inflation lumen tubing 55." Ex. 1023, 5:22–26. This is depicted in Figure 1. *Id.* at Fig. 1.

iii. "a first member coupled to the first tubular member and positioned within the balloon . . . including a distal stop with a tapered distal portion . . . [which] includes a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft"

Petitioner contends that Jendersee teaches a "first member" as claimed (i.e., retainer 54). Pet. 83. According to Petitioner, retainer 54 is a distal stop with a tapered distal portion and a proximal end face perpendicular to the longitudinal axis of the shaft. *Id.* (citing Ex. 1016, 3:49–52, 5:9–11, 7:33–54, Fig. 8). Patent Owner does not dispute Petitioner's contentions regarding Jendersee's teachings. PO Resp. 15–25.

We are persuaded by Petitioner's contention. Jendersee discloses "conventional retainers 54 . . . placed within the balloon 36," i.e., a distal stop. Ex. 1016, 7:46–49. The distal-most retainer 54, shown to the left of Figure 8, is coupled to the tubular shaft and includes a tapered distal portion and a proximal end face extending substantially perpendicular to the longitudinal axis of the catheter shaft, as claimed. *Id.* at Fig. 8.

Petitioner also contends that a POSITA "would have been motivated to add one or both of the conical retainers taught by Jendersee" to the system disclosed by Rupp, "to further enhance the securement of the stent, which would yield the same benefits of enhanced securement and trackability." Pet. 81–82. We address this contention in Section II.F.2.a.vi., below.

iv. "a second member coupled to the first tubular member and positioned within the balloon . . . having a distal end disposed proximal of the distal stop"

Petitioner contends that Rupp discloses a "second member" substantially as claimed (i.e., built up section 20 made of built-up layers 40, 50, and 60). Pet. 84. According to Petitioner, built up section 20 is coupled to the first inner lumen tubing 30 and is positioned within the balloon.

We are persuaded by Petitioner's contention. Rupp discloses that "a section of inner lumen tubing under the area of the stent can be built up," i.e., "built up section 20." Ex. 1023, 4:56–62. As depicted in Figure 1, built up section 20 is coupled to inner lumen tubing 30 and positioned within balloon 35. *Id.* at 4:56–67.

Petitioner also contends that a POSITA "would have been motivated to add one or both of the conical retainers taught by Jendersee as a useful adjunct to [the] built-up layer of Rupp to further enhance the securement of the stent, which would yield the same benefits of enhanced securement and trackability." Pet. 81–82. In this proposed combination, Petitioner contends that Rupp's built up section 20 has a distal end located proximal of Jendersee's distal retainer 54, as claimed. *Id.* at 82, 84; Ex. 1003 ¶ 146. We address this contention in Section II.F.2.a.vi., below.

v. "a medical implant coupled to the shaft and positioned adjacent to the balloon"

Petitioner contends that Rupp discloses a "medical implant" (i.e., stent 100) coupled to the shaft and positioned adjacent the balloon. Pet. 84 (citing Ex. 1023, 4:58–67, Fig. 1). Patent Owner does not dispute Petitioner's contention. PO Resp. 15–25.

We are persuaded by Petitioner's contention. Rupp discloses that "stent 100 is crimped upon a balloon 35." *Id.* at 5:38. As shown in Figure 1, the stent is coupled to the shaft and positioned adjacent balloon 35. *Id.* at Fig. 1.

vi. Reasons to Combine

As discussed above, Petitioner contends that a "POSITA would have been motivated to add one or both of the conical retainers taught by Jendersee [i.e., the claimed 'first member'] as a useful adjunct to [the] built-up layer of Rupp [i.e., the claimed 'second member'] to further enhance the securement of the stent, which would yield the same benefits of enhanced securement and trackability." Pet. 81–82 (citing Ex. 1003 ¶ 146; Ex. 1016, 7:33–54). Petitioner contends that the distal end of Rupp's built up layer 20 would be proximal Jendersee's distal retainer 54, in the proposed combination. *Id.* at 82 (providing an annotated version of Rupp's Figure 1, indicating where retainers 54 would be positioned), 84.

Patent Owner disagrees. PO Resp. 15–25. First, according to Patent Owner, Petitioner fails to provide articulated reasoning with rational underpinning to support the conclusion of obviousness. *Id.* at 15–18. Patent Owner argues that Rupp is not directed "to stent securement at all," and Petitioner "fails to point to anything in Rupp that might have prompted a [POSITA] to provide a stent securement feature. Nor has Petitioner explained how the addition of Jendersee's retainer to Rupp's built-up layer would 'yield the same benefits of enhanced [] securement and trackability discussed above.'" *Id.* at 17.

Patent Owner also argues that a POSITA would have been dissuaded from combining Rupp and Jendersee for "a plethora of reasons." PO

Resp. 18. Patent Owner again argues that Rupp and the '062 patent address different problems—stent expansion and stent securement, respectively—such that a POSITA would not have considered Rupp in relation to securement. *Id.* at 19; *see also id.* at 15–18. Moreover, Patent Owner argues that Jendersee relates to yet a different problem—stent encapsulation. *Id.* at 20–21. According to Patent Owner, "[g]iven the divergent methodologies employed by Rupp, Jendersee, and the ['062 patent, a skilled artisan would find no reason to combine the teachings of Rupp and Jendersee to derive the claimed invention." *Id.* at 21 (also arguing that Jendersee criticizes crimping and uneven outer surfaces). Patent Owner also argues that Rupp's built up layer 20 increases the profile of the delivery system, contrary to the prevailing desire to *decrease* profile. *Id.* at 19–20, 22–23.

We have considered the parties' arguments and cited evidence. We are persuaded that Petitioner has provided articulated reasoning with rational underpinning to support the legal conclusion that a POSITA would have found it obvious to include Jendersee's retainers in Rupp's stent delivery system, to "further enhance the securement of the stent." Pet. 81–82.

As an initial matter, we disagree with Patent Owner's characterization of the invention claimed in the '062 patent. Throughout its briefing, Patent Owner describes the '062 patent as solving problems related to "stent securement." *See, e.g.*, PO Resp. 3–5, 19 ("[T]he problem encountered by the inventors of the '062 patent relates to stent securement."); Tr. 19:24–25 ("The '062 patent is about a unique combination of two structural features underneath the balloon to help secure a balloon expandable stent."). However, challenged claims 1–26 do not include any limitations directed to stent securement. Claim 1, for example, recites a "second member coupled

to the first tubular member and positioned within the balloon . . .," but does not recite structure or functional limitations related to securing the stent in any manner. *See, e.g.*, Ex. 1028, 32:3–6; Tr. 22:2–3 ("[W]e don't dispute that there's no functional language in claim 1."). Although the specification of the '062 patent discloses that the mounting body "support[s] and hold[s] the stent and secure[s] it during crimping," the challenged independent claims do not recite such a limitation. Ex. 1001, 9:28–32; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'") (citation omitted). As such, Patent Owner's attempts to distinguish the claimed invention from the prior art due to alleged differences in the prior art's ability or intention to secure a stent, are not commensurate with the claim scope and are unpersuasive.

Nonetheless, we also disagree with Patent Owner's contention that Rupp does not relate to stent securement at all, such that a POSITA would not have had reason to "further secure" the stent. PO Resp. 17, 19. Although stent expansion is a primary objective disclosed by Rupp (*see, e.g.*, Ex. 1023, 2:40–43), Rupp also concerns stent securement. Indeed, Patent Owner's declarant, Dr. Solar, testified that, prior to expansion, Rupp's stent and balloon are crimped onto Rupp's catheter, such that the system can be advanced to the intended expansion site with "confidence that the stent would not slip off." Ex. 1028, 72:4–76:17; Ex. 1027 (Dr. Solar's annotations to Rupp's Figure 1, depicting the stent and balloon in the pre-expansion condition); *see also* Ex. 1028, 21:22–25 (testifying that it was

known in the mid-1990s to address stent securement issues); Ex. 2004 ¶ 54 (Dr. Solar's testimony that Rupp concerns stent expansion "after the stent has already safely traveled to the treatment site," which presumes that the stent was secured on the device during travel).

Moreover, Rupp explains that the stent "is crimped upon a balloon 35"— the same technique used to secure the stent to the balloon catheter in the '062 patent. *Compare* Ex. 1001, 8:26–27 (crimping), *with* Ex. 1023, 5:38–39 (crimping). Rupp further explains, however, that crimping may "cause pin hole leaks." Ex. 1023, 5:38–41. Thus, Rupp provides built up layer 20 to, *inter alia*, protect the balloon against punctures. *Id.* at 5:41–45, 7:8–11; *see also* Ex. 1028, 71:5–21. Accordingly, we are not persuaded by Patent Owner's argument that "Rupp is directed to stent expansion, not to stent securement at all." PO Resp. 17. To the contrary, stent securement (e.g., crimping) is a necessary and expressly disclosed aspect of Rupp.

Turning to the proposed combination, Jendersee supports Petitioner's contention that a POSITA would have been motivated to combine the references as proposed, to improve the securement of Rupp's stent onto the delivery device. For example, Jendersee specifies that retainers are used to "*further secure the stent* segment 10 to the balloon 36 and create a smooth transition between the balloon/stent area of the delivery device and the distal and proximal surfaces of the delivery device." Ex. 1016, 7:36–40 (emphasis added). Thus, the prior art itself suggests a reason to modify the references as proposed by Petitioner. "The suggestion to combine [references] may be found in explicit or implicit teachings within the references themselves." *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999).

Additionally, Mr. Trotta testified that modifying Rupp to include Jendersee's retainers would "further enhance the securement of the stent," "would not affect operation of the balloon[,] . . . and would provide a tapered profile under the cone regions of the balloon to help further secure the stent."[2] Ex. 1003 ¶ 146; *see also id.* ¶ 15 (explaining that a "transition cone region" is present on each side of an inflated balloon catheter, where the balloon transitions to the remainder of the catheter body). This testimony is consistent with Jendersee's disclosure that retainers further secure the stent and create a smooth transition between the stent area and the remainder of the delivery device. Ex. 1016, 7:36–40. Thus, we do not agree with Patent Owner's argument that Petitioner and Mr. Trotta provide only conclusory assertions regarding motivation to combine the references. PO Resp. 17. Rather, the motivation is disclosed expressly by Jendersee.

We are also unpersuaded by Patent Owner's argument that Jendersee relates to stent encapsulation, a different problem than that addressed by either the '062 patent or Rupp, such that "a skilled artisan would find no reason to combine the teachings of Rupp and Jendersee." PO Resp. 20–21. We appreciate that Jendersee discloses "unique procedures" related to its encapsulated stent. Ex. 1016, 6:58–7:33. However, we do not agree that these encapsulation procedures remove Jendersee from the consideration of a POSITA. We determine that Jendersee and Rupp are within the same field of endeavor as each other and as the '062 patent, i.e., stent delivery devices.

[2] The cited portion of Mr. Trotta's declaration states "would not affect operation of the balloon *or reinforcement 9*." Ex. 1003 ¶ 146 (emphasis added). We agree with Dr. Solar that the reference to "reinforcement 9" appears to be a typographical error, perhaps in reference to Sugiyama's "reinforcement 9." Ex. 2004 ¶¶ 51–52 n.2; Ex. 1009, Fig. 1.

Compare Ex. 1001, 1:27–29 ("The invention relates to an assembly and method for delivering and deploying an inflation expandable stent."), *with* Ex. 1016, [57] ("A[n] encapsulated stent device for implantation within the vascular system"), *and* Ex. 1023, [57] ("An intravascular catheter for implanting a radially expandable stent within a body vessel"). Moreover, Rupp and Jendersee—like the '062 patent—also concern stent securement. *Compare* Ex. 1001, 3:13–20 (disclosing a securement device underneath the balloon), *with* Ex. 1016, 3:11–16 (disclosing a long felt need for a delivery method that ensures positional stability, i.e., securement, of the stent), *and* Ex. 1023, 5:38–40 (disclosing that stent 100 is crimped upon balloon 35). Finally, the features of Jendersee upon which Petitioner relies—conventional retainers used to secure the stent—do not depend upon or implicate the unique encapsulation procedures to which Patent Owner refers. *See* Ex. 1016, 7:46–49.

We have also considered Patent Owner's argument that Rupp's built up layer 20 increases the profile of the delivery system, contrary to the prevailing desire to *decrease* profile size, e.g., the "so-called profile wars." PO Resp. 19–20, 22–25. Ample evidence of record indicates the importance of profile size to catheter design. *See, e.g.*, Ex. 1003 ¶ 41 (testifying that it is "important that the delivery device have a small diameter or profile"); Ex. 1016, 3:4–7 ("[I]ncreas[ing] the crossing profile of the delivery device thereby decreas[es] the device's ability to track through narrowed and tortuous vasculature."); Ex. 2004 ¶ 56 (testifying that companies "competed with each other to develop and market stents or stent delivery systems with the lowest profiles"); Ex. 2008, 53:15–22 (testifying that a profile reduction of "thousandths of an inch" would be "tremendous"). However, Patent

Owner's argument is misplaced, because the modification proposed by Petitioner does not seek to add Rupp's built up layer to another device. Rather, Petitioner simply proposes adding Jendersee's conventional retainers 54 to Rupp's device, which already includes Rupp's built up section 20. Pet. 81–82; Ex. 1023, Fig. 1. In the Patent Owner Response, Patent Owner has not argued or shown that the inclusion of Jendersee's retainers into Rupp's system would further increase the profile of the system over that present in Rupp's unmodified state. *See* Reply 14 (citing Ex. 1016, 7:46–54, Fig. 8; Ex. 1028, 89:24–90:9). Thus, we are not persuaded that a POSITA "would be discouraged from employing the built-up layer of Rupp—which could add significantly to the system's profile—as a delivery system design option," because the built up layer is already present in Rupp's device.[3]

For the foregoing reasons, we are persuaded by Petitioner's contention that it would have been obvious for a POSITA "to add one or both of the conical retainers taught by Jendersee as a useful adjunct to built-up layer of Rupp to further enhance the securement of the stent." Pet. 81–82. Moreover, in the proposed combination, we are also persuaded that Rupp's built up section 20 has a distal end located proximal of Jendersee's distal retainer 54, as claimed. *Id.* at 82, 84; Ex. 1003 ¶ 146 (providing an annotated version of Rupp's Figure 1, indicating where retainers 54 would be positioned).

[3] Likewise, we are unpersuaded by Patent Owner's argument that Jendersee criticizes crimping and uneven outer surfaces. PO Resp. 21. Even if true, Petitioner does not propose modifying Rupp or Jendersee to add these features. Petitioner only proposes modifying Rupp, which already includes crimping and uneven surfaces, to add Jendersee's retainers.

vii. Secondary Considerations

Patent Owner argues that, "[b]y adding physical structures under the balloon—thereby potentially increasing the system's profile, the inventors of the ['062 patent took a path against the conventional wisdom of lowering the profile," which "is a strong indication of non-obviousness of the claimed invention." PO Resp. 20. Patent Owner also references Mr. Trotta's prior work in designing a stent delivery system in 1997. *Id.* at 23. Patent Owner explains that Mr. Trotta designed a system with a reduced profile and improved flexibility, and contends that this was "the conventional approach." *Id.* at 23–24 (citing Ex. 1003 ¶¶ 27, 28, 41), 25 (citing Ex. 2008, 48:9–49:5 (Mr. Trotta testifying that he did not consider adding a structure underneath the balloon)). According to Patent Owner, this prior work "highlight[s] the unconventional, non-obvious path taken by the inventors of the ['062 patent by adding structures under the balloon to solve the stent securement problem." *Id.* at 24.

We recognize that "proceed[ing] contrary to the accepted wisdom of the prior art . . . is strong evidence of nonobviousness." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552 (Fed. Cir. 1983) (citing *United States v. Adams*, 383 U.S. 39, 52 (1966) ("[K]nown disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness.")). The evidence of record, however, demonstrates that while an increase in profile size may have "discouraged a [POSITA] from employing Rupp's design" (Ex. 2004 ¶ 56), profile size is simply one characteristic among many to be balanced when designing a stent delivery system. For example, Mr. Trotta testified that differences in profile size—as little as one or two "thousandths of an

inch"—matter, and that a small profile is important. Ex. 2008, 53:15–54:1; Ex. 1003 ¶ 41. However, Mr. Trotta also testified that stent delivery devices must have sufficient flexibility (Ex. 1003 ¶ 41) and an appropriate shape (*id.* ¶ 42), and that a POSITA could make adjustments to balance these characteristics, e.g., a decrease in flexibility could be compensated with a change in material (Ex. 2008, 55:10–56:12). Likewise, during his deposition, Dr. Solar testified that "there are many factors to consider" in designing a stent delivery system, including stiffness and flexibility. Ex. 1028, 93:4–94:2.

Thus, the evidence demonstrates that a small profile was important, and that it was within the capabilities of a POSITA to weigh and balance a myriad of system characteristics, including profile, flexibility, shape, stiffness, and material, when designing a device. *See also supra* Section II.F.2.a.vi. (determining that Patent Owner has not shown that the proposed modification to Rupp increases Rupp's profile over that of its unmodified state); *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another."). Accordingly, Patent Owner has not presented sufficiently persuasive evidence that the '062 patent "took a path against the conventional wisdom," sufficient to overcome the evidence of obviousness discussed in Sections II.F.2.a.i–vi., above.

b. Independent Claim 13

Patent Owner does not dispute Petitioner's contentions regarding independent claim 13 separately from the arguments discussed above regarding claim 1. We are persuaded by Petitioner's contentions regarding claim 13, which are substantially similar to those discussed with respect to claim 1. Pet. 89–90. Specifically, we are persuaded that the combined teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA would have rendered obvious the subject matter of claim 13, for the same reasons discussed *supra* in Section II.F.2.a.

Namely, Rupp discloses a catheter shaft including first and second tubular members (inner lumen tubing 30 and inflation lumen tubing 55); a balloon (balloon 35) coupled to the catheter shaft; a proximal member (built up section 20) attached to the inner tubular member and positioned underneath the balloon; and a cardiovascular implant (stent 100) disposed along the catheter shaft, wherein the implant shifts between a first configuration and an expanded configuration. *See, e.g.*, Ex. 1023, Fig. 1; Ex. 1027, 2 (annotations depicting stent and balloon in first configuration).

Jendersee teaches a distal stop (conventional retainer 54) including a tapered distal portion, which is attached to a catheter shaft and positioned at least partially underneath a balloon, and which has a proximal end face substantially perpendicular to a longitudinal axis of a catheter shaft. Ex. 1016, Fig. 8.

For the reasons articulated in Section II.F.2.a.vi., we are persuaded that a POSITA would have found it obvious to modify Rupp in light of Jendersee, for the reasons provided by Petitioner. *See* Pet. 81–82. We are

also persuaded that, in such a combination, the distal end of the proximal member would be proximal to the distal stop. Ex. 1003 ¶ 146.

c. Independent Claim 21

Patent Owner does not dispute Petitioner's contentions regarding independent claim 21 separately from the arguments discussed above regarding claim 1. We are persuaded by Petitioner's contentions regarding claim 21, which are substantially similar to those discussed with respect to claim 1. Pet. 92–95. Specifically, we are persuaded that the combined teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA would have rendered obvious the subject matter of claim 21, for the same reasons discussed *supra* in Section II.F.2.a.

Namely, Rupp discloses a catheter shaft including inner and outer tubular members (inner lumen tubing 30 and inflation lumen tubing 55); a balloon (balloon 35) attached to the catheter shaft, wherein the balloon has a proximal portion coupled to the outer tubular member (55) and a distal portion coupled to the inner tubular member (30), wherein an inflation lumen (lumen 140) is defined between the inner and outer tubular members (30, 55) and is in fluid communication with the balloon (35), and wherein a body portion of the balloon extends over an implant receiving region of the inner tubular member (30); a proximal member (built up section 20) attached to the implant receiving region and positioned between the implant receiving region and the body portion of the balloon; and an implantable endoprosthesis (stent 100) disposed along the catheter shaft, and configured to be received along the implant receiving region. *See, e.g.*, Ex. 1023, 5:17–26 (disclosing attachment of balloon 35 to lumen tubing 30, 55, and defining inflation lumen 140 therebetween), Fig. 1.

Jendersee teaches a distal stop (conventional retainer 54) including a tapered distal portion and a proximal end face substantially perpendicular to a longitudinal axis of the catheter shaft, which is attached to a catheter shaft adjacent an implant receiving region of the shaft. Ex. 1016, Figs. 3, 8.

For the reasons articulated in Section II.F.2.a.vi., we are persuaded that a POSITA would have found it obvious to modify Rupp in light of Jendersee, for the reasons provided by Petitioner. *See* Pet. 81–82. We are also persuaded that, in such a combination, the distal end of the proximal member would be proximal to the distal stop, and at least a portion of the distal stop would be disposed within the balloon. Ex. 1003 ¶ 146.

d. Independent Claim 26

Patent Owner does not dispute Petitioner's contentions regarding independent claim 26 separately from the arguments discussed above regarding claim 1. We are persuaded by Petitioner's contentions regarding claim 26, which are substantially similar to those discussed with respect to claim 1. Pet. 96–100. Specifically, we are persuaded that the combined teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA would have rendered obvious the subject matter of claim 26, for the same reasons discussed *supra* in Section II.F.2.a.

Namely, Rupp discloses a catheter shaft including inner and outer tubular members (inner lumen tubing 30 and inflation lumen tubing 55), wherein the inner tubular member (30) extends distally beyond a distal end of the outer tubular member (55) and defines a guidewire lumen; a balloon (balloon 35) attached to the catheter shaft and configured to shift between collapsed and expanded configurations, wherein the balloon has a proximal portion coupled to the outer tubular member (55) and a distal portion

coupled to inner tubular member (30), and wherein an inflation lumen (lumen 140) is defined between the inner and outer tubular members (30, 55) and is in fluid communication with the balloon (35), and wherein a body portion of the balloon extends over an implant receiving region of the inner tubular member (30); a proximal member (built up section 20) attached to the implant receiving region and positioned between the implant receiving region and the body portion of the balloon; first and second radiopaque markers (band 45, bands 65) disposed along the implant receiving region, wherein the second marker is positioned adjacent the proximal member (20), and the first marker is axially spaced from the second marker and positioned within the balloon; and an implantable endoprosthesis (stent 100) disposed along the catheter shaft, configured to be received along the implant receiving region, and configured to be expanded by the balloon. *See, e.g.*, Ex. 1023, 4:56–62 (disclosing expansion of stent 100 and balloon 35), 5:14–25 (disclosing inner lumen tubing 30 is a guidewire passage), 5:17–26 (disclosing attachment of balloon 35 to tubing 30, 55, with inflation lumen 140 therebetween), 5:28–33 (disclosing marker bands 45, 65), Figs. 1, 10.

Jendersee teaches a distal stop (conventional retainer 54) including a tapered portion, which is attached to a catheter shaft adjacent to an implant receiving region of the shaft and at least partially between a balloon and the catheter shaft. Ex. 1016, Figs. 3, 8.

For the reasons articulated in Section II.F.2.a.vi., we are persuaded that a POSITA would have found it obvious to modify Rupp in light of Jendersee, for the reasons provided by Petitioner. *See* Pet. 81–82. We are also persuaded that, in such a combination, the distal stop would be axially spaced from the proximal member, at least a portion of the distal stop would

be disposed within the balloon, and the first radiopaque marker would be positioned adjacent the distal stop. Ex. 1003 ¶¶ 141 (explaining that built up layer 20 surrounds marker band 45, and marker bands 65 are located proximally and distally of the stent), 146 (depicting that Jendersee's retainers would be placed within balloon 35, axially spaced from built up layer 20, and proximal and distal to the stent).

e. Dependent Claim 2

We are persuaded by Petitioner's undisputed contention that Rupp discloses the subject matter of this claim. Pet. 85. Rupp's inner lumen tubing 30 is an inner tubular member, and inflation lumen tubing 55 is an outer tubular member. *See* Ex. 1023, 5:18–20, Fig. 1.

f. Dependent Claims 3 and 14

We are persuaded by Petitioner's undisputed contention that Rupp discloses the subject matter of these claims. Pet. 85–86, 90. Rupp discloses that inflation lumen 140 is defined between inner lumen tubing 30 and inflation lumen tubing 55, and is in fluid communication with balloon 35. *See* Ex. 1023, 5:17–26, Figs. 1–2.

g. Dependent Claims 4 and 15

We are persuaded by Petitioner's undisputed contention that Rupp discloses the subject matter of these claims. Pet. 86, 91. Rupp discloses that balloon 35 has a proximal portion coupled to inflation lumen tubing 55 and a distal portion coupled to inner lumen tubing 30. Ex. 1023, 5:22–26, Fig. 1.

h. Dependent Claims 5 and 6

We are persuaded by Petitioner's undisputed contention that the combined teachings of Rupp, Jendersee, Sugiyama, and the knowledge of a POSITA render obvious the subject matter of these claims. Pet. 86. As

noted with respect to claims 4 and 15, Rupp discloses that the balloon is "sealed" to inflation lumen tubing 55 and inner lumen tubing 30. Ex. 1023, 5:22–26, Fig. 1. Rupp does not specify that the balloon and lumen tubing are sealed by adhesive bonding. However, it was known to use adhesive bonding to secure a balloon to the lumen tubing of a coaxial catheter, as testified to by Mr. Trotta, and as taught by Sugiyama. Ex. 1003 ¶ 144; Ex. 1009, 4:12–17. We are persuaded that modifying Rupp's teachings to include adhesive sealing as taught by Sugiyama would have been obvious to a skilled artisan as a well-known technique to achieve a secure bond. *See* Pet. 80, 86; Ex. 1003 ¶¶ 114, 144.

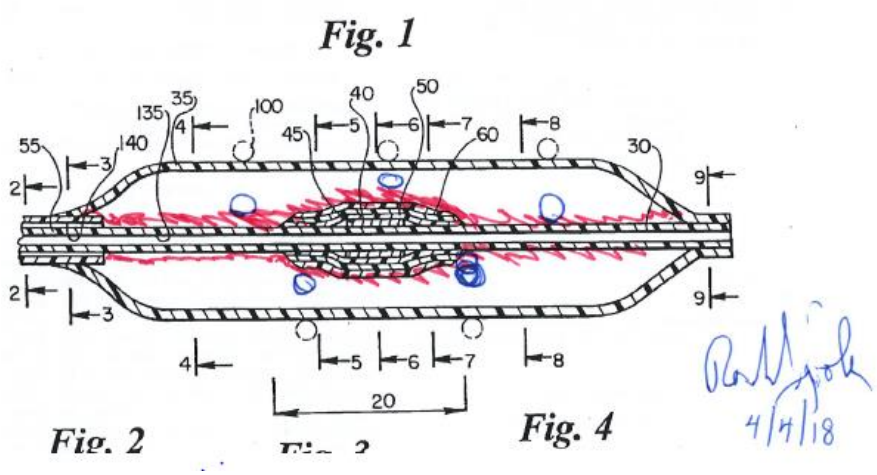
i. Dependent Claim 7

Dependent claim 7 recites that "the second member is a support member configured to support the medical implant." Petitioner contends that "Rupp's built up section 20 is a support member designed to support the stent." Pet. 87 (citing Ex. 1023, 4:62–5:12, 5:38–45, 6:1–3).

Patent Owner disputes Petitioner's contention. PO Resp. 25–27. According to Patent Owner, Petitioner and Mr. Trotta fail to explain how the cited portions of Rupp satisfy claim 7. *Id.* at 26–27 (citing Ex. 1003 ¶¶ 142–143). Patent Owner relies upon Dr. Solar's testimony that Rupp's built up layer 20 is not a support member because built up layer 20 "helps expand the stent, to provide uniform expansion, not support the stent to secure the stent during tracking and delivery." Ex. 2004 ¶ 42; PO Resp. 27 (citing Ex. 2004 ¶¶ 39–44). Dr. Solar also contrasts Rupp's disclosure "with the '062 patent's disclosure on stent securement." *Id.* ¶ 43. Finally, Dr. Solar testifies that "the built-up layer in Rupp is designed to prevent tight crimping

of the center of the stent, allowing it to expand first, which is the opposite of supporting a stent required in claim 7 of the [']062 patent." *Id.* ¶ 44.

We have considered the parties' arguments and cited evidence, and we are persuaded by Petitioner's contention. Rupp explains that "stent 100 is crimped upon a balloon 35." Ex. 1023, 5:38–40. Rupp's Figure 1 depicts the stent and balloon in an inflated, expanded condition. *Id.* at Fig. 1. As Dr. Solar acknowledges, when the stent and balloon are in the pre-expansion condition, the balloon and stent lay against inflation lumen tubing 30 and built up section 20, to which they have been crimped. Ex. 1027, 2; Ex. 1028, 72:9–76:17. Indeed, during his deposition, Dr. Solar depicted this condition, with annotations to Rupp's Figure 1, reproduced below.



The figure reproduced above depicts Dr. Solar's annotations to Rupp's Figure 1, showing balloon 35 (red, jagged annotations) and stent 100 (blue, circular annotations) in a pre-expansion condition. *See* Ex. 1027, 2; Ex. 1028, 72:9–76:17. As shown in the annotated figure, built up section 20 is a support member configured to support the stent, because the built up section carries, or holds up, the stent that has been crimped against it, consistent with the term's ordinary meaning. *See* Ex. 1027, 2; *see* Webster's

Ninth New Collegiate Dictionary 1186 (1985) (defining "support" as, *inter alia*, "to carry" or "to hold up or serve as a foundation or prop for") (Ex. 3002). Patent Owner does not propose that "support" be construed in a manner different than its ordinary meaning. Tr. 29:11–12 ("[S]upport is ordinary meaning."), 30:6–7, 30:23–25. Moreover, during the oral hearing, Patent Owner's counsel was unable to articulate what the term "support" requires, beyond its plain meaning. *Id.* at 29:11–31:5, 39:15–41:15. Rather, Patent Owner's argument, and Dr. Solar's testimony, attempt to import into claim 7 a requirement that a support member must "support the stent to secure the stent during tracking and delivery." Ex. 2004 ¶ 42; PO Resp. 27. Claim 7, however, does not reference stent securement, or tracking and delivery, as Dr. Solar testified on cross-examination. *See, e.g.*, Ex. 1028, 30:7–11, 32:3–10. As such, Patent Owner's argument is unpersuasive.

j. Dependent Claims 9, 17, and 23

We are persuaded by Petitioner's undisputed contention that the combined teachings of Rupp, Jendersee, Sugiyama, and the knowledge of a POSITA render obvious the subject matter of these claims. Pet. 87. As discussed in Sections II.F.2.a.iv. and II.F.2.a.vi., *supra*, Rupp's built up section 20 would be longitudinally and axially spaced from the conventional retainer taught by Jendersee, in the proposed combination. Ex. 1003 ¶ 146 (providing annotations to Rupp's Figure 1, showing where the retainers would be located, when combined with Rupp).

k. Dependent Claims 10, 11, 18, 19, and 24

We are persuaded by Petitioner's undisputed contention that Rupp discloses the subject matter of these claims. Pet. 87–88, 91–92, 95. Rupp

discloses stent 100, which is expandable by inflation of balloon 35. Ex. 1023, 4:56–62, 5:38–40, Fig. 1.

l. Dependent Claims 12, 20, and 25

We are persuaded by Petitioner's undisputed contention that Rupp discloses the subject matter of these claims. Pet. 88, 92, 96. Rupp discloses that built up section 20 includes radiopaque marker band 45 coupled to the inner lumen tubing 30. Ex. 1023, 5:28–30, Fig. 1; *see also id.* at Fig. 10 (depicting marker bands 65).

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated that claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent are unpatentable by a preponderance of the evidence. Also, for the foregoing reasons, we determine that Petitioner has *not* demonstrated that claims 8, 16, and 22 of the '062 patent are unpatentable by a preponderance of the evidence.

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent are unpatentable;

FURTHER ORDERED that claims 8, 16, and 22 of the '062 patent have not been shown to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written 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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