

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 8,709,062 B2

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

WIEKER, *Administrative Patent Judge*.

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

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 have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the information presented in the Petition 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.” *See also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”). Taking into account the arguments presented in the Preliminary Response, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail with respect to challenged claims 1–7, 9–15, 17–21, and 23–26, but not with respect to challenged claims 8, 16, and 22.

B. Related Proceeding

The parties represent that the ’062 patent is at issue in *Boston Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp.*, No. 16-cv-730 (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.

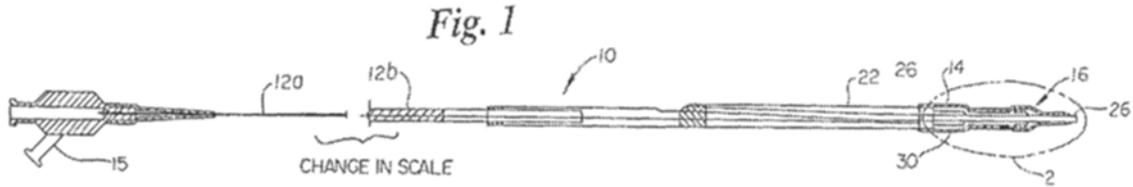


Figure 1 depicts an isometric view of a balloon catheter. Ex. 1001, 5:53–65. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 16, to which stent 18 is fixed. *Id.* at 8:15–18, 26–27 (stent not shown in Figure 1). In use, catheter 12 is advanced through a patient’s vasculature to a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

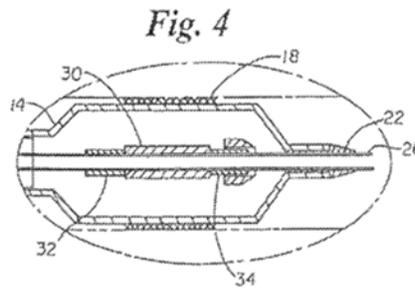


Figure 4 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 6:3–6. As shown in Figure 4, “mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent 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 (“Trotta Declaration,” Ex. 1003). Pet. 20–21, 46, 78.

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
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

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–10 and 13 of the '040 patent based on the following grounds. Pet. 20, 21, 46, 78.¹

References	Basis	Claims Challenged
Fischell '274 in View of Burton in Further View of the Knowledge of a Person of Ordinary Skill in the Art and/or Sugiyama	§ 103(a)	1–26
Sugiyama in View of Fischell '507 and in Further View of Jendersee	§ 103(a)	1–26
Rupp in View of the Knowledge of a Person of Ordinary Skill in the Art and/or Sugiyama and in Further View of Jendersee	§ 103(a)	1–7, 9–15, 17–21, and 23–26

¹ Petitioner's allegation that the challenged claims are unpatentable over "the references identified below, alone or in combination with each other" (*see* Pet. 20) lacks the particularity and specificity required by 35 U.S.C § 312(a)(3) and 37 C.F.R. § 42.104(b)(2). Furthermore, Petitioner's identification of the grounds as outlined above, through the use of "and/or" expands what is identified as three grounds of unpatentability into several distinct combinations of references. The function of the Board is not to comb through Petitioner's arguments in order to decipher the strongest argument or to determine the strongest combination of references to challenge the claims. *See generally LG Elecs., Inc. v. Rosetta-Wireless Corp.*, Case IPR2016-01516 (PTAB Apr. 3, 2017) (Paper 25). As such, for each identified ground, we exercise our discretion and consider all of the references in combination as one ground of unpatentability, as this is the most consistent reading of the Petition and claim charts.

II. DISCUSSION

A. Claim Construction

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.

Based on the record before us, at this stage of the proceeding, we need not provide express constructions for 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) objective evidence of nonobviousness, i.e., secondary considerations.² *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is

² The Preliminary Response does not identify any secondary considerations. Prelim. Resp. 8 n.2.

unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

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 person of ordinary skill in the art (“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 a relevant skill level. *See generally* Prelim. Resp.

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, we apply Petitioner’s assessment for purposes of this Decision. Further, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Obviousness over the Combined Teachings of Fischell '274, Burton, Sugiyama, and the Knowledge of a POSITA

Petitioner contends that challenged claims 1–26 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. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 8–21. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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.

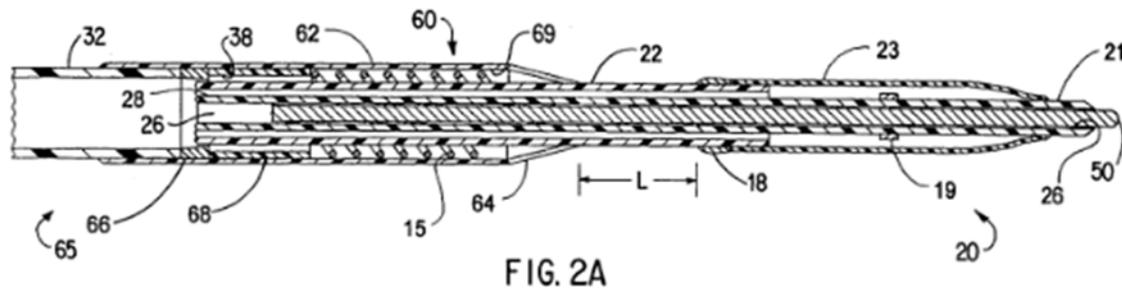


Figure 2A depicts a longitudinal cross-section of preferred integrated catheter system 60, which includes balloon angioplasty catheter 20 with inflatable balloon 23, and stent catheter 65 with stent 15 retained in containment cavity 69. *Id.* at 3:29–30, 4:50–57; *see also id.* at Fig. 1 (depicting a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

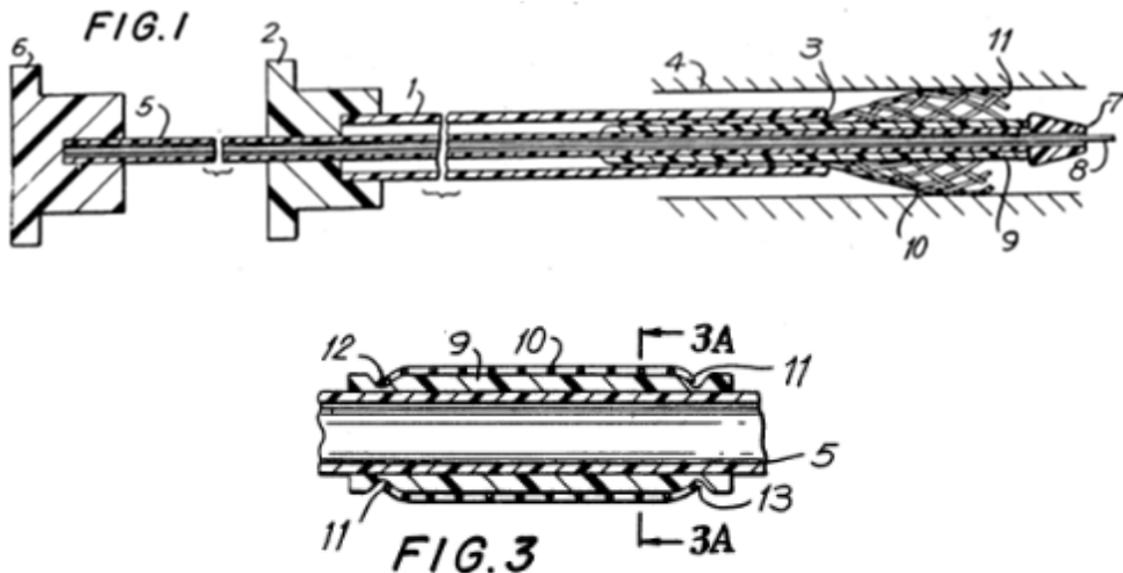


Figure 1 depicts an instrument for holding and deploying self-expanding stent 10, wherein the instrument includes grip member 9, one embodiment of which is depicted in greater detail in Figure 3. *Id.* at Abstract, 5:11–12, 5:15–16. Burton explains that grip member 9 engages stent 10 with a high-friction surface material (*id.* at Figs. 3–3A), with a coating of releasable adhesive (*id.* at Fig. 4), 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.

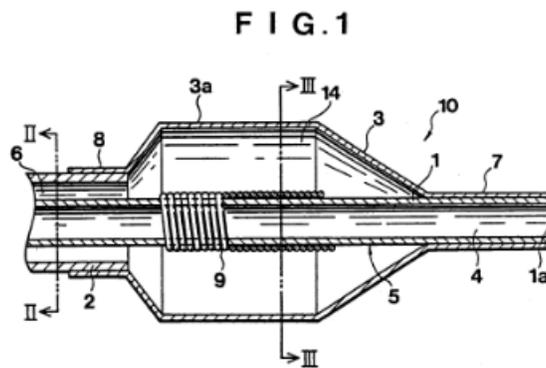


Figure 1 depicts an enlarged sectional view of the distal end of a balloon catheter. *Id.* at 2:47–48. As reflected in Figure 1, “reinforcement 9 is wound about a predetermined portion of the outer surface of the inner tube 1 which is enclosed within the balloon 3 [Accordingly], the inner tube is rendered 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*

a. *Independent Claim 1*

Petitioner contends that Fischell '274 discloses a medical device substantially as claimed including, *inter alia*, 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 '273 “lacks any under-balloon securement mechanism,” akin to the claimed “second member . . . positioned within the balloon,” but notes that Fischell '274 “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 over the balloon while the sheath was being withdrawn.” *Id.* at 22 (citing Ex. 1013, 6:34–38).

Accordingly, Petitioner contends that the stent delivery system of Fischell '274 “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” 9. Pet. 22–23, 25–26. According to Petitioner, “[t]his modification 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); *see also id.* at 28–29.³

³ Regarding dependent claims 5 and 6, Petitioner also relies on Sugiyama’s teachings of adhesive bonding of catheter balloons to catheter shafts. *Id.* at 26–27, 32.

Patent Owner argues that Petitioner has not shown sufficiently that a person of ordinary skill in the art would have modified Fischell '274 to arrive at the claimed invention. Prelim. Resp. 18. We agree.

Petitioner's proposed modification to Fischell '274 places Burton's grip member 9 underneath Fischell 274's balloon 23 and stent 15, purportedly to "ensure stent securement." Pet 25 (also contending such a combination would simplify delivery system operation and decrease the catheter profile) (citing Ex. 1003 ¶¶ 108–109), 28–29. However, Burton explains that grip member 9 retains stent 10 due to *physical contact* between the grip member and the stent, 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; *see also id.* at 3:48–56 ("[A]n important characteristic of the grip member is that it should be capable of gripping or holding a stent . . . it is necessary when the grip member is a sleeve of material, that said material has a surface which offers high resistance to sliding motion."). Neither Petitioner nor Mr. Trotta explain sufficiently how, in the proposed modification, the grip member would serve to retain Fischell 274's stent when Fischell 274's 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. In particular, we find nothing in the cited portion of Mr. Trotta's declaration that addresses how Burton's grip member would secure a stent under the proposed modified structure, namely, in the absence of direct contact between the stent and grip member. *See, e.g.*, Ex. 1003 ¶¶ 107–111; *see also In re Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration

warrants discounting the opinions expressed in the declarations.”); *see also* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

We agree with Patent Owner that, in the proposed combination, the grip member seemingly “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.” Prelim. Resp. 20. As such, we are not persuaded that Petitioner presents a sufficient rationale to show that it would have been obvious for a person of ordinary skill in the art to have combined Fischell ’274 and Burton to ensure stent securement, simplify delivery system operation, or decrease the catheter profile, as Petitioner contends. Pet. 25–26.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Fischell ’274, Burton, Sugiyama, and the knowledge of a POSITA render obvious independent claim 1, or claims 2–12, which depend from claim 1.

b. Independent Claims 13, 21, and 26

We have reviewed carefully the evidence presented by Petitioner regarding independent claims 13, 21, and 26. Pet. 35–46. Importantly, 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. *Id.* at 36, 41, 45.

Based on the record before us, and for the same reasons discussed above regarding claim 1, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Fischell '274, Burton, Sugiyama, and the knowledge of a POSITA render obvious independent claims 13, 21, or 26. For the same reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to claims 14–20, which depend from claim 13 or claims 22–25, which depend from claim 21.

E. Alleged Obviousness over the Combined Teachings of Sugiyama, Fischell '507, and Jendersee

Petitioner contends that challenged claims 1–26 are unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Sugiyama, Fischell '507, and Jendersee. Pet. 46–78. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 22–26. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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.

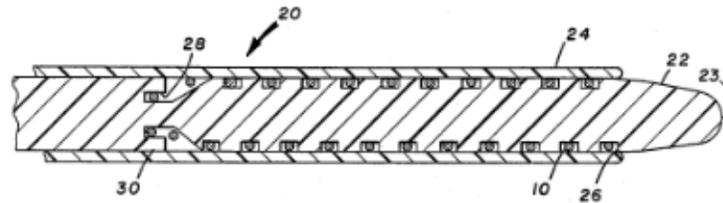


FIG. 3

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.

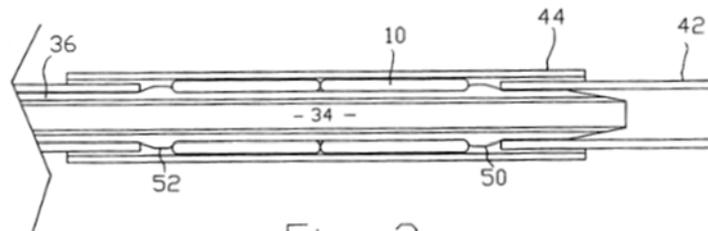


Fig. 3

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 6:41–33 (explaining that the encapsulation process includes steps of compressing stent 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.

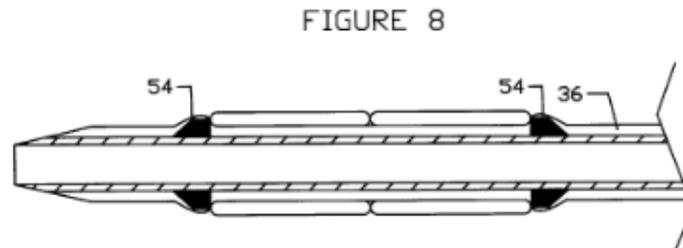


Figure 8 depicts a longitudinal cross sectional view of the stent assembly with “conventional retainers 54” located within the balloon to secure the stent to the balloon and to create a smooth transition across the assembly. *Id.* at 5:9–11, 7:36–40, 7:46–52.

3. *Analysis of Applied Art*

a. *Independent Claim 1*

Petitioner contends that Sugiyama discloses a medical device substantially as claimed including, *inter alia*, a catheter having first inner tubular member 1, second tubular member 2, and balloon 3, wherein coil-

shaped reinforcement 9 is positioned within balloon 3. Pet. 46–49, 56–59. Petitioner does not contend that Sugiyama discloses a stent, but instead 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, simultaneously expanding the stenosis and deploying a mounted stent.” *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.*; *see also id.* at 52. Petitioner contends that Fischell ’507 discloses a catheter for placing coil spring stent 10, wherein the catheter includes spiral grooves 26 into which the stent is placed, for deployment after balloon dilation of a vessel. *Id.* at 51, 59. According to Petitioner, a person of ordinary skill in the art would have recognized that “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. Accordingly, a POSITA would have been

motivated to add the coil stent taught by Fischell '507 to the balloon catheter of Sugiyama '032.” *Id.* at 52–53 (citing Ex. 1003 ¶¶ 131).⁴

Patent Owner argues that Petitioner has not shown sufficiently that a person of ordinary skill in the art would have had reason to use Sugiyama's balloon catheter with the stent disclosed by Fischell '507 to arrive at the claimed invention. Prelim. Resp. 22. We agree.

Petitioner's proposed modification to Sugiyama places Fischell '507's coil stent 10 over Sugiyama's balloon 3 and spiral reinforcement 9, purportedly to “help secure the stent during delivery” and to reduce the profile of the assembly. Pet. 52–53 (providing annotated version of Sugiyama's Figure 13); Ex. 1003 ¶ 130. We agree with Patent Owner's argument, however, that the fundamental differences between Fischell '507's coil stent and Sugiyama's catheter shaft and balloon would not have led a person of ordinary skill in the art to have combined the references, as Petitioner proposes. Prelim. Resp. 22–24. Petitioner provides insufficient reasoning as to why a person of ordinary skill in the art would have added Fischell '507's coil stent to the outside of Sugiyama's balloon. As discussed above, Fischell '507's 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 an impermissible use of hindsight, rather than on a rational basis to combine the references.

⁴ Petitioner also relies on Jendersee's teachings of tapered distal stops. *Id.* at 53–58.

Additionally, Fischell '507 explains that stent 10 is secured to Fischell 507's catheter by forcing the entire length of stent 10 to fit into grooves 26, 28 along the length of catheter core 22. *See, e.g.*, Ex. 1010, 3:47–55, 3:67–4:27 (using pliers to force the stent, including its distal and proximal ends, into grooves in the catheter core). Neither Petitioner nor Mr. Trotta explain sufficiently how, in the proposed modification, Fischell '507's stent would be secured on Sugiyama's catheter when Sugiyama's balloon 3 would be located between the spiral reinforcement and the stent, precluding the force-fit relied upon to secure the stent of Fischell '507. *See* Pet. 52–53; Ex. 1003 ¶¶ 129–131.

We agree with Patent Owner that, in the proposed combination, 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 [Sugiyama's] balloon, they lose direct contact with the stent, thus fundamentally altering the mechanism of action of Fischell '507.” Prelim. Resp. 23–24 (also persuasively arguing that such a modification would puncture Sugiyama's balloon). As such, we are not persuaded that Petitioner presents a sufficient rationale to show that it would have been obvious for a person of ordinary skill in the art to have combined Sugiyama and Fischell '507 to help secure the stent during delivery, as Petitioner contends. Pet. 52–53.

Based on the record before us, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Sugiyama, Fischell '507, and Jendersee render obvious independent claim 1, or claims 2–12, which depend from claim 1.

b. Independent Claims 13, 21, and 26

We have reviewed carefully the evidence presented by Petitioner regarding independent claims 13, 21, and 26. Pet. 65–78. Importantly, 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.

Based on the record before us, and for the same reasons discussed above regarding claim 1, we determine that Petitioner has not established a reasonable likelihood of prevailing on its contention that the combined teachings of Sugiyama, Fischell ’507, and Jendersee render obvious independent claims 13, 21, or 26. For the same reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to claims 14–20, which depend from claim 13 or claims 22–25, which depend from claim 21.

F. Alleged Obviousness over the Combined Teachings of Rupp, Sugiyama, Jendersee, and the Knowledge of a POSITA

Petitioner contends that challenged claims 1–7, 9–15, 17–21, and 23–26 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. Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 26–32. For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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.

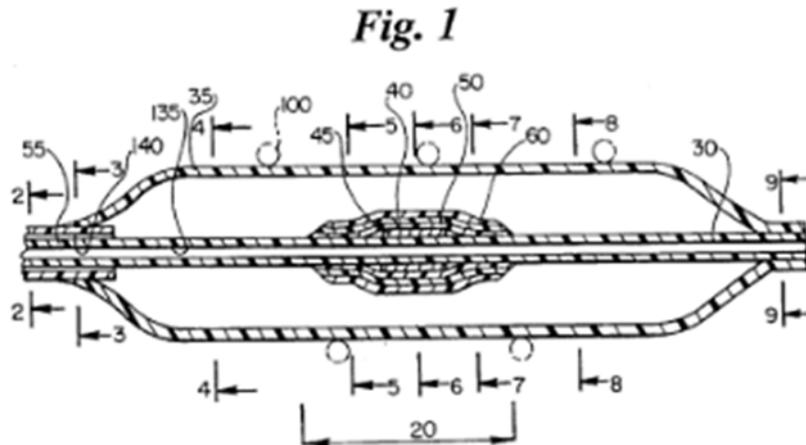


Figure 1 depicts a longitudinal cross-section of a stent deployment device that has multiple built-up layers. *Id.* at 2:63–65. As shown in Figure 1, Rupp discloses a catheter having inner lumen 30, inflation lumen tubing 55, and balloon 35, wherein stent 100 is crimped upon balloon 35. *Id.* at 5:12–26, 5:38–40. Rupp discloses that built-up section 20 (comprising layers 40, 50, 60) is affixed to inner lumen 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 35 U.S.C. § 325(d)

As an initial matter, Patent Owner argues that we should exercise our discretion under 35 U.S.C. § 325(d) to deny this alleged ground of unpatentability because it “is based entirely on the same or substantially the same art that was before the examiner during prosecution.” Prelim. Resp. 27. Patent Owner contends that the Examiner rejected pending claims in

light of Rupp, and that Jendersee was cited to the Examiner during prosecution. *Id.* at 27–28. Patent Owner also alleges that Sugiyama “is substantially similar” to another reference cited by the Examiner during prosecution. *Id.* at 28.

a. Relevant Prosecution History

The ’062 patent issued on April 29, 2014, from U.S. Patent Application No. 13/619,231 (“the ’231 application”), which was filed on September 14, 2012. Ex. 1001, (21), (22), (45). Issued independent claim 1 of the ’062 patent corresponds to application independent claim 1 of the ’231 application. *Compare* Ex. 1001, 25:30–44, *with* Ex. 1002, 215 (Nov. 22, 2013, Claim Amendment), 233 (Dec. 6, 2013, Notice of Allowability). Further, issued independent claim 13 corresponds with application independent claim 15; issued independent claim 21 corresponds with application independent claim 24; and issued independent claim 26 corresponds with application independent claim 30. *Compare* Ex. 1001, 26:11–30, 26:51–27:13, 27:22–28:32, *with* Ex. 1002, 216–220, 233. A brief review of the prosecution history follows.

On February 22, 2013, the ’231 applicant filed an Information Disclosure Statement (“IDS”) under 37 C.F.R. § 1.97(b), identifying 151 prior art references including, *inter alia*, Rupp and Jendersee. Ex. 1002, 123–141; *see id.* at 127.

On March 21, 2013, the Examiner acknowledged the IDS, allowed application independent claim 30, and rejected application claims 1–29. *Id.* at 147–170. Specifically, the Examiner rejected application claims 1, 8, 15, and 18 under 35 U.S.C. § 102(e) as anticipated by Rupp, finding that Rupp

disclosed “1st member/distal stop 40 having a tapered distal portion” and “2nd member/proximal member 50.” *Id.* at 148–149 (citations omitted).

On June 21, 2013, the ’231 applicant amended, *inter alia*, application independent claim 1 to require that the “first member” include a distal stop with a “tapered distal portion” and to require that the “second member” have a “distal end disposed proximal of the distal stop,” and made similar amendments to application independent claims 15 and 24. *Id.* at 187, 188, 190. Dependent claims 8, 18, and 25 were also amended in the application to require that the distal stop include a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft.” *Id.* at 188–190. The ’231 appellant argued that these amendments distinguished over Rupp. *Id.* at 194.

On August 28, 2013, the Examiner finally rejected application claims 1–4, 9–17, 19–24, and 26–29 under 35 U.S.C. § 102(e) over Rupp; rejected application claims 5–6 claims as unpatentable over Rupp and Sullivan (U.S. Patent No. 5,209,730); and rejected claims 11, 20, and 27 over Rupp and Fischell ’932 (U.S. Patent No. 5,669,932). In rejecting the independent application claims, the Examiner found that Rupp disclosed a “1st member/distal stop 40/50/60 having a tapered distal portion, [and a] 2nd member/proximal member 45 having a distal end disposed proximal of the distal stop 40/50/60 having a tapered portion.” *Id.* at 209 (citations and emphasis omitted). Further, although the first page of the Office Action indicates that claims 1–29 were rejected, the Examiner did not issue a substantive rejection for dependent claims 8, 18, and 25. *Compare id.* at 208, *with id.* at 209–211.

On November 22, 2013, the '231 applicant amended application independent claims 1, 15, and 24 to include the subject matter of dependent claims 8, 18, and 25, namely a distal stop that “includes a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft.” *Id.* at 215, 217, 218.

Subsequently, on December 6, 2013, the Examiner allowed the claims, without providing a statement of the Examiner’s Reasons for Allowance. *Id.* at 227–233.

b. 35 U.S.C. § 325(d)

Section 325(d) provides the following,

In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

In determining whether to exercise our discretion under Section 325(d), our first inquiry is to examine whether the Petition presents “the same or substantially the same prior art or arguments” as those previously presented to the Office. If that first inquiry is satisfied, we then determine whether it is appropriate to exercise our discretion to deny institution, in this case.

(1) Similarity of the Prior Art or Arguments

Petitioner acknowledges that Rupp was presented previously to the Office during prosecution of the '231 application. *See* Pet. 15, 16–17, 21, 80–81. Further, although Petitioner does not concede as much, the Jendersee reference was included in an IDS submitted during prosecution of the '231 application and, therefore, also was presented previously to the Office. *Compare id.* at 21, *with* Ex. 1001, (56); Ex. 1002, 127; Prelim.

Resp. 27. The final reference in this asserted ground of unpatentability—Sugiyama—was not presented to the Office during prosecution of the '231 application. *See* Ex. 1001, (56). Nonetheless, we agree with Patent Owner that the Office considered prior art substantially similar to Sugiyama during prosecution of the '231 patent. Prelim. Resp. 28. Specifically, Petitioner relies upon Sugiyama's disclosure of adhesive bonding to secure a balloon to a catheter shaft, which is similar to the teachings of Sullivan (U.S. Patent No. 5,209,730), which was considered by the Office during prosecution. *Compare* Pet. 80 (relying upon Sugiyama's disclosure of "adhesive bonding of balloons to catheters"), *with* Ex. 1002, 210 (finding that Sullivan taught "using adhesive to . . . secure and seal balloon 16 to the catheter 10").

Accordingly, we determine that the Petition presents "the same or substantially the same prior art or arguments" as those previously presented to the Office.

(2) Discretion

Having found that the Petition raises the same or substantially the same prior art as that presented to the Office previously, 35 U.S.C. § 325(d) states that we may take this fact into consideration when determining whether to institute trial. The question, therefore, is whether we should exercise our discretion to deny the Petition as to Rupp, Jendersee, and Sugiyama after weighing the particular circumstances of this proceeding, the interests of the parties, and the needs of the Board.

Petitioner argues that "the Examiner only contended that Rupp's built-up layer was a tapered distal stop," under 35 U.S.C. § 102(e), but "never addressed whether it would have been obvious to add an additional, prior art tapered distal stop to Rupp's delivery system," under 35 U.S.C. § 103(a).

Pet. 81. In response, Patent Owner contends that “by not asserting Jendersee in any rejection, [the Examiner] indicated that the combination of Rupp and Jendersee did not provide a basis to reject the pending claims.” Prelim. Resp. 28.

On the facts of this case, we decline to deny institution on the basis of 35 U.S.C. § 325(d). Fundamentally, although the same art may have been before the Examiner during prosecution, we determine that the Petitioner’s and the Examiner’s reliance on Rupp is substantially different. The Examiner considered Rupp to be anticipating, under 35 U.S.C. § 102(e), because Rupp disclosed, essentially, a composite “distal stop” (layers 40/50/60) and “second member” (marker 45), inasmuch as the Examiner found Rupp’s marker 45 to be located within and underneath Rupp’s built-up layers 40, 50, 60. Ex. 1002, 209. As a result of the claim amendment requiring a “proximal end face” on the distal stop, the Examiner withdrew this § 102(e) rejection over Rupp. *Id.* at 214–233. The Examiner, however, apparently did not consider whether such a feature may have been obvious, under 35 U.S.C. § 103(a), over Rupp in combination with additional prior art directed to distal stops, such as Jendersee, as proposed by Petitioner. *Id.* Thus, in this circumstance, we agree with Petitioner’s contention that such an obviousness analysis was appropriate during prosecution, and remains appropriate now, in this *inter partes* review proceeding.

Accordingly, we do not exercise our discretion to deny institution under 35 U.S.C. § 325(d) and, instead, turn our attention to the merits of Petitioner’s contentions.

3. *Analysis of Applied Art*

a. *Independent Claim 1*

(1) “*first tubular member,*” “*second tubular member,*”
“*balloon,*” and “*medical implant*”

Petitioner contends that Rupp discloses a stent delivery system substantially as claimed, including a “first tubular member” (i.e., Rupp’s inner lumen tubing 30), a “second tubular member” (i.e., Rupp’s inflation lumen tubing 55), a “balloon coupled to the shaft” (i.e., Rupp’s balloon 35 coupled to lumens 55, 30), and a “medical implant coupled to the shaft and positioned adjacent the balloon” (i.e., Rupp’s stent 100 positioned adjacent balloon 35). Pet. 82–84.

On the current record, we are persuaded by Petitioner. Rupp discloses a “typical catheter” with “inner lumen tubing 30,” “inflation lumen tubing 55,” and “balloon 35.” Ex. 1023, 5:12, 5:15–17, Fig. 1. Rupp explains 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.” *Id.* at 5:22–26, Fig. 1. Rupp also discloses that “stent 100 is crimped upon a balloon 35.” *Id.* at 5:38.

(2) “*first member*” and “*second member*”

Petitioner does not contend that Rupp includes the claimed “first member” but asserts that a person of ordinary skill in the art “would have been motivated 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, which would yield the same benefits of enhanced securement and trackability.” Pet. 81–82 (providing an annotated version of Rupp’s Figure 1, indicating where retainers 54 would be positioned).

Petitioner contends that Jendersee's distal retainer 54 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 83.

Petitioner also contends that Rupp's built-up section 20 is a "second member" as claimed, which is coupled to the first tubular inner lumen 30 and whose distal end would be located proximal of distal retainer 54, in the proposed combination with Jendersee. *Id.* at 84; *see also id.* at 79–80, 82.

On the current record, we are persuaded by Petitioner's contentions regarding the "first member." As depicted in Jendersee's Figure 8, Jendersee discloses "conventional retainers 54 . . . placed within the balloon 36." Ex. 1016, 7:46–49. The distal-most retainer 54, shown to the left in Figure 8, 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. On this record, we are also persuaded by Petitioner's position that modifying Rupp's teachings to include conventional retainers as taught by Jendersee would have been obvious to a skilled artisan to, *inter alia*, "further enhance the securement of the stent, which would yield the same benefits of enhanced securement and trackability." *See* Pet. 81–82. For example, Jendersee specifies that the use of retainers, *e.g.*, retainers 50, 52, 54, "further secure[s] the stent segment 10 to the balloon 36 and create[s] 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; Ex. 1003 ¶ 146.

On the current record, we also are persuaded by Petitioner's contentions regarding the "second member." As depicted in Rupp's Figure 1, Rupp's built-up section 20 is coupled to Rupp's inner lumen tubing 30

and is positioned within balloon 35, as claimed. *See also* Ex. 1023, 4:56–67. On the current record, we are also persuaded that and the distal end of built-up section 20 would be located proximal of distal retainer 54, in the proposed combination with Jendersee, to achieve Jendersee’s stated purpose of stent securement. Pet. 82; Ex. 1003 ¶ 146; Ex. 1016, 7:36–40.

We have considered Patent Owner’s argument that “Petitioner has not made any specific argument or provided any specific evidence to support a motivation to combine,” *inter alia*, Rupp and Jendersee. Prelim. Resp. 29; *see also id.* at 31 (arguing that the references solve different problems). We appreciate that Jendersee discloses “unique procedures” related to its encapsulated stent, for example, pressurizing the balloon, heating the assembly, and then cooling the assembly. *Id.*; Ex. 6:58–7:33. However, we do not agree that these encapsulation procedures remove Jendersee from the consideration of a person of ordinary skill in the art. We determine that Jendersee and Rupp are within the same field of endeavor, i.e., stent delivery devices. *Compare* Ex. 1016, [57] (“A[n] encapsulated stent device for implantation within the vascular system”), *with* Ex. 1023, [57] (“An intravascular catheter for implanting a radially expandable stent within a body vessel”). Furthermore, the features of Jendersee upon which Petitioner relies—conventional retainers 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 (explaining that retainers 54, in Figure 8, are placed underneath balloon 36).

We have also considered Patent Owner’s argument that including Jendersee’s retainers under Rupp’s balloon would increase the profile of the device. Prelim. Resp. 30. However, Patent Owner’s argument does not

account for the fact that Rupp's built-up section 20 is already present underneath the balloon. *See, e.g.*, Pet. 82; Ex. 1003 ¶ 146 (annotated Figures). It is not apparent, and Patent Owner has not shown sufficiently that, in the modified device, the assembly's profile would be increased beyond the profile necessary to accommodate built-up section 20 such that a person of ordinary skill in the art would have avoided such a combination.

Finally, at this stage of the proceeding, the record lacks competent evidence to support Patent Owner's argument that the proposed modification would render Rupp ineffective to achieve the stated purpose of allowing uniform stent expansion. Prelim. Resp. 30–31. We recognize that Rupp provides its built-up section 20 to minimize the “dumbbell” expansion effect seen in the prior art, due to the relatively greater hoop strength present at the center of the stent. *See, e.g.*, Ex. 1023, 2:18–36, 4:56–58. However, Patent Owner has not shown or explained sufficiently how the size, shape, or arrangement of Jendersee's conventional retainers, when placed underneath Rupp's balloon at the identified locations, would “pre-dilate[]” the ends of the stent or would cause the stent to be positioned so far above the built-up layer that the built-up layer becomes ineffective. *Id.* At this stage, Patent Owner has not rebutted sufficiently Mr. Trotta's opinion that “[a]dding stops at the ends of Rupp's stent would not affect operation of the balloon or reinforcement 9, and would provide a tapered profile under the cone regions of the balloon to help further secure the stent.” Ex. 1003 ¶ 146. At this stage of the proceeding, we credit Mr. Trotta's testimony. *See* 37 C.F.R. § 42.108(c).

Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combined

teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA render obvious independent claim 1.

b. Dependent Claims 2–7 and 9–12

We have reviewed carefully the evidence presented by Petitioner regarding challenged claims 2–7 and 9–12, which depend from claim 1. *See* Pet. 85–88.

With respect to dependent claims 5–6, Petitioner acknowledges that Rupp does not disclose adhesive bonding between its balloon and catheter shaft, but relies on Sugiyama’s teachings that adhesive bonding was a well-known technique used to secure catheter balloons to catheter shafts. Pet. 80, 86. On the current record, we are persuaded by Petitioner. Rupp explains that balloon 35 “may be sealed” to the lumens, but does not specify a sealing mechanism. Ex. 1023, 5:22–26. Sugiyama specifies that balloons may be sealed to catheter lumens with, *e.g.*, adhesive. Ex. 1009, 4:12–17. On this record, 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. *Cf.* Prelim. Resp. 29.

With respect to dependent claims 2–4, 7, and 9–12, we are persuaded that the cited evidence supports Petitioner’s contentions, at this stage of the proceedings. *See* Pet. 85–88; *see also* Ex. 1023, 5:17–18 (disclosing inflation lumen 55), 5:18–20 (disclosing a coaxial arrangement), 5:28–33 (disclosing radiopaque markers 45, 65); Ex. 1016, 7:58–61 (disclosing radiopaque markers).

Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combined

teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA render obvious claims 2–7 and 9–12.

c. Claims 13–15, 17–21, and 23–26

We have reviewed carefully the evidence presented by Petitioner regarding independent claims 13, 21, and 26, and their dependent claims. Pet. 89–100. For substantially the same reasons discussed above regarding claim 1, and its dependent claims, we are persuaded that Petitioner has established a reasonable likelihood of prevailing on its contentions that the combined teachings of Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA render obvious claims 13–15, 17–21, and 23–26.

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent, but has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claims 8, 16, or 22.

At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim or as to the construction of any claim term.

IV. ORDER

For the reasons given, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–7, 9–15, 17–21, and 23–26 of the '062 patent on the following asserted ground:

IPR2017-01295
Patent 8,709,062 B2

Claims 1–7, 9–15, 17–21, and 23–26 under 35 U.S.C. § 103(a) as unpatentable over Rupp, Sugiyama, Jendersee, and the knowledge of a POSITA.

FURTHER ORDERED that the trial is limited to the ground identified above, and no other grounds are authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this Decision.

IPR2017-01295
Patent 8,709,062 B2

PETITIONER:

A. James Isbester
KILPATRICK TOWNSEND & STOCKTON LLP
jisbester@kilpatricktownsend.com

Craig S. Summers
Joshua Stowell
KNOBBE, MARTENS, OLSON & BEAR, LLP
2css@knobbe.com
Joshua.Stowell@knobbe.com

PATENT OWNER:

Wallace Wu
Jennifer A. Sklenar
Nicholas M. Nyemah
ARNOLD & PORTER KAYE SCHOLER LLP
Wallace.Wu@apks.com
Jennifer.Sklenar@apks.com
Nicholas.Nyemah@apks.com