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Paper 7
Entered: March 6, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION,
Petitioner,

v.

ORTHOPHOENIX, LLC,
Patent Owner.

Case IPR2014-01519
Patent 6,623,505 B2

Before JOSIAH C. COCKS, RICHARD E. RICE, and SCOTT A. DANIELS, *Administrative Patent Judges.*

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

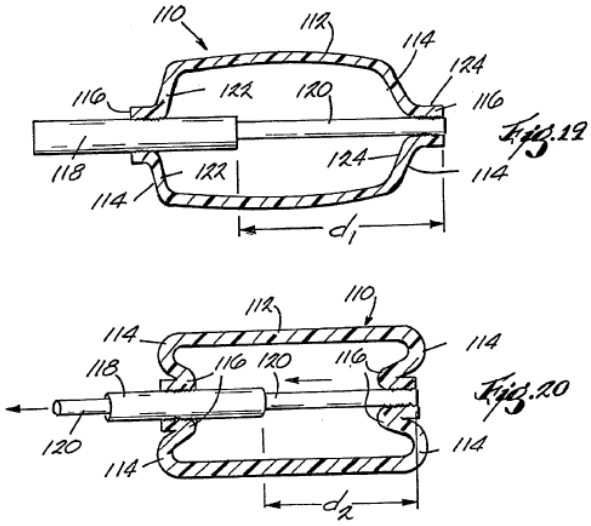
Stryker Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–12 of U.S. Patent No. 6,623,505 B2 (Ex. 1001, "the '505 Patent"). Orthophoenix, LLC ("Patent Owner") filed a Preliminary Response (Paper 5, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). We determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to all of challenged claims 1–12 of the '505 Patent. Accordingly, we institute an *inter partes* review with respect to the challenged claims.

A. Related Proceedings

Petitioner is named in a federal district court case involving the '505 Patent (*Orthophoenix, LLC. v. Stryker Corporation,* Case No. 13-1628-LPS (D. Del.)). Pet. 1; Paper 3, 2.

B. The '505 Patent

The '505 Patent relates "to expandable structures, which, in use, are deployed in interior body regions of humans and other animals." Ex. 1001, 1:12–14. Figures 19 and 20 of the '505 Patent are reproduced below.



Figures 19 and 20 depict side section views of expandable structure 110 at different stages of manufacture. *Id.* at 3:41–51, 10:14–59. As depicted in Figure 19, expandable structure 110 includes inner catheter tube 120, which is slidable within outer catheter tube 118, and located a distance d1 beyond the outer catheter tube. *Id.* at 3:41–45, 10:19–32. At this stage, the proximal end of expandable structure 110 has been bonded to the distal end of outer catheter tube 118, and the distal end of expandable structure 110 is bonded to the distal end of inner catheter tube 120. *Id.* at 3:41–45, 10:32–36. Figure 20 shows the expandable structure of Figure 19 at a later stage, after sliding the inner catheter tube a distance d2 (shorter than d1) from the end of outer catheter tube 118. *Id.*at 3:46–47, 10:40–43. At that stage, the relative position of the outer and inner catheter tubes 118 and 120 are secured against further movement, for example, by adhesive. *Id.* at 10:46–49.

In another embodiment, materials selected for the inner catheter tube and the expandable body are more compliant (i.e., more elastic) than the

materials selected for the outer catheter tube, such that, during expansion, the expandable body and the inner catheter tube are capable of increasing in length relative to the outer catheter tube. *Id.* at 11:15–39.

Figures 26 and 27 of the '505 Patent are reproduced below.

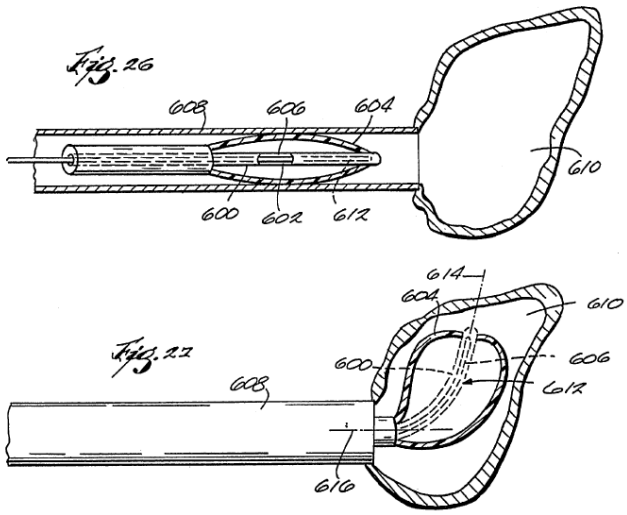


Figure 26 is a side view, with parts broken away and in section, of expandable structure 604. *Id.* at 4:3–6, 12:35–47. Figure 27 is a side view of expandable structure 604, after deployment in targeted interior body region 610. *Id.* at 4:7–12, 12:48–63. As shown in Figure 26, lumen 602 of inner catheter tube 600 accommodates the passage of stiffening member or stylet 606. *Id.* at 12:36–39. As depicted in Figure 27, the stylet includes distal region 612, which has a preformed bend that deflects expandable structure 604 and the distal end of inner catheter tube 600 relative to the axis of guide sheath 608 as the stylet is advanced free of the guide sheath and into targeted interior region 610. *Id.* at 12:48–58, Fig. 27.

C. Illustrative Claim

Claims 1, 5, and 9 are independent. Claim 1 is illustrative and is reproduced below:

> 1. A device for deployment into bone comprising
>
> an outer catheter tube having a distal end,
>
> an inner catheter tube extending at least in part within the outer catheter tube and having a distal end region that extends at least in part beyond the distal end of the outer catheter tube,
>
> an inflatable structure having a proximal end secured to the outer catheter tube and a distal end secured to the inner catheter tube, the inflatable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube, and
>
> a flow passage between the outer and inner catheter tubes communicating with the inflatable structure and adapted to convey an inflation medium into the inflatable structure to inflate the inflatable structure.

Id. at 15:62–16:9.

D. The Asserted References

Petitioner relies upon the following references (Pet. 3):

Andersen	US 4,706,670	Nov. 17, 1987	Ex. 1005
Valley	US 5,766,151	June 16, 1998 (filed June 7, 1995)	Ex. 1007
Pathak	WO 94/24962	Nov. 10, 1994	Ex. 1003
Barbere	EP 0405831	June 7, 1995	Ex. 1004
Reiley	WO 95/20362	Aug. 3, 1995	Ex. 1006

E. The Asserted Grounds

Petitioner challenges claims 1–12 of the '505 Patent on the following grounds (Pet. 3–4, 55 n.11):

Reference(s)	Basis	Claims Challenged
Pathak	§ 102(b)	1, 3, 5, 7, 9, and 11
Andersen	§ 102(b)	1, 3–5, 7-9, 11, and 12
Valley	§ 102(e)	1–12
Barbere	§ 102(b)	1, 3, 5, 7, 9, and 11
Valley	§ 103(a)	1–12
Reiley and Andersen	§ 103(a)	1–12
Pathak and Valley	§ 103(a)	2, 4, 6, 8, 10, and 12

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC.*, No. 2014-1301, slip op. at 16, 19 (Fed. Cir. Feb. 4, 2015) ("Congress implicitly adopted the broadest

reasonable interpretation standard in enacting the AIA," and "the standard was properly adopted by PTO regulation.").

1. The Preambles of Claims 1, 5, and 9

The preambles of claims 1 and 5 each recite: "A device for deployment into bone." The preamble of claim 9 recites: "A system for treating bone." The parties disagree as to whether the preambles are claim limitations. *Compare* Pet. 14–15 (arguing that the preambles simply recite the intended use for the claimed device and do not serve as claim limitations) *with* Prelim. Resp. 13–14 (arguing that the preambles breathe life and meaning into the claims and are limiting).

With respect to claims 5 and 9, Patent Owner argues that the term "bone" in the preamble provides antecedent basis for the term "bone" in the body of the claim and should be construed as limiting under *Bell Commc'ns Research v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 621 (Fed. Cir. 1995). Prelim. Resp. 13. Claims 5 and 9 each recite "the inflatable structure being sized and configured for passage within a cannula into *bone*" (emphasis added). We are not persuaded that the term "bone" in the preamble provides any distinct definition of the term "bone" in the body of the claim. Accordingly, *Bell* is inapposite.[1]

[1] In *Bell*, the Federal Circuit found that the body of the claim, by referring to "said packet," expressly incorporated by reference the preamble phrase "said packet including a source address and a destination address," thus according the preamble definitional status. 55 F.3d at 621.

Patent Owner also argues that the preambles of claims 1, 5, and 9 should be construed as limiting because the Specification describes devices for use in bone. Prelim. Resp. 13–14 (quoting Ex. 1001, 1:65–2:22). We disagree. Nothing in the Specification limits the claimed invention to use in bone. Indeed, the Specification describes a preferred embodiment for use in blood vessels. Ex. 1001, 4:28–30, 11:50–12:25.

Accordingly, for purposes of this Decision, we determine that the body of each of claims 1, 5, and 9 fully and intrinsically sets forth all of the limitations of the claim, and that the preamble is not a limitation. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) ("[A] preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.") (citations and internal quotation marks omitted).

2. "Sized and configured for passage within a cannula into bone"

Patent Owner contends that the included term "sized and configured" in the phrase "sized and configured for passage within a cannula into bone," recited in claim 5 (and similarly in claim 9), means "having a specified size, set up for operation in a particular way." Prelim. Resp. 16. In support of that contention, Patent Owner quotes from the Specification that "the expandable structure is sized and configured for passage within a cannula into bone when the expandable structure is in a collapsed condition." Prelim. Resp. 15–16; *see* Ex. 1001, 2:9–11. This passage from the

Specification closely tracks the claim language. Petitioner does not propose a construction for the included term "sized and configured."

Rather, Petitioner proposes to construe the phrase "sized and configured for passage within a cannula into bone" to mean a structure that is "capable of performing the recited function," specifically, a structure "of a size and configuration such that it is capable of passing within a cannula into bone." Pet. 15–16. We agree with Petitioner's analysis, and note that this claim interpretation is consistent with the passage from the Specification on which Patent Owner relies. *See* Ex. 1001, 2:9–11.

Accordingly, at this stage of the proceeding, we determine that the broadest reasonable construction consistent with the Specification of "sized and configured for passage within a cannula into bone" means having a structure of a size and configuration such that it is capable of passing within a cannula into bone. It is not necessary for us to interpret separately the included term "sized and configured."

3. "The inner catheter tube is moveable in relation to the outer catheter tube"

Neither party proposes a construction of the limitation "the inner catheter tube is moveable in relation to the outer catheter tube," recited in each of claims 4, 8, and 12. Petitioner contends, nevertheless, that this limitation is met by Anderson's disclosure of inner and outer catheter tubes that are "axially displaceable with respect to each other." *E.g.*, Pet. 38. On this record, we do not agree with Petitioner's implicit claim construction. The broadest reasonable construction consistent with the Specification of

"the inner catheter tube is moveable in relation to the outer catheter tube" requires the inner catheter tube to be capable of movement relative to the outer catheter tube. *See* Ex. 1001, 11:15–39. Petitioner's implicit claim construction would encompass a device wherein the outer catheter tube is capable of movement relative to the inner catheter tube, but not vice versa.

B. Asserted Anticipation or Obviousness of Claims 1–12 by Valley

Petitioner challenges claims 1–12 as anticipated by Valley. Pet. 47–55. As discussed below, we are persuaded on the current record that Valley anticipates the challenged claims.

Petitioner alternatively asserts that claims 1–12 would have been obvious over Valley in view of the knowledge of a person of ordinary skill in the art. *See* Pet. 55 n.11 (citing Ex. 1002 ¶¶ 110–114). As discussed below, we are persuaded on the current record that claims 1–12 would have been obvious over Valley in view of the knowledge of a person of ordinary skill in the art.

1. Overview of Valley

Valley "relates to a catheter based system for isolating the heart and coronary blood vessels of a patient from the remainder of the arterial system and for infusing a cardioplegic agent into the patient's coronary arteries to induce cardioplegic arrest in the heart." Ex. 1007, 1:43–48. Figure 8A of Valley shows coaxial catheters and a deflated balloon. *Id.* at Fig. 8A. We refer to Petitioner's colorized, cropped version of Figure 8A, which is reproduced below:

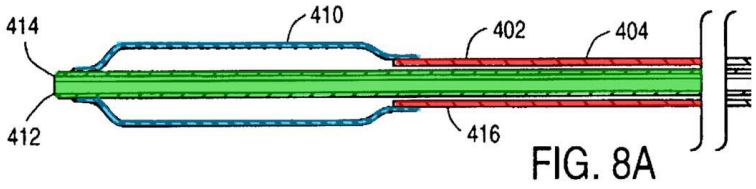


FIG. 8A

Pet. 48; Ex. 1002 (Sheehan Decl.) ¶ 74.

As illustrated in Petitioner's Figure 8A, the distal end of balloon 410 (shown in blue) extends outside and beyond the distal end of outer catheter tube 404 (shown in red), and the balloon encloses a portion of inner catheter tube 402 (shown in green). *See* Pet. 48. The proximal end of balloon 410 is attached to the distal end of outer tube 404, and the distal end of balloon 410 is attached to the distal end of inner tube 402, with the inner catheter tube extending beyond the distal end of the outer catheter tube. *See id.* Inner tube 402 is moveable in relation to outer tube 404. Ex. 1007, 24:27–30, 24:67–25:17.

2. Analysis

On the current record, we are persuaded that Valley discloses each limitation of claims 1–12. *See* Pet. 47–55; Ex. 1002 ¶¶ 74–93.

To anticipate a patent claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates, even though artisans of ordinary skill may not have recognized the inherent characteristics or functioning of the prior art. *MEHL/Biophile Int'l Corp. v.*

Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (citation omitted); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–50 (Fed. Cir. 2002).

Patent Owner argues that "[t]he '505 patent requires devices for deployment or use in bone, not ones that are used in the cardiac system." Prelim. Resp. 36. As discussed above, however, the preamble language on which Patent Owner relies is not a claim limitation. *See* section II.A.1 *supra*. Further, on the current record, it is undisputed that Valley discloses a balloon of a size and configuration such that it is capable of passing within a cannula into bone, as required by claims 5 and 9. *See* Ex. 1002 ¶ 88; section II.A.2 *supra*. Patent Owner also argues that balloons for bone are structurally different from those used in the vascular system, with respect to inflation pressure and balloon thickness. Prelim. Resp. 36. Patent Owner's argument is not, however, commensurate with the scope of the claims, which are not limited as to inflation pressure or balloon thickness.

Finally, Patent Owner argues that "Valley cannot anticipate claims 1 or 5, or their respective dependent claims, claims, 2–4 or 6–8, because Valley does not disclose balloons for use in creating cavities in bone." *Id.* Again, this argument is not commensurate with the scope of the claims, because claims 1 and 5 do not recite "creating cavities in bone."

Claims 3 and 7 recite "the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone." At this stage of the proceeding, we are persuaded that Valley's balloons are inherently capable of compressing cancellous bone. *See* Ex. 1006, 5:29 ("Current medical balloons can compress bone . . . ."); Ex. 1002 ¶ 82 ("A person of ordinary skill would understand that the Valley

balloons are inflatable structures that have a structure and configuration so as to be capable of compressing cancellous bone upon inflation."); *cf.* Ex. 1001, 4:60–62 (referring to "reticulated cancellous, or spongy, bone 32 (also called medullary bone or trabecular bone)").

We agree, moreover, on the current record, that claims 1–12 would have been obvious over Valley in view of the knowledge of a person of ordinary skill in the art. *See* Pet. 55 n.11 (citing Ex. 1002 ¶¶ 110–114). We are persuaded that

that

> [e]ither the knowledge of a person of ordinary skill in the art or the explicit disclosure of Reiley teach[es] the use of the balloon catheter disclosed in Valley "for deployment into bone," "for treating bone," or "to compress cancellous bone upon inflation of the inflatable structure in bone," or "within a cannula into bone."

Ex. 1002 ¶ 113. We discuss Patent Owner's arguments with respect to secondary considerations below. *See* section II.C.2 *infra*.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge that Valley anticipates claims 1–12, and renders obvious claims 1–12 in view of the knowledge of a person of ordinary skill in the art.

C. Asserted Obviousness of Claims 1–12 over Reiley and Andersen

Petitioner challenges claims 1–12 as obvious over Reiley and Andersen. Pet. 41–47.

1. Overview of Reiley and Andersen

Reiley discloses an inflatable balloon-like device for use in treating bone conditions. Ex. 1006, 1:9–11. According to Reiley, prior art methods disclosed balloon devices that are inserted and inflated in bone to compact cancellous bone and to enlarge the cavity in the bone. *Id.* at 2:9–16. Reiley discloses that while prior art methods are adequate for the fixation of bone, it has been found that the compacting of cancellous bone against the inner surface of the cortical wall can be "significantly improved with the use of inflatable devices that incorporate additional engineering features not heretofore described and not properly controlled with prior inflatable devices." *Id.* at 2:32–3:5. Reiley further discloses that "[a] need has therefore arisen for improvements in the shape, construction and size of inflatable devices for use with the foregoing apparatus and method." *Id.* at 3:6–8.

Anderson, according to Petitioner, "discloses the well-known balloon catheter design of a 'coaxial catheter with a flexible inner tubing and an outer tubing." Pet 32–33 (citing Ex. 1005, 2:17-18). Petitioner's colorized version of Figure 4a of Andersen is reproduced below.

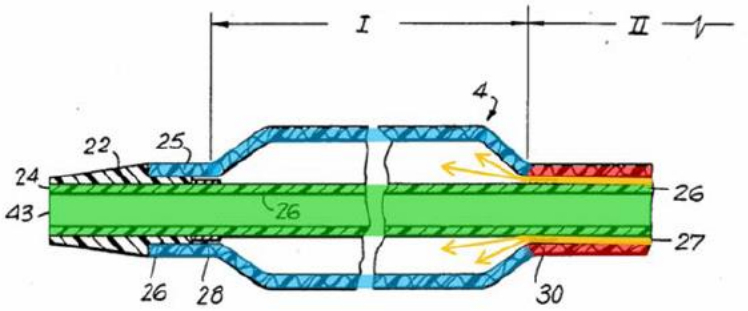


FIG. 4a

According to Petitioner, colorized Figure 4a depicts an inflatable balloon portion (shown in blue) formed at the distal end of the outer tubing (shown in red) and anchored to the distal end of the inner tubing (shown in green). *Id.* at 33 (citing Ex. 1005, 2:19–22; Ex. 1002 ¶ 105). As depicted, the balloon extends outside and beyond the distal end of the outer catheter tube and encloses a portion of the inner catheter tube. According to Petitioner, Andersen discloses that the two tubes are axially displaceable with respect to each other. *Id.* at 38 (citing Ex. 1005, 2:22–29, 4:53–56, 6:26–34, 10:20–21; Ex. 1002 ¶ 108 (claim 4 chart)).

2. Analysis

On the current record, we are persuaded that the combination of Reiley and Andersen renders obvious claims 1–3, 5–7, and 9–11, but not claims 4, 8, and 12. *See* Pet. 41–47; Ex. 1002 ¶¶ 102–109.

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A

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

Patent Owner argues that there is no apparent reason for a person of ordinary skill in the art to combine Reiley and Andersen. Prelim. Resp. 33–35. Specifically, Patent Owner asserts that Reiley teaches away from the combination. *Id.* at 34–35.

On the current record, we are not persuaded that Reiley would have discouraged combining the teachings of the references. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (requiring, in order to "teach away," that a reference must "criticize, discredit, or otherwise discourage the solution claimed"). Rather, we are persuaded that "Reiley praises the catheter design of intravascular catheters specifically identifying the Andersen catheter as '[a] particular improvement.'" Ex. 1002 ¶ 104; *see* Pet. 43 (citing Ex. 1006, 4:21–34). As Petitioner asserts, Reiley states that "[c]urrent medical balloons can compress bone." Pet. 44 (citing Ex. 1006, 5:22–23; Ex. 1002 ¶ 104). Although Reiley also states that such balloons are "too small and generally have the wrong configuration and are generally not strong enough to accomplish adequate cavity formation" (Ex. 1006, 5:30–32), this statement does not amount to teaching away from the claimed invention.

Patent Owner also asserts that secondary considerations, such as commercial success, weigh in favor of nonobviousness. Prelim. Resp. 41–42. In particular, Patent Owner argues:

> With regards to commercial success, Kyphon, Inc. was founded by Mr. Arie Scholten, an engineer and inventor of surgical products, Dr. Mark Reiley, an orthopedic surgeon from Berkeley, California and named inventor of the Reiley patent cited herein, and Dr. Karen Talmadge, a Harvard University biochemist. In 1998 Kyphon received Federal Drug Administration (FDA) approval for an inflatable bone tamp and the first balloon kyphoplasty procedure was performed. In 2007, Medtronic, Inc. purchased Kyphon, Inc. for *$4.2 billion dollars*. Ex. 2002 (emphasis added). As of 2007, over 11,000 physicians had been trained to perform balloon kyphoplasty, becoming the industry standard for the procedure.

Id. at 41.

We are not persuaded by Patent Owner's argument at this stage of the proceeding, because the evidence of record is insufficient to be accorded substantial weight. For example, Patent Owner has not established sufficiently a nexus between the evidence of commercial success and the challenged claims of the '505 Patent. *See In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*.") (internal quotation marks and citation omitted).

Based on the current record, Petitioner has shown sufficiently that the combination of Reiley and Andersen teaches the subject matter of claims 1–3, 5–7, and 9–11, and that a person of ordinary skill in the art would have

had a reason to combine the references in the manner recited by the claims with a reasonable expectation of success.

We also have considered the arguments and evidence as to claims 4, 8, and 12, which require the inner catheter tube to be moveable in relation to the outer catheter tube. *See* Pet. 38, 46 (citing Ex. 1005, 2:22–29, 4:53–56, 6:26-34, 10:20–21, 46; Ex. 1002 ¶ 108 (claim charts)). We are not persuaded that Andersen's inner catheter tube is capable of movement relative to the outer catheter tube, as the claims require. *See* section II.A.3 *supra*. Andersen teaches, for example, that "corrections in the position of the inner tubing relative to the outer tubing of the catheter are not needed," because changes in length of the balloon portion as it is pressurized are offset by corresponding changes in length of the outer tubing. Ex. 1005, 2:22–37. Anderson also states that "In [the] catheter of the invention, the proximal end of the inner tubing is fixed, relative to the outer tubing of the catheter." *Id.* at 2:63–65.

Accordingly, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 1–3, 5–7, and 9–11, but not claims 4, 8, and 12, are unpatentable as obvious over Reiley and Andersen.

D. Remaining Challenges

Petitioner additionally asserts that: claims 1, 3, 5, 7, 9, and 11 are anticipated by each of Pathak and Barbere; claims 1, 3–5, 7– 9, 11, and 12 are anticipated by Andersen; and claims 2, 4, 6, 8,10, and 12 would have been obvious over the combination of Pathak and Valley. Pet. 17–41, 55–

58. In view of the grounds on which we have determined to institute an *inter partes* review of claims 1–12, we exercise our discretion not to institute a review on these additional grounds. *See* 37 C.F.R. § 42.108(a).

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenges to: claims 1–12 as anticipated by Valley; claims 1–12 as obvious over Valley in view of the knowledge of a person of ordinary skill in the art; and claims 1–3, 5–7, and 9–11 as obvious over Reiley and Andersen. The Board has not made a final determination concerning patentability of any of the challenged claims.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that an *inter partes* review of claims 1–12 of the ’505 Patent is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the ’505 Patent is hereby instituted commencing on the entry date of this Order, and 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; and

FURTHER ORDERED that the trial is limited to the following grounds: claims 1–12 as anticipated by Valley; claims 1–12 as obvious over Valley in view of the knowledge of a person of ordinary skill in the art; and claims 1–3, 5–7, and 9–11 as obvious over Reiley and Andersen.

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