

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*.

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

I. INTRODUCTION

A. Background/Summary

Stryker Corporation (“Petitioner”) filed a Petition (Paper 1, “Petition” or “Pet.”) for *inter partes* review of claims 1–12 of U.S. Patent No. 6,623,505 B2 (Ex. 1001, “the ’505 Patent”). We instituted an *inter partes* review as to all claims. Paper 7 (“Dec.”), 19. After institution, Orthophoenix, LLC (“Patent Owner”) filed a Patent Owner Response (Paper 14, “PO Resp.”), to which Petitioner filed a Reply (Paper 17, “Pet. Reply”).

The grounds for trial were as follows:

References	Basis	Claims Challenged
Valley ¹	§ 102(b)	1–12
Valley	§ 103(a)	1–12
Reiley ² and Anderson ³	§ 103(a)	1–3, 5–7, and 9–11

Petitioner relied on the first and second declarations of Neil J. Sheehan. (Exs. 1002, 1041). Patent Owner relied on the declaration of Gamal Baroud, Ph.D. (Ex. 2018).

¹ U.S. Patent No. 5,766,151 filed June 7, 1995, issued June 16, 1998 (Ex. 1007).

² International Publication No. WO 95/20362, published Aug. 3, 1995 (Ex. 1006).

³ U.S. Patent No. 4,706,670, issued November 17, 1987 (Ex. 1005).

Patent Owner filed Observations on the cross-examination of Mr. Sheehan (Paper 19), to which Petitioner filed a Response (Paper 24).

A consolidated Oral Hearing for this proceeding and case IPR2014-01535 was held on November 4, 2015. A transcript of the Hearing has been entered in the record. Paper 26 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

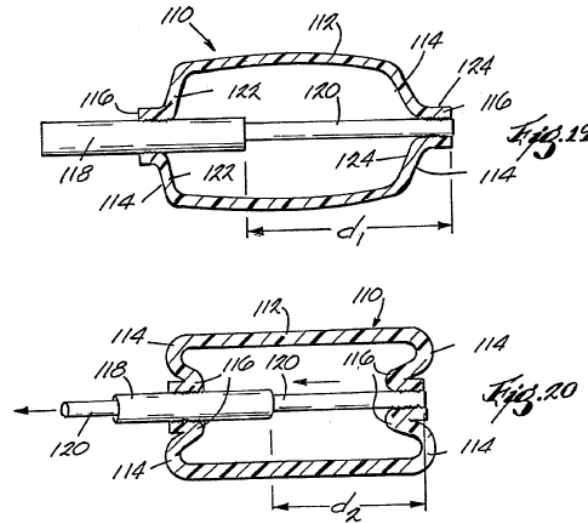
For the reasons explained below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 4–6, 8–10, and 12 are unpatentable as anticipated by Valley and claims 1–12 are unpatentable as obvious over Valley; however, Petitioner has *not* shown by a preponderance of the evidence that claims 1–3, 5–7, and 9–11 are unpatentable as obvious over Reiley and Anderson.

B. Related Proceedings

Petitioner and Patent Owner are parties to a federal district court case involving the ’505 Patent (*Orthophoenix, LLC. v. Stryker Corp.*, No. 13-1628-LPS (D. Del.)). Pet. 1. They also are parties to an *inter partes* review of U.S. Patent No. 6,280,456 B1, which is related to the ’505 Patent. *See* IPR2014-01535, Paper 1.

C. 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 d_1 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 d_2 (shorter than d_1) 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, Fig. 21. Figure 21 of the '505 Patent is reproduced below.

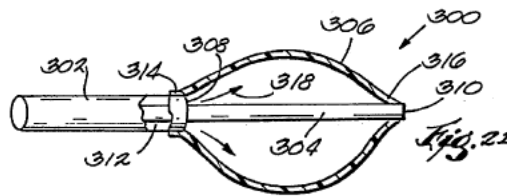


Figure 21 depicts expandable structure 300, including inner catheter tube 304, expandable body 306, and outer catheter tube 302. *Id.* at 10:60–11:7. Materials selected for inner catheter tube 304 and expandable body 306 are more compliant than materials selected for outer catheter tube 302. *Id.* at 11:15–18. “Due to the differential selection of materials, the lack of compliance of the outer catheter tube 302 at the proximal body end 314 is counterpoised during expansion of the body 306 against the compliance of the inner catheter tube 304 at the distal body end 316.” *Id.* at 11:27–31.

The '505 Patent describes passing a stiffening member or stylet through an interior lumen of the expandable structure. *Id.* at 12:35–40. Figures 26 and 27 of the '505 Patent are reproduced below.

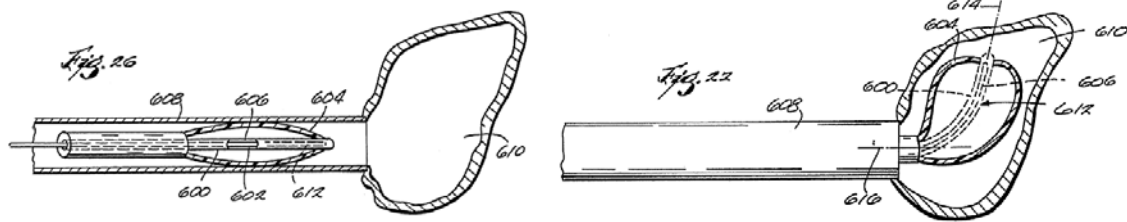


Figure 26 is a side view of expandable structure 604. *Id.* at 4:3–6, 12:35–47. Figure 27 is a side view of expandable structure 604, after deployment in targeted interior body region 610. *Id.* at 4:7–12, 12:48–63. As shown in Figure 26, lumen 602 of inner catheter tube 600 accommodates the passage of stiffening member or stylet 606. *Id.* at 12:36–39, Fig. 26. As shown 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.

D. Illustrative Claims

Claims 1, 5, and 9 are independent. Claims 1 and 3 are illustrative and are 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.

3. A device according to claim 1 wherein the inflatable structure is adapted and configured to compress cancellous⁴ bone upon inflation of the inflatable structure in bone.

Id. at 15:62–16:9, 16:15–18.

II. ANALYSIS

A. Claim Construction and Person of Ordinary Skill in the Art

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation 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*, 793 F.3d 1268, 1278, 1279 (Fed. Cir. 2015) (“We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA” and “the standard was properly adopted by PTO regulation.”), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 84 U.S.L.W. 3218 (Jan. 15, 2016) (No. 15-446). Under that

⁴ With reference to Figures 1 and 2, the Specification states that vertebral body 26 includes an exterior formed from compact cortical bone 28, which encloses “interior volume 30 of reticulated cancellous, or spongy, bone 32 (also called medullary bone or trabecular bone).” *Id.* at 4:57–61, Figs. 1, 2.

standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See Superguide Corp. v. DirectTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The parties do not agree on the level of ordinary skill in the art. Petitioner's expert, Mr. Sheehan, testifies to the following definition of a person of ordinary skill:

A person of ordinary skill in the relevant art would have a mechanical engineering degree, industrial design degree, or similar technical degree, or equivalent work experience, and at least 5 years of working in the area of medical device design, including experience with catheters carrying an expandable or inflatable structure, such as a typical balloon catheter.

Ex. 1002 ¶ 31. In contrast, Dr. Baroud testifies:

Based on my experience, a person of ordinary skill in the art would have had advanced training in mechanical and biomechanical engineering and would have had specific experience with the mechanics and properties of bones as well as more specifically, with the field of bone augmentation. Bone

augmentation includes bone strengthening, increasing osseous dimensions as well as vertebroplasty and kyphoplasty.

Ex. 2018 ¶ 13. We credit Mr. Sheehan’s definition over that of Dr. Baroud. As the field of the ’505 Patent is expandable structures, Ex. 1001, 1:12–14, a relevant technical degree or equivalent work experience involving the design of expandable structures, whether in bone or vasculature, is all that the level of ordinary skill would have required. *See* Ex. 1041 ¶ 28.

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 *with* PO Resp. 13–15.

“Whether to treat a preamble as a limitation is a determination ‘resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.’” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989)). “In general, a preamble limits the invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Id.* (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). “Conversely, 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.” *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

In this case, Patent Owner argues that “when read in the context of the claim, the preamble requires the claimed device to possess structure and properties compatible with, i.e., designed and constructed for, use in bone and thus forecloses interpretations of the claim inconsistent with suitability of the claimed device for such use.” PO Resp. 13–14 (citing *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987)). Patent Owner asserts that “the words of the preamble ‘for deployment into bone’ or ‘for treating bone’ serve to limit the prior art against which patentability is measured to devices designed and constructed for deployment in bone.” *Id.* Patent Owner further asserts that “[w]ithout significant modification of mechanical and structural properties of the balloons, bone catheters outfitted with bone balloons cannot be used in blood vessels, nor can blood vessel catheters outfitted with vascular balloons be used in bone. *Id.* (citing Ex. 2018 ¶¶ 21–22.

Patent Owner also argues that “claims 5 and 9 state *within the claim body* that the claimed inflatable structure is *sized and configured for passage within a cannula into bone*, and claims 7 and 11 indicate *within the claim body* that the inflatable structure is *adapted and configured for compression of cancellous bone*. *Id.* at 14–15. Patent Owner further argues that “[i]n each case the claim body references the bone recited in the preamble.” *Id.* at 15.

We have considered Patent Owner’s arguments, but agree with Petitioner that the preambles of claims 1, 5, and 9 each “merely state the

intended use for the claimed device and system.” Pet. Reply 3. As Petitioner argues, the body of each of these claims describes “structurally complete . . . inventions (*e.g.*, outer and inner catheter tubes, an inflatable structure, and a flow passage between the tubes).” *Id.* We also agree with Petitioner that nothing in the Specification or prosecution history of the ’505 Patent supports interpreting the claim preambles as limitations. *See id.* at 5; Ex. 1001, 4:28–40, 5:31–43, 11:50–12:25, Figs. 22, 23; Ex. 1016, 79–83, 94–101. Indeed, contrary to Patent Owner’s arguments, the Specification describes “vasculature” as “present[ing] an environment well suited to receive the benefits of the invention.” Ex. 1001, 4:30–32.

We recognize that claims 5 and 9 each recite “the inflatable structure being sized and configured for passage within a cannula into *bone*” (emphasis added). As we stated in the Institution Decision, however, 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. Dec. 7. For that reason, the preamble is not necessary to give meaning to, or define, the term “bone” in the body of the claim. *See Catalina Mktg. Int’l*, 289 F.3d at 808.

The Federal Circuit’s decision in *Stencel* is distinguishable. In that case, the claim related to a driver device intended for use with a particular threaded lobed collar. 828 F.2d at 752. The Federal Circuit determined that the driver was limited by language defining the structure of the collar on which it acted. *Id.* at 754. The body of the claim recited “the collar” and the preamble defined the collar as “a threaded collar . . . having plastically deformable lobes.” *Id.* at 752–53, 754. In contrast, here, the preamble does not assist to define the term “bone” in the body of the claim.

Accordingly, we maintain our determination in the Institution Decision 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 preambles are not claim limitations. Dec. 8.

2. “*Wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone*”

Patent Owner contends the phrase “wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone,” recited in claims 3, 7, and 11, requires “a device having a structure and properties not only suitable for the claimed use but specifically designed and constructed to perform the claimed function and thus constitute[s] a limitation.” PO Resp. 15 (citing *In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014)). Patent Owner further argues that the recited phrase means “that the inflatable structure must be designed and constructed to compress cancellous bone upon inflation *in a manner that creates uniform and predictable compression in the cancellous bone[,] but must not apply so much pressure as to compromise the structural integrity of the bone.*” *Id.* at 16 (emphasis added; citing Ex. 2018 ¶¶ 21–22).

Dr. Baroud testifies in support of Patent Owner’s claim construction that “the inflatable structure must be designed and constructed to compress cancellous bone upon inflation in a manner that creates a relatively uniform and predictable compression in the cancellous bone.” Ex. 2018 ¶ 21 (referencing his discussion of Figures 17–20 of the ’505 Patent); *see id.* ¶¶ 28–29. Petitioner disagrees, and asserts that the disputed phrase merely

requires an inflatable structure that is capable of compressing cancellous bone upon inflation. Pet. 15–16; Pet. Reply 8.

In *Giannelli*, cited by Patent Owner, the claims at issue required a “first handle portion *adapted to* be moved from a first position to a second position by a pulling force . . . in a rowing motion.” 739 F.3d at 1379 (emphasis added). Recognizing that the claim term “adapted to” can mean “made to,” “designed to,” or “configured to,” as well as “capable of” or “suitable for,” the Federal Circuit gave the term the first, narrower meaning because the written description “ma[de] clear” that the claimed machine was “designed or constructed to be used as a rowing machine whereby a pulling force is exerted on the handles.” *Id.* The Federal Circuit explained that the patent specification described “how the position of the handles relative to the primary and secondary lever arms and the resistance mechanism renders them ‘adapted’ to be moved by the user’s pulling force.” *Id.* Based on its claim interpretation, the Federal Circuit determined that the relevant question for patentability in that case was whether the apparatus disclosed in the prior art was “made to,” “designed to,” or “configured to,” allow the user to perform a rowing exercise by pulling on the handles as claimed. *Id.* at 1381.

In this case, unlike *Giannelli*, the claim interpretation issue does not revolve about the meaning of “adapted to,” but rather the term “adapted and configured to.” By inclusion of “configured,” the term “adapted and configured to” expressly invokes the narrower meaning of “adapted to” considered by the Federal Circuit in *Giannelli*, i.e., “made to,” “designed to,” or “*configured to.*” *Giannelli*, 739 F.3d at 1379, 1381 (emphasis

added). Further, interpreting “adapted and configured to” more broadly to mean “capable of” or “suitable for” would render “configured” superfluous in the term “adapted and configured to.” *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (stating that “claims are interpreted with an eye toward giving effect to all terms in the claim”).

The phrase “wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone,” however, does not indicate how the inflatable structure should be designed or constructed to perform the recited function of compressing cancellous bone upon inflation, or specify any particular manner of performing that function. That the Specification describes embodiments designed or constructed to compress cancellous bone as recited in the claims does not justify reading limitations from those embodiments into the claims, contrary to Patent Owner’s argument. *See* PO Resp. 5–9 (citing Ex. 1001, 9:24–67, 10:14–59, Figs. 17, 18, 19), 15–16; Tr. 34:15–36:16. Accordingly, we do not agree with Patent Owner that “adapted and configured to,” in claims 3, 7, and 11, means that “that the inflatable structure must be designed and constructed to compress cancellous bone upon inflation in a manner that creates uniform and predictable compression in the cancellous bone[,] but must not apply so much pressure as to compromise the structural integrity of the bone.” *See* PO Resp. 16. Nor do we agree with Patent Owner’s argument at the Oral Hearing that the inflatable structure must have tapered ends. *See* Tr. 36:14–16.

We determine that the broadest reasonable interpretation consistent with the Specification of an “inflatable structure [that] is adapted and

configured to compress cancellous bone upon inflation of the inflatable structure in bone” is an inflatable structure that is designed or made to compress cancellous bone upon inflation of the inflatable structure in bone.

B. Asserted Anticipation of Claims 1–12 by Valley

To anticipate a patent claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation.”

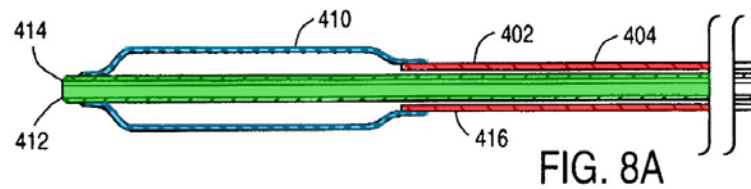
Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1334 (Fed. Cir. 2008).

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).

In this case, Petitioner challenges claims 1–12 as anticipated by Valley. Pet. 47–55. As discussed below, we are persuaded that Valley anticipates claims 1, 2, 4–6, 8–10, 12, but not claims 3, 7, and 11.

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:



Pet. 48; Ex. 1002 ¶ 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—Claims 1, 2, 4–6, 8–10, and 12

Upon review of the arguments and evidence presented by the parties, we determine that Petitioner has shown by a preponderance of the evidence that Valley anticipates claims 1, 2, 4–6, 8–10, and 12. We are persuaded that Petitioner—through claim charts and the testimony of Mr. Sheehan—has shown sufficiently that Valley discloses each limitation of claims 1, 2, 4–6, 8–10, and 12. *See* Pet. 47–55; Ex. 1002 ¶¶ 74–93.

Patent Owner argues that the balloon catheter device of Valley does not meet the preamble requirements of independent claims 1, 5, and 9 for “deployment into bone” or “treating bone.” PO Resp. 20. We disagree with

Patent Owner's argument because, as discussed above, the preambles of claims 1, 5, and 9 are not claim limitations. *See supra* section II.A.1.

With respect to claims 5 and 9, we determine that Valley discloses, inherently, an inflatable structure that is "sized and configured for passage within a cannula into bone," as recited in those claims. *See* Ex. 1002 ¶ 88. In this regard, we credit Mr. Sheehan's testimony:

The balloon of Valley is capable of insertion into the disclosed introducer sheath, which is a cannula. A person of ordinary skill would understand that the collapsed balloon of Valley is sized and configured for passage within a cannula that could be used in bone. While the disclosed catheter of Valley focuses on use in vasculature, one of ordinary skill in the art would understand that such a cannula, like the disclosed balloon catheter, would also be used for entry into bone. Furthermore, given that the architecture of vasculature is generally smaller than that of bone, it would follow that anything sized for a vasculature application would not be subject to any dimensional limitations vis-à-vis bone. Accordingly, a person of ordinary skill would understand that if the inflatable structure of Valley is capable of passing within the cannula of Valley for entry into the vascular system, the inflatable structure of Valley is also capable of passage within a cannula into bone.

Id.

Patent Owner does not dispute the testimony of Mr. Sheehan that a person of ordinary skill in the art would have understood that the collapsed balloon of Valley is sized and configured for passage within a cannula that could be used in bone. *See id.* Rather, Patent Owner challenges Mr. Sheehan's credibility based on his admission during cross-examination that he had never designed a balloon catheter device for use in bone.

PO Resp. 19–20 (quoting Ex. 2017, 10:15–11:7). Although Mr. Sheehan has not designed a balloon catheter for use in bone, we find that Mr. Sheehan’s experience designing balloon catheters for use in other body regions qualifies him to opine on the challenged claims of the ’505 Patent. *See* Ex. 2017, 9:13–10:14.⁵

For the reasons given, we conclude that Petitioner has shown by a preponderance of the evidence that Valley anticipates independent claims 1, 5, and 9. Patent Owner presents arguments only as to independent claims 1, 5, and 9 and relies on those arguments as to dependent claims 2, 4, 6, 8, 10, and 12. Having considered Petitioner’s arguments and Mr. Sheehan’s testimony with respect to dependent claims 2, 4, 6, 8, 10, and 12, we are persuaded that Petitioner has shown by a preponderance of the evidence that Valley also anticipates those claims. *See* Pet. 47–55; Ex. 1002 ¶¶ 74–93.

3. *Analysis—Claims 3, 7, and 11*

Upon review of the arguments and evidence presented by the parties, we determine that Petitioner has *not* shown by a preponderance of the evidence that Valley anticipates claims 3, 7, and 11.

Claims 3, 7, and 11 each recite that “the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone.” As discussed above, this phrase requires an inflatable

⁵ We note that Patent Owner’s declarant, Dr. Baroud, testified that he has never designed *any* type of balloon catheter, whether for use in vasculature or bone. Ex. 1040, 96:5–16.

structure that is designed or made to compress cancellous bone upon inflation of the inflatable structure in bone. *See supra* Section II.A.2.

In arguing that Valley discloses this limitation, Petitioner asserts that “a person of ordinary skill in the art would understand that [Valley’s] disclosure of nondistensible materials, including polyethylene and PET,⁶ is consistent with balloons that can compress cancellous bone as disclosed in the 505 patent.” Pet. 52 (citing Ex. 1002 ¶¶ 81–83). We are not persuaded by this argument because it improperly relies on the ’505 Patent disclosure as evidence of what would have been known to those of ordinary skill in the art at the time of the invention. *See W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1547 (Fed. Cir. 1983) (identifying as error the lower court’s attribution of “that which only the inventor taught . . . to the prior art”).

In the Patent Owner Response, Patent Owner argues that the Valley balloon is not designed to compress cancellous bone as required by the claims because “[p]ressures typically required to compress various types of cancellous bone are much higher than those described in Valley.” PO Resp. 20 (citing Ex. 2018 ¶¶ 23–25), 23. Patent Owner argues that “at the pressure specified in the ’505 patent, 250–500 psi, the balloon in Valley will most likely rupture or be punctured by individual trabeculae of the cancellous bone.” *Id.* at 20–21 (citing Ex. 2018 ¶ 26). Patent Owner also argues that “[t]he balloon in Valley is designed to operate in soft vasculature, a preexisting cavity, and all of Valley’s teachings are specific to vascular applications.” *Id.* at 21 (citing Ex. 1007, 5:29–67, 6:1–10). Patent

⁶ Polyethylene terephthalate. *See* Ex. 1002 ¶ 82.

Owner further argues that “the balloon in Valley is formed from elastomeric materials which are by nature soft and comparatively atraumatic when pressed against an anatomic structure such as [a] blood vessel.” *Id.* (citing Ex. 1007, 21:32–46; Ex. 2018 ¶ 27).

In the Reply, Petitioner argues that Valley’s balloons “fall squarely within” the teaching of the ’505 Patent of materials and thicknesses that can withstand pressures up to 250–500 psi. Pet. Reply 9 (citing Ex. 1001, 12:64–13:4; Ex. 1002 ¶ 83; Ex. 1041 ¶¶ 5–6; Ex. 1040, 48:21–49:22). Petitioner argues that materials (“polyethylene, polyurethane, and polyethylene terephthalate (PET)”) and wall thicknesses (“0.090 to 0.130 mm”) disclosed in Valley are capable of withstanding pressures up to 250–500 psi. *Id.* at 9–10 (citing Ex. 1007, 8:25–32, 21:64–65). Petitioner also argues that Valley discloses “inelastic materials.” *Id.* at 9 n.5 (citing Ex. 1007, 8:29–32).

We are not persuaded that Valley discloses, expressly or inherently, an inflatable structure that is designed or made to compress cancellous bone, as required under our claim interpretation. *See supra* Section II.A.2. Petitioner’s arguments in the Reply depend on improperly combining elements from distinct Valley embodiments. *See Net MoneyIN v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (“[I]t is not enough [for anticipation] that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.”) (citing *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (“[T]he [prior art] reference must clearly and

unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”)).

For balloon wall thicknesses from 0.090 mm to 0.130 mm, Petitioner cites Valley’s disclosure relating to the embodiment depicted in Figure 6A. Pet. Reply 10 (citing Ex. 1007, 21:64–65). In that embodiment, “balloon 210 is preferably made from an *elastomeric* material such as latex, silicone, or polyurethane.” Ex. 1007, 22:9–12 (emphasis added); *see also id.* at 8:26–28 (again describing latex, silicone, and polyurethane as elastomeric materials). Even if a balloon formed from polyurethane and having a wall thickness within the range disclosed in Valley would withstand pressures of 250–500 psi, as Petitioner argues (Pet. Reply 9–10), we agree with Patent Owner that Petitioner has failed to show sufficiently that any balloon made from an elastomeric material, such as polyurethane, can be used to compress cancellous bone. *See* PO Resp. 21.

For balloons made from “inelastic” materials such as polyethylene or PET, Petitioner relies upon other Valley embodiments. Pet. Reply 9 n.5 (citing Ex. 1007, 8:29–32, describing polyethylene and PET as nondistensible balloon materials). We are not persuaded, however, that Valley discloses a wall thickness for a balloon made from an “inelastic” material such as polyethylene or PET. In the Reply, Petitioner extrapolates the wall thickness range of 0.090 mm–0.130 mm, which Valley discloses for balloons made from elastomeric materials, to balloons made from “inelastic” materials such as polyethylene and PET. *Id.* at 9–10 (citing Ex. 1007,

21:64–65), n.5. Petitioner has not pointed to any teaching in Valley supporting such extrapolation.

Mr. Sheehan’s testimony that a balloon capable of compressing cancellous bone “can be formed” from materials disclosed in Valley also is insufficient to prove inherency. *See* Ex. 1002 ¶ 82. That is, for inherency, Mr. Sheehan’s testimony would need to establish that a Valley balloon, as designed or made, *necessarily* functions to compress cancellous bone upon inflation of the balloon in bone. *See MEHL/Biophile Int’l*, 192 F.3d at 1365 (“Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”).

Petitioner argues, based on calculations performed by Dr. Baroud on cross-examination, that “the Valley balloons are capable of withstanding pressures above 250 psi.” Pet. Reply 14 (citing Ex. 1007, 5:37, Figs. 8B, 11, 13; Ex. 1041 ¶ 13; Ex. 1040, 137:18–138:5, 140:19–141:23). As discussed above, however, to the extent Dr. Baroud’s calculations pertain to balloons made from nondistensible materials such as polyethylene and PET, the calculations are based on wall thicknesses that have not been shown to be disclosed by Valley. Further, Dr. Baroud testified that his calculations show a capability of withstanding pressures above 250 psi “with a safety factor of 2” or “roughly 2” (*see* Ex. 1040, 138:5, 141:22–23), but that “a safety factor of at least 5” was required for medical devices because of the potential for variations in materials and the need for safety in such devices. *Id.* at 118:4–119:25.

Petitioner also argues that Dr. Baroud testified on cross-examination that pressures well below 250 psi are capable of compressing cancellous

bone, including pressures as low as 50 psi. *Id.* at 12–13 (citing Ex. 1040, 81:20–84.2). For the reasons discussed above, we are not persuaded that a Valley balloon, as designed or made, necessarily functions to compress cancellous bone at those pressures.

For the reasons given, we conclude that Petitioner has *not* shown by a preponderance of the evidence that Valley anticipates claims 3, 7, and 11.

C. Asserted Obviousness of Claims 1–12 over Valley

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. 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, if in evidence.⁷ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Upon review of the arguments and evidence presented by the parties, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–12 would have been obvious over Valley and the knowledge of a person of ordinary skill in the art. Petitioner contends, and we agree, that it would have been obvious to use the Valley catheter in bone. *See* Pet. 55 n.11 (citing Ex. 1002 ¶¶ 110–114). We credit Dr. Sheehan’s testimony that “[i]n designing a catheter with an inflatable structure for use within a bone lumen, a person of ordinary skill in the art would [have] look[ed] to prior art balloon catheters, especially those utilized in vasculature.” Ex. 1002 ¶ 111. We also credit Dr. Sheehan’s testimony, with regard to the level of skill in the art, that “with the advent of balloon-assisted vertebroplasty,⁸ or vertebral kyphoplasty, in the late 1980s, it became well-known . . . that balloon catheter designs originally conceived for cardiovascular purposes could be used in bone.” *Id.* ¶ 16.

Dr. Sheehan further testifies that “Reiley illustrates that a person of ordinary skill would have used the balloon catheter disclosed in Valley to

⁷ Patent Owner does not assert any secondary considerations in the Patent Owner Response.

⁸ A procedure involving injecting bone cement into a vertebral body after creating a cavity in the bone using a balloon catheter. *Id.* at 5 n.5.

treat bone.” *Id.* ¶ 112. As explained by Dr. Sheehan, Reiley teaches modifying a coaxial intravascular catheter with inner and outer tubing, similar to the catheter disclosed in Valley, to compress cancellous bone. *Id.* (citing Ex. 1006, Abstract, 4:21–25). We credit Dr. Sheehan’s testimony that:

Either 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.”

Id. ¶ 113.

While Valley does not disclose a balloon that is designed or made to compress cancellous bone, as required by claims 3, 7, and 11 (*see supra* Section II.B.3), we credit Dr. Sheehan’s testimony that a person of ordinary skill in the art would have been motivated to modify Valley’s balloon for use in bone and, more particularly, to design or make a balloon for use in compressing cancellous bone. With respect to Patent Owner’s argument that Valley discloses balloons made from elastomeric materials, such as polyurethane, which cannot be used to compress cancellous bone, Dr. Sheehan explains that Valley also discloses “nondistensible materials, which as the name implies are the opposite of elastic.” Ex. 1041 5 n.1. With respect to Patent Owner’s argument that Valley’s balloons cannot withstand the higher pressures required to compress cancellous bone, Dr. Sheehan explains that increasing the wall thickness of a balloon or balloon catheter at the time of the invention was routine and well-known.

Id. ¶ 12. We credit Dr. Sheehan’s testimony on these issues and conclude that modifying Valley’s balloon to design or make a balloon for use in compressing cancellous bone would have been within the skill in the art, and the result would have been predictable.

In opposition, Patent Owner repeats its arguments with respect to anticipation, discussed *supra* in Section II.B. PO Resp. 23. Patent Owner also argues that:

Modifying Valley for bone would fundamentally change the principle of operation of Valley by forcing the balloon in Valley to operate at significantly higher pressures, thereby risking damage to the vasculature or making the balloon susceptible to rupture if it were inserted into bone and by completely altering the shape of the balloon upon expansion to enable it to uniformly compress a cavity. *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, No. 2013007786, 2014 WL 2033101 (P.T.A.B. Jan 17, 2014).

Id. at 23–24. We are not persuaded that modifying Valley for bone would have changed its principle of operation. As Dr. Sheehan explains, increasing the wall thickness of a balloon or balloon catheter at the time of the invention was routine and well-known. *See* Ex. 1041 ¶ 12. No credible evidence supports the argument that a Valley balloon made from a nondistensible material, such as polyethylene or PET, and having a wall thickness designed or made to compress cancellous bone, would be “susceptible to rupture if it were inserted into bone.” *See* PO Resp. at 23–24. Further, Petitioner’s argument with respect to “altering the shape of the balloon upon expansion to enable it to uniformly compress a cavity” is not commensurate with the scope of the claims, which do not require uniformly compressing a cavity.

Based on the arguments and evidence of record, including the evidence and arguments discussed above in connection with Petitioner's challenge to claims 1–12 as anticipated by Valley (*see supra* Section II.B), we conclude that Petitioner has shown by a preponderance of the evidence that Valley renders obvious claims 1–12 in view of the knowledge of a person of ordinary skill in the art.

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

Petitioner challenges claims 1–12 as obvious over Reiley and Anderson. Upon review of the arguments and evidence presented by the parties, we determine that Petitioner has *not* shown by a preponderance of the evidence that claims 1–12 would have been obvious over Reiley and Andersen.

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.

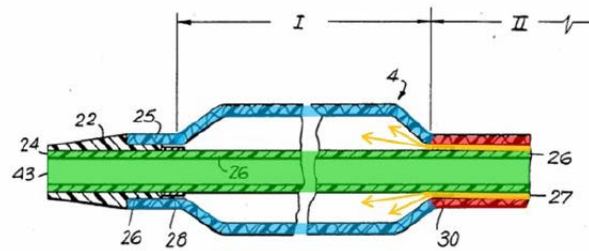


FIG. 4a

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). Petitioner asserts that “Figure 4a shows the inflatable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube.” *Id.* (citing Ex. 1002 ¶¶ 105, 108).

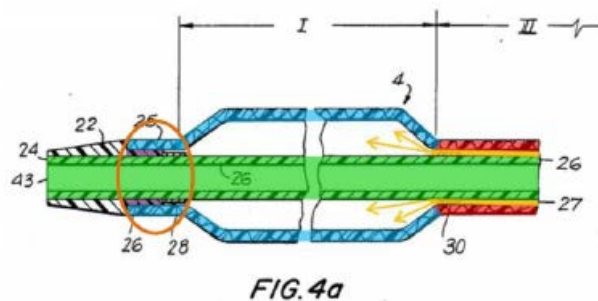
2. Analysis

Petitioner argues that Anderson discloses the limitations of independent claims 1, 5, and 9. Pet. 44. In particular, Petitioner argues that the portion of the outer tubing shown in red (in colorized Figure 4a above) corresponds to “an outer catheter tube having *a distal end* (emphasis added),” as recited in the claims. *Id.* at 34. Petitioner also argues that the

inflatable balloon portion (shown in blue) corresponds to “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” (emphasis added), as recited in the claims. *Id.* at 35.

Patent Owner contends that Petitioner erroneously depicts the outer catheter tube (shown in red) as having a distal end that is coterminous with the proximal end of the balloon portion (shown in blue). PO Resp. 25. Patent Owner argues that Anderson itself “treats the balloon as part of the outer catheter tube and therefore actually has the distal end of the outer catheter tube extending past the balloon—to the ‘left’ of the balloon in Fig. 4a.” *Id.* (citing Ex. 2018 ¶¶ 32–35). Patent Owner further argues: “Thus, the distal end of the outer catheter tube is NOT in the position shown by Mr. Sheehan (Ex. 1002, claim chart at ¶ 108) in red, but at position 25 in FIG. 4(a).” *Id.* at 26–27.

In the Reply, Petitioner provides a second colored version of Figure 4a. Pet. Reply 21. Petitioner’s second colored Figure 4a is reproduced below:



Petitioner argues, referencing the figure above, that “Andersen depicts an inflatable structure (blue) extending outside and beyond the outer catheter tube (red).” *Id.* Petitioner further argues that the blue area circled in orange is a part of the balloon portion, as evidenced by Anderson’s disclosure that “[a]n inflatable balloon portion is formed at the distal end of the outer tubing and is anchored to the distal end of the inner tubing.” *Id.* at 21–22 (citing Ex. 1005, 2:19–23; Ex. 1002 ¶¶ 105, 108; Ex. 1041 ¶¶ 18–21). Petitioner also relies on Anderson’s disclosure that “[n]eck 26 [shown in purple in the second colorized figure above] is sealed to the distal end of the balloon portion I of the shaft 4.” *Id.* at 22 (citing Ex. 1005, 5:26–34; Ex. 1002 ¶¶ 105, 108; Ex. 1041 ¶ 21).

We have considered all of Petitioner’s arguments, but conclude that Petitioner has not shown sufficiently that Anderson teaches an inflatable balloon structure that extends “outside and beyond the outer catheter tube,” as required by independent claims 1, 5, and 9. As Patent Owner argues, Anderson divides the length of catheter shaft 4 into three portions, including “balloon portion I” and “movable shaft portion II,”⁹ which are identified as elements “I” and “II” in Figure 4a. *See* PO Resp. 28; Ex. 1005, 4:53–56, Fig. 4a. Even assuming, as Petitioner argues, that Anderson teaches that balloon portion I can extend into the blue area circled in orange on Petitioner’s second colorized Figure 4a, the balloon portion still would be a

⁹ Anderson discloses that the balloon and other portions of the outer tubing are divided into segments that exhibit different behavior when the catheter is internally pressurized, such that a balloon portion becomes shorter in length and a moving portion becomes larger. Ex. 1005, 2:22–29.

part of catheter shaft 4 and, as such, would not extend outside and beyond catheter shaft 4, as the claims require.

In a footnote in the Reply, Petitioner argues that even if Andersen does not disclose an inflatable structure extending outside and beyond the outer catheter tube, “Reiley discloses balloon catheters where the inflatable structure extends outside and beyond the outer catheter tube,” and a skilled artisan “would have known how to integrate” Anderson’s coaxial catheter design with the balloon catheters disclosed in Reiley. Pet. Reply 23 n.15 (citing Ex. 1006 at Figs. 1–4, 6, 8, 10, 12, 15; Ex. 1041 ¶ 25). Petitioner’s argument is beyond the scope of a proper reply. *See* 37 C.F.R. § 42.23(b) (“A reply may only respond to arguments raised in the corresponding opposition or patent owner response.”). Moreover, Petitioner’s new argument does not provide articulated reasoning with rational underpinning sufficient to support a legal conclusion of obviousness. *See KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In particular, Petitioner has not articulated *any reason* why a skilled person would have integrated Anderson’s coaxial catheter design with a known balloon catheter where the inflatable structure extends outside and beyond the outer catheter tube.

For the reasons given, we conclude that Petitioner has *not* shown by a preponderance of the evidence that independent claims 1, 5, and 9 would have been obvious over Reiley and Andersen. In arguing that dependent claims 2–4, 6–8, and 10–12 would have been obvious over Reiley and Andersen, Petitioner does not present any additional arguments with respect to the limitations of the independent claims. Pet. 41–47; Ex. 1002 ¶¶ 102–

109. Accordingly, for the same reasons as discussed above in connection with the independent claims, Petitioner has *not* shown by a preponderance of the evidence that dependent claims 2–4, 6–8, and 10–12 would have been obvious over Reiley and Andersen.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–12 are unpatentable.

III. ORDER

In view of the foregoing, it is hereby:

ORDERED that claims 1–12 of U.S. Patent No. 6,623,505 B2 are unpatentable.

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.

IPR2014-01519
Patent 6,623,505 B2

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