

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION,
Petitioner,

v.

ORTHOPHOENIX, LLC,
Patent Owner.

Case IPR2014-01535
Patent 6,280,456 B1

Before RICHARD E. RICE, SHERIDAN K. SNEDDEN, and
TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Stryker Corporation (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–10 of U.S. Patent No. 6,280,456 B1 (Ex. 1001, “the ’456 patent”). Paper 1 (“Pet.”). Orthophoenix, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 5 (“Prelim. Resp.”). On February 25, 2015, we instituted an *inter partes* review of claims 1–3 and 6–10. Paper 6 (“Dec. Inst.”), 12. Patent Owner filed a Response to the Petition. Paper 13 (“PO Resp.”). And Petitioner filed a Reply to Patent Owner’s Response. Paper 16 (“Pet. Reply”).

Patent Owner filed Observations on the cross-examination of Petitioner’s declarant, Neil J. Sheehan. Paper 18. Petitioner filed a Response to Patent Owner’s Observations. Paper 23.

A consolidated oral hearing for this proceeding and case IPR2014-01519 was held on November 4, 2015. A transcript of the hearing has been entered in the record. Paper 25 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3 and 6–10 are unpatentable.

A. *Related Proceedings*

The parties state that the ’456 patent is asserted in the copending district court case, *Orthophoenix, LLC v. Stryker Corp.*, No. 13-1628-LPS (D. Del.). Pet. 1; Paper 3, 2. Petitioner also states that it filed a petition for *inter partes* review of related U.S. Patent No. 6,623,505. Pet. 1 (referring to *Stryker Corp. v. Orthophoenix, LLC*, IPR2014-01519 (PTAB)).

B. The '456 Patent (Ex. 1001)

The '456 patent relates to a method for treating bone using a tool with an expandable structure. Ex. 1001, Abstract. Figure 19, reproduced below, depicts one embodiment of the tool:

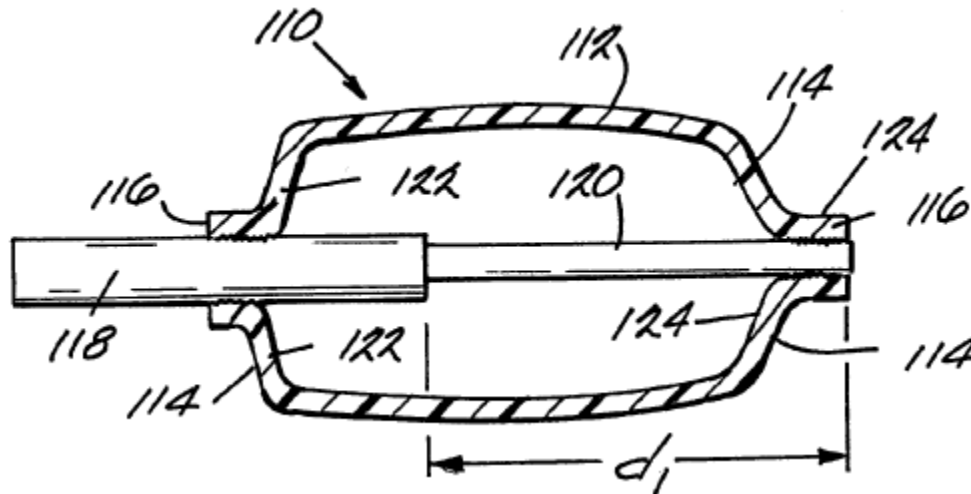


Figure 19 shows a tool comprising a two-piece catheter tube comprising outer catheter tube 118 and inner catheter tube 120. *Id.* at 10:21–27. Inner catheter tube 120 slides within outer catheter tube 118. *Id.* at 10:27–28. Proximal end 122 of tubular structure 110 is bonded to the distal end of outer catheter tube 118, and distal end 124 of tubular structure 110 is bonded to the distal end of inner catheter tube 120. *Id.* at 10:34–38. Thus, the distal end region of the inner catheter is enclosed within the expandable structure. *Id.* at 2:4–5.

C. Illustrative Claim

We instituted an *inter partes* review of claims 1–3 and 6–10 of the '456 patent. Claim 1, the only independent claim, is illustrative and is reproduced below:

1. A method for treating bone comprising the steps of providing a tool comprising an outer catheter tube having a distal end, an inner catheter tube extending within the outer

catheter tube and having a distal end region that extends beyond the distal end of the outer catheter tube, and an expandable structure having a proximal end secured to the distal end of the outer catheter tube and a distal end secured to the distal end region of the inner catheter tube, whereby the distal end region of the inner catheter tube is enclosed within the expandable structure,

manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry, and

causing the expandable structure to assume an expanded geometry inside bone.

D. Ground of Unpatentability Instituted for Trial

We instituted trial based on the following ground of unpatentability:

References	Basis	Claims challenged
Reiley ¹ and Valley ²	§ 103	1–3 and 6–10

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. *See In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 84 U.S.L.W. 3218 (U.S. Jan. 15, 2016) (No. 15-446); 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the

¹ Reiley et al., WO 95/20362, published Aug. 3, 1995 (Ex. 1004).

² Valley et al., US 5,766,151, issued June 16, 1998 (Ex. 1006).

time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

In our Decision on Institution, we determined that the broadest reasonable construction of the term “cavity” in claim 3 is “a space.” Dec. Inst. 5. Because nothing in the full record developed during trial persuades us to deviate from our prior construction, we adopt our prior construction for purposes of this Decision.

B. Principles of Law

To prevail in this *inter partes* review of the challenged claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the

relevant field to combine elements in the way the claimed new invention does.” *Id.* Moreover, a person of ordinary skill in the art must have had a reasonable expectation of success of doing so. *PAR Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

We analyze the instituted ground of unpatentability in accordance with the above-stated principles.

C. Obviousness over Reiley (Ex. 1004) and Valley (Ex. 1006)

Relying on the testimony of Mr. Sheehan, Petitioner asserts that claims 1–3 and 6–10 are unpatentable as obvious over Reiley and Valley. Pet. 41–49; Ex. 1002 ¶¶ 84–91. Patent Owner opposes Petitioner’s challenge, relying on the Declaration of Gamal Baroud, Ph.D. PO Resp. 9–17; Ex. 2018 ¶¶ 19–32.

i. Reiley

Reiley describes an inflatable device for use in treating bone conditions. Ex. 1004, 1. According to Reiley, prior art methods disclosed balloon devices that are inserted into bone and inflated in the bone, compacting the cancellous bone to enlarge the cavity in the bone. *Id.* at 2. A flowable biocompatible filling material is then directed to the cavity and allowed to harden to provide structural support for the bone. *Id.* Reiley states that while prior art methods are adequate for the fixation of bone, it has been found that the compacting of the 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 2–3. As such, Reiley states, “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.

ii. Valley

Valley relates to a catheter-based system for isolating the heart and coronary blood vessels of a surgical patient from the rest of the arterial system, and for infusing a cardioplegic agent into the coronary arteries to induce cardioplegic arrest in the heart. Ex. 1006, 1:42–47. Figure 8A shows one embodiment of Valley and is reproduced (in part) below:

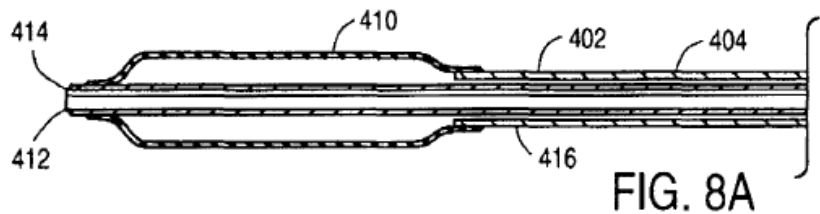


Figure 8A illustrates a catheter in which inner tube 402 and outer tube 404 are axially movable with respect to one another. *Id.* at 24:27–30. As seen in Figure 8A, the proximal end of balloon 410 is attached to the distal end of outer tube 404, and the distal end of balloon 410 is attached to the distal end of inner tube 402. *Id.*, Fig. 8A; *see also id.* at 26:7–13 (describing similar configuration in Figures 9A and 9B).

iii. Analysis

We have reviewed the arguments and evidence presented by both parties, and we are persuaded that Petitioner has shown by a preponderance of the evidence that the challenged claims are unpatentable as obvious over Reiley and Valley.

First, we are persuaded that Petitioner—through claim charts and the testimony of Mr. Sheehan—has shown sufficiently that the combination of Reiley and Valley teach or suggest each limitation of the challenged claims. *See* Pet. 41–49; Ex. 1002 ¶¶ 85, 90 (claim charts). For example, regarding claim 1, Reiley teaches an inflatable balloon-like device for use in treating bone conditions. Ex. 1004, 1:7–11; Pet. 45. Moreover, the coaxial balloon

catheter structure provided in the method of claim 1 is taught by Figure 8A of Valley. Ex. 1006, Fig. 8A; Pet. 45–46. Finally, Reiley teaches the last two steps of introducing the balloon into bone while collapsed and then causing the balloon to expand inside bone. Ex. 1004, 18:26–19:6; Pet. 46.

We are also persuaded that Petitioner has shown sufficiently that a person of ordinary skill in the art would have had a reason to modify Reiley’s method for treating bone using a balloon catheter by using Valley’s coaxial balloon catheter design in the manner recited in the claims. As Mr. Sheehan states, Reiley teaches that a “particular improvement in the catheter art with respect to this patent, namely U.S. Patent 4,706,670 [Anderson], is the use of a coaxial catheter with inner and outer tubing formed and reinforced by continuous helical filaments.” Ex. 1004, 4:21–25; Ex. 1002 ¶¶ 72, 79, 88. Reiley also points to Anderson for examples of restraints that can be used to make the claimed balloons. Ex. 1004, 10:12–14 (“The restraints can be made of a flexible, inelastic high tensile strength material including, but not limited to, those described in U.S. Patent 4,706,670.”); *see also* Ex. 1002 ¶¶ 72, 79, 88. Thus, in light of Reiley’s references to Andersen’s cardiac balloon catheter, we credit Mr. Sheehan’s testimony stating that a person of ordinary skill in the art “would understand that Reiley provides a specific reason, basis, or motivation to combine Reiley with Valley because Valley has a balloon catheter very similar to Andersen, namely a balloon catheter with the claimed inner and outer tubing arrangement.” Ex. 1002 ¶ 88.

In its Response, Patent Owner does not dispute that the combination of Reiley and Valley teaches or suggests each limitation of the claims. Patent Owner does argue, however, that Reiley and Valley “are not

combinable” for several reasons. PO Resp. 1. We address each argument in turn.

As an initial matter, Patent Owner challenges the credibility of Petitioner’s declarant, Mr. Sheehan, because he admitted during cross-examination that he has never designed a balloon catheter device for bone. *Id.* at 9–10. Although Mr. Sheehan has not designed a balloon catheter for use in bone, we find Mr. Sheehan has sufficient experience with designing balloon catheters for use in other body regions to opine on the obviousness of the challenged claims of the ’456 patent. *See* Ex. 2017, 9:13–10:14. We further note that although he has tested balloon catheters in bone, Patent Owner’s declarant, Dr. Baroud, testified that he has never designed a balloon catheter for use in bone, either. Ex. 1040, 96:5–19.

Regarding the combination of Valley and Reiley, Patent Owner argues that combining the references would “change the fundamental principle of operation of Valley as it is designed to work only in the cardiovascular system at low pressure, not in bone at comparatively higher pressures.” PO Resp. at 9. Specifically, Patent Owner argues that the peak inflation pressure of the Valley balloon is 35 psi, which is insufficient to compress cancellous bone effectively. *Id.* at 11 (citing Ex. 1006, 21:1–4; Ex. 2018 ¶¶ 19–21).

We are not persuaded by Patent Owner’s argument. That Valley describes a balloon for a cardiovascular system and not bone does not remove Valley from consideration by a person of ordinary skill in the art. Rather, we credit the testimony of Mr. Sheehan that a person of ordinary skill in the art would have routinely looked to cardiovascular balloons when designing balloon catheters for bone. Ex. 1002 ¶ 28 (“A person of ordinary skill in the art looking to design a balloon catheter for bone applications

would consider both bone and vasculature related prior art.”); *see also id.* ¶ 29 (“It was not uncommon for practitioners and inventors to look at angioplasty balloon catheters to solve problems related to the treatment of bone.”) (citing references). We further find that Reiley’s citations to the cardiovascular coaxial balloon catheter of Andersen (US 4,706,670, Ex. 1005) is evidence that a person of ordinary skill in the art would have looked to cardiovascular balloons (like Valley) when designing balloon catheters for bone. Ex. 1004, 4:21–25, 10:12–14.

Patent Owner also argues that Reiley teaches away from using prior art balloon catheter designs for bone. PO Resp. 13. Specifically, Patent Owner cites the statement in Reiley that the prior art

does not teach the shape of the balloon which creates a cavity that best supports the bone when appropriately filled. It does not teach how to prevent balloons from being spherical when inflated, when this is desired. Current medical balloons can compress bone but are too small and generally have the wrong configuration and are generally not strong enough to accomplish adequate cavity formation in either the vertebral bodies or long bones of the body.

Ex. 1004, 5:25–33. Patent Owner then argues that although Reiley specifically refers to Andersen, Andersen “cannot create a cavity which allows for near uniform compaction of the cancellous bone, that best supports the bone, as required by the ’505 [sic, ’456] patent.” PO Resp. 14 (citing Ex. 1001, 10:51–59).

“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). For a reference to teach away, however, it must state more

than a general preference for an alternative invention—it must “‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)).

We are not persuaded that Reiley’s criticism of the prior art catheters amounts to teaching away, as Patent Owner suggests. As Petitioner notes, Reiley states that “[a] particular improvement in the catheter art with respect to this patent, namely [Andersen], is the use of a coaxial catheter with inner and outer tubing formed and reinforced by continuous helical filaments.” Ex. 1004, 4:21–25; Pet. 43–44. Petitioner also notes that Reiley states that “[c]urrent medical balloons can compress bone.” Pet. 29 (citing Ex. 1004, 5). Reiley continues, however, stating that such balloons are “too small and generally have the wrong configuration and are generally not strong enough to accomplish adequate cavity formation in either the vertebral bodies or long bones of the body.” Ex. 1004, 5:29–33. But this statement, that current balloons *generally* have the wrong configuration and *generally* are not strong enough to form cavities, does not amount to teaching away from the claimed invention. On the contrary, according to Mr. Sheehan, a person of ordinary skill in the art would “understand that Reiley provides a specific reason, basis, or motivation to combine Reiley with Valley because Valley has a balloon catheter very similar to Andersen, namely a balloon catheter with the claimed inner and outer tubing arrangement.” Ex. 1002 ¶ 88.

We are also not persuaded that combining Valley and Reiley would “require substantial reconstruction and redesign of the elements” in the prior art or cause a “change in the basic principles” in which the prior art was designed to operate. See PO Resp. 17 (quoting *In re Ratti*, 270 F.2d 810,

813 (CCPA 1959)). Patent Owner has not explained sufficiently what substantial reconstruction or redesign of elements would be required in Valley that would allegedly change Valley's basic principles of operation. To the extent Patent Owner argues that the balloon in Valley would need to be redesigned to create a cavity that "allows for relatively uniform compaction of the cancellous bone" (PO Resp. 12), we are not persuaded, because the claims do not require uniform compaction.

And to the extent Patent Owner argues that applying the balloon in Valley to bone would cause a change in Valley's basic principle of operation in vasculature, we are not persuaded because, as stated above, a person of ordinary skill in the art would understand that balloons designed for use in the vasculature could be used to compress bone. Ex. 1002 ¶ 30; Ex. 1004, 5:29–33 (stating "[c]urrent medical balloons can compress bone"). Moreover, the range of pressures required to compact cancellous bone and form cavities appears to vary widely. Ex. 1041 ¶ 4 (citing references reporting balloon-assisted compression of bone at 50 and 70 psi). Indeed, Patent Owner's declarant, Dr. Baroud, testified that that pressure can hypothetically be as low as 45 psi. Ex. 1040, 90:7–12. Furthermore, Dr. Baroud testified that the Valley balloon is capable of operating at pressures of 250 psi. Ex. 1040, 141:16–23. Thus, we are not persuaded by Patent Owner's argument that modifying Valley to compress bone would change Valley's principle of operation, as it appears Valley is capable of compressing bone. Ex. 1041 ¶ 3.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Reiley and Valley teaches the subject matter of claim 1, 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. Patent Owner does not assert separate arguments for dependent claims 2, 3, and 6–10. Having considered Petitioner’s arguments and the testimony of Mr. Sheehan, we are persuaded that Petitioner has shown by a preponderance of the evidence that those claims are unpatentable as obvious over the combination of Reiley and Valley, as well. *See* Pet. 46–49; Ex. 1002 ¶¶ 84–91.

III. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–3 and 6–10 of the ’456 patent are unpatentable under 35 U.S.C. § 103.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3 and 6–10 of the ’456 patent have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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