

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*.

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

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.”).

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). Upon considering the Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–10. Accordingly, we institute an *inter partes* review of those claims.

A. *Related Proceedings*

Petitioner states that Patent Owner asserted the ’456 patent against it in the copending district court case, *Orthophoenix, LLC v. Stryker Corp.*, No. 13-1628-LPS (D. Del.). Pet. 1. Petitioner also states that it filed a petition for *inter partes* review of related U.S. Patent No. 6,623,505. *Id.* (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:

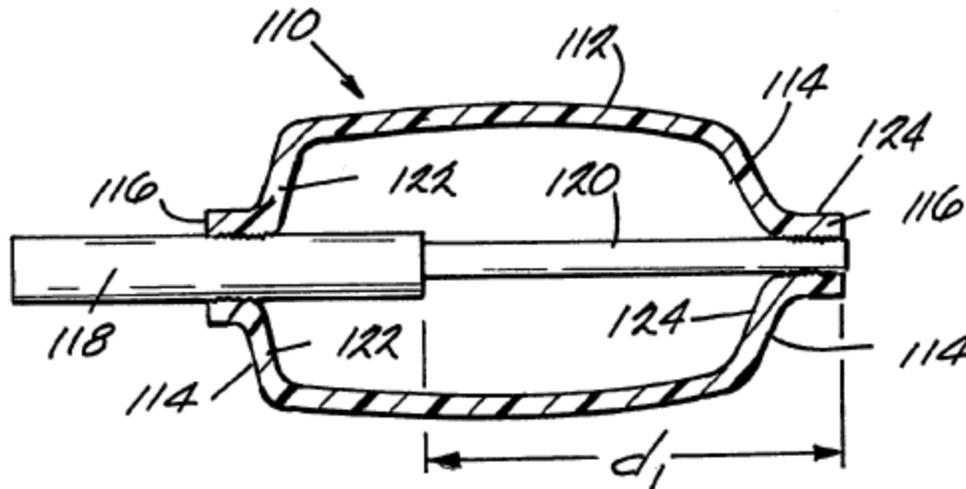


Figure 19 shows a tool comprising a two-piece catheter tube comprising outer catheter tube 118 and inner catheter tube 120. *Id.* at 10:21–27. Inner catheter tube 120 slides within outer catheter tube 118. *Id.* at 10:27–28. Proximal end 122 of tubular structure 110 is bonded to the distal end of outer 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

Petitioner challenges claims 1–10 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. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–10 of the '456 patent on the following grounds (Pet. 17–57):

References	Basis	Claims challenged
Pathak ¹	§ 102(b)	1–4
Pathak and Reiley ²	§ 103	1–7
Reiley and Andersen ³	§ 103	1–7, 9, and 10
Reiley and Valley ⁴	§ 103	1–10
Reiley and Antoshkiw ⁵	§ 103	1–8

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*, No. 2014-1301, 2015 WL 448667, at *5–*8 (Fed. Cir. Feb. 4, 2015); 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary

¹ Pathak et al., WO 94/24962, published Nov. 10, 1994 (Ex. 1003).

² Reiley et al., WO 95/20362, published Aug. 3, 1995 (Ex. 1004).

³ Andersen et al., US 4,706,670, issued Nov. 17, 1987 (Ex. 1005).

⁴ Valley et al., US 5,766,151, issued June 16, 1998 (Ex. 1006).

⁵ Antoshkiw et al., US 4,024,873, issued May 24, 1977 (Ex. 1007).

meaning, as would be understood by one of ordinary skill in the art at the 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).

i. “cavity”

The term “cavity” appears in claims 3 and 4. Petitioner does not propose an express construction for the term. Patent Owner asserts that the term should be construed to mean “a space created by expansion of an expandable structure.” Prelim. Resp. 13. Patent Owner’s construction, however, is redundant of the language of claim 3, which recites that “the expandable structure compacts cancellous bone and forms a cavity.” Thus, claim 3 already states that the cavity is formed by expansion of the expandable structure. We, therefore, determine that the broadest reasonable construction consistent with the Specification of the term “cavity” is “a space.” *See Ex. 1001, 2:12–14.*

Claim 4 requires the additional step of “convey [sic] material into *the cavity.*” As Petitioner notes, however, the term “cavity” in claim 4 (and therefore claim 5, which depends from claim 4) lacks antecedent basis in claim 1. Pet. 16–17. Patent Owner does not address the antecedent basis issue in its Preliminary Response.

Based on this record, we agree with Petitioner that claims 4 and 5 lack antecedent basis for the term “the cavity.” Although it appears likely that claim 4 should depend from claim 3, which recites “a cavity,” we are not inclined to correct any alleged substantive errors in the claims in this *inter partes* review proceeding. Because it is unclear what “cavity” claims 4 and

5 are referring to, we exercise our discretion and decline to evaluate claims 4 and 5 further.

ii. Remaining Claim Terms

We determine that, for purposes of this Decision, none of the other terms in the challenged claims requires express construction at this time.

B. Anticipation by Pathak (Ex. 1003)

Petitioner asserts that Pathak anticipates claims 1–4 of the '456 patent. Pet. 17–25. We determine, on the current record, that Petitioner has not established a reasonable likelihood that it would prevail in showing that Pathak anticipates any of those claims.

i. Pathak

Pathak relates to devices for intraluminal implantation of polymeric materials. Ex. 1003, 1. Pathak teaches various proposed uses of such materials, such as alteration of tissue and the creation of lumens for the passage of fluids. *Id.* Figure 2A depicts an embodiment of the Pathak device and is reproduced (in part without hub assembly 27) below:

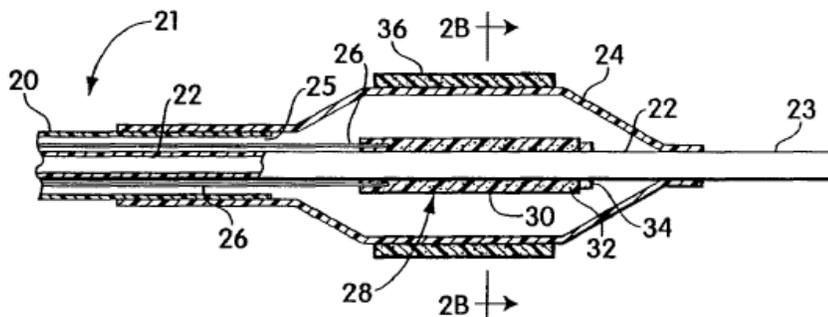


Figure 2A depicts device 21, which comprises outer elongated flexible tube 20 and inner elongated flexible tube 22 within the lumen of outer tube 20. *Id.* at 21. Distal end 23 of inner tube 22 extends distally beyond the distal end of outer tube 20. Pathak further states, “a radially

expandable, inflatable balloon 24 is mounted on the distal end of the device such that the proximal end of the balloon 24 is secured near the distal end of the outer tube, and the distal end of the balloon is secured near the distal end of the inner tube.” *Id.*

ii. Analysis

Petitioner asserts that Pathak anticipates claims 1–4. As support, Petitioner submits the testimony of Dr. Neil J. Sheehan. Ex. 1002.

Independent claim 1 requires the use of a tool with 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.” Petitioner asserts that the catheter configuration of Figure 2A teaches this limitation. Pet. 21; Ex. 1002 ¶ 61.

We are not persuaded. As Petitioner notes, Pathak states that “the distal end of the balloon is secured *near* the distal end of the inner tube.” Pet. 21 (quoting Ex. 1003, 21) (emphasis added). Claim 1, however, requires that the distal end of the balloon (i.e., expandable structure) be “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.” Thus, securing the balloon *near* the distal ends of the inner tube does not teach securing the balloon *to* the distal end of the inner tube. Moreover, Figure 2A—relied upon by Petitioner—shows that the distal end region of the inner catheter tube (i.e., item 23) is protruding from the distal end of the balloon, and is not “enclosed within the expandable structure,” as required by the claim.

Accordingly, based on the record, we conclude that Petitioner has failed to establish a reasonable likelihood that it would prevail in showing that Pathak anticipates claim 1. For the same reasons, we determine that Petitioner has not made a sufficient showing as to dependent claims 2–4, either.

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

Relying on the testimony of Dr. Sheehan, Petitioner asserts that claims 1–10 are unpatentable as obvious over Reiley and Valley. Pet. 41–49. We determine, on the current record, that Petitioner has established a reasonable likelihood that it would prevail on this assertion as to each of the claims, except claims 4 and 5 due to the lack of antecedent basis, as explained above.

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 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:

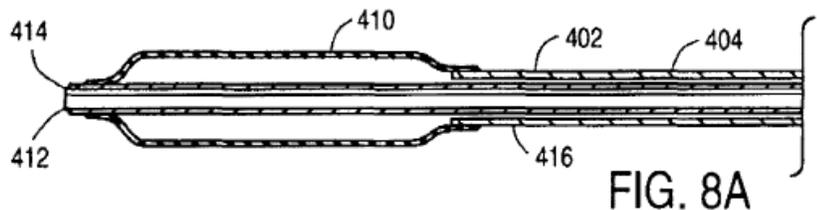


Figure 8A illustrates a catheter in which inner tube 402 and outer tube 404 are axially movable with respect to one another. *Id.* at 24:27–30. As seen in Figure 8A, the proximal end of balloon 410 is attached to the distal end of outer tube 404, and the distal end of balloon 410 is attached to the distal 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

On the current record, we are persuaded that Petitioner—through the claim chart and testimony of Dr. Sheehan—has shown sufficiently that the combination of Reiley and Valley teach or suggest each limitation of claim 1. *See* Pet. 41–46. We also note that, at this stage of the proceeding, Patent Owner has not asserted otherwise.

Patent Owner does argue, however, that there is no apparent reason for a person of ordinary skill in the art to combine Reiley and Valley with a reasonable expectation of success. Prelim. Resp. 36–37. Specifically, Patent Owner asserts that balloons for bone (as disclosed in Reiley) are structurally different than those used in the vascular system (as disclosed in

Valley), and that balloons for vascular devices would not be expected to work in bone. Prelim. Resp. 36–37. Moreover, Patent Owner argues that Reiley teaches away from making the combination. *Id.* at 37.

At this stage of the proceeding, we are not persuaded by Patent Owner’s argument. “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)).

On the current record, we are not persuaded that Reiley criticizes the prior art catheters, as Patent Owner suggests. As Petitioner notes, Reiley states “[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.” Pet. 43–44 (citing Ex. 1004, 4). Petitioner also notes that Reiley states that “[c]urrent medical balloons can compress bone.” Pet. 29 (citing Ex. 1004, 5). 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 in either the vertebral bodies or long bones of the body,” this generic statement does not amount to teaching away from the claimed invention. On the contrary, according to Petitioner’s declarant, 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.

Patent Owner also argues that secondary considerations, such as commercial success, weigh in favor of showing the claims are not unpatentable as obvious. Prelim. Resp. 39–40. On the current record, we are not persuaded by Patent Owner’s argument. To rely on secondary considerations, Patent Owner must establish a nexus between the claimed invention and, for example, the commercial success. *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*.”) (citation omitted). At this stage of the proceeding, however, Patent Owner has not established that, for example, the sale of Kyphon, Inc. to Medtronic was due to the merits of the claimed invention.

Thus, based on the current record, Petitioner has shown sufficiently 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. We have also considered the arguments and evidence as to claims 2, 3, and 6–10, and determine that Petitioner has made a sufficient showing as to those claims, as well. Pet. 46–49; Ex. 1002 ¶¶ 84–91. Accordingly, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 1–3 and 6–10 are unpatentable as obvious over Reiley and Valley.

D. Remaining Challenges

Petitioner also asserts that the challenged claims of the '456 patent are unpatentable as obvious over Pathak and Reiley, Reiley and Andersen, and Reiley and Antoshkiw. Pet. 25–41, 49–56. In light of our findings above with respect to Reiley and Valley, we exercise our discretion not to institute an *inter partes* review on these asserted grounds. See 37 C.F.R. § 42.108(a).

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–3 and 6–10 of the '456 patent are unpatentable.

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

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. §314(a), an *inter partes* review is hereby instituted on the ground that claims 1–3 and 6–10 as obvious over Reiley and Valley.

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized.

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

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