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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAMES GAMMIE,
RAHUL PATEL, and MEHRDAD GHOREISHI

Appeal 2017-010538
Application 14/478,325
Technology Center 3700

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134 involving claims to a method for performing cardiac valve repairs. The Examiner rejected the claims as indefinite, lacking written description, anticipated, and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

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[1] Appellants identify the Real Parties in Interest as the University of Maryland, Baltimore and Harpoon Medical, Inc. (*see* App. Br. 3).

[2] We have considered and herein refer to the Specification of Sept. 5, 2014 ("Spec."); Final Office Action of Aug. 17, 2016 ("Final Act."); Appeal Brief of Mar. 21, 2017 ("App. Br."); Examiner's Answer of June 15, 2017 ("Ans."); and Reply Brief of Aug. 8, 2017 ("Reply Br.").

Statement of the Case

Background

The human heart includes two atrioventricular valves that separate the atria from the ventricles (Spec. ¶ 4). Valve regurgitation may occur when one or more valve leaflets prolapse "above the plane of coaptation" (Spec. ¶ 10). "This is the most common cause of mitral regurgitation, and is often caused by the stretching or rupturing of chordae tendinae normally connected to the leaflet" (*id.*). Leaflet sparing procedures "involve the implantation of sutures . . . so as to form artificial chordae in the valve" (*id.* ¶ 15). "[C]onventional methods currently being practiced for the implantation of the artificial chordae are particularly problematic. Because the conventional approach requires the heart to be stopped . . . it is difficult to accurately . . . secure the appropriate chordal length" (*id.* ¶ 17). The Specification teaches chordal replacement procedures, which do not require cardiac arrest and "ensure the appropriate chordal length and spacing so as to produce a competent valve" (*id.* ¶ 18).

The Claims

Claims 1–5, 7–9, 11, 12, and 16–32 are on appeal. Independent claim 1 is representative and reads as follows:

> 1. A method of repairing a prolapsed leaflet of a valve of a heart comprising:
>
> introducing into a ventricle of the heart a distal portion of a delivery system having a distal tip and carrying an artificial chordae having a distal portion and a proximal portion;
>
> disposing the distal tip of the delivery system in contact with a ventricular side of the leaflet;

while maintaining the entire distal portion of the delivery system on the ventricular side of the leaflet, extending from the distal tip of the delivery system a needle having a distal portion carrying the distal portion of the artificial chordae to pierce a prolapsed segment of the leaflet from the ventricular side of the leaflet to an atrial side of the leaflet to form an opening in the leaflet;

passing through the opening from the ventricular side to the atrial side the distal portion of the artificial chordae disposed in a first configuration, and with the proximal portion of the artificial chordae remaining on the ventricular side of the leaflet;

causing the distal portion of the artificial chordae to change from the first configuration to a second configuration, the second configuration being larger than the opening in the leaflet; and

securing the artificial chordae to an apex region of the heart to reduce prolapse of the leaflet.

The Issues

A. The Examiner rejected claims 26–32 under 35 U.S.C. § 112(pre-AIA), second paragraph as indefinite (Final Act. 3–4).

B. The Examiner rejected claims 18–23, 25,[3] 28, and 30 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement (Final Act. 2–3).

C. The Examiner rejected claims 1, 2, 7, 9, 11, 12, 25, and 29 under 35 U.S.C. § 102(b) as being anticipated by Alkhatib[4] (Final Act. 4–7).

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[3] While the Examiner inadvertently omitted claim 25 from the statement of rejection, claim 25 was included in the body of the rejection, so we consider the rejection to include this claim (*see* Final Act. 2–3).

[4] Alkhatib, US 2008/0228223 A1, published Sept. 18, 2008.

D. The Examiner rejected claims 1, 2, 9, 11, and 12 under 35 U.S.C. § 102(b) as being anticipated by Kudlik[5] (Final Act. 8–9).

E. The Examiner rejected claims 3, 8, 26, and 27 under 35 U.S.C. § 103(a) as obvious over Alkhatib or Kudlik, and DiMatteo[6] (Final Act. 9–13).

F. The Examiner rejected claims 18–20, 22, and 23 under 35 U.S.C. § 103(a) as obvious over Alkhatib and Allen[7] (Final Act. 15–17).

G. The Examiner rejected claim 24 under 35 U.S.C. § 103(a) as obvious over Alkhatib and Zlotnick[8] (Final Act. 14–15).

H. The Examiner rejected claims 4 and 5 under 35 U.S.C. § 103(a) as obvious over Alkhatib, DiMatteo, and Hart[9], or Kudlik, DiMatteo and Hart (Final Act. 13–14).

I. The Examiner rejected claim 16 under 35 U.S.C. § 103(a) as obvious over Alkhatib, Allen, and DiMatteo (Final Act. 17–18).

J. The Examiner rejected claim 17 under 35 U.S.C. § 103(a) as obvious over Alkhatib, Allen, DiMatteo, and Hart (Final Act. 18–20).

K. The Examiner rejected claim 21 under 35 U.S.C. § 103(a) as being obvious over Alkhatib, Allen, and Zlotnick (Final Act. 20).

L. The Examiner rejected claims 28 and 30 under 35 U.S.C. § 103(a) as being obvious over Alkhatib, DiMatteo, and Allen, or Kudlik, DiMatteo, and Allen (Final Act. 20–22).

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[5] Kudlik et al., US 2014/0031926 A1, published Jan. 30, 2014 (As the Examiner did, we also rely on provisional applications US 61/741,497 and US 61/473,873).
[6] DiMatteo et al., US 2011/0022083 A1, published Jan. 27, 2011.
[7] Allen et al., US 6,626,930 B1, issued Sept. 30, 2003.
[8] Zlotnick et al., US 2011/0029071 A1, published Feb. 3, 2011.
[9] Hart, US 5,626,614, issued May 6, 1997.

M. The Examiner rejected claims 31 and 32 under 35 U.S.C. § 103(a) as obvious over Alkhatib, DiMatteo, Allen, and Lattouf[10] (Final Act. 22).

A. 35 U.S.C. § 112, second paragraph

The Examiner finds claims 26, 30, and 31 indefinite for lacking antecedent basis (Final Act. 3–4). The Examiner finds claim 29 unclear for a second recitation of "a first perimeter" (*id.*). The Examiner finds "[n]o arguments were presented for the 35 U.S.C. [§] 112, second paragraph rejections" (Ans. 2).

Appellants failed to contest the indefiniteness rejections on appeal. "When the appellant fails to contest a ground of rejection to the Board . . . the Board may treat any argument with respect to that ground of rejection as waived. In the event of such a waiver, the PTO may affirm the rejection of the group of claims that the examiner rejected on that ground without considering the merits of those rejections." *Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008).

In the absence of Appellants' argument on indefiniteness, we consider the argument waived and summarily affirm the Examiner's rejection. *See* 37 C.F.R. § 41.37(c)(1)(iv) ("[A]ny arguments or authorities not included in the appeal brief will be refused consideration by the Board for purposes of the present appeal.").

B. 35 U.S.C. § 112, first paragraph

The Examiner finds:

[10] Lattouf et al., US 2008/0004597 A1, published Jan. 3, 2008.

> [A]ppellant's figs. 5–7 and 10–20 . . . do *not* show "while contacting the prolapsed leaflet *only* on the ventricular side of the prolapsed leaflet," "extending . . . the needle while contacting the prolapsed leaflet *only* on the ventricular side of the prolapsed leaflet," or "extending . . . the needle while applying a forward force against the ventricular side of the prolapsed leaflet.

(Ans. 2–3; emphasis in original).

Appellants respond that support for "*only with the ventricular side*" and "*only on the ventricular side*" "can [be] found throughout various embodiments in the Specification" in particular citing "at least paragraphs [0063]–[0068][11] and [0072] of the Specification in conjunction with FIGS. 5–7 and 12A–12C" (Reply Br. 2–3).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the claims fail to comply with the written description requirement?

Findings of Fact

1. Figure 7 of the Specification is reproduced below:

[11] Appellants' citations use the paragraph numbers of the published application corresponding to paragraphs 61–66 and 70 of the original Specification.

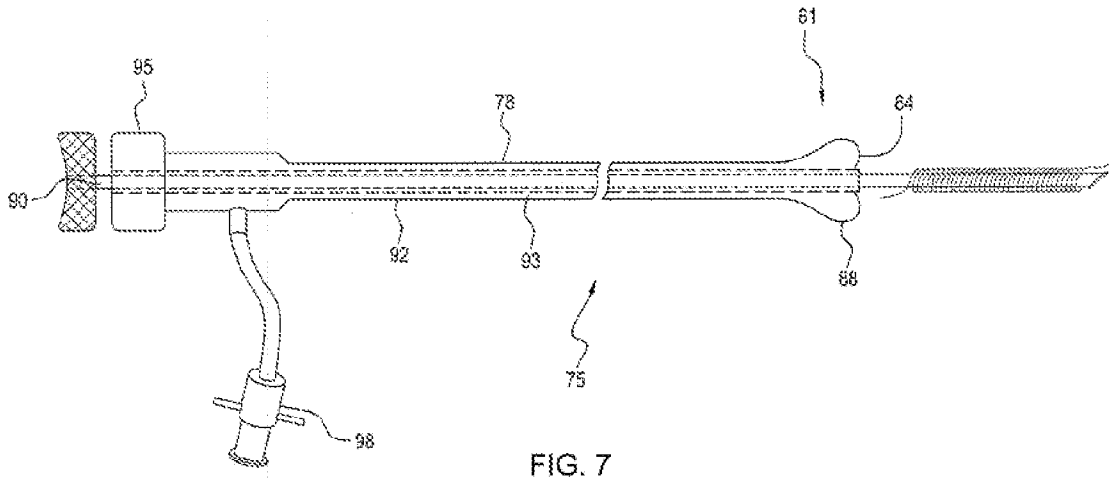

FIG. 7

Figure 7 shows instrument 75 with elongate member 78, distal portion 81, and tip 84, where "characteristics of the end surface of the tip 84 include ease of location on the leaflet, tendency to remain in one location, does not harm the leaflet by penetration, and can serve as a platform to deploy one or more needle" (Spec. ¶ 66).

2. Figure 5 of the Specification is reproduced below:

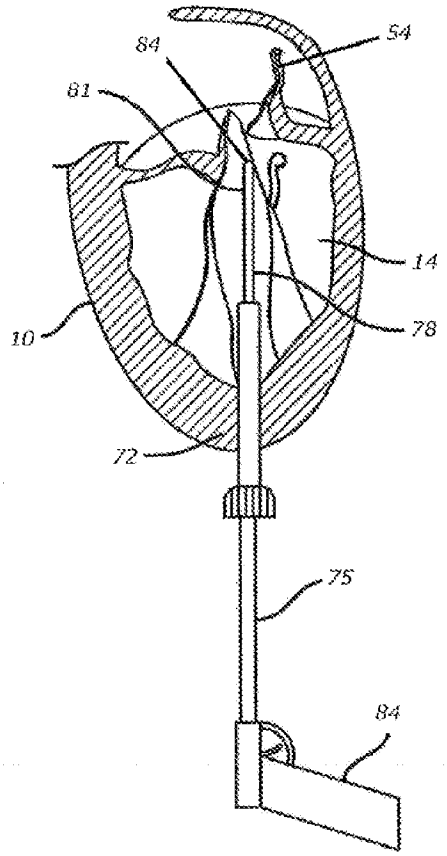

FIG. 5

Figure 5 illustrates instrument 75 that is introduced through the heart apex 72 into ventricle 14 "and advanced in such a manner so as to contact . . . a leaflet" (Spec. ¶ 61).

3. The Specification teaches "[a] suitable instrument 75 . . . will typically include an elongate member 78 with a functional distal portion 81 having a tip 84 configured for repairing a cardiac valve tissue, for instance, a mitral valve leaflet 52, 54" (Spec. ¶ 62).

4. The Specification teaches "[w]hile a smaller seating surface enables the tip 84 to be more easily localized, it may be more likely to

perforate the leaflet. . . . [T]he delivery system may have a blunt end, to avoid pushing the entire device through the leaflet" (Spec. ¶ 64).

5. Figures 12a–12c of the Specification are reproduced below:

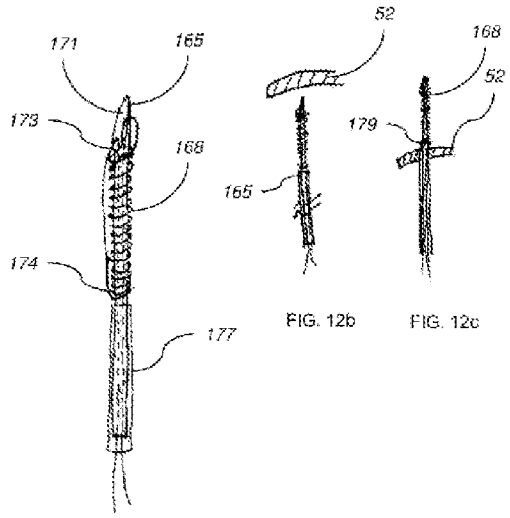

FIG. 12a FIG. 12b FIG. 12c

Figure 12a shows "needle 165 [with] a suture 168 tightly wrapped around one end. . . . [I]n Figure 12b, the wrapped needle 165 is inserted into the heart toward the mitral valve leaflet 52 . . . [and] advanced across the mitral valve leaflet 52 . . . in Figure 12c." (Spec. ¶ 70).

Principles of Law

"[I]t is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010)

Analysis

Claims 18–23, 28, and 30

We agree with the Examiner that the claims contain subject matter that was not described in the Specification in such a way as to convey possession of the claimed invention. Final Act. 2. None of the Figures cited by the Appellants, or the accompanying descriptive text, disclose an "embodiment of contacting *only* the ventricle side" (Ans. 3). Figures 5–7 and 12A–12C do not show the distal tip of the delivery device contacting a leaflet (*see* FF 1, 2, and 5). As admitted by Appellants, "FIG. 12 omits the distal tip of the delivery system for ease of explanation of the needle 165 and anchor deployment" (Reply Br. 4). Likewise, the Specification describes contacting the leaflet from the ventricular side, but does not support the newly added "only" claim limitations. Although Appellants argue that "the concept . . . (1) is central to the solution to problems associated with conventional approaches and (2) fulfils the 'need for new procedures and devices for performing cardiac valve repairs'" (Reply Br. 3), Appellants provide no evidence based on the Specification supporting these statements. At best, use of the term "only" is an obvious alternative that is not described by the original Specification, and therefore does not satisfy the written description requirement.

Claim 25

Appellants did not contest the rejection of claim 25 on appeal. In the absence of Appellants' argument on claim 25, we consider the argument waived and affirm the Examiner's written description rejection of claim 25.

Conclusions of Law

The evidence of record supports the Examiner's conclusion that claims 18–23, 25, 28, and 30 represent new matter.

C. 35 U.S.C. § 102(b) over Alkhatib

The Examiner finds:

> Alkhatib discloses a method of repairing a prolapsed leaflet of a valve of a heart (abstract; paragraph 95) comprised of introducing into a ventricle of the heart (Fig. 1; paragraph 48) a distal *portion* (Fig. 25A []) of a delivery system **30a** having a distal tip (Figs. 1, 25A- see distal end of **30a**), and carrying an artificial chordae 130, 132, 138 (Figs. 23, 24, 25A-29) having a distal and proximal portion (Figs. 23, 24, 25A-29); disposing the distal tip of the delivery system 30a in contact with a ventricular side of the leaflet (Fig. 25A); while maintaining the entire distal *portion* (Figs. 25A, B) of the delivery system on the ventricular side of the leaflet (paragraph 74) extending from the distal tip a needle 140 having a distal portion carrying the distal portion of the artificial chordae to pierce a prolapsed segment of the leaflet from a ventricular side to an atrial side (Figs. 25A-25C) to form an opening in the leaflet.

(Final Act. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Alkhatib anticipates claims 1 and 29?

Findings of Fact

6. Alkhatib teaches a heart valve leaflet tether attaching apparatus with a shaft that is inserted "through the apex of the patient's heart to extend up through the left or right ventricle to the patient's heart valve to be repaired" (¶ 48).

7. Figure 25A of Alkhatib is reproduced below:

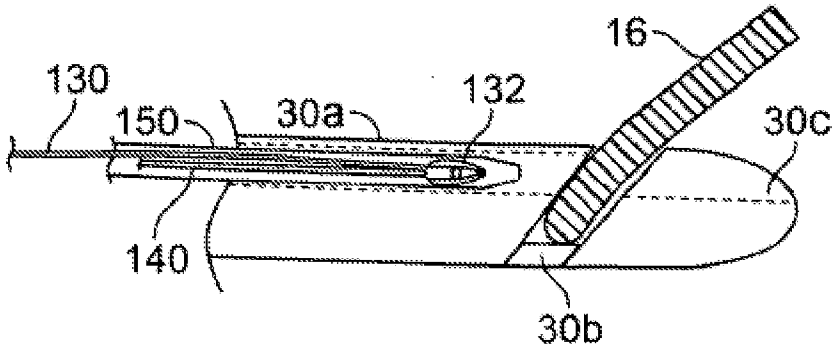

FIG. 25A

Alkhatib teaches:

> In FIG. 25(a) leaflet **16** is captured between the jaws **40** near the distal end of shaft **30**. Tether structure **130/132** is pushed distally along a needle lumen **112** using needle **140** until anchor **132** has passed through leaflet tissue (FIG. 25(b)). After passing through tissue **16**, anchor **132** can enter a space in the distal shaft portion **30c**.

(Alkhatib ¶ 74).

Principles of Law

The Examiner bears the initial burden of establishing a prima facie case of anticipation. *In re King*, 801 F.2d 1324, 1326–27 (Fed. Cir. 1986). Anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

Analysis

We begin with claim interpretation because before a claim is properly interpreted, its scope cannot be compared to the prior art. Here, the dispute centers over the term "entire distal portion" in claims 1 and 29.

Appellants contend "it is improper to read 'while maintaining the entire distal portion of the delivery system on the ventricular side of the leaflet' onto a less-than-entire portion of a prior art device" (App. Br. 12). Appellants contend "during delivery of the tether structure, *Alkhatib's* entire delivery system, which must include the distal shaft portion 30c, is **not** maintained on the ventricular side of the leaflet" (App. Br. 11).

The Examiner responds that "30c was *not* used in the rejection" and instead cites "**30a** as the delivery system, which is maintained on the ventricular side" (Ans. 5). The Examiner further argues that the transitional phrase "comprising" "does not exclude additional, unrecited element[s] or method steps, was used in the claim. Thus, the claims do *not* exclude additional, unrecited elements," such as 30c of Alkhatib (Ans. 4).

We agree with Appellants that the plain language of claims 1 and 29 "maintaining the entire distal portion of the delivery system on the ventricular side of the leaflet" is a limitation on the method that precludes the distal portion of the delivery device from extending to an atrial side of the leaflet (*see* Claim 1). The Specification reinforces this interpretation by disclosing at least one embodiment of a tip that does not perforate the ventricular side of the leaflet, and prevents the distal portion from being pushed through the leaflet (FF 3–4).

While we agree with the Examiner that "comprising" may allow additional elements (*see* Ans. 4), that presumption may be overcome when

"there is evidence of a clear intent to limit the claims." *Scanner Technologies Corp. v. ICOS Vision Systems Corp. N.V.*, 365 F.3d 1299, 1305–6 (Fed. Cir. 2004). In this case, we disagree with the Examiner's interpretation based on "comprising" because of the express exclusion in claim 1 that the disposing step must occur "while maintaining the entire distal portion . . . on the ventricular side of the leaflet." We note that "every limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines." *In re Wilder*, 429 F.2d 447, 450 (CCPA 1970).

The method of Alkhatib, which disposes "distal shaft portion 30c" on the atrial side of the leaflet (*see* Alkhatib ¶¶ 51 and FF 7), does not teach "maintaining the entire distal portion on the ventricular side." As such, Alkhatib does not teach all the limitations of the claimed methods.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that Alkhatib anticipates claims 1, 2, 7, 9, 11, 12, 25, and 29.

D. 35 U.S.C. § 102(b) over Kudlik

The Examiner finds:

> Kudlik discloses a method of repairing a prolapsed leaflet of a valve of a heart (see page 2 of provisional application nos. 61/741,497 and 61/473,873) comprised of introducing into a ventricle of the heart (see Figs. 4a-4c of provisional applications) a distal *portion* (the part of '25' that contacts the leaflet) of a delivery system **23** having a distal tip **25** (Fig. 3 of the provisional applications) and carrying an artificial chordae 2, 12, 14 (see Figs. 1, 2 of provisional applications) having a distal and proximal portion; disposing the distal tip **25** of the delivery system in contact with a ventricular side of the leaflet (Figs. 4a-4c of provisional applications); while maintaining the

> entire distal *portion* (the part of '25' that contacts the leaflet) of the delivery system on the ventricular side, extending from the distal tip a needle 22 (Figs. 4b, 3 of the provisional applications) having a distal portion carrying the distal portion of the artificial chordae to pierce a prolapsed segment of the leaflet from a ventricular side to an atrial side (see Figs. 3-4c of provisional applications) to form an opening in the leaflet

(Final Act. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Kudlik anticipates claim 1?

Findings of Fact

8. Kudlik teaches:

> [A] method for deploying the device **2** for treatment of a prolapsed mitral valve. . . . The tip **25** of the catheter **23** is inserted through the myocardium **38** until the catheter **25** is juxtaposed to the underside of the leaflet **32**. . . . With the heart still beating . . . the catheter **27** is rotated so as to screw the spiral wire **27** into the underside of the valve leaflet **32**. Then as shown in Fig. 4b, the sharp tip **24** of the needle **22** is made to pierce through the leaflet **32.**

(Kudlik US 61/471,497 4:11–22).

Analysis

Appellants contend "[d]uring deployment of Kudlik's device 50, Kudlik's entire delivery system, which necessarily includes the spiral wire 27, is in fact **not** maintained on the ventricular side of the leaflet" (App. Br. 11; emphasis is original). Instead, "[t]he spiral wire 27 is configured to screw into the underside of the valve leaflet being treated . . . and must be unscrewed before the delivery system can be removed" (*id.*).

As discussed above, we agree with Appellants that "maintaining the **entire** distal portion of the delivery system on the ventricular side of the leaflet" is a limitation on the method precluding the distal portion from piercing through to the atrial side. However, we agree with the Examiner that this limitation is taught by Kudlik.

As noted by the Examiner, Kudlik teaches juxtaposing tip 25 of the delivery system 23 with a ventricular side of the leaflet during the method of treating the prolapsed leaflet (FF 8). Even if spiral wire 27 is part of the "distal portion of the delivery system," it is screwed into and maintained in the underside, or ventricular side, of the valve leaflet (FF 8). Kudlik does not teach that the spiral wire 27 pierces through the leaflet, i.e., to the atrial side.

Appellants also contend that the spiral wire of Kudlik "must be unscrewed before the delivery system can be removed" (App. Br. 11).[12] Claim 1 does not preclude an unscrewing step, particularly where the transitional phrase "'comprising' would not exclude additional method steps" (*cf.* App. Br. 11). "[W]hile it is true that claims are to be interpreted *in light of* the specification . . . , it does not follow that limitations from the specification may be read into the claims. . . . [T]he claims define the invention." *Sjolund v. Musland*, 847 F.2d 1573, 1581–82 (Fed. Cir. 1988). Because both the tip 25 and the spiral wire 27 are maintained on the ventricular side of the leaflet, a reasonable reading of Kudlik and a

[12] Appellants also argue improper reconstruction citing *In re Ratti*, 270 F.2d 813 (CCPA 1959). Reconstruction, as discussed in *Ratti*, deals with obviousness, not anticipation, and therefore does not apply.

reasonable interpretation of claim 1 support the Examiner's anticipation position.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Kudlik anticipates claims 1.

E. 35 U.S.C. § 103(a) over Alkhatib or Kudlik, and DiMatteo

The Examiner finds:

> Alkhatib **or** Kudlik do not expressly disclose drawing the proximal and distal portion of the artificial chordae towards each other to form a loop, the distal portion of the chordae being formed as a coil having a plurality of turns; the coil being straight in the first configuration and the coil being the loop in the second configuration.

(Final Act. 12).

The Examiner finds:

> DiMatteo, in the analogous art of anchoring sutures to tissue, teaches a suture having a first configuration (Fig. 2c) and a second configuration (Fig. 2d), the second configuration being larger than an opening in the tissue, the distal portion of the suture being formed as a coil having a plurality of turns (Fig. 2b), the coil being a loop in the second configuration (Fig. 2d), and the coil being straight in the first configuration (Fig. 2c), and causing the suture to change from the first to the second configuration by proximal pulling of a proximal portion (paragraph 48), for the purpose of maximizing the retention strength of the anchor in tissue, minimizing the risk of anchor breakage or pullout from the tissue when the suture is tensioned, and for a less traumatic surgical incision, shallower penetration into or through the tissue, less vertical access needed to deploy the anchor, and for reducing surgical trauma (paragraphs 4, 6, 38).

(*Id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Alkhatib and DiMatteo or Kudlik and DiMatteo render the claims obvious?

Findings of Fact

9. Figures 2b–2d of DiMatteo are reproduced below:

FIG. 2b

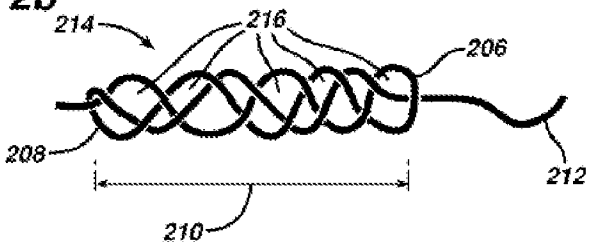

FIG. 2c

FIG. 2d

Figures 2b–2d illustrate a twisted braid suture anchoring device, where Figure 2b illustrates a configured suture head **214** with "[a] loop **204** . . . repetitively twisted to provide a plurality of openings" (DiMatteo ¶ 46). Figure 2c "illustrates the suture head **214** in a compressed cross section form **218**, as for disposition in a delivery needle" (DiMatteo ¶ 47). Figure 2d illustrates suture head **214** "collapsed [into] anchoring knot **220**" (*id.*).

10. DiMatteo teaches:

> (pulling) the first suture tail **212** away from the suture head **214**, so that the portion of the first suture tail **212** that is woven through the plurality of openings **216** is pulled further through the plurality of openings **216** and through the first head end **206**, thereby gathering or bunching the twisted suture along [with] the head length **210** into the anchoring knot **220**.

(DiMatteo ¶ 48).

Analysis

Alkhatib and DiMatteo

Claims 3 and 8

Claims 3 and 8 depend from claim 1. Having reversed the rejection of claim 1 over Alkhatib, we also necessarily reverse the obviousness rejection of claims 3 and 8 because the Examiner does not identify where DiMatteo suggests "maintaining the entire distal portion of the delivery system on the ventricular side of the leaflet."

Claim 26

Appellants contend "nowhere does *DiMatteo* disclose or suggest deflecting a distal end of the distal portion of the artificial chordae **laterally;** rather *DiMatteo* discloses merely collapsing **longitudinally** . . . its suture head to an anchoring knot by tensioning the suture tail with respect to the head" (App. Br. 14). Appellants further cite to their previous arguments regarding the distal portions of the delivery systems of Alkhatib 30a and 30c and Kudlik (*id.*).

The Examiner responds that "[t]he distal end of the suture . . . bends/gathers/bunches (see Fig. 2b) when collapsed, and thus it deflects laterally when collapsed" (Ans. 8).

First, we address the Appellants' earlier arguments regarding the "entire distal portion" as recited by claims 1 and 29. Unlike claims 1 and 29, claim 26 does not require "maintaining the entire distal portion . . . on the ventricular side of the leaflet." We, therefore, interpret claim 26 to allow for the distal portion of the delivery device to extend beyond the ventricular side of the leaflet. "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 783–84 (Fed. Cir. 1988) (citation omitted). Thus, the method of Alkhatib is not excluded from claim 26, and we find that Alkhatib teaches the steps of disposing the distal tip of the delivery device in contact with the ventricular side of the leaflet as indicated by the Examiner.

Appellants are correct in that Figures 2a–2d of DiMatteo illustrate longitudinal collapse (FF 13). However, we find this argument unpersuasive because we agree with the Examiner that the distal end of the suture also deflects laterally during the longitudinal collapse. As claim 26 does not exclude longitudinal collapse in addition to lateral deflection, a reasonable reading of DiMatteo and a reasonable interpretation of claim 26 support the Examiner's obviousness position.

Kudlik and DiMatteo

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 12, FF 9 and 10) and agree that claims 3, 8, 26, and 27 are rendered obvious by Kudlik and DiMatteo,

incorporating the discussion of DiMatteo above. Appellants provide no other arguments specific to this combination.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that claims 3, 8, 26, and 27 would have been obvious.

F. 35 U.S.C. § 103(a) over Alkhatib and Allen

The Examiner finds:

> Alkhatib does not expressly disclose while contacting the prolapsed leaflet only on the ventricular side of the prolapsed leaflet.
>
> Allen . . . teaches contacting only a ventricular side of a prolapsed leaflet (see **column 3, lines 4-18[]**) . . . to repair the mitral valve . . . . Using a vacuum and contacting only one side of a leaflet is an art recognized equivalent of clamping both sides of the leaflet (see Figs. 1b, 4a–c; column 3, lines 4-18) . . . . Therefore, because vacuum and clamping delivery systems were art recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the clamp delivery system with a vacuum delivery system since both are capable of stabilizing leaflets/tissue.

(Final Act. 16–17; emphasis in original).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Alkhatib and Allen render claim 18 obvious?

Findings of Fact

11. Allen teaches a mitral valve repair procedure in Figure 1b using a probe that "has a size suitable for minimally invasive surgery" with the

"ability to perform valve repair surgery on a beating heart" (Allen 6:41–7:13).

12. Figure 1b of Allen is reproduced below:

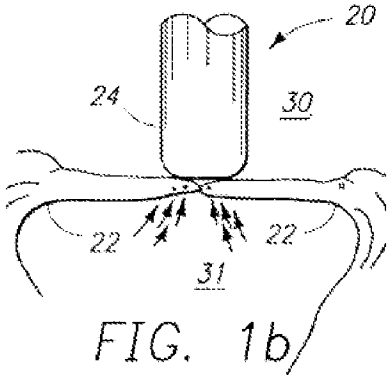

FIG. 1b

Figure 1b shows a tissue stabilizer 20 with a cylindrical probe 24 contacting heart valve leaflets 22 with vacuum indicated by arrows pointing to the probe through the leaflets (Allen 6:41–7:13).

13. Allen teaches the device can be delivered "transapically . . . [or] through . . . the left ventricle" (Allen 3:4–18).

14. Figure 4a is reproduced below:

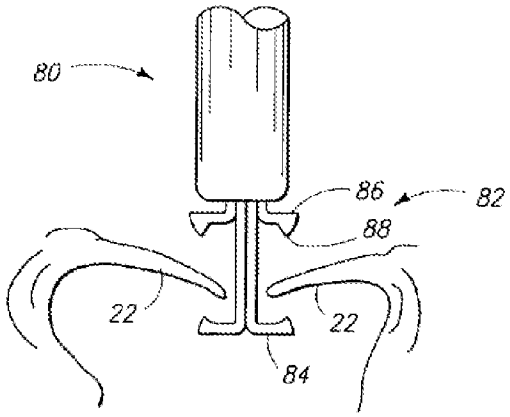

FIG. 4a

Figure 4a "shows a mechanical tissue stabilizer **80** with a four-part, linearly displaceable tissue clamp **82**" (Allen 7:66–8:8).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Moreover, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). As noted by the Court in *KSR*, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." 550 U.S. at 421.

Analysis

Appellants contend that "Allen explicitly teaches away from applying vacuum stabilization to a leaflet from the ventricle side of the leaflet (i.e.[,] transapically)" (App. Br. 13). Appellants contend Figure 1b, cited by the Examiner, is directed to an "approach from the left atrium 30" due to lower pressure in the atrium, and that "every disclosed embodiment is transatrial" (App. Br. 13).

While Appellants are correct that the teaching of Figure 1b is transatrial due to lower pressure in the atrium, this does not amount to a teaching away. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed. . . ." *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

We find the Appellants' argument unpersuasive. The Examiner has shown that vacuum and clamping delivery systems were art recognized equivalents used in valve repair procedures with a ventricular approach (*see* FF 12–14). Allen merely expresses a general preference for applying

vacuum stabilization to a leaflet from a transatrial approach, but does not discourage a ventricle side approach. Allen's specific teaching is not a teaching away when it does not criticize, discredit, or discourage the other approach. *Fulton*, 391 F.3d at 1201. As argued by Appellants, Alkhatib teaches a clamping delivery system for repairing cardiac valves using a ventricular approach (*see* App. Br. 10). The combination of the art teaches repairing a valve by disposing the distal tip of the delivery system in contact with only a ventricular side of the prolapsed leaflet.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Alkhatib and Allen suggest a method of repairing a prolapsed heart valve as required by claim 18.

G. 35 U.S.C. § 103(a) over Alkhatib and Zlotnick

The Examiner rejects claim 24 as obvious over Alkhatib in view of Zlotnick. Having reversed the rejection of claim 1 over Alkhatib, we also necessarily reverse this obviousness rejection because Zlotnick does not teach or suggest the limitation of "while maintaining the entire distal portion of the delivery system on the ventricular side of the leaflet."

H. 35 U.S.C. § 103(a) over Alkhatib, DiMatteo, and Hart or Kudlik, DiMatteo, and Hart

Claims 4 and 5 depend from claim 1. Having reversed the rejection of claim 1 over Alkhatib, we also necessarily reverse the obviousness rejection of claims 4 and 5 because the Examiner does not identify where DiMatteo or

Hart suggest "maintaining the entire distal portion of the delivery system on the ventricular side of the leaflet."

Appellants do not separately argue the obviousness rejections of claims 4 and 5, instead relying on their arguments to overcome Kudlik. The Examiner provides sound fact-based reasoning combining Kudlik, DiMatteo, and Hart (*see* Final Act. 13–14). Having affirmed the rejection of claim 1, from which these claims depend for the reasons given above, we also conclude the claims would have been obvious for the reasons given by the Examiner.

I.–M. 35 U.S.C. § 103(a)

Appellants do not separately argue the obviousness rejections of claims 16, 17, 19–23, and 27–32, instead relying on their arguments to overcome Alkhatib, Kudlik, Allen, and DiMatteo. The Examiner provides sound fact-based reasoning combining each of Hart, Zlotnick, and Lattouf (*see* Final Act. 13–22). Having affirmed the rejections of claims 18 and 26 from which these claims depend for the reasons given above, we also conclude the claims would have been obvious for the reasons given by the Examiner.

SUMMARY

In summary, we affirm the rejection of claims 26–32 under 35 U.S.C. § 112, second paragraph as indefinite.

We affirm the rejection of claims 18–23, 25, 28, and 30 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

We reverse the rejection of claims 1, 2, 7, 9, 11, 12, 25, and 29 under 35 U.S.C. § 102(b) as anticipated by Alkhatib.

We affirm the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Kudlik. Claims 2, 9, 11, and 12 fall with claim 1.

We reverse the rejection of claims 3 and 8 under 35 U.S.C. § 103(a) as obvious over Alkhatib and DiMatteo.

We affirm the rejection of claims 3 and 8 under 35 U.S.C. § 103(a) as obvious over Kudlik and DiMatteo.

We affirm the rejection of claims 26 and 27 under 35 U.S.C. § 103(a) as obvious over Alkhatib and DiMatteo, or Kudlik and DiMatteo.

We reverse the rejection of claim 24 under 35 U.S.C. § 103(a) as obvious over Alkhatib and Zlotnick.

We reverse the rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as obvious over Alkhatib, DiMatteo, and Hart.

We affirm the rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as obvious over Kudlik, DiMatteo, and Hart.

We affirm the rejection of claim 18 under 35 U.S.C. § 103(a) as obvious over Alkhatib and Allen. Claims 19, 20, 22, and 23 fall with claim 18.

We affirm the rejection of claims 16 under 35 U.S.C. § 103(a) as obvious over Alkhatib, Allen, and DiMatteo.

We affirm the rejection of claims 17 under 35 U.S.C. § 103(a) as obvious over Alkhatib, Allen, DiMatteo, and Hart.

We affirm the rejection of claim 21 under 35 U.S.C. § 103(a) as being obvious over Alkhatib, Allen, and Zlotnick.

We affirm the rejection of claims 28 and 30 under 35 U.S.C. § 103(a) as being obvious over Alkhatib, DiMatteo, and Allen, or Kudlik, DiMatteo, and Allen.

We affirm the rejection of claims 31 and 32 under 35 U.S.C. § 103(a) as obvious over Alkhatib, DiMatteo, Allen, and Lattouf.

We therefore note that claims 7 and 24 are not subject to an affirmed rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART