

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOCHORD, INC.,
Petitioner,

v.

UNIVERSITY OF MARYLAND, BALTIMORE and
HARPOON MEDICAL, INC.,
Patent Owner.

Case IPR2016-00208
Patent 7,635,386 B1

Before SALLY C. MEDLEY, ERICA A. FRANKLIN, and
JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

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

I. INTRODUCTION

On November 18, 2015, Petitioner NeoChord, Inc. filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–23 of U.S. Patent No. 7,635,386 B1 (the ’386 patent, Ex. 1001). No Preliminary Response was filed.

The University of Maryland, Baltimore, filed a mandatory notice pursuant to 37 C.F.R. § 42.8, representing that it is the Patent Owner and a real party-in-interest. Paper 5, 2. The University of Maryland, Baltimore, further states that Harpoon Medical, Inc. is the exclusive licensee and is also a real party-in-interest. *Id.*

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under section 311 and any response filed under section 313 shows that 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); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–23 of the ’386 patent are unpatentable.

Accordingly, we institute an *inter partes* review for the challenged claims.

A. *Related Matters*

The parties state that they are unaware of any related judicial or administrative proceedings. Pet. 2; Paper 5, 2.

B. *The ’386 Patent (Ex. 1001)*

The ’386 patent is titled “Methods and Devices for Performing Cardiac Valve Repair,” and relates to methods for performing repairs to

cardiac valves, and in particular, the mitral and tricuspid valves. Ex. 1001, at [57], 1:14–16. Such repairs may include implantation of artificial chordae tendinae,¹ valve resection, implantation of an annuloplasty ring, and bow-tie repair. *Id.* at [57], 4:59–5:11.

The '386 patent states that the conventional approach for valve repair is problematic because it requires stopping the heart, which makes it difficult to accurately determine, assess, and secure the appropriate length for artificial chordae to ensure proper functioning of the valve. *Id.* at 4:36–47. Further, the '386 states that as a general matter, cardiopulmonary bypass required by the conventional approach may adversely affect almost all of the organ systems of the body, and lead to strokes, myocardial damage, respiratory failure, kidney failure, bleeding, or death. *Id.* at 4:10–35.

The '386 patent is directed to a minimally invasive surgical approach in which valve repair may be performed while the heart is still beating with small incisions using specialized instruments under audio or visual guidance. *Id.* at 4:59–64, 6:13–14, 6:22–27. The '386 patent describes accessing the heart through a small incision between the ribs or through the abdomen, followed by a small incision in the heart wall at or near the apex of the heart. *Id.* at 6:54–67, 9:43–10:2. An access port, including a manifold, may be inserted into the site of entry. *Id.* at 10:13–14. The '386 patent describes, as an alternative approach to the heart, a percutaneous, endovascular approach through the femoral or internal jugular veins, or through the femoral artery, using needle puncture to access the apical region of the heart. *Id.* at 6:27–31, 10:2–7.

¹ The '386 patent refers to these structures with alternate spellings, i.e., both as “chordae tendinae” and as “chordae tendineae.”

The surgical approach described in the '386 patent is depicted below in Figure 6:

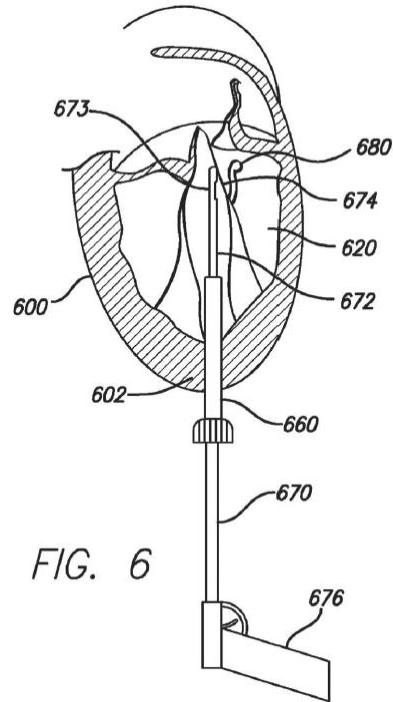


Figure 6 depicts an instrument inserted through an incision in the apex of the heart. For a repair that inserts artificial chordae tendinae, the instrument may attach a suture to a leaflet of the mitral valve, and attach the other end of the suture near the apex of the heart. *Id.* at 13:60–14:5. See Figure 9 below:

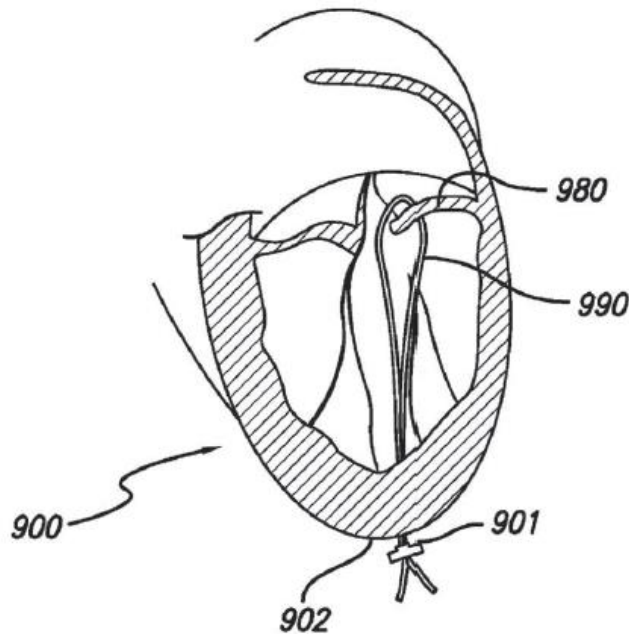


FIG. 9

Figure 9 shows suture placement in one embodiment to form an artificial chorda.

C. Illustrative Claims

The Petition challenges claims 1–23 of the '386 patent. Of these, claims 1 and 19 are recited as independent claims directed to methods.

Independent claim 1, reproduced below, is representative of the subject matter on appeal:

1. A method for repairing a defective mitral or tricuspid valve, comprising:
 - creating an access in an apical region of a heart through which a defective cardiac valve is accessed;
 - introducing a device through said access; and
 - repairing said cardiac valve by use of said device, wherein the repairing comprises replacing one or more chordae tendineae, and using said device to implant one or more artificial chordae tendineae, and

wherein the one or more artificial chordae comprises a suture with one or more leaflets of the heart.

Ex. 1001, 20:41–52.

D. The Alleged Grounds of Unpatentability

In the Petition, Petitioner set forth its contentions that claims 1–23 are unpatentable on the following grounds (Pet. 20–60):

References	Basis	Claims challenged
Speziali ²	§ 102	1, 3, 7–17, 19, 22, 23
Speziali	§ 103	2, 4
Speziali and Bachman ³	§ 103	5, 6, 18, 20, 21
Lattouf I ⁴ and Carpentier ⁵	§ 103	1–9, 11–15, 17–19, 22, 23
Lattouf I, Carpentier, and Downing ⁶	§ 103	10, 16, 20, 21

² Speziali, U.S. Patent No. 8,465,500 B2, iss. June 18, 2013 (Ex. 1006).

³ Bachman, U.S. Patent Application Pub. No. 2004/0044365 A1, pub. Mar. 4, 2004 (Ex. 1008).

⁴ Lattouf, U.S. Patent No. 6,978,176 B2, iss. Dec. 20, 2005 (Ex. 1004) (“Lattouf I”).

⁵ Alain Carpentier, *Cardiac valve surgery—the “French correction,”* 86 THE JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY 323–337 (Sept. 1983) (Ex. 1009) (“Carpentier”).

⁶ Downing, U.S. Patent No. 6,840,246 B2, iss. Jan. 11, 2005 (Ex. 1005).

References	Basis	Claims challenged
Lattouf I and Bachman	§ 103	1–9, 11, 14, 15, 17– 23 ⁷
Lattouf I and Downing	§ 103	1–23
Lattouf II ⁸	§ 102	1, 3, 6–9, 11–15, 17– 19, 22, 23
Lattouf II and Downing	§ 103	2, 4, 10, 16, 20, 21
Downing and Oz ⁹	§ 103	1–13, 19–23
Downing, Oz, and Lattouf I	§ 103	14–18

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. 37 C.F.R. § 42.100(b); *see In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (mem.) (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as

⁷ This chart reflects the listing of claims on page 8 of the Petition. We note that, for this ground and for certain other grounds, the Petition does not analyze in its discussion each of the claims listed on page 8.

⁸ Lattouf, U.S. Patent No. 7,871,433 B2, iss. Jan. 18, 2011 (Ex. 1007) (“Lattouf II”).

⁹ Oz, U.S. Patent No. 6,269,819 B1, iss. Aug. 7, 2001 (Ex. 1010).

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).

Petitioner proposes constructions of “creating an access in an apical region of a heart” in claim 1; “percutaneously accessing an apical region of a heart” in claim 19; “replacing . . . chordae tendin[e]ae” in claims 1 and 19; “a suture with one or more leaflets of the heart,” in claims 1 and 19; and “endovascularly via [an antegrade/a retrograde] approach” in claims 20 and 21. Pet. 9–17.

We construe only claim terms relevant to issues in dispute and only to the extent necessary to resolve the issues presented by the Petition. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). For purposes of this Decision, we provide an express construction for the limitations “creating an access in an apical region of a heart” and “a suture with one or more leaflets of the heart,” requested by Petitioner. In addition, we construe an additional limitation relevant to one of the asserted grounds, “an optimal configuration of the one or more artificial chordae,” as set forth below.

1. “creating an access in an apical region of a heart”

Petitioner asserts that the broadest reasonable construction of the limitation “creating an access in an apical region of a heart” (claim 1) is “creating an incision or puncture in a wall of the heart in the region near the apex of the heart.” Pet. 10–11 (citing Ex. 1011 ¶ 44). Petitioner observes

that there are no natural openings in the apex of the heart, and identifies the recited “access” with entry 504 of Figure 5 of the ’386 patent. Pet. 9–10.

The Specification discloses that “[t]ypically, access into the left ventricular (**420**), for instance, so as to perform a mitral valve repair, is gained through making a small incision into the apical region” Ex. 1001, 9:47–49; *see also* 9:51–55 (similarly describing incision into the right ventricular for tricuspid valve repair). The Specification also discloses needle puncture as an alternative to an incision, in the context of a percutaneous approach. *Id.* at 10:2–7. On this record, we agree that an “access” may be an incision or a puncture in the heart.

With respect to Figure 5, to which Petitioner refers, we note that the Specification describes that an “access port (**550**)” may be inserted into entry (504) to prevent blood loss. *Id.* at 10:13–17. However, the Specification refers to the incision as creating the “access” before noting that “if necessary,” a retraction device may create “greater access,” and describing the insertion of an access port. *Id.* at 9:47–49; 9:51–55; 10:8–15. As such, on this record, the “access” of claim 1 is not limited to the use of any additional structure, such as a port. We therefore determine, on this record, that the broadest reasonable construction of the limitation “creating an access in an apical region of a heart” is “creating an incision or puncture in a wall of the heart at or near the apex of the heart.”

2. “*a suture with one or more leaflets of the heart*”

Petitioner asserts that the broadest reasonable construction of “a suture with one or more leaflets of the heart” (claims 1 and 19) is “a suture inserted directly through the tissue of a native leaflet of a heart and not indirectly through a clip or other device that is in turn attached to the native

leaflet.” Pet. 15 (citing Ex. 1011 ¶ 50). Petitioner states that its proposed construction is consistent with the Specification of the ’386 patent. Pet. 15 (citing Ex. 1001, 12:2–13:46; Fig. 9).

On this record, we agree with Petitioner that, in claims 1 and 19, the limitation “a suture with one or more leaflets of the heart,” refers to a suture which is connected directly to the valve leaflet. This understanding is consistent with the prosecution history. During prosecution, the patentee traversed a rejection by the Examiner based on Lattouf I by arguing that Lattouf I lacked a suture connected to the valve leaflet. Ex. 1003, 9–10.¹⁰ We, therefore, construe “a suture with one or more leaflets of the heart” to be “a suture which is directly connected to the valve leaflet.”

3. “*an optimal configuration of the one or more artificial chordae*”

Claim 15 ultimately depends from claim 1, and recites “determining an optimal configuration of the one or more artificial chordae before anchoring the artificial chordae.” Petitioner does not propose a construction for “optimal configuration,” but states in a footnote as follows:

Petitioner notes that the phrase “optimal configuration” appears ambiguous in view of the recitation of “optimal arrangement, length, placement and configuration” in the specification. Ex.1001, 14:6–9. Although not at issue in this proceeding, the use of the term “optimal configuration” presents 35 U.S.C. § 112 issues for these reasons. For purposes of this Petition and this limitation in this ground, the term “optimal configuration” does

¹⁰ The patentee was essentially arguing that Lattouf I used a suture connected to a clip that was connected to the valve leaflet. *See id.* In its Petition, Petitioner asserts that Lattouf I discloses an additional embodiment using a suture as an artificial chorda without a clip, and that this embodiment was not the focus of prosecution before the Examiner. Pet. 30, 33 (citing Ex.1004, 3:58-62; Ex. 1011 ¶¶ 64, 79). *See discussion infra.*

not need to be defined as the exact same term is used in Spezialli [sic].

Pet. 26 n.7. We do not agree with Petitioner that the term “optimal configuration” is rendered ambiguous by the Specification’s listing of a series of related surgical considerations, i.e., optimal arrangement, length, placement and configuration. Although the Specification does not describe the limitation in the form of a definition, the Specification states as follows:

It is to be noted that a fundamental challenge in successfully replacing one or more chordae tendineae and restoring proper functioning of a cardiac valve, is determining the appropriate artificial cord length and securing the artificial cord at a location so as to ensure the optimal replacement chordae length. The valve will not function properly if the length of the artificial cord is too long or too short. Because the heart is stopped using conventional techniques, it is virtually impossible to ensure that the cords are of the correct length and are appropriately spaced inside the ventricle to produce a competent valve. Accordingly, methods of the invention include the measuring and determining of the optimal arrangement, length, placement, and configuration of an implanted suture, for instance, a replacement cord length, while the heart is still beating and, typically, before the access site of the heart is closed. An optimal arrangement of a suture, for instance, an optimal cord length, is that arrangement that effectuates said repair, for instance, by minimizing reperfusion as determined by means well known in the art, for instance, by direct echo guidance.

Ex. 1001, 14:63–15:15. Based on the ordinary and customary meaning of the terms in the context of the Specification, we ascertain that the broadest reasonable interpretation of “determining an optimal configuration of the one or more artificial chordae before anchoring the artificial chordae” is “determining the location of the attachment points for each end of the suture

and the length of the suture to restore proper valve functioning prior to attaching the suture as an artificial chorda.”

B. Anticipation by Speziali (Ex. 1006)

Relying on the Declaration of Dr. Lishan Aklog (Ex. 1011), Petitioner contends that Speziali anticipates claims 1, 3, 7–17, 19, 22, and 23. Pet. 20–26. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 1, 3, 7–14, 19, 22, and 23, but not as to claims 15–17.

1. Overview of Speziali

Petitioner asserts Speziali is prior art under pre-AIA 35 U.S.C. §102(e). Pet. 20. The Speziali reference is an issued patent, U.S. Patent No. 8,465,500 B2, filed July 11, 2007 as a national stage of the PCT Application No. PCT/US06/[0]01699, filed January 19, 2006. *Id.* Petitioner further asserts that Speziali claims priority to U.S. Provisional Application No. 60/645,677, filed January 21, 2005. *Id.*¹¹

Speziali relates to a “thoroscopic heart valve repair method and apparatus.” Ex. 1006, at [54]. Speziali discloses the steps of inserting an instrument through the patient’s chest wall and heart wall, capturing a valve leaflet with a movable tip on an instrument, operating a needle to penetrate the captured leaflet and draw a suture through the leaflet, withdrawing the instrument from the heart chamber, and anchoring the suture to the heart wall, e.g., tying the suture off at the apex of the heart after adjusting its tension for optimal valve operation as observed with ultrasonic imaging. *Id.*, at [57], 3:1–10.

¹¹ We do not determine the priority date of Speziali at this time.

2. *Analysis*

Petitioner sets forth in the Petition how each limitation of claims 1, 3, 7–17, 19, 22, and 23 would be understood to be disclosed by Speziali. Pet. 20–26. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 1, 3, 7–14, 19, 22, and 23, but not as to claims 15–17.

i. Claim 1

Petitioner maps Speziali to the limitations of claim 1. Pet. 20–26. In particular, Petitioner relies on Speziali’s disclosure of repair of mitral valve 16 using instrument 10 through a stab incision for the preamble and the method steps of “creating an access in an apical region of a heart through which a defective cardiac valve is accessed” and “introducing a device through said access,” as recited by claim 1. Pet. 20–23 (citing Ex. 1006, 5:14–21). Petitioner relies on Speziali’s disclosure of grasping a prolapsing edge of mitral valve 16 with instrument 10 to secure an artificial chorda and pulling suture 18 through a leaflet for the steps of “repairing said cardiac valve by use of said device, wherein the repairing comprises replacing one or more chordae tendineae, and using said device to implant one or more artificial chordae tendineae,” and “wherein the one or more artificial chordae comprises a suture with one or more leaflets of the heart,” as recited by claim 1. *Id.* at 21–23 (citing Ex. 1006, 5:19–21, 6:10–12, 6:61–62).

Based on the supporting declaration of Dr. Aklog, and on our independent review of the evidence, we determine that Petitioner has established a sufficient showing, at this stage of the proceeding, that Speziali discloses the recited steps of claim 1. On this record, we therefore determine

that Petitioner has established a reasonable likelihood of prevailing on its assertion that Speziali anticipates claim 1.

ii. Claims 3, 7–17, 19, 22, and 23

Petitioner also maps Speziali to the limitations of claims 3, 7–17, 19, 22, and 23. Pet. 20–26. We have similarly reviewed the evidence relating to these claims. Based on our independent review of the evidence at this stage of the proceeding, we determine that Petitioner has established a sufficient showing that Speziali discloses the limitations of claims 3, 7–14, 19, 22, and 23, but not claims 15–17.

Claim 15 ultimately depends from claim 1 and further recites the step of “determining an optimal configuration of the one or more artificial chordae before anchoring the artificial chordae.” Petitioner relies for this limitation on the disclosure in Speziali of adjusting the tension of the suture for optimal valve operation before tying off the suture. Pet. 26 (citing Ex. 1006, 3:8–10). There are at least two deficiencies in the Petition’s explanation of how this disclosure in Speziali meets the limitation. First, Petitioner does not explain the temporal relationship between anchoring and tying off. Second, Speziali discloses an optimization of *valve* configuration or operation rather than an optimization of *artificial chordae* configuration, as recited by claim 15. To the extent that Speziali’s optimization of the valve is based on adjusting the suture tension, a change in suture (artificial chordae) tension does not necessarily result in a change in the configuration thereof. Indeed, applying the construction of the limitation set forth in the claim construction section above, the configuration of the artificial chordae relates to suture placement and length. The statute and rules place the burden on the Petitioner to provide a sufficient explanation for its case-in-

chief in the Petition. 35 U.S.C. §§ 312(a)(3), 316(e); 37 C.F.R. § 42.104(b)(4),(5). For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion as to claim 15 and claims 16 and 17, which depend therefrom.

Thus, we determine, on this record, that Petitioner has established a reasonable likelihood of prevailing on its assertion that Speziali anticipates claims 3, 7–14, 19, 22, and 23, but not claims 15–17.

C. Obviousness Over Speziali

In its Petition, Petitioner alleges how each limitation of claims 2 and 4 would be understood to be disclosed by Speziali, and why the claims would have been obvious in view of the entirety of Speziali's disclosure. Pet. 26–27. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 2 and 4. Claims 2 and 4 depend from claim 1, and recite further limitations relating to the resection of leaflets and performing annuloplasty.

Petitioner contends that it would have been obvious to modify the method of Speziali to perform additionally leaflet resection and annuloplasty on the same valves based on the discussion in the background section of Speziali. Pet. 26–27. In the background section of the reference, Speziali explains that valve resection and annuloplasty were other repairs performed as part of the state of the art. Pet. 26–27 (citing Ex. 1006, 1:58–61). Petitioner argues that it would have been obvious for a person of ordinary skill in the art to perform additional procedures together based on the professional judgment of the surgeon with a reasonable expectation of success, as the combination of a finite number of mitral valve repair techniques. Pet. 27 (citing Ex. 1011 ¶ 57).

Based on our review of the evidence, including the Declaration, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 2 and 4.

D. Obviousness over Speziali and Bachman (Ex. 1008)

Petitioner contends the combination of Speziali and Bachman renders obvious claims 5, 6, 18, 20, and 21. Pet. 27–29. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 5, 6, 18, 20, and 21.

1. Overview of Bachman

Bachman relates to “a single catheter mitral valve repair device for stabilizing a tissue portion and selectively applying a tissue fastener thereto.” Ex. 1008, at [57]. Bachman discloses the steps of inserting a guidewire endovascularly to the left atrium, advancing elongated body 14 of the instrument towards the mitral valve, using a vacuum force to capture a tissue portion of the mitral valve, stabilizing tissue portion 72, using a deployable needle 64 to attach fastener material 62, and then attaching the fastener material to tissue portion 74 on the mitral valve which is nearby tissue portion 72 on the mitral valve. *Id.* ¶¶ 42–43. Bachman discloses that the repair device may approach the mitral valve from an antegrade position or from a retrograde position. *Id.*

2. Analysis

Claims 5, 6, and 18 depend from claim 1, and further recite stapling or suturing an annulus for the valve repair, performance of a bow-tie procedure, and the application of a vacuum. Claims 20 and 21 depend from claim 19, and further specify that accessing an apical region of the heart is performed endovascularly via an antegrade approach or a retrograde approach.

In its Petition, Petitioner alleges how each limitation of claims 5, 6, 18, 20, and 21 would be understood to be disclosed by the combination of Speziali and Bachman, and why such a combination would have been obvious. Pet. 27–30 (citing Ex. 1008 ¶¶ 6–9, 42). For example, with respect to dependent claim 5, Petitioner relies on the disclosure in Bachman of implantation of a prosthetic ring for valvular remodeling. Pet. 29 (citing Ex. 1008 ¶ 6). Based on the supporting declaration of Dr. Aklog, and on our independent review of the evidence, we determine that Petitioner has established a sufficient showing, at this stage of the proceeding, that Bachman discloses the additional recitations of claims 5, 6, 18, 20, and 21.

Petitioner argues that a person of ordinary skill would have used professional judgment to combine the teachings of Bachman relating to “well known” additional repair techniques with the teachings of Speziali in order to effectuate a repair that mimics the techniques employed in open procedures, and as selected from a finite number of options. Pet. 28–29 (citing Ex. 1011 ¶¶ 60–61). On this record, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that the combination of Speziali and Bachman renders obvious claims 5, 6, 18, 20, and 21.

E. Obviousness over Lattouf I (Ex. 1004) and Carpentier (Ex. 1009)

Petitioner contends the combination of Lattouf I and Carpentier renders obvious claims 1–9, 11–15, 17–19, 22, 23. Pet. 31–38. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion.

1. Overview of Lattouf I

Lattouf I is directed to the treatment of patients with congestive heart failure and discloses two minimally invasive procedures, a procedure for connecting the leaflets of the patient's heart valve and a procedure for implanting a pacemaker. Ex. 1004, at [54], [57]. As to the first procedure, Lattouf I discloses a method of gaining access to a patient's heart chamber through the wall of the heart, such as at the apex, by piercing the heart wall and placing a valved passageway within the heart wall. *Id.* at [57], 2:10–14, 2:44–61. Lattouf I describes the use of an elongated grasping device that may be inserted into the heart to engage and grip the valve leaflets, e.g., to place the valve in position for a bow-tie technique. *Id.* at 3:24–35. Lattouf I describes joining together the valve leaflets using clips or staples. *Id.* at 3:35–45. In the alternative, Lattouf I discloses that, when a bow-tie will not prevent reshaping of the ventricular architecture, the surgeon “provid[es] an artificial chordae tendinae such as a strand extending between the valve leaflets and the heart wall” *Id.* at 3:46–58. In one embodiment, a strand has one end secured to the closed end of the leaflet clip, and another end secured to the ventricular wall. *Id.* at 8:36–53, Fig. 27.

2. Overview of Carpentier

Carpentier is a copy of an address by Dr. Carpentier read at an annual meeting of the American Association for Thoracic Surgery in 1983, and published in *The Journal of Thoracic and Cardiovascular Surgery* in that year. Ex. 1009, 323. Carpentier lists three types of valve disease and their etiologies. *Id.* at 326 and Table II. Carpentier describes several types of valve repair, including prosthetic ring annuloplasty, leaflet fixation on secondary chordae, transposition of chordae, commisurotomy, and

reconstruction. *Id.* at 327–337. Carpentier is primarily directed to traditional surgical methods involving cooling the patient, stopping the heart, and making an incision in the heart with adequate exposure. *See id.* at 326; Ex. 1011 ¶ 65. Carpentier discloses a surgical treatment of chordal rupture in which a suture is passed through secondary chordae and then through the valve leaflet. *Id.* at 328.

3. Analysis

In its Petition, Petitioner alleges how each limitation of claims 1–9, 11–15, 17–19, 22, and 23 would be understood to be disclosed by the combination of Lattouf I and Carpentier, and why such a combination would have been obvious. Pet. 31–38.

Petitioner asserts that Lattouf I discloses the entirety of the valve repair through an apical access, as recited by independent claim 1. Pet. 33 (citing Ex. 1004, 2:10–14, 2:46–48, 3:24–35, 3:46–58, 7:63–8:5). As set forth above, during prosecution, the patentee traversed a rejection based on Lattouf I by arguing that Lattouf I does not disclose suturing the leaflet of the valve. Ex. 1003, 4, 9–10, 23. Nevertheless, Petitioner asserts that Lattouf I discloses two embodiments, the main embodiment in which a clip attaches to the valve leaflet, and an alternative embodiment in which a suture attaches directly to the leaflet. Pet. 30, 33 (citing Ex. 1004, 3:58–62; Ex. 1011 ¶¶ 64, 79).

Petitioner does not rely on Lattouf I for suturing, but rather argues that even under the understanding of Lattouf I argued by the patentee during prosecution, it would have been obvious to substitute the clip attached to the valve leaflet in Lattouf I with Carpentier’s technique of directly suturing the valve leaflet. Pet. 30 n.8, 32–33 (citing Ex. 1009, 328). Based on the

current record, we determine that Petitioner has established a sufficient showing that Lattouf I and Carpentier disclose the limitations of independent claim 1.¹²

Petitioner argues that it would have been obvious to mimic an open surgical approach (and retain Carpentier's use of a suture) while using the minimally invasive beating heart approach of Lattouf I in order to mimic the preferred repair. Pet. 32–33 (citing Ex. 1011, ¶¶ 66–67). Based on the declaration of Dr. Aklog, we determine that Petitioner has established a reasonable likelihood that the combination of Lattouf I and Carpentier renders obvious independent claim 1.

We have similarly reviewed the evidence relating to claims 2–9, 11–15, 17–19, 22, and 23. Based on our independent review of the evidence at this stage of the proceeding, we determine that Petitioner has established a sufficient showing that Lattouf I and Carpentier disclose the limitations of claims 2–9, 11–15, 17–19, 22, and 23. For similar reasons as for claim 1, we determine that Petitioner has established a reasonable likelihood that the combination of Lattouf I and Carpentier renders obvious claims 2–9, 11–15, 17–19, 22, and 23.

¹² On this record, we agree with Petitioner that, apart from Carpentier, Lattouf I also discloses an embodiment that directly attaches a suture to the valve leaflet. Ex. 1004, 3:58–63 (“***One end of the strand is secured to*** the connecting element securing the free edges of the valve leaflets ***or the free edges themselves*** and the other end . . . is secured to a location on the heart wall, preferably on the exterior of the heart wall.”) (emphasis added); see Pet. 30, 33.

F. Obviousness over Lattouf I, Carpentier, and Downing (Ex. 1005)

Petitioner contends the combination of Lattouf I, Carpentier, and Downing renders obvious claims 10, 16, 20, and 21. Pet. 38–39. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 10 and 16 but not 20 and 21.

1. Overview of Downing

Downing is directed to apparatuses and methods for performing minimally invasive diagnostic and surgical procedures inside a beating heart, and in particular for accessing the heart chamber for the repair of the aortic, mitral, pulmonary, and tricuspid valves and the atrial and ventricular septums. Ex. 1005, at [54], [57], 1:12–22. Downing discloses the insertion of a port through a chamber wall of a heart, and in particular in an atrial wall. *Id.* at 3:43–4:37, Figs. 7–14, 18, 21, 22. With respect to valvular repair, Downing discloses that a suture can be fired into the papillary muscle and the free ends of the suture brought through the edge of the mitral leaflet. *Id.* at 15:1–12. Downing further describes stapled annuloplasty and bow-tie procedures, ring annuloplasty, and the use of echocardiography or real-time CT scanning or magnetic resonance imaging for visualization. *Id.* at 11:32–43, 12:4–12:15, 15:12–16:41. Downing also discloses that valve resection was part of the state of the art. *Id.* at 11:60–12:15.

2. Analysis

In its Petition, Petitioner alleges how each limitation of claims 10, 16, 20, and 21 would be understood to be disclosed by the combination of

Lattouf I, Carpentier, and Downing, and why such a combination would have been obvious. Pet. 38–39.

Claims 10 and 16 ultimately depend from claim 1, and further recite the use of sonography or visualization. Petitioner relies on the disclosure in Downing of echocardiography for these limitations. Pet. 39 (citing Ex. 1005, 11:34–38, 18:40–53). On the basis of the current record, we determine that Petitioner has made a sufficient showing that Downing meets the further limitations of claims 10 and 16. Petitioner argues that it would have been obvious to further combine the teachings of Lattouf I and Carpentier with the visualization of Downing in order to mimic an open access procedure. Pet. 38–39 (citing Ex. 1011 ¶ 71). In this connection, Dr. Aklog explains that a person of ordinary skill would attempt to gain the visualization in a minimally invasive procedure that would have been available in an open access procedure. Ex. 1011 ¶ 71. On the basis of the current record, we determine that Petitioner has established a reasonable likelihood that the combination of Lattouf I, Carpentier, and Downing renders obvious claims 10 and 16.

Claims 20 and 21 depend from claim 19, and further recite accessing the heart endovascularly, respectively “via an antegrade” or “via a retrograde” approach. For these limitations, Petitioner relies on the disclosure in Downing that “the apparatuses and methods are compatible with several types of diagnostic and surgical techniques, including mitral valve repair, repair of atrial or ventricular septal defects, endovascular aortic surgery, and electrophysiologic studies.” Pet. 39 (quoting Ex. 1005, 3:38–42). The only explicit reference therein to an endovascular approach is to endovascular aortic surgery. We determine that Petitioner has not made a

sufficient showing that Downing discloses an endovascular approach for repair of a mitral or tricuspid valve, antegrade or retrograde, as required by claims 20 and 21. We, therefore, determine that Petitioner has not established a reasonable likelihood of prevailing of its assertion that the combination of Lattouf I, Carpentier, and Downing renders obvious claims 20 and 21.

G. Obviousness over Lattouf I and Bachman

Petitioner contends the combination of Lattouf I and Bachman renders obvious claims 1–9, 11, 14, 15, 17–23. Pet. 8, 40–43. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion with respect to claims 1, 4–6, and 18–21.

1. Claim 1

Petitioner relies on Bachman’s disclosure of using suture to connect two points on the valve to meet the limitation “wherein the one or more artificial chordae comprises a suture with one or more leaflets of the heart,” as recited by claim 1. Pet. 42 (citing Ex. 1008 ¶ 42). Based on the current record, we determine that Petitioner has made a sufficient showing that Bachman discloses attaching a suture directly to the valve leaflet for a valve repair. Ex. 1008 ¶ 42. Petitioner argues that it would have been obvious to a person of ordinary skill to use Bachman’s suturing technique in performing the repair of Lattouf I. Pet. 40–42 (citing Ex. 1011 ¶ 73). Petitioner argues that it would have been obvious to modify Lattouf I’s disclosure of anchoring the valve leaflet to the heart wall, e.g., using a clip, with the suturing technique of Bachman, in order to more closely mimic what a surgeon would do in an open surgical approach. *Id.* We determine on the basis of the current record that Petitioner has established a reasonable

likelihood that the combination of Lattouf I and Bachman renders obvious claim 1.¹³

2. Claims 4–6 and 18–21

In its Petition, Petitioner alleges how each limitation of claims 4–6 and 18–21 would be understood to be disclosed by the combination of Lattouf I and Bachman. Pet. 40–43. Based on our independent review of the evidence at this stage of the proceeding, we determine that Petitioner has established a sufficient showing that Lattouf I and Bachman disclose the limitations of claims 4–6 and 18–21. For similar reasons as for claim 1, we determine that Petitioner has established a reasonable likelihood that the combination of Lattouf I and Bachman renders obvious claims 4–6 and 18–21.

3. Claims 2, 3, 7–9, 11, 14, 15, 17, 22, and 23

As noted above, there is a mismatch between the statement of claims asserted in the ground on pages 8 and 41 of the Petition, and the claims for which analysis is provided. The Petition does not provide claim charts or evidence for its assertion that the combination of Lattouf I and Bachman renders obvious claims 2, 3, 7–9, 11, 14, 15, 17, 22, and 23. To the extent that Petitioner attempts to incorporate other parts of the Petition by reference, it is unclear upon what aspects of Bachman Petitioner relies. As such, we do not institute review on this ground with respect to claims 2, 3, 7–9, 11, 14, 15, 17, 22, and 23. *See* 37 C.F.R. § 42.104(b)(3)–(5).

¹³ On this record, Petitioner has also made a sufficient showing, apart from Bachman, that Lattouf I discloses an embodiment that uses a suture attached directly to the valve leaflet. *See supra*.

H. Obviousness over Lattouf I and Downing

Petitioner contends the combination of Lattouf I and Downing renders obvious claims 1–23. Pet. 43–47. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 1, 2, 4, 5, and 19.

1. Claim 1

Petitioner relies on Downing’s disclosure of placing a suture to connect the valve and papillary muscle to meet the limitation “wherein the one or more artificial chordae comprises a suture with one or more leaflets of the heart,” as recited by claim 1. Pet. 44–46 (citing Ex. 1005, 15:2–12). Based on the current record, we determine that Petitioner has made a sufficient showing that Downing discloses attaching a suture directly to the valve leaflet for a valve repair. Petitioner has demonstrated a reasonable likelihood that it would have been obvious to substitute the clip of Lattouf I with the suture of Downing, in order to more closely mimic what a surgeon would do in an open surgical approach. Pet. 45–46 (citing Ex. 1011 ¶ 76).¹⁴ On this record, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that the combination of Lattouf I and Downing renders obvious claim 1.

2. Claims 2, 4, 5, and 19

In its Petition, Petitioner alleges how each limitation of claims 2, 4, 5, and 19 would be understood to be disclosed by the combination of Lattouf I and Downing. Pet. 43–47. Based on our independent review of the

¹⁴ On this record, Petitioner has also made a sufficient showing, apart from Downing, that Lattouf I discloses an embodiment that uses a suture attached directly to the valve leaflet. *See supra*.

evidence at this stage of the proceeding, we determine that Petitioner has established a sufficient showing that Lattouf I and Downing disclose the limitations of claims 2, 4, 5, and 19. For similar reasons as for claim 1, we determine that Petitioner has established a reasonable likelihood that the combination of Lattouf I and Downing renders obvious claims 2, 4, 5, and 19.

3. Claims 3, 6–18, and 20–23

As with the ground based on the combination of Lattouf I and Bachman, there is a mismatch between the listing of claims asserted on pages 8 and 46 of the Petition, and the claims for which analysis is provided at pages 43–47. The Petition does not provide separate analysis and claim charts for its assertion that the combination of Lattouf I and Downing renders obvious claims 3, 6–18, and 20–23. In this manner, the Petition does not satisfy the requirements of 37 C.F.R. § 42.104(b)(3)–(5).

I. Other Grounds

Having determined to institute an *inter partes* review of claims 1–23 variously on the grounds discussed above, we exercise our discretion and determine not to institute review on the additional grounds asserted in the Petition. *See* 35 U.S.C. § 314(a).

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–23 of the '386 patent are unpatentable.

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 following grounds:

Claims 1, 3, 7–14, 19, 22, and 23 as anticipated by Speziali;

Claims 2 and 4 as obvious over Speziali;

Claims 5, 6, 18, 20, and 21 as obvious over Speziali and Bachman;

Claims 1–9, 11–15, 17–19, 22, and 23 as obvious over Lattouf I and Carpentier;

Claims 10 and 16 as obvious over Lattouf I, Carpentier, and Downing;

Claims 1, 4–6, 18–21 as obvious over Lattouf I and Bachman; and

Claims 1, 2, 4, 5, and 19 as obvious over Lattouf I and Downing;

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized; and

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.

IPR2016-00208
Patent 7,635,386 B1

PETITIONER:

Patterson Thunte Pedersen, P.A.
Brad D. Pedersen
Eric H. Chadwick
Chad J. Wickman

pedersen@ptslaw.com
chadwick@ptslaw.com
wickman@ptslaw.com

PATENT OWNER:

Cooley LLP
C. Scott Talbot
Erik B. Milch
Nancy A. Vashaw

stalbot@cooley.com
IPR2016-00208@cooley.com
emilch@cooley.com
nvashaw@cooley.com

physical copy by MAIL to:
Harpoon Medical, Inc.
198 Log Canoe Circle
Stevensville, MD 21666

Harpoon Medical Inc.
c/o William Niland, agent
955 Nelson Place
Arnold, MD 21012