

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORP. AND  
EDWARDS LIFESCIENCES LLC,  
Petitioner,

v.

EVALVE, INC.,  
Patent Owner.

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Case IPR2019-01301  
Patent 8,057,493 B2

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Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and  
DAVID COTTA, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314, 37 C.F.R. § 42.4

## INTRODUCTION

### *A. Background*

On July 3, 2019, Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively, “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–12, 15, 20–31, and 34 (the “challenged claims”) of U.S. Patent No. 8,057,493 (Exhibit 1001, “the ‘493 Patent”). See 35 U.S.C. §§ 311–319. On October 18, 2019, Evalve, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”). On November 26, 2019, Patent Owner filed additional briefing regarding claim construction. Paper 7. Petitioner filed a response to Patent Owner’s additional briefing regarding claim construction on December 2, 2019. Paper 11. On December 3, 2019, Petitioner filed an authorized Reply to Patent Owner’s Preliminary Response addressing whether the Board should deny institution under 35 U.S.C. § 314(a) or 35 U.S.C. § 325(d). Paper 13 (“Reply”). On December 12, 2019, Patent Owner filed an authorized Sur-Reply to Petitioner’s Reply. Paper 14 (“Sur-Reply”).

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4. We may not institute an *inter partes* review “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). For the reasons provided below, we determine that the Petitioners have not satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Therefore, we do not institute an *inter partes* review of the challenged claims.

### *B. Real Parties in Interest*

Petitioner identifies itself, Edwards Lifesciences Corp. and Edwards Lifesciences LLC, as the real parties in interest. Pet. 1. Patent Owner

identifies itself as the assignee of the '493 Patent and Abbott Cardiovascular Systems, Inc. as the exclusive licensee of the '493 patent. Paper 4, 2.

*C. Related Proceedings*

The parties identify an ongoing court proceeding involving the '493 Patent: *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. 1:19-cv-00149-MN (D. Del.). U.S. Patent No. 7,563,267 ("the '267 patent"), which is a family member of the '493 Patent, is also involved in the Delaware litigation.

Petitioner has also filed a request for *inter partes* review of the '267 patent, Case IPR2019-01132. Pet. 1. The '493 Patent claims priority to the '267 patent. Institution of *inter partes* review was denied in IPR2019-01132. See IPR2019-01132, Paper 15.

*D. The '493 Patent*

The '493 Patent, entitled "Fixation Devices, Systems and Methods for Engaging Tissue," generally relates to medical devices "adapted for fixation of tissue at a treatment site." Ex. 1001, 3:31–32. More particularly, the '493 Patent describes a medical device used to repair "cardiac valves, and particularly the mitral valve, as a therapy for regurgitation. The invention enables two or more valve leaflets to be coapted using an 'edge-to-edge' or 'bow-tie' technique to reduce regurgitation, yet does not require open surgery through the chest and heart wall as in conventional approaches." *Id.* at 3:38–43. The '493 Patent also states that the medical devices "are adapted to be reversible and removable from the patient at any point without interference with or trauma to internal tissues." *Id.* at 3:27–29.

Figures 10A and 10B of the '493 Patent, set forth below, show fixation device 14 in the closed position. *Id.* at 20:15–16, 23–25.

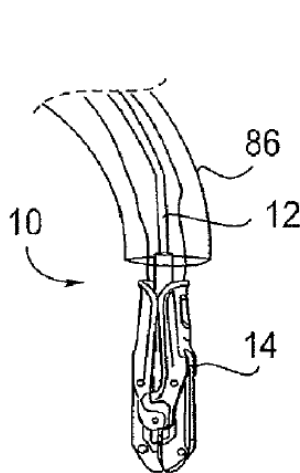


FIG. 10A

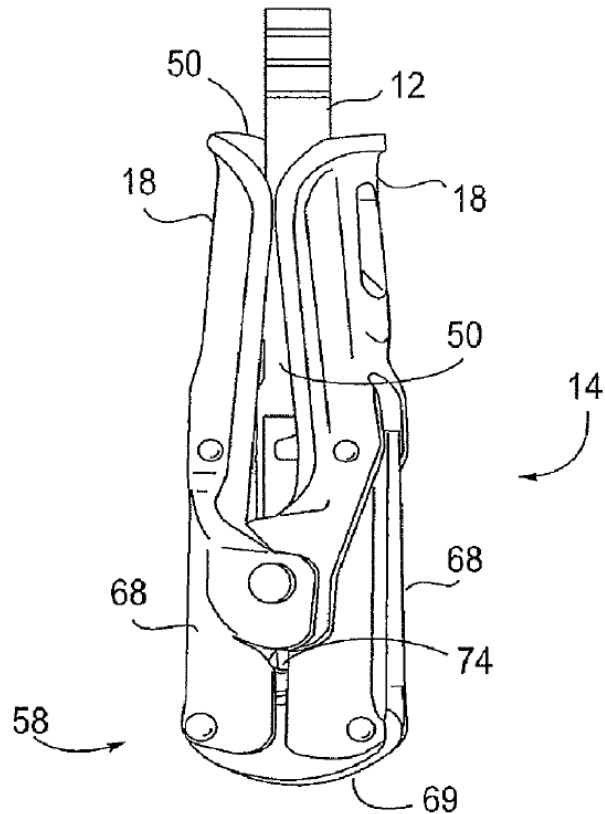


FIG. 10B

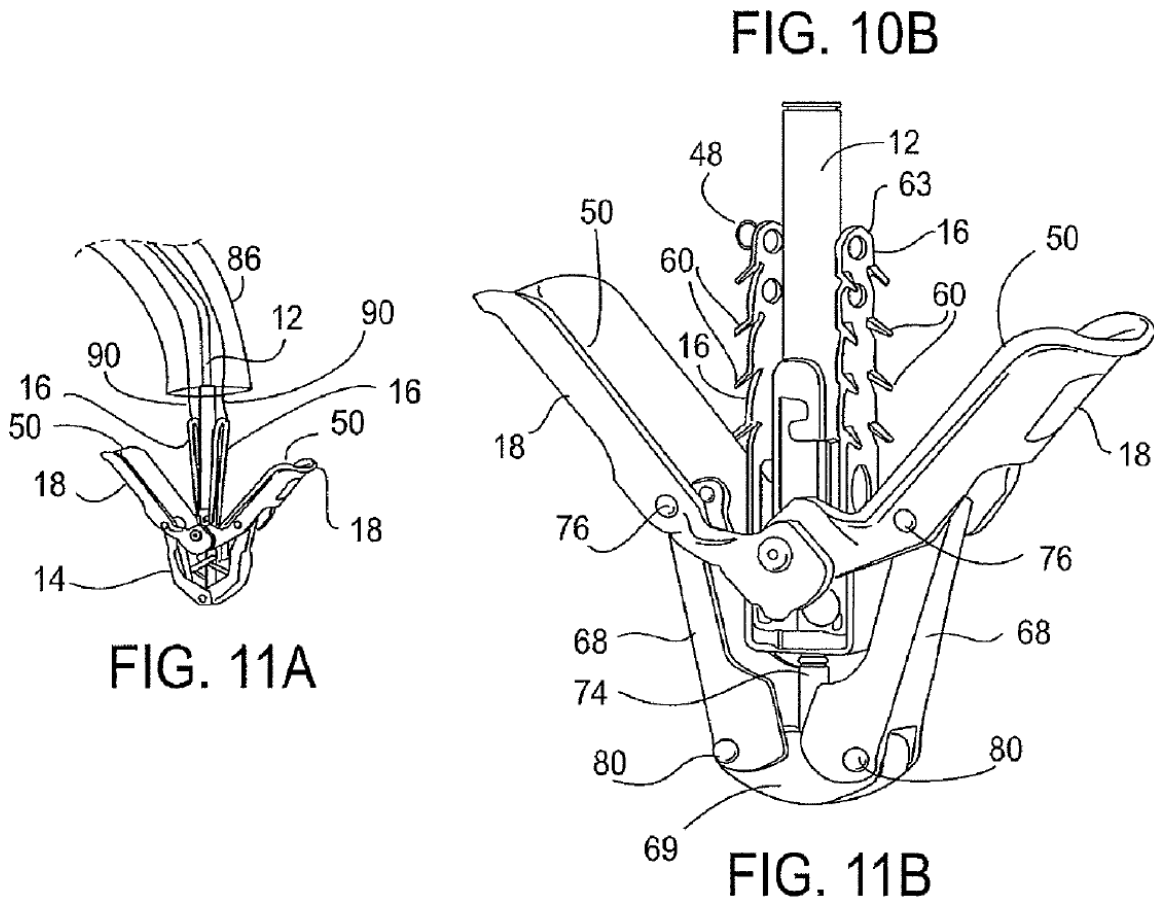
Figure 10A shows an embodiment of interventional tool 10 that includes fixation device 14 coupled to shaft 12 that is delivered through catheter 86 in the closed position. *Id.* at 20:15–16. Figure 10B, a larger view of Figure 10A, depicts actuation mechanism 58, which moves distal elements 18 between the open, closed, and inverted positions. *Id.* at 6:28–30, 20:23–25, 33–34. These two figures are further described as follows:

In the closed position, the opposed pair of distal elements 18 are positioned so that the engagement surfaces 50 face each other. Each distal element 18 comprises an elongate arm 53 having a cupped or concave shape so that together the arms 53 surround the shaft 12 and optionally contact each other on opposite sides of the shaft. This provides a low profile for the fixation device 14 which is readily passable through the catheter 86 and through any anatomical structures, such as the mitral valve . . . . [T]he actuation mechanism 58 comprises two legs 68 which are each

movably coupled to a base 69. The base 69 is joined with an actuator rod 64 which extends through the shaft 12 and is used to manipulate the fixation device 14.

*Id.* at 20:25–38.

Figures 11A and 11B of the '493 Patent, reproduced below, show fixation device 14 in the open position.



In the open position, fixation device 14 can engage the tissue which is to be treated. *Id.* at 21:21–45. To repair the mitral valve,

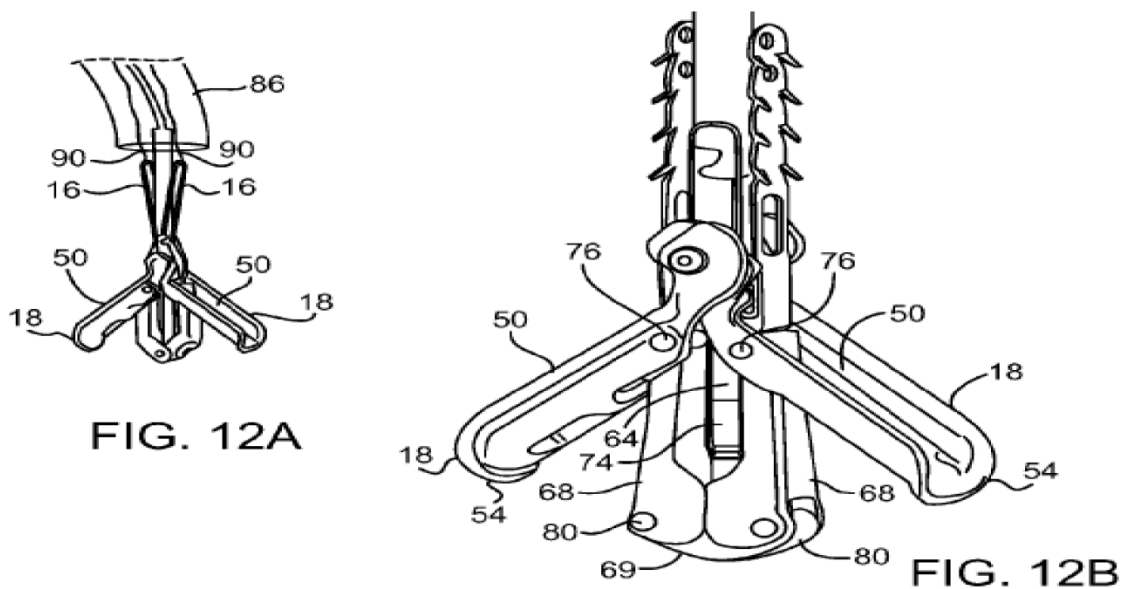
interventional tool 10 is advanced through the mitral valve from the left atrium to the left ventricle. The distal elements 18 are oriented to be perpendicular to the line of coaptation and then positioned so that the engagement surfaces 50 contact the ventricular surface of the valve leaflets, thereby grasping the leaflets. The proximal elements 16 remain on the atrial side of

the valve leaflets so that the leaflets lie between the proximal and distal elements. In this embodiment, the proximal element 16 have frictional accessories, such as barbs 60 which are directed toward the distal elements 18. However, neither the proximal elements 16 nor the barbs 60 contact the leaflets at this time.

The interventional tool 10 may be repeatedly manipulated to reposition the fixation device 14 so that the leaflets are properly contacted or grasped at a desired location. Repositioning is achieved with the fixation device in the open position.

*Id.* at 21:34–50.

The '493 Patent also describes inverting fixation device 14 to aid in repositioning or removal of the device. *Id.* at 21:55–22:18. Figures 12A and 12B, reproduced below, depict fixation device 14 in the inverted position. *Id.* at 21:56–58.



Figures 12A and 12B above, depicting a fixation device 14 in the inverted position, demonstrate that when stud 74 is further advanced relative to coupling member 19, distal elements 18 are further rotated. The rotation of

distal elements 18 causes engagement surfaces 50 to face outwardly and free ends 54 to point distally, forming an obtuse angle between each arm 53 and shaft 12. *Id.* at 21:58–62. The '493 Patent further states:

In this illustration, the proximal elements 16 remain positioned against the shaft 12 by exerting tension on the proximal element lines 90. Thus, a relatively large space may be created between the elements 16, 18 for repositioning. In addition, the inverted position allows withdrawal of the fixation device 14 through the valve while minimizing trauma to the leaflets. Engagement surfaces 50 provide an atraumatic surface for deflecting tissue as the fixation device is retracted proximally. It should be further noted that barbs 60 are angled slightly in the distal direction (away from the free ends of the proximal elements 16), reducing the risk that the barbs will catch on or lacerate tissue as the fixation device is withdrawn.

*Id.* at 22:6–18.

#### *E. Challenged Claims*

Petitioner challenges claims 1–12, 15, 20–31, and 34 of the '493 Patent. Claims 1 and 20 are the only independent claims challenged. Challenged claims 2–12 and 15 depend directly or indirectly from claim 1, and challenged claims 21–31 and 34 depend directly or indirectly from claim 20. Claim 1 recites:

1. A fixation device for engaging tissue comprising:
  - a pair of fixation elements each having a first end, a free end opposite the first end, and an engagement surface therebetween for engaging the tissue, the first ends being movably couple together such that the fixation elements are moveable between a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other; and
  - an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the first open position; and
  - a pair of gripping elements, each gripping element moveable with respect to one of the fixation elements and being disposed in opposition to one

of the engagement surfaces so as to capture tissue therebetween when the pair of fixing elements are in the first open position, wherein each fixation element is at least partially concave and each gripping element is at least partially recessed within the fixation element in the deployed configuration, and wherein the gripping elements are movable from an undeployed configuration in which each gripping element is separated from an opposing engagement surface, to a deployed configuration in which the gripping element is closer to the opposing engagement surface.

Ex. 1001, 54:27–52.

Claim 20 recites:

20. A fixation device for engaging tissue comprising:  
a pair of fixation elements each having a first end, a free end opposite the first end, and an engagement surface therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements are moveable between a closed position wherein the engagement surfaces face each other to an inverted position wherein the engagement surfaces face away from each other; and  
an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the inverted position; and  
a pair of gripping elements, each gripping element moveable with respect to one of the fixation elements and being disposed in opposition to one of the engagement surface so as to capture tissue therebetween when the pair of fixation elements are in a position other than the closed position,  
wherein each gripping element is at least partially positionable within the fixation element in the deployed configuration, and  
wherein the gripping elements are moveable from an undeployed configuration in which each gripping element is separated from an opposing engagement surface, to a deployed configuration in which the gripping element is closer to the opposing engagement surface.

Ex. 1001, 54:46–67, 55:1–5.

*F. Prior Art and Asserted Grounds of Unpatentability*

Petitioner argues that claims 1–12, 15, 20–31, and 34 would have been unpatentable based on the following grounds:

| <b>Claim(s) Challenged</b> | <b>35 U.S.C. §</b> | <b>References</b>                     |
|----------------------------|--------------------|---------------------------------------|
| 1–12, 20–31                | 103(a)             | Kuehn, <sup>1</sup> Roth <sup>2</sup> |
| 15, 34                     | 103(a)             | Kuehn, Roth, Skelton <sup>3</sup>     |

Petitioner submits the Declaration of Dr. Ivan Vesely in support of its petition. Ex. 1002.

ANALYSIS

*A. Application of 35 U.S.C. § 314(a) or 35 U.S.C. § 325(d)*

Patent Owner requests that we use our discretion under 35 U.S.C. §315(a) or 325(d) to deny *inter partes* review in this case. Prelim. Resp. 7–17. Specifically, Patent Owner asserts that we should exercise such discretion because we would duplicate the district court’s efforts in a well-advanced parallel proceeding scheduled for resolution over half a year before this proceeding would likely conclude. Patent Owner also urges the Board to exercise discretion because the Examiner considered the same or materially identical prior art to that asserted by Petitioner. *Id.* at 7.

Patent Owner states that, in the district court proceedings, the parties have taken nearly 50 depositions, produced numerous pages of documents, and the trial is scheduled for May 4, 2020, which is well before the Board is expected to issue any final written decision if *inter partes* review is instituted. Prelim. Resp. 7–9; Paper 14, 5.

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<sup>1</sup> Kuehn, U.S. Patent No. 6,165,183, Dec. 26, 2000 (Ex. 1005) (“Kuehn”).

<sup>2</sup> Roth, U.S. Patent No. 6,346,074 B1, Feb. 12, 2002 (Ex. 1006) (“Roth”).

<sup>3</sup> Skelton, U.S. Patent No. 4,340,091, July 20, 1982 (Ex. 1007) (“Skelton”).

Petitioner counters that it diligently filed its Petition only five months after Patent Owner filed its district court complaint. Reply 1–3. Petitioner further argues that the claims at issue in the district court litigations are not the same as in this proceedings and asserts that the parallel proceeding is not at an advanced stage because “[s]chedules, including trial dates, however, are not set in stone and final judgement often comes many months, sometimes years after a trial.” *Id.* at 4–5.

Regarding Patent Owner’s assertion that we should use our discretion to deny institution under 35 U.S.C. § 325 (d), Patent Owner asserts that Kuehn, the main reference applied in each of Petitioner’s challenges to the claims, was considered by the Examiner during prosecution and was used by the Examiner in two separate search strategies for additional prior art. Prelim. Resp. 13–14. Patent Owner also asserts that Roth, a second reference used by Petitioner in each of its challenges to the claims of the ’493 Patent, essentially was before the Examiner because a related Roth patent with the identical relevant disclosure was submitted and made of record during prosecution. *Id.* at 15. As for the third reference used in the second of Petitioner’s challenges, Skelton, Patent Owner asserts that substantially similar teachings were before the Examiner during prosecution. *Id.* at 16–17. Petitioner responds that “the references relied on were not applied against the claims nor were they substantively discussed by the Examiner,” which does not weigh in favor of the Board exercising discretion under 35 U.S.C. § 325(d). Reply 7.

Instead of analyzing whether to exercise our discretion under either 35 U.S.C. § 314(a) or 35 U.S.C. § 325(d), we find it more efficient to resolve our decision on institution on the merits presented in the Petition. Because we find that the Petitioner has failed to show a reasonable likelihood of

prevailing on either ground presented in the Petition and, therefore, deny institution, we decline to exercise our discretion under either 35 U.S.C. § 314(a) or 35 U.S.C. § 325(d) to deny the Petition.

*B. Level of Ordinary Skill in the Art*

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art. *KSR Internat’l Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007) (stating that obviousness is determined against the backdrop of the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art). Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner asserts:

[a] person of ordinary skill in the art (“POSITA”) at the time of the claimed invention would have been either (1) a mechanical or biomedical engineer with at least three years of experience in designing or developing medical devices who would, where necessary or desired, work or consult with others including a physician to develop such a medical device; or (2) an interventional cardiologist or cardiac surgeon with at least three years of experience developing and/or using medical devices in the heart, and who would, where necessary, work or consult with others including an engineer to develop such a medical device.

Pet. 21–22 (citing Ex. 1002 ¶¶ 30–34). Patent Owner applies Petitioner’s definition of a POSITA for the purpose of its preliminary response. Prelim. Resp. 30.

On this record, we adopt Petitioner’s definition of the level of ordinary skill in the art because it is undisputed at this time and consistent with the evidence of the record.

### *C. Claim Construction*

We construe claims “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100 (2019). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art (“POSITA”), at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.* Only those terms that are in controversy need be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner offers proposed claim constructions for the claim terms “moveable,” “adapted to move the fixation elements between the [first open/inverted] position,” “actuation mechanism,” and “coupling member for detachably coupling the fixation device to a delivery device.” For purposes of this decision, we need only construe the limitation requiring that the actuation mechanism be “adapted to move the fixation elements between the [first open/inverted] position.” Pet. 22–27.

Petitioner asserts that the phrase “between the closed position and the [first open/inverted] position” as used in the actuation mechanism limitation indicates movement in either direction, but not necessarily in both directions. Pet. 24 (citing Ex. 1002 ¶ 61). Petitioner applies the ordinary meaning of “between” that refers to the space that separates two things to conclude that “between” does not connote a particular direction. *Id.* “In other words, the phrase ‘move between A and B’ does not require movement from A to B, because moving from B to A would also be movement between the two positions (A and B).” *Id.* at 24–25 (citing Ex. 1002 ¶ 63).

Patent Owner counters that movement *between* two positions indicates back-and-forth movement. Prelim. Resp. 31. Patent Owner’s constructions of the limitation at issue, as well as a related limitation specifying the position of the fixation elements, are as follows:

| Term                                                                                                                                                                                                                                                                      | Abbot’s Proposed Construction                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| “an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the [first open (claim 1)/inverted (claim 20)] position”                                                                                   | “an actuation mechanism adapted to move the fixation elements from a closed position to [a first open (claim 1)/an inverted (claim 20)] position and also from [a first open (claim 1)/an inverted (claim 20)] position to a closed position, <i>i.e.</i> it allows a back-and-forth movement” |
| “the fixation element are moveable between a closed position wherein the engagement surfaces face each other to [a first open (claim 1)/an inverted (claim 20)] position wherein the engagement surfaces [are positioned (claim 1)/face (claim 20)] away from each other” | “the fixation elements are moveable from a closed position to [a first open (claim1)/an inverted (claim 20)] position”                                                                                                                                                                         |

*Id.* at 31–32.

Patent Owner asserts that the claim language describing the fixation elements as moveable between a closed position *to* an inverted position is unambiguous and indicates “motion in the direction of” the inverted position. Prelim. Resp. 32. Patent Owner asserts that Petitioner “ignores the express claim language, which refutes its position that the claims only require the reverse movement—from an inverted, ‘through the first open position, to a closed position.’” *Id.* (citing Pet. at 24–25; Ex. 2001 ¶¶ 37–39). Patent Owner also asserts that “between” strongly suggests coverage of movement both ways, to and from. *Id.* (citations and emphasis omitted). Patent Owner asserts that the Specification of the ’493 Patent supports its view because the back-and-forth movement is important for repositioning the device. *Id.* at 33.

We find, for purposes of this decision, that “an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the [first open (claim 1)/inverted (claim 20)] position” requires adaptation to move the fixation elements from the closed to the first open/inverted position and from the first open/inverted position to the closed position, i.e. adapted for back-and-forth movement. As we have discussed above when describing the ’493 Patent, the fixation device is delivered through the catheter in the closed position and then moved by the actuation mechanism to the open position to engage the leaflets of the mitral valve to repair it. *See supra* I.D.

As Patent Owner points out, the Specification of the ’493 Patent specifically contemplates “repositioning and optional removal of a fixation device prior to fixation to ensure optimal placement,” which requires movement from a closed to an open position and optionally an inverted position. Ex. 1001 2:20–23, 12:60–65. For instance, the ’493 Patent states:

In some situations, it may be desired to reposition or remove the fixation device 14 after the proximal elements 16, distal elements 18, or both have been deployed to capture the leaflets LF. Such repositioning or removal may be desired for a variety of reasons, such as to reapproach the valve in an attempt to achieve better valve function, more optimal positioning of the device 14 on the leaflets, better purchase on the leaflets, to detangle the device 14 from surrounding tissue such as chordae, to exchange the device 14 with one having a different design, or to abort the fixation procedure, to name a few. To facilitate repositioning or removal of the fixation device 14 the distal elements 18 are releasable and optionally invertible to a configuration suitable for withdrawal of the device 14 from the valve without tangling or interfering with or damaging the chordae, leaflets or other tissue.

*Id.* at 14:1–16.

Accordingly, for purposes of this decision and based on the current record, we conclude that back-and-forth movement is at least required for “an actuation mechanism . . . adapted to move the fixation elements between the closed and inverted position.” This determination is consistent with the District Court’s construction. *See* Ex. 2058. We find that no other claim terms need to be construed expressly.

#### *D. Patentability Analysis*

##### *1. Principles of Law*

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR*, 550 U.S. at 406. The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the

art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). “Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

In that regard, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; see *In re Translogic Tech, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). In *KSR*, the Supreme Court also stated that an invention may be found obvious if trying a course of conduct would have been obvious to a POSITA:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. “*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless ‘the improvement is more than the predictable use of prior art elements according to their established functions.’” *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles. In making such an analysis, we find that Petitioner has failed to show a reasonable likelihood of prevailing for any claim on any ground asserted in the Petition because for each challenge,

Petitioner has failed to show that all of the limitations of any challenged claim are taught or suggested by the asserted art.

## 2. *Obviousness Over Kuehn and Roth*

Petitioner asserts that claims 1–12 and 20–31 would have been obvious over the combination of Kuehn and Roth. Pet. 29. Petitioner provides an analysis of how each claim element is taught or otherwise suggested by one or both of these references. *Id.* at 31–77. Petitioner relies on the declaration of Dr. Vesely in support of its positions. *See generally* Ex. 1002. We focus our analysis on claims 1 and 20 as they are the only independent claims and the primary focus of the parties’ arguments.

Patent Owner argues that the asserted combination does not teach all of the limitations of each challenged claim and that the Petition fails to establish a clear reason as to how or why the teachings of the asserted references could be combined to arrive at the claimed invention with a reasonable expectation of success. *See* Prelim. Resp. 4–7, 17–66. Patent Owner relies on the declarations of Christopher G. Quinn and Joshua D. Rovin, M.D., in support of its positions. *See generally* Exs. 2001, 2003, respectively. Patent Owner also presents objective evidence of non-obviousness that we need not consider in light of our findings below. Prelim. Resp. 66–76.

We find, for the following reasons, that Petitioner has failed to show a reasonable likelihood of success in establishing that any of the challenged claims (claims 1–12 and 20–31) would have been obvious over Kuehn and Roth. We begin our analysis of Petitioner’s first challenge with a description of the pertinent teachings of Kuehn and Roth.

i. *Kuehn (Ex. 1005)*

Kuehn describes edge-to-edge fastening of heart valves by a catheter that enters the heart. Ex. 1005, Abstract. Figure 14A of Kuehn, reproduced below, illustrates a leaflet fastener applicator 300.

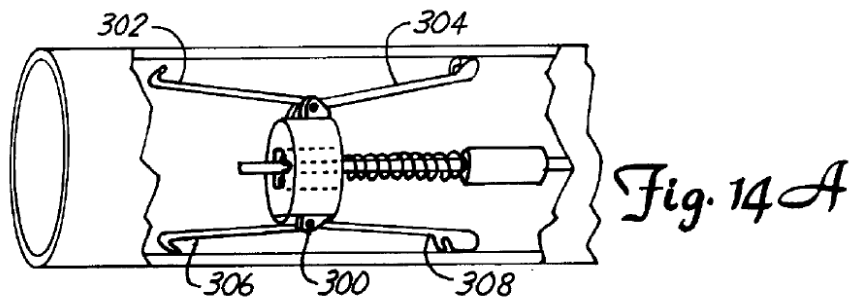
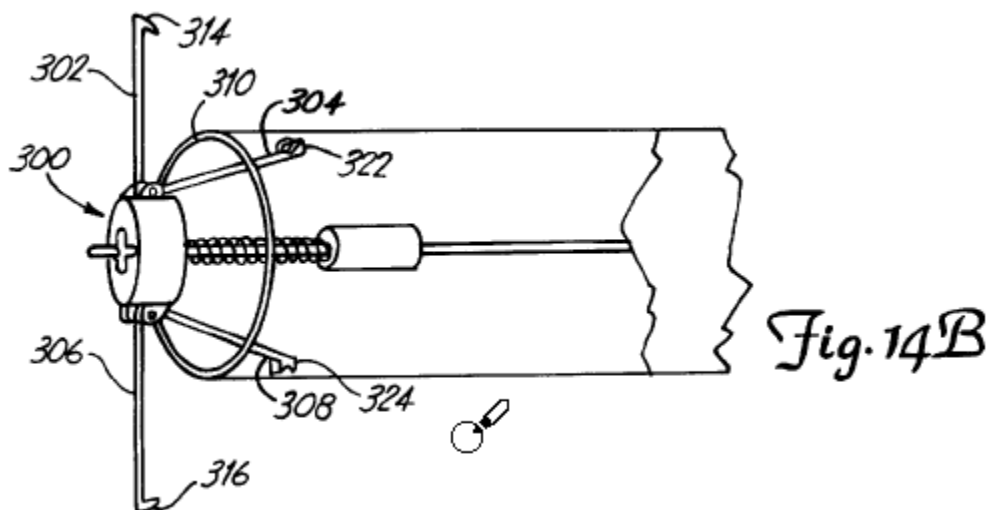


Figure 14A is described as a “single element gripper/fastener applicator 300, arms 302, 304, 306, 308 are spring loaded. As arms 302, 304, 306, 308 are pushed free of the end 310 of cardiac catheter 126, they extend due to the spring loading feature.” Ex. 1005, 8:13–16. Figure 14B depicted below shows the leaflet fastener applicator 300 being deployed.



In Figure 14B of Kuehn set forth above, “gripper/fastener applicator 300 is depicted with arms 302, 306 extended. Arms 302, 306 have pointed tips 314, 316 that can pierce leaflets 122, 124” (not shown). *Id.* at 8:16–19.

Figure 14C of Kuehn set forth above depicts the fastener after it has been released from the cardiac catheter 126. *Id.* at 8:19–23.

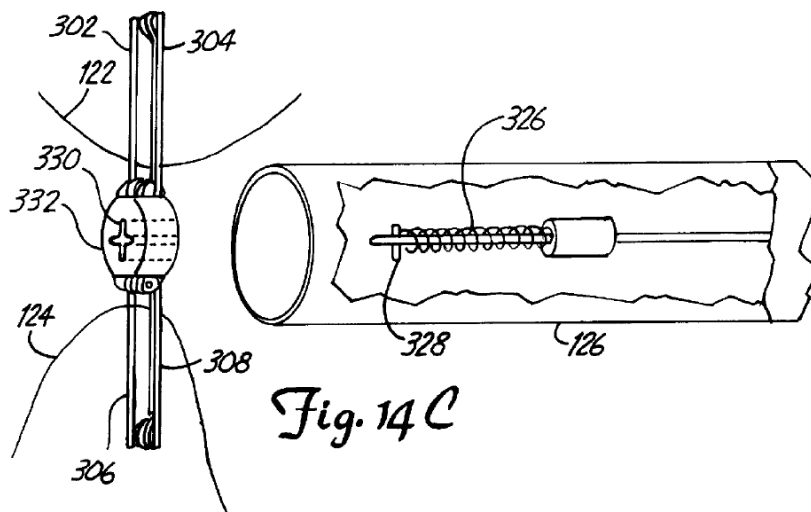


Figure 14C of Kuehn is described as follows.

[O]nce arms 304, 308 are free of the cardiac catheter 126, arms 304, 308 extend on one side of the leaflets to grasp leaflets 122, 124 along with arms 302, 306, which extend on the other side of leaflets 122, 124. Arms 304, 308 have clasps 322, 324 that engage pointed tips 314, 316 such that arms 302, 304, 306, 308 firmly grasp leaflets 122, 124 therebetween. Grasper/fastener applicator 300 is released from applicator 326 by rotating knob 328 such that knob 328 passes through passageway 330 within base 332. In an alternative embodiment, arms 302, 304, 306, 308 are curved as depicted in FIG. 14D.

*Id.* at 8:19–30. Figure 14D is reproduced below.



ii. *Roth (Ex. 1006)*

Roth describes devices for accessing the interior of the heart. Ex. 1006 Abstract. More specifically, Roth teaches a delivery shaft for accessing the heart thoracoscopically. *Id.* at 3:15–26, 18:13–16. Roth further teaches that access device 22 can be used to inspect and repair mitral valves. *Id.* at 32:47–48. Figure 8A of Roth, reproduced below, depicts access device 22 providing access to heart 100 through the chest.

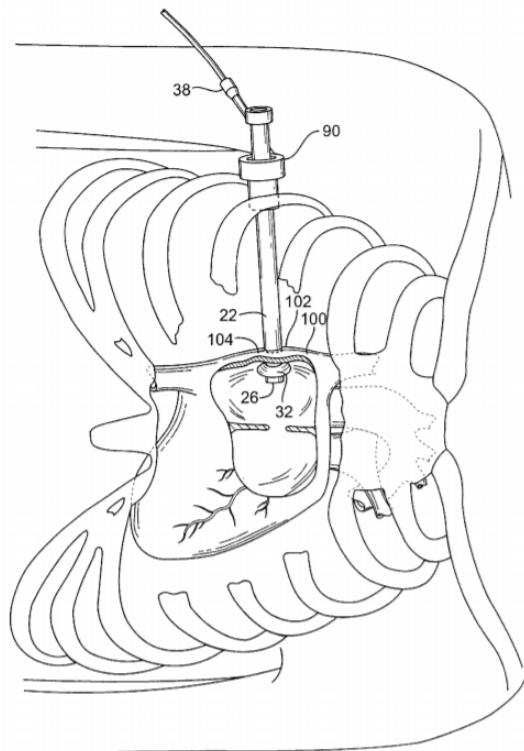


FIG. 8A

Roth also teaches systems and methods for repairing atrial septal defects. *Id.* at Abstract, 16:42–44. Figure 16 of Roth, shown below, depicts an umbrella-type patch for repairing a defect D in the atrial septum S. *Id.* at 16:59–63. The patch is designed to completely block blood flow across defect D. *Id.* at 18:32. Roth explains that tie wires 194 may be used to reposition and remove the patch 164. *Id.* 18:41–43. Tensioning tie wires 194 allows for patch repositioning or removal by collapsing struts 148 back into a collapsed position. *Id.* 18:43–48.

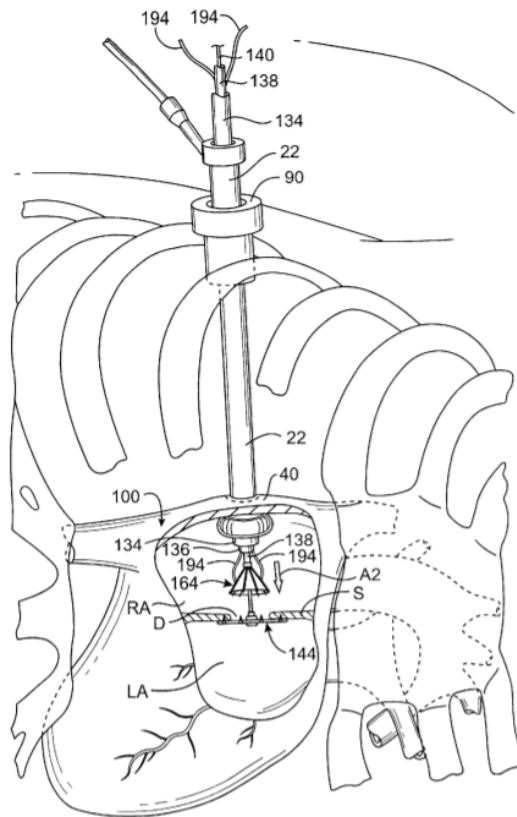


FIG. 16

When describing the benefits of the disclosed invention, Roth describes the risks of open chest surgery. *Id.* at 1:50–67, 2:1–3. Roth then proceeds to discuss intravascular devices and the challenges and risks of using intravascular devices to repair the heart. *Id.* at 2:16–20. Roth describes these problems as follows:

One such problem is the difficulty in manipulating the artificial patches into position across a defect using only the proximal end of a long and flexible delivery catheter positioned through a tortuous arterial or venous lumen. Also problematic is the inadequacy of fixation of endovascularly-placed patches, creating a tendency of such patches to migrate to embolize after placement, which can allow blood to again shunt through the defect. In addition, once such a patch has been placed and the delivery catheter detached from the patch, relocating and repositioning the patch with the catheter is difficult, if not impossible, and may require open surgical correction.

*Id.* at 2:20–30. Roth also states that intravascular approaches in young children is particularly problematic as their peripheral vessels are extremely small and avoiding damage to them is paramount for proper growth of the child. *Id.* at 2:21–36.

Roth’s background of the invention section concludes by stating that the disclosed device overcomes the previously described problems with intravascular techniques. *Id.* at 2:65–3:12.

### *iii. Analysis*

Petitioner primarily relies on Kuehn as teaching the majority of the limitations of each of claims 1–12 and 20–31. Pet. 31–77. For instance, Petitioner asserts that Kuehn discloses a “leaflet fastener applicator” that Petitioner asserts corresponds to the claim “fixation device for engaging tissue” for repairing heart valves, such as a mitral valve. Pet. 34 (citing Ex. 1002 ¶ 85).

Petitioner further states, with reference to Figure 14B, that:

[E]ach of Kuehn's fixation elements 304, 308 has a first end connected to the central hub, a free end located opposite the first end, and an engagement surface in between for engaging the mitral valve leaflets.

Pet. 35 (citing Ex. 1002 ¶ 87).

To show that the fixation elements are "movably coupled together,"

Petitioner states that:

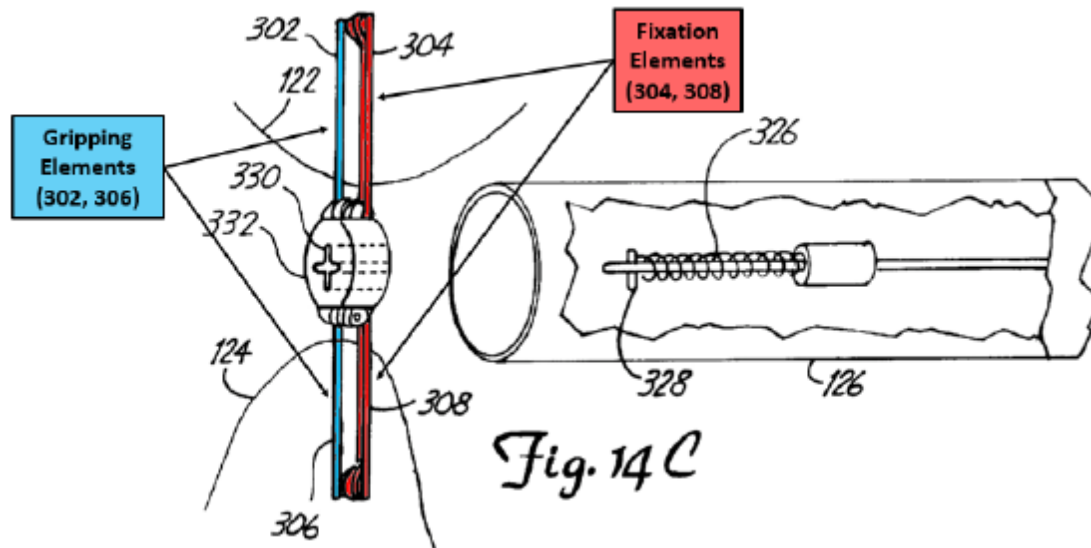
Here, the Kuehn arms are capable of rotating in either direction, either through an applied force (such as pressure from a finger pushing on the arms or tie wires pulling on the arms) or the force from Kuehn's "spring-loading feature." Ex. 1002 ¶¶ 90–92; Ex. 1005, 8:12–30, Figs. 14A–C.

Pet. 36.

Petitioner points to Figures 14A–C of Kuehn to show that Kuehn also teaches the "actuation mechanism . . . adapted to move the fixation elements between the closed and inverted positions." Pet. 37–48. Specifically,

Petitioner states:

Kuehn discloses that fixation elements 304, 308 move to at least the position shown in Figure 14C, which is an example of a first open position. In this position, the fixation elements are positioned away from each other, and the mitral leaflets are shown being captured between the fixation and gripping (302, 306) elements:



Ex. 1005, Fig. 14C; Ex. 1002 ¶ 100.

Furthermore, a POSITA would have been motivated to modify the device so the arms can be in a position that would allow the leaflets to maintain a more natural shape, which is to naturally curve downward and toward the left ventricle . . . .

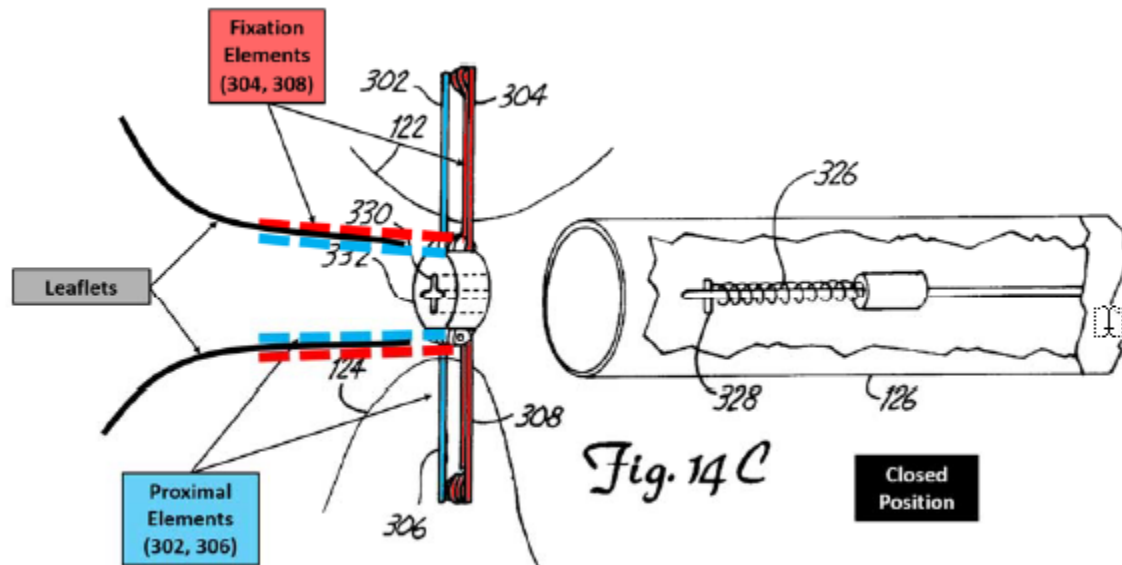
Pet. 40–41, Fig. 14C (as annotated by Petitioner). Petitioner points to Figure 23 and 24 in Kuehn to show acknowledgement that the leaflets of a valve curve downward. Pet. 40–42.

Petitioner also relies on its declarant, Dr. Vesely, to establish that one of ordinary skill in the art would have been motivated to match the normal curvature of the leaflets in a valve when capturing the leaflets. Pet 44–48.

Petitioner asserts that:

As Dr. Vesely explains, one way to accomplish this would be to adjust the relative spring forces of each arm, causing the springs to apply greater force to the fixation elements (304, 308) than the gripping elements (302, 306). Ex. 1002 ¶ 103. Because mitral leaflets have a downwardly curving shape, when a physician deploys the modified Kuehn device using a ventricular approach, the fixation elements (304, 308) would rotate past the position shown in Figure 14C and capture the leaflets in their native shape. *Id.*; Ex. 1005, 8:12–30. When fully rotated, the fixation elements would be closer

together and pressed against the ventricular side of the leaflets and, in this position, their engagement surfaces face each other, which the claims recite as the closed position. The annotated figure below shows what the Kuehn device, as modified by a POSITA to allow the leaflets to maintain their natural shape, would look like when implanted in a mitral valve:



Ex. 1002 ¶ 103. Thus, the fixation elements would be in a closed position wherein the engagement surface face each other. *Id.*

Pet. 44–45.

Petitioner asserts that a POSITA would have been motivated to make these adjustments to Kuehn’s device shown in Figures 14A–C because:

1. A POSITA would have understood that Kuehn’s device would be most successful in decreasing mitral regurgitation if its arms adjusted to a more natural leaflet shape to minimize trauma and stress on the leaflets, Pet. 45 (citing Ex. 1002 ¶ 104);

2. A POSITA would have understood that following the natural curve of the leaflets would increase the likelihood of capturing both leaflets and, thus, the device would be easier to implant, Pet. 45–46 (citing Ex. 1002 ¶ 105);

3. Kuehn itself shows that the leaflets point downward in a natural configuration in Figures 23 and 24 such that a POSITA would have understood that modifying the “spring loading feature” so that the deployed arms maintain a more natural shape of the leaflets would accomplish the grasping of the leaflets, Pet. 46–47 (citing Ex. 1002 ¶ 106);

4. The proposed modification of Kuehn “applies a known technique (matching the natural shape of the leaflets) to a known device and method (Kuehn’s device) that is ready for improvement and yield predictable results (a version of Kuehn’s device that [is able to] capture the leaflets in a more natural shape).” Pet. 47 (citing Ex. 1002 ¶ 107; *KSR*, 550 U.S. at 417); and

5. The proposed modification of Kuehn is a choice from a finite number of identifiable, predictable solutions, Pet. 44–45 (citing Ex. 1002 ¶ 105; *KSR*, 550 U.S. at 421).

Finally, Petitioner asserts that a POSITA would have had a reasonable expectation of success in modifying Kuehn’s device as set forth above because “[a]ny necessary modification to achieve the desire orientation would be minimal. Ex. 1002 ¶ 109. Therefore, a POSITA would have had a reasonable degree of confidence that any modification would be successful. *Id.*” Pet. 48 (citing Ex. 1002 ¶ 109).

Petitioner asserts that, to the extent the claims require that the actuation mechanism permit back-and-forth movement between the closed and inverted positions, which we have found that they do (*see supra* Section IIC), adding the tie wires of Roth to the Kuehn device would achieve such movement from a closed position to an inverted position. Pet. 48–53 (citing Ex. 1002 ¶¶ 111–121).

Petitioner asserts that a POSITA would have been motivated to use the tie wires of Roth in combination with Kuehn’s spring-loaded actuation

mechanism to be able to move the fixation elements in a back-and-forth movement because “[a] POSITA would have known that Kuehn’s fixation device, once it has been released from the delivery catheter, cannot be repositioned and would be difficult to recapture because the spring loading feature biases the pairs of arms toward each other without the ability to control either pair of arms after closure.” Pet. 50 (citing Ex. 1002 ¶ 114). Therefore, to be able to reposition Kuehn’s device and enhance the ability to capture the leaflets, a POSITA would apply Roth’s tie wires to allow for “more granular” control of the arms and the ability for gradual deployment of the arms to prevent impact damage to the leaflets. Pet. 50–51.

Petitioner points to a reference in Roth to the mitral valves as an express disclosure that Roth’s devices and techniques are useful for repair of mitral valves, *see* Pet. 52 (citing Ex. 1006, 32:43–48), and the use of such tie wires in the ’493 Patent itself, *see* Pet. 52–53 (citing Ex. 1002 ¶ 124; Ex. 101, 20:65–21:29). Because such tie wires were used successfully in the ’493 Patent, Petitioner argues, “a POSITA would have had a reasonable expectation of success in including Roth’s tie wires in Kuehn’s device.” Pet. 52 (citing Ex. 1002 ¶ 124).

Petitioner points to clasps 322, 324 that engage pointed tips 314, 316 as teaching fixation elements that are at least partially concave. Pet. 59–62. Petitioner also asserts that Kuehn teaches the claimed gripping elements that are moveable between an undeployed configuration to a deployed configuration. *Id.* at 63–65.

Patent Owner counters that no one of ordinary skill in the art would have begun with the embodiments of Kuehn in Figure 14, which “is a single-shot, snap-into-place application of ‘spring loaded arms,’ with leaflet-‘pierc[ing],’ ‘pointed tips.’” Prelim. Resp. 25 (citing Ex. 1002, 3:29–32,

8:18–19; Ex. 2001 ¶ 44). Patent Owner further states that “[n]ot only is Kuehn’s Figure 14 device designed to capture leaflets in a lateral position—not in axial alignment with the catheter as proposed in Edwards’ Petition—but Kuehn’s springing arm movement is automatic, uncontrolled, and irreversible, akin to a mitral mousetrap.” *Id.* at 27.

To capture leaflets in an axial position, Patent Owner asserts that a POSITA would have begun with another Kuehn embodiment, such as in Figure 23 that shows capturing the leaflets in axial alignment. Prelim. Resp. 37–38 (citing Ex. 2001 ¶¶ 56–60). Patent Owner also points to problems with the embodiment shown in Figures 14A–C as having passageways and gaps through which blood could jet backwards through the valve creating continued regurgitation, a problem which would “secure the leaflets in their malfunctioning state, with minimal to no therapeutic effect.” Prelim Resp. 39–40.

Patent Owner also asserts that Petitioner fails to show where Kuehn teaches “a closed position wherein the engagement surfaces face each other” as required by claim 1 and instead uses a modified version of a Kuehn device that is disclosed nowhere in Kuehn. Prelim. Resp. 41–45 (emphasis omitted).

We agree with Patent Owner that Petitioner has not shown sufficiently why or how one of ordinary skill in the art would have been motivated to begin with Kuehn’s device as shown in Figures 14A–C to achieve a closed position wherein the engagement surfaces face each other. In explaining how and why one of skill in the art would be motivated to bias the spring-loaded action of this device to force the fixation elements to come together in a closed position such that the engagement surfaces face each other, Dr. Vesely opines that keeping the leaflets of a valve in a more naturally

oriented position would be better. However, Dr. Vesely does not identify persuasive support from the art that such a goal would have caused one of ordinary skill in the art to make the proposed modification to the device shown in Kuehn's Figure 14A–C. *See* Ex. 1002 ¶¶ 100–110.

To support his position, Dr. Vesely relies on the two embodiments depicted in Kuehn's Figures 23 and 24 that show capture of leaflets in an axial manner where the leaflets are maintained in a downward curving manner. *Id.* ¶ 106. As Mr. Quinn and Dr. Rovin point out, the disclosure in Kuehn of devices that contemplate lateral leaflet capturing, rather than axial leaflet capturing, diminishes the motivation to modify Figure 14. Ex. 2001 ¶¶ 56–61; Ex. 2003 ¶¶ 134–136. In fact, the leaflets shown captured in a more natural shape utilize a different mechanism for capture than that shown in Figures 14A–D, suggesting that one of skill in the art, seeking to capture leaflets in a downward position in an axial manner, would not look to Figure 14. *See* Ex. 2001 ¶ 73; Ex. 2003 ¶ 119.

We also agree with Patent Owner that Petitioner has not sufficiently shown how the modification to Kuehn would work to capture the leaflets of the mitral valve in a more natural downward shape to prevent regurgitation and that Petitioner has not shown that one of skill in the art would have a reasonable expectation of success in doing so. *See* Prelim. Resp. 50–54. For instance, if fixation elements 304, 308 were overbiased to rotate past the position shown in Figure 14C, it is unclear how the device would capture the leaflets in their native shape as Dr. Vesely claims.

As Figure 14B shows, when the gripping elements emerge from the catheter, they rotate to a 180 degree, lateral position. *See* Ex. 1005, Fig. 14B. Before the over biased fixation elements 304 and 308 could rotate into the axial or closed position, they would meet the gripping elements in the lateral

position, “at which point the barb on arm 302 would engage the tissue and embed in the clasp at the end of arm 304. Similarly, the bottom leaflet would be captured at the moment that arm 308 met arm 306.” Ex. 2001 ¶ 78.

Therefore, instead of capturing the leaflets in their native shape, the fixation elements would first capture the tissue in the same way as the unmodified Kuehn device operates, and then rotate to the axial position *after* tissue capture. *Id.* ¶¶ 79, 89.

As we have determined in our construction of the claim terms set forth above, the actuation mechanism requires back and forth movement between the inverted and closed positions. *See supra* Section II.C. As Patent Owner has stated, Kuehn discloses a one-shot device that deploys from an inverted to a closed position, but not the reverse. *See* Prelim. Resp. 25–28. Petitioner admits that “[a] POSITA would have known that Kuehn’s fixation device, once it has been released from the delivery catheter, cannot be repositioned and would be difficult to recapture because the spring loading feature biases the pairs of arms toward each other without the ability to control either pair of arms after closure.” Pet. 50 (citing Ex. 1002 ¶ 114). Therefore, Petitioner acknowledges that the Kuehn device once deployed to a closed position, cannot be moved again to the inverted position.

Petitioner offers the combination with Roth to teach this back-and-forth movement. *Id.* (stating a POSITA would have been motivated in view of Roth to attach tie wires to Kuehn’s fixation elements (304,308)). We find, however, that Petitioner has not identified persuasive motivation to combine Kuehn with Roth.

As explained by Patent Owner, we do not believe Petitioner sufficiently explained why a POSITA would look to Roth to improve Kuehn’s device. Prelim. Resp. 57–58. Roth does not disclose any mitral

valve repair device, Roth does not teach edge-to-edge valve repair, and Roth does not disclose how tie wires could be used for edge-to-edge valve repair. *Id.* Further, as explained above in our discussion of Roth, *see supra* Section II.D.2.iii., Roth does not relate to intravenous heart diagnostics or repair. Roth discloses methods for inspecting or repairing heart defects thoracoscopically. Ex. 1006, 3:15–26, 18:13 –16. In fact, Roth discourages using its methods and devices for catheter-delivered heart diagnostics or repair. *Id.* at 2:16–24.

For at least these reasons, we find that Petitioner has failed to show a reasonable likelihood of prevailing in its assertion that claims 1–12 and 20–31 are unpatentable over Kuehn and Roth.

### 3. *Obviousness Over Kuehn, Roth, and Skelton*

Petitioner asserts that claims 15 and 34 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kuehn, Roth, and Skelton. Pet. 77–80. Skelton is offered by Petitioner only to teach the requirement of claims 15 and 34 of “a covering on the fixation elements adapted for promoting tissue growth.” *Id.* For the same reasons that we set forth above, we find that Petitioner has failed to show a reasonable likelihood of success in establishing that challenged claims 15 and 34 would have been obvious over Kuehn, Roth, and Skelton.

## IV. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1–12, 15, 20–31, and 34 are unpatentable.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '493 Patent and no trial is instituted.

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Patent 8,057,493 B2

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