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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC,
Petitioners,

v.

EVALVE, INC.,
Patent Owner.

Case No. IPR2019-01132
Patent No. 7,563,267

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-9, 12, AND 17 OF U.S. PATENT NO. 7,563,267

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 7,563,267 ("the '267 patent")
1002	Declaration of Ivan Vesely, Ph.D.
1003	Curriculum Vitae of Ivan Vesely, Ph.D.
1004	Excerpts from the '267 Patent File History
1005	U.S. Patent No. 6,165,183 ("Kuehn")
1006	U.S. Patent No. 6,346,074 ("Roth")
1007	U.S. Patent No. 4,340,091 ("Skelton")
1008	U.S. Patent Publication No. 2002/0013571
1009	U.S. Provisional Application No. 60/128,690
1010	Randas J. V. Batista et al., *Partial Left Ventriculectomy to Treat End-Stage Heart Disease*, 64 Ann. Thorac. Surg. 634-38 (1997) ("Batista")
1011	C. Fucci et al., *Improved Results with Mitral Valve Repair Using New Surgical Techniques*, 9 Eur. J. Cardiothorac. Surg. 621-27 (1995) ("Fucci")
1012	Excerpts from *Webster's New World College Dictionary* (3d ed. 1997)
1013	Excerpts from *The New Oxford Dictionary of English* (3d ed. 2001)
1014	Excerpts from *Random House Webster's College Dictionary* (2d ed. 1992)
1015	Excerpts from *The Ciba Collection of Medical Illustrations*, Vol. 5, *Heart* (Frank H. Netter ed., 1969) ("Netter")
1016	Gregg W. Stone et al., *Clinical Trial Design Principles and Endpoint Definitions for Transcatheter Mitral Valve Repair and Replacement: Part 1: Clinical Trial Design Principles: A Consensus Document From the Mitral Valve Academic Research Consortium*, 66 J. Am. Coll. Cardiol. 278-307 (2015) ("Stone")

Exhibit No.	Description
1017	International Patent Publication No. WO 2003/020179 A1 ("Tremulis")
1018	U.S. Patent No. 5,741,297 ("Simon")
1019	U.S. Patent No 3,874,388 ("King")
1020	U.S. Patent No. 5,716,417 ("Girard")
1021	Arthur C. Beall et al., *Clinical Experience with a Dacron Velour-Covered Teflon-Disc Mitral Valve Prosthesis*, 5 Ann. Thorac. Surg. 402-10 (1968) ("Beall")
1022	Excerpts from Complaint (Dkt. 1) in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.)
1023	Excerpts from Abbott MitraClip Instructions for Use (Ex. 97 to Dkt. 15) in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.)
1024	Excerpts from Plaintiffs' Opening Brief in Support of Motion for Preliminary Injunction (Redacted) (Dkt. 14) in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.)
1025	Excerpts from Transcript of Hearing on Preliminary Injunction Motion (Redacted) in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.)
1026	Excerpts from Declaration and Expert Report of Dr. Ajit Yoganathan (Ex. 6 to Dkt. 15-2) in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.)
1027	Excerpts from Keller Letter to Judge Noreika (Redacted) (Dkt. 147) in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.)

Exhibit No.	Description
1028	Gina Kolata, *Tiny Device Is a 'Huge Advance' for Treatment of Severe Heart Failure*, N.Y. Times, Sept. 23, 2018

Petitioners Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively "Petitioners" or "Edwards") respectfully request *inter partes* review in accordance with 35 U.S.C. §§311-319 and 37 C.F.R. §42.100 *et seq.* of claims 1-9, 12, and 17 of U.S. Patent No. 7,563,267, which issued on July 21, 2009 and is purportedly owned by Evalve, Inc. ("Patent Owner").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(A)(1)

The following mandatory notices identified in 37 C.F.R. § 42.8(b) are provided below as part of this Petition.

A. Real Party-in-Interest Under 37 C.F.R. § 42.8(b)(1)

Edwards Lifesciences Corporation and Edwards Lifesciences LLC are the real parties-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

On January 28, 2019, Patent Owner and its purported exclusive licensee asserted the '267 patent against Edwards in *Abbott Cardiovascular Sys., Inc. & Evalve, Inc. v. Edwards Lifesciences Corp. & Edwards Lifesciences, LLC*, No. 1:19-cv-00149-MN (D. Del.).

C. Lead and Backup Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioners provide the following designation of counsel:

Lead Counsel	Backup Counsel
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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this petition. The above identified lead and backup counsel are registered practitioners associated with Customer No. 20,995 listed in that Power of Attorney.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to lead and back-up counsel at the address shown above. Petitioners also consent to electronic service by email to: BoxEdwards10-2@knobbe.com.

E. Payment of Fees Pursuant to 37 C.F.R. § 42.103

The fee set forth in 37 C.F.R. § 42.15(a) for this petition has been paid. The undersigned further authorizes payment for any additional fees that may be due in

connection with this petition to be charged to Deposit Account 11-1410.

F. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioners certify that the '267 patent is available for IPR and that Petitioners are not barred or estopped from requesting this IPR. Petitioners filed this Petition within one year of Patent Owner serving the Complaint in *Abbott Cardiovascular Sys. v. Edwards Lifesciences Corp.*, No. 1:19-cv-00149-MN (D. Del.).

II. SUMMARY OF ISSUES PRESENTED

This Petition challenges independent claim 1 and dependent claims 2-9, 12, and 17, which recite a fixation device for engaging tissue. Claim 1 recites a fixation device comprising two pairs of opposing arms referred to as "fixation elements" and "gripping elements." The fixation and gripping elements are moveable relative to each other, so that they can come together to "capture" tissue between them. The claim also recites an "actuation mechanism" that can move the fixation elements (which have "engagement surfaces") between closed and inverted positions. In the closed position, the engagement surfaces face each other, and in the inverted position, the engagement surfaces face away from each other. Some dependent claims include limitations relating to the relative positions of the fixation elements, including moving to an open position.

While the claims are not limited to engaging any particular type of tissue,

the specification provides that the "present invention" relates to the repair of heart valves, including coapting (bringing together) the two leaflets of the mitral valve to treat mitral regurgitation (a potentially severe condition in which the mitral valve allows blood to leak in the wrong direction). Ex. 1001, 1:34-58. To this end, the '267 patent describes several embodiments using devices with two pairs of opposing arms to capture the mitral leaflets.

Such devices, however, were not patentable at the time of the '267 patent's earliest possible priority date in April 1999.[1] By that time, devices with opposing arms for repairing the mitral valve had been described and were known in the art. Ex. 1002 ¶¶42-45. For example, in 1998, Kuehn disclosed a device having two pairs of opposing arms (302, 306 and 304, 308) that deploy in the mitral valve to capture the leaflets (122 and 124):

[1] As explained herein, Petitioners dispute that the '267 patent is entitled to the earliest claimed priority date.

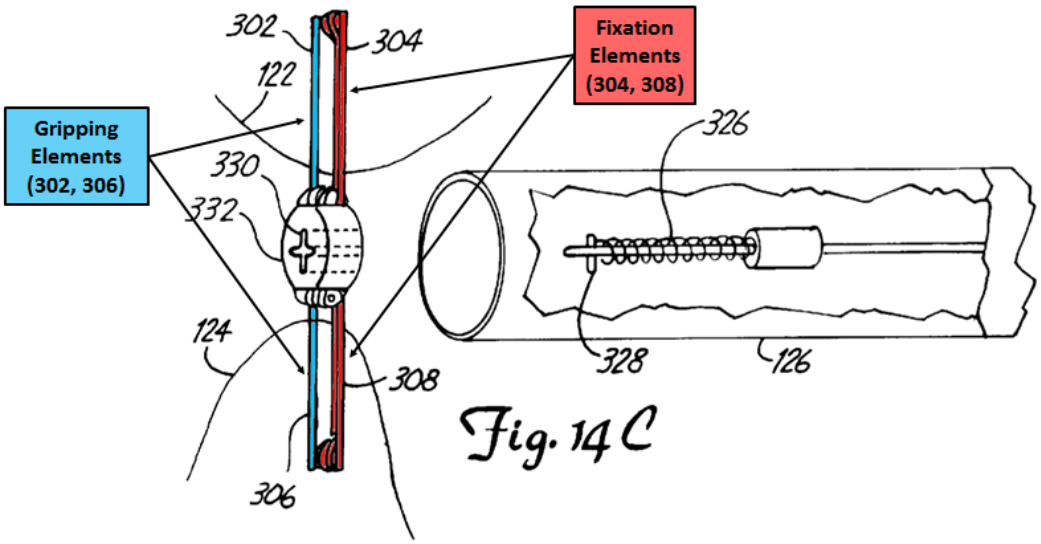


Fig. 14C

Ex. 1005, Fig. 14C.[2] The Kuehn device also includes an actuation mechanism that allows the fixation elements to move between positions. For example, Figure 14A below shows the fixation elements in a different position than shown in Figure 14C:

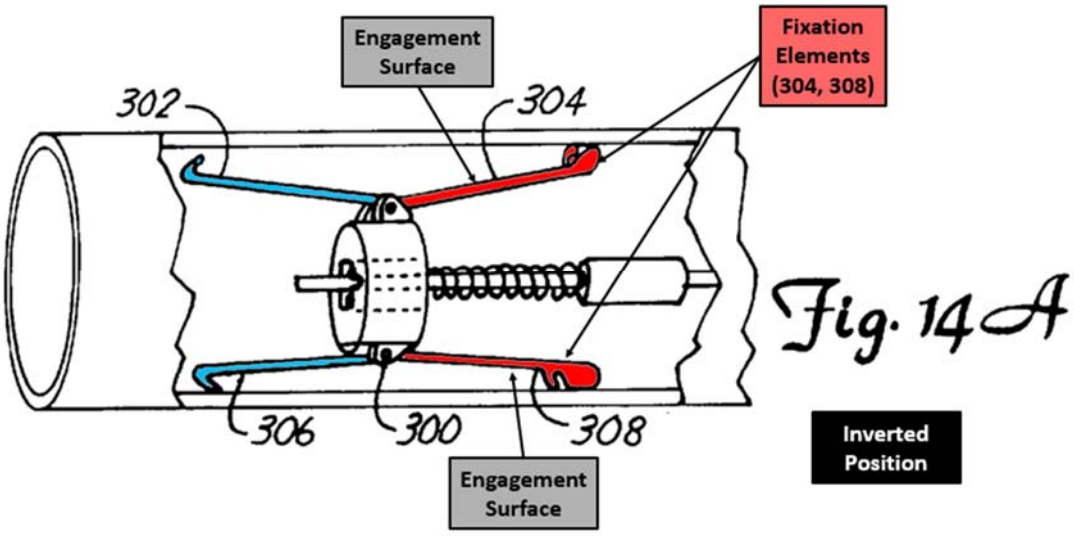


Fig. 14A

Id., Fig. 14A. A second example, Tremulis, discloses a similar device for mitral

[2] Figures have been colored and annotated for clarity.

valve repair that also includes two pairs of opposing arms that move between positions and extend on either side of a leaflet to capture it:

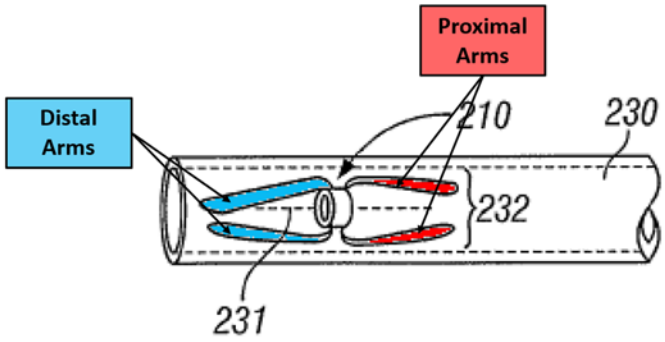


FIG. 28

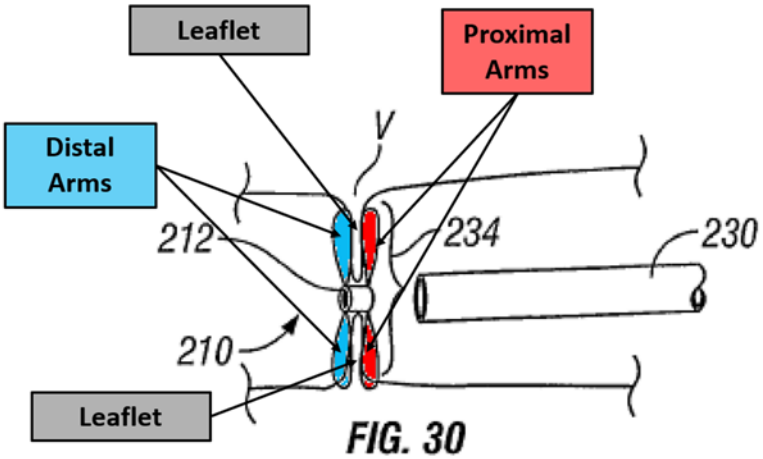


FIG. 30

Ex. 1017, Figs. 28, 30.

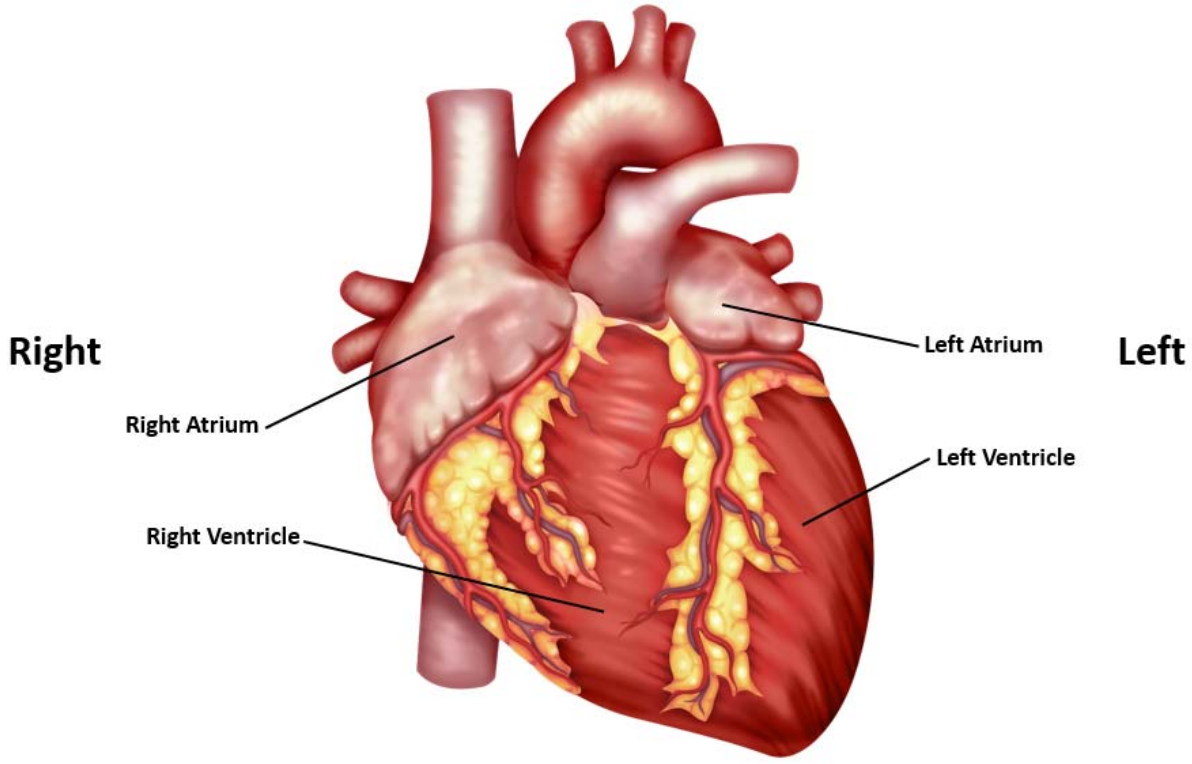
In view of the prior art describing devices with opposing arms for grasping mitral valve leaflets, Patent Owner's claims never should have issued. But such prior art references were not applied by the Examiner. Instead, the Examiner allowed the claims after Patent Owner made amendments and added limitations to overcome different references, none of which disclosed opposing arms that come together to capture tissue. Once opposing-arms references, like Kuehn, are

applied, it is clear the challenged claims of the ’267 patent are unpatentable and, therefore, should be canceled.

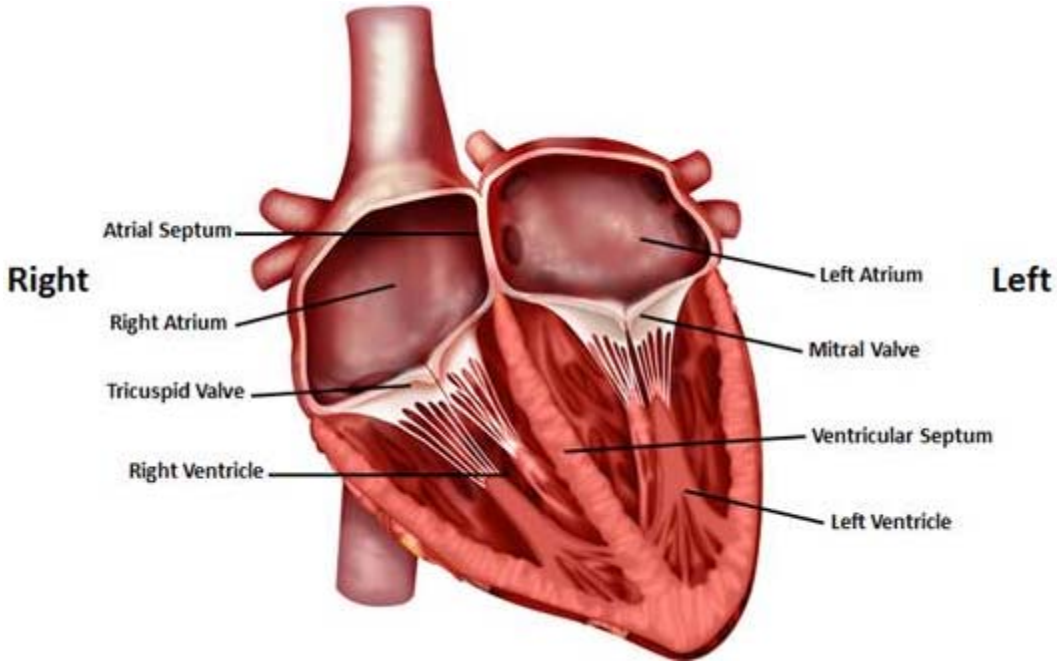
III. BACKGROUND AND STATE OF THE ART

A. Heart Anatomy

The human heart has four chambers, including two upper chambers (the left and right atriums) and two lower chambers (the left and right ventricles). Ex. 1002 ¶35.

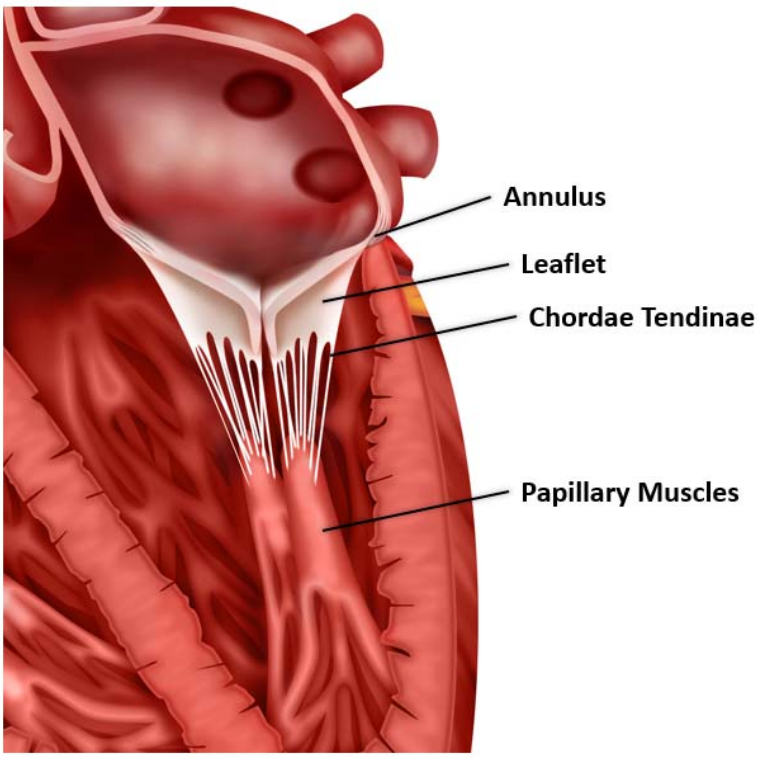


Id. Partitions, called the atrial and ventricular septums, separate the upper and lower chambers, respectively. *Id.* ¶36. On the left side of the heart, the mitral valve connects the left atrium and the left ventricle. *Id.*



Id.

The mitral valve includes an annulus, which is a ring of fibrous tissue that surrounds the valve orifice. The mitral valve also includes a pair of leaflets, or flaps of tissue, that extend from the annulus down into the ventricle. *Id.* ¶37; Ex. 1001, 3:14-22. The leaflets are connected to the papillary muscles in the left ventricle by chordae tendinae (or chords). Ex. 1002 ¶37.

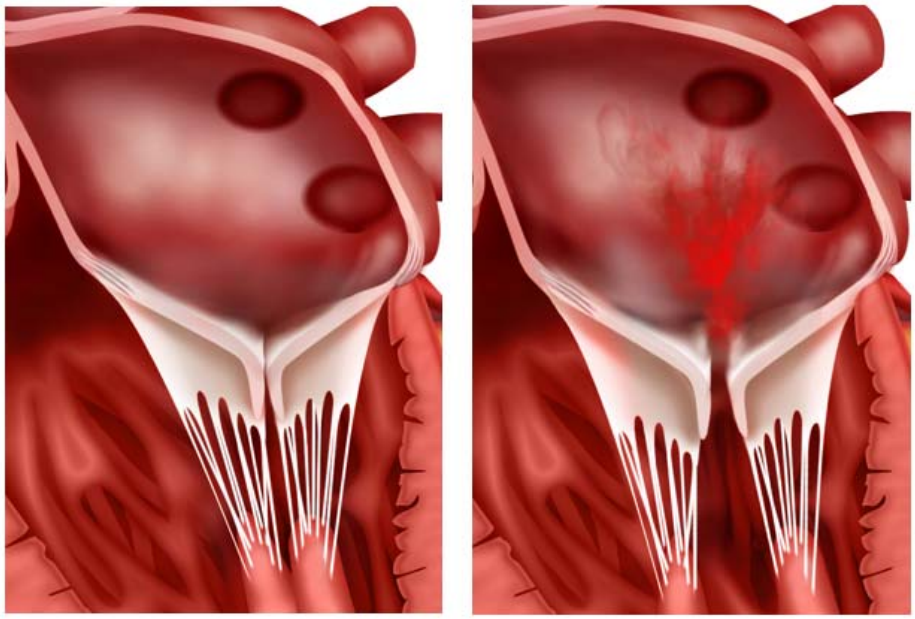


Id.

When the mitral valve is functioning normally, the leaflets operate as a one-way valve to allow blood to flow downward from the left atrium into the left ventricle and to prevent the backflow of blood upward from the left ventricle to the left atrium. *Id.* ¶38; Ex. 1001, 1:52-56. When the left atrium contracts and the left ventricle relaxes (known as "diastole"), the pressure in the left atrium becomes greater than the pressure in the left ventricle. Ex. 1002 ¶38. This pressure difference causes the mitral leaflets to separate and open the valve, allowing blood to flow from the left atrium into the left ventricle. *Id.* Then, when the left atrium relaxes and the left ventricle contracts (known as "systole"), the leaflets come

together and close the valve so that blood cannot flow back into the left atrium. *Id.* To prevent the leaflets from folding back into the left atrium under pressure, the chordae tendinae in the left ventricle tether the leaflets to the heart wall via the papillary muscles. *Id.*

Mitral regurgitation is a common problem that can occur in a defective mitral valve. *Id.* ¶39. Mitral regurgitation occurs when the mitral valve leaflets fail to coapt properly (i.e., completely come together) in systole, which creates an opening in the valve that allows blood to flow backward from the left ventricle into the left atrium. *Id.*



Id.

B. Treatments for Mitral Regurgitation

A well-known treatment for mitral regurgitation involves attaching the leaflets together via a repair technique known as the "bow tie" or "edge-to-edge" technique. Ex. 1002 ¶40; *see generally* Exs. 1010-1011. This repair technique brings the two leaflets together and reduces or eliminates the regurgitation by essentially converting the single mitral valve orifice into two smaller orifices, with similar forward flow but with substantially reduced regurgitation. Ex. 1002 ¶40. Figure 5A from the '267 patent's immediate parent application shows the bow-tie repair using a single suture:

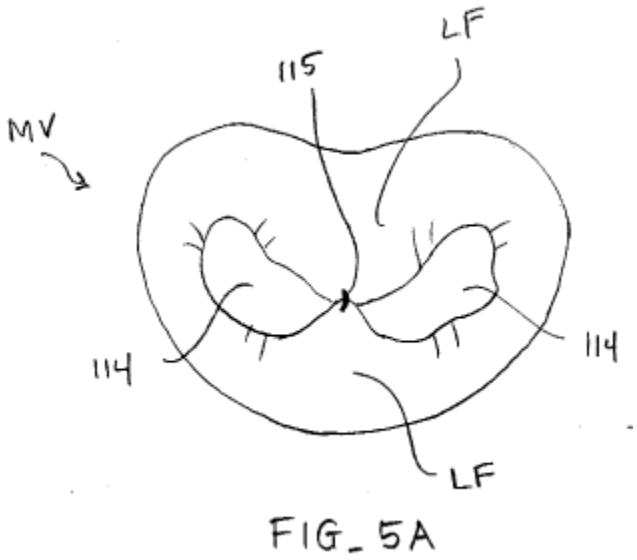
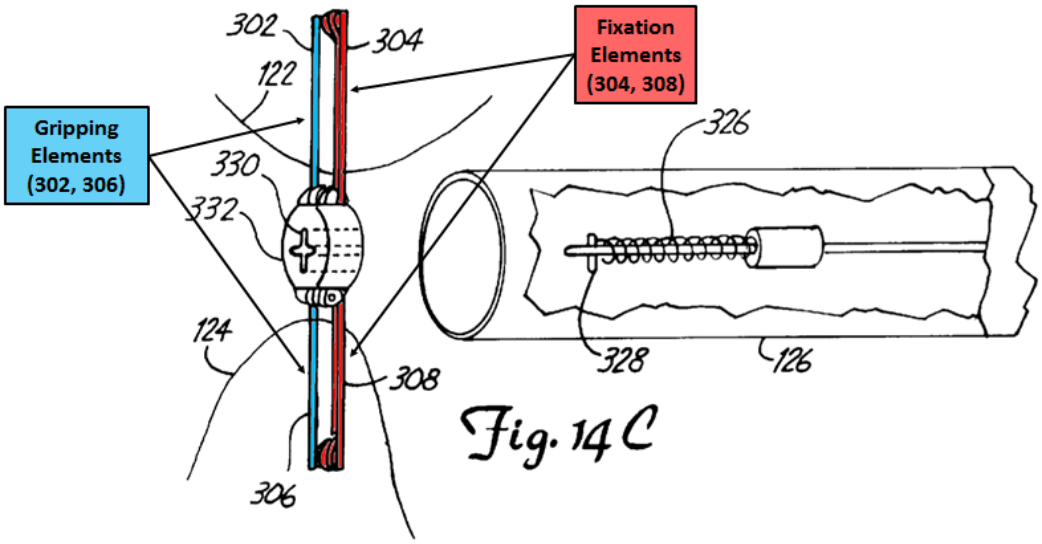


FIG_5A

Ex. 1008, Fig. 5A, ¶[0083]. Dr. Ottavio Alfieri is credited with originating this procedure many years before Patent Owner filed the '267 patent or any application the '267 patent claims priority to, including the earliest provisional application filed in April 1999. He and others initially performed the procedure using a single

suture in an open-heart surgical operation. Ex. 1002 ¶41; *see generally* Exs. 1010-1011. However, open-heart surgery is highly invasive, prone to complications, and traumatic for the patient. Ex. 1002 ¶41.

As an alternative to open-heart surgery, others have developed various techniques to perform the "bow tie" procedure using instruments delivered via catheter. *Id.* ¶¶40-43. Using these techniques, a physician introduces a catheter, usually through the femoral artery or vein, and advances it into the heart to perform the procedure. *Id.* ¶41. Rather than a single suture, opposing arms grasp and fix the leaflets (122, 124) closer to each other; for example, as shown in Kuehn:



Ex. 1005, Fig. 14C.

IV. THE '267 PATENT

A. Overview of the '267 Patent

The '267 patent claims previously known opposing-arms devices for engaging tissue in order to repair a heart valve. Ex. 1002 ¶¶42-46. One embodiment of the '267 device uses two pairs of opposing arms (e.g., a pair of distal or "fixation" elements and a pair of proximal or "gripping" elements). Ex. 1001, 17:66-19:34. Upon deployment in the mitral valve, the two pairs of arms capture the mitral valve leaflets between the proximal and distal arms on each side. *Id.*, 20:11-22:52. After capturing the leaflets, the device may be left behind in the heart. *Id.* Figure 11B shows one embodiment of the device:

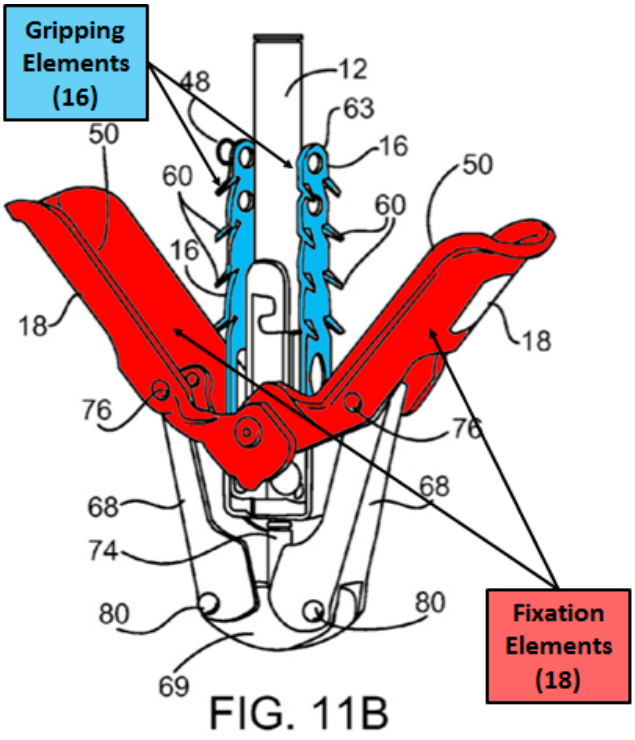


FIG. 11B

Id., Fig. 11B.

B. Prosecution of the ’267 Patent

Patent Owner filed the application for the ’267 patent on May 19, 2003. The Patent Office originally rejected the independent claims as anticipated by Gifford, which discloses a staple device for vascular anastomosis (the surgical joining of biological tissues, such as blood vessels and arteries). Ex. 1004 at 298-300. The Patent Office determined that Gifford disclosed all the claimed limitations, including a pair of fixation elements having a first end and a free end, and an engagement surface therebetween, with the first ends being movably coupled together, and an actuation mechanism coupled to the fixation elements that is capable of moving the fixation elements between closed, open, and inverted positions. Patent Owner overcame the rejection by amending claim 1 to add a second pair of arms, i.e., the pair of gripping elements. *Id.* at 314-23.

The Patent Office subsequently rejected the independent claims as anticipated by Shichman, which discloses a surgical staple device (for fastening skin in order to close a wound). *Id.* at 338-41. The Patent Office determined that Shichman disclosed the same claim limitations as Gifford, as well as the recently added pair of gripping elements. Patent Owner overcame the rejection by amending claim 1 to add two new limitations: the requirements that (1) the gripping elements partially nest within the fixation elements (i.e., each fixation element be at least partially concave and each gripping element be at least partially

recessed within the fixation element), and (2) the gripping elements be moveable from an undeployed configuration to a deployed configuration. Following this amendment, the Patent Office allowed the claims. *Id.* at 395-99.

During prosecution, Patent Owner submitted the Kuehn reference relied on herein to the Patent Office, but did so at the same time it submitted over 150 other references. *Id.* at 199-207. The Examiner never applied Kuehn, nor any reference like Kuehn disclosing devices for capturing mitral leaflets with two pairs of opposing arms that nest within each other. Rather, the Patent Office applied only two surgical staple device references, neither of which had two pairs of opposing arms for repairing a heart valve.

The other two references relied on herein, Roth and Skelton, were neither submitted to the Patent Office, nor cited by the Examiner, and, thus, were not of record during prosecution.

C. Claims

The challenged claims of the ’267 patent are directed to a fixation device for engaging tissue (e.g., a device to repair heart valves by capturing the leaflets). Independent claim 1 recites:

1. A fixation device for engaging tissue comprising:

[a] a pair of fixation elements each having a first end, a free end opposite the first end, 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

[b] an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the inverted position; and

[c] 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,

[d] 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

[e] 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.

Dependent claims 2-8 specify further details about the fixation and gripping elements. Dependent claim 9 recites a coupling member for detachably coupling the claimed fixation device to a delivery device. Dependent claim 12 recites a

covering on the fixation elements for promoting tissue growth. Dependent claim 17 specifies the angle between the engagement surfaces of the fixation elements when those elements are in the closed position.

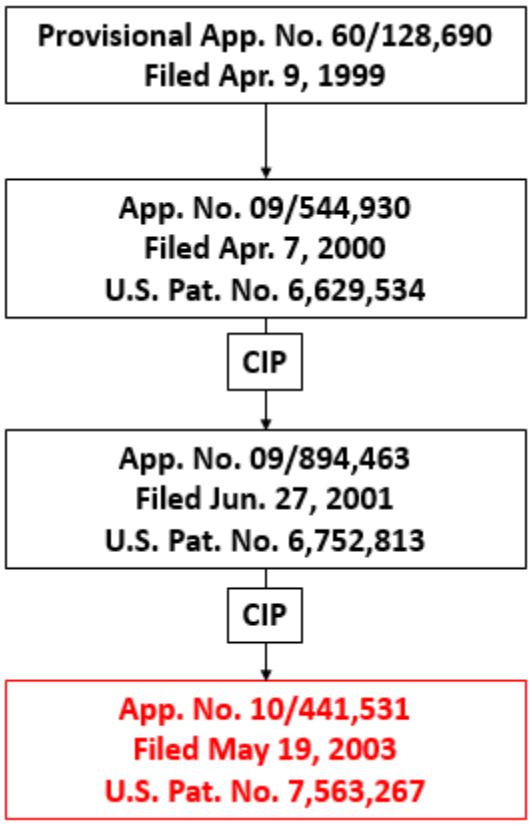
D. Priority

On May 19, 2003, Patent Owner filed Application No. 10/441,531, which ultimately issued as the '267 patent. In the original specification and application data sheet (ADS), Patent Owner identified the '531 application as a continuation-in-part of Application No. 09/894,463 filed on June 27, 2001, and identified the '463 application as a continuation-in-part of Application No. 09/544,930 filed on April 7, 2000. Ex. 1004 at 6, 8.

The Patent Owner further identified the '930 application as claiming the benefit of Provisional Application No. 60/128,690 filed on April 9, 1999 under 37 C.F.R. § 1.78(a), but did so only in the original specification of the '531 application. Ex. 1004 at 8. The concurrently filed ADS listed the '690 provisional application, but did so in the wrong field and did not identify the '930 application as claiming the benefit of the '690 provisional application.[3] *Id.* at 6.

[3] The cover of the '267 patent misidentifies the '930 application as a division of the '690 application; however, the '690 application is a provisional application, so a divisional application could not have been filed based on it. Ex. 1001.

The flow diagram below shows the ’267 patent’s purported priority chain, including the alleged benefit claim to the ‘690 application:



Even though the ’531 application was a continuation-in-part application, the patent examiner never analyzed whether the prior applications supported the new claims during prosecution.

For the reasons explained below, the ’267 patent is not entitled to the priority benefit of the earlier applications. The Board need not address priority, however, unless Patent Owner attempts to: (1) establish a priority date earlier than the ’531 application’s actual filing date and (2) swear behind the prior art references relied upon herein, including making a showing of reasonably

continuous diligence in reducing the claimed subject matter to practice.

1. Lack of Written Description Support for the Challenged Claims in the Earlier Applications

The ’267 patent challenged claims are not entitled to a priority date earlier than the May 19, 2003 filing date of the ’531 application. As a CIP, the ’531 application contains new disclosure that was not present in the immediate parent application (the ’463 application). As explained in Section VIII herein, Patent Owner has the burden to establish entitlement to an earlier priority date, but cannot do so because the disclosure in the immediate parent application does not support the challenged claims. Because the challenged claims lack written description support in the immediate parent application, the priority chain is broken and the challenged claims are limited to the May 19, 2003 filing date.

2. Break in Continuity of Inventors

Even if Patent Owner could show written description support for the challenged claims in the earlier applications, the ’531 application would not be entitled to the benefit of the April 9, 1999 provisional filing date due to a break in continuity of inventors.

The ’531 application does not name at least one common joint inventor with the inventors named in the ’690 provisional application. The ’690 provisional application identifies five inventors, none of whom are named in the ’531

application as inventors. Ex. 1009 at 1-2; Ex. 1004 at 3-7. Failure to name one of the provisional application inventors in the'531 application breaks the priority chain. MPEP § 211.01, subsection II; 35 U.S.C. §120 (pre-AIA). Accordingly, the '531 application is not entitled to the benefit of the April 9, 1999 provisional filing date.

E. Level of Ordinary Skill in the Art

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. Ex. 1002 ¶¶29-33.

V. CLAIM CONSTRUCTION

In an *inter partes* review proceeding, the claims shall be construed using the same claim construction standard that would be used to construe the claims in a civil action, including giving the claim language its ordinary and customary meaning as understood by a POSITA at the time of filing and in accordance with

the specification and the prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

A. "moveable"

Independent claim 1 requires that the first ends of the fixation elements are "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." Ex. 1001, claim 1 (emphasis added).

The claim term "moveable" means capable of being moved, but does not require actual movement. Ex. 1002 ¶60. "Moveable" is not a term of art in medicine or medical device design. *Id.* Therefore, a POSITA would have understood the term to have its plain and ordinary meaning as commonly used in the English language, which is simply "capable of being moved." *Id.*; Ex. 1012 at 7 (defining "movable" as "that can be moved from one place to another; not fixed"); Ex. 1013 at 9-10 (defining "movable" as "capable of being moved"); Ex. 1014 at 6 (defining "movable" as "capable of being moved; not fixed in one place, position, or posture").

The language and the structure of claim 1 confirms this plain and ordinary meaning. Ex. 1002 ¶61. In the "fixation element" limitation in which the term "moveable" appears, claim 1 does not recite any structure for moving the fixation

elements. *Id.* As such, a POSITA would not have understood "moveable" to require actual movement, because at that point in the claim, no structure for causing actual movement has been recited. *Id.* Rather, a later limitation requiring "an actuation mechanism" provides the structure that is "adapted to move the fixation elements."

Moreover, the '267 patent's specification confirms that "moveable" should be given its ordinary meaning. Ex. 1002 ¶62. In a paragraph discussing elongated bodies in the delivery catheter shaft, the specification uses the term "moveable" to mean "free to move," which is consistent with the ordinary meaning of "capable of being moved." *See* Ex. 1001, 34:45-66. Nothing in the specification or the prosecution history provides a special definition for the term "moveable," nor does the intrinsic evidence limit the ordinary meaning of the term in any way. Thus, "moveable" should be given its ordinary meaning of "capable of being moved."

B. "adapted to move the fixation elements between the closed position and the inverted position"

Independent claim 1 requires an actuation mechanism that is coupled to the fixation elements and is "adapted to move the fixation elements between the closed position and the inverted position." The phrase "between the closed position and the inverted position" indicates movement in either direction between the positions. Ex. 1002 ¶64. "Between" is not a term of art in medicine or medical

device design. *Id.* Therefore, a POSITA would have understood the term to have its plain and ordinary meaning as commonly used in the English language, which simply refers to the space that separates two things. *Id.*; Ex. 1012 at 4 (defining "between" as "from one to the other of" and "in or through the space that separates"); Ex. 1013 at 4-5 (defining "between" as "at, into, or across the space separating" two things); Ex. 1014 at 4 (defining "between" as "in the space separating"). The ordinary meaning of "between" does not connote a particular direction. 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). Nothing in the specification or prosecution history varies from this ordinary meaning of "between." Ex. 1002 ¶65. Thus, the Board should give the claim language this ordinary meaning.

Therefore, the plain and ordinary meaning of "adapted to move . . . between" means the mechanism is adapted to move the fixation elements from the closed position to the inverted position or from the inverted position to the closed position, but the mechanism is not required to do both. *Id.* ¶66.

C. "actuation mechanism"

Independent claim 1 recites "an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the inverted position." Petitioners do not believe that the term "actuation

mechanism" is subject to 35 U.S.C. §112, ¶6, and Patent Owner has not suggested otherwise in the district court litigation. Ex. 1026 at 5. For the reasons that follow, this limitation should be given its plain and ordinary meaning.

The absence of the word "means" from a claim limitation, as here, creates a rebuttable presumption that §112, ¶6 does not apply. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc). Patent Owner cannot overcome the presumption unless it can demonstrate that the claim term fails to recite sufficiently definite structure or recites function without reciting sufficient structure for performing that function. *Id.* Patent Owner can demonstrate neither here. Rather than simply recite a "means," the claim here recites a "mechanism" with the adjectival qualifier "actuation." A POSITA would have understood that an actuation mechanism is a mechanical structure responsible for moving and controlling another feature. Ex. 1002 ¶69; *see Flo Healthcare Soln's, LLC v. Kappos*, 697 F.3d 1367, 1373-75 (Fed. Cir. 2012) (holding that "height adjustment mechanism" designates "a class of structures that are generally understood to persons of skill in the art"), *overruled as to the strength of the §112, ¶6 presumption by Williamson*, 792 F.3d at 1349; *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583-84 (Fed. Cir. 1996) (holding that "detent mechanism" recites sufficient structure under the rebuttable presumption standard). As Dr. Vesely explains, moving fixation elements between positions in medical

devices is achieved by a class of generally understood structures, including springs, tie wires, push rods, levers, pulleys, and the like. Ex. 1002 ¶69. This is consistent with the '267 patent's specification, which describes using springs, push rods, or link members to move the fixation elements and tie wires to move the gripper/proximal elements. Ex. 1001, 6:28-42, 16:15-35, 17:5-28, 19:25-55, 20:33-46, 20:65-21:29, 21:55-23:12, Figs. 7A-7D, 10A, 11A, 12A, 13A, 14, 15; *see EnOcean GmbH v. Face Int'l Corp.*, 742 F.3d 955, 960 (Fed. Cir. 2014) ("We have stated previously that just because the disputed term is not limited to a single structure does not disqualify it as a corresponding structure, as long as the class of structures is identifiable by a person of ordinary skill in the art."). A POSITA would have understood this structure to be both definite and adequate to accomplish the recited function. Ex. 1002 ¶69. Thus, the claim limitation is not subject to §112, ¶6, and should be given its plain and ordinary meaning.

To the extent the Board finds that the limitation is subject to §112, ¶6, however, Petitioners believe that the associated function is "moving the fixation elements." A POSITA would have found the corresponding structure to include, at least, a spring-loaded mechanical system or tie wire system as disclosed in the '267 patent. Ex. 1001, 16:15-35, 17:5-28, 20:65-21:29, 23:4-12, Figs. 7A-D, 10-15; Ex. 1002 ¶70.

D. "coupling member for detachably coupling the fixation device to a delivery device"

Claim 9 recites "a coupling member for detachably coupling the fixation device to a delivery device." Petitioners do not believe that this limitation is subject to 35 U.S.C. §112, ¶6, and Patent Owner has not suggested otherwise in the district court litigation. Ex. 1026 at 6-8; *see also* Ex. 1027 at 2 (construing "coupled to the coupling member" in a related patent with no means plus function analysis). For the reasons that follow, this limitation should be given its plain and ordinary meaning.

As discussed above, the absence of the word "means" from a claim limitation, as here, creates a rebuttable presumption that §112, ¶6 does not apply and which can be overcome only if it is demonstrated that the claim term fails to recite sufficiently definite structure or recites function without reciting sufficient structure for performing that function. *Williamson*, 792 F.3d at 1348. Such a showing cannot be made here. Rather than recite a "means" together with some function, claim 9 recites a "coupling member." "Coupling" is a noun which means "a flexible or rigid mechanical device or part for joining parts together." Ex. 1012 at 5; *see also* Ex. 1013 at 6. A POSITA would have understood that the claimed "coupling member" is a component or components that include a feature that connects two or more components together. Ex. 1002 ¶72. The '267 patent

provides examples of such components and features that couple pieces of the device together. *See, e.g.*, Ex. 1001, 6:43-65, 14:55-15:31. For example, the '267 patent discloses embodiments that have an upper shaft and a lower shaft which interlock, as shown in the figures below:

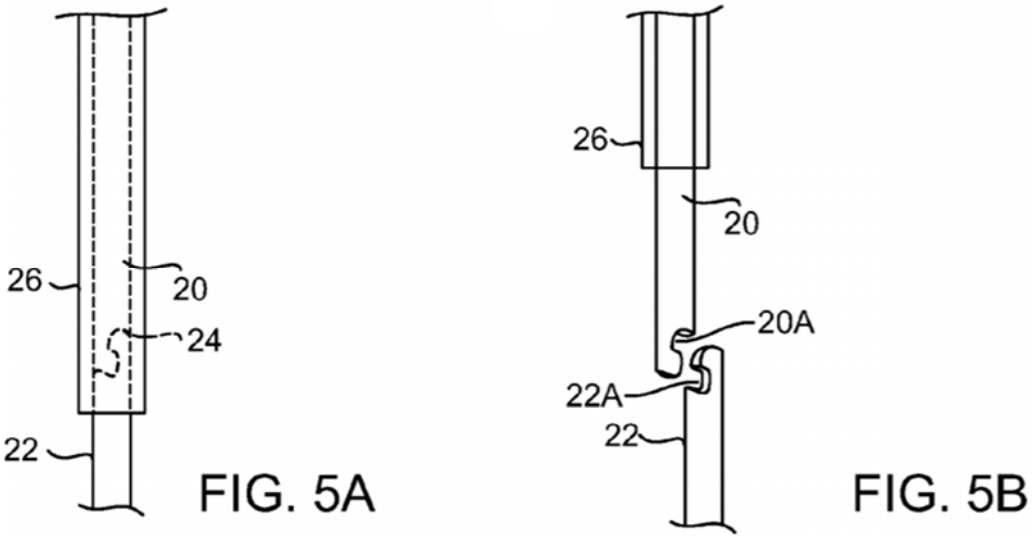


FIG. 5A FIG. 5B

Id., Figs. 5A-5B. A POSITA would have understood the structure of the "coupling member" to be sufficiently definite and adequate to achieve the function recited. Ex. 1002 ¶72. Thus, the claim limitation is not subject to §112, ¶6, and should be given its plain and ordinary meaning.

To the extent the Board finds that the limitation is subject to §112, ¶6, however, Petitioners believe that the associated function is "detachably coupling the fixation device to a delivery device." A POSITA would have found the corresponding structure to include, at least, one or more components that are configured to mate or physically interlock, as disclosed in the '267 patent. Ex.

1001, 6:43-65, 14:55-15:31, 15:54-63, Figs. 5A-B, 6A-B, 7A-D; Ex. 1002 ¶73.

Petitioners do not believe that any further claim construction is necessary to resolve the issues presented in this petition. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

VI. STATEMENT OF PRECISE RELIEF REQUESTED

A. Grounds

Ground 1: Claims 1-9 and 17 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kuehn in view of Roth and the knowledge of a POSITA.

Ground 2: Claim 12 is unpatentable under 35 U.S.C. § 103(a) as obvious over Kuehn in view of Roth, Skelton, and the knowledge of a POSITA.

Additional support is included in the accompanying Declaration of Ivan Vesely, Ph.D. (Ex. 1002).

B. Status of References as Prior Art

Kuehn, Roth, and Skelton are prior art under 35 U.S.C. §102(b) because they each issued more than one year prior to the priority date of the challenged claims, i.e., May 19, 2003. Kuehn issued on December 26, 2000; Roth issued on February 12, 2002; and Skelton issued on July 20, 1982.

Even if the '267 patent were entitled to a priority date of April 9, 1999 or April 7, 2000, which it is not, Kuehn and Roth would be prior art under at least 35 U.S.C. §102(e), because they are patents that issued from applications filed before

either of those dates. Kuehn was filed on July 15, 1998, and Roth was filed on June 12, 1996. In addition, Skelton would remain prior art under 35 U.S.C. §102(b).

Each of these references constitutes analogous art and may be used in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). As set forth in more detail below, each of the references is from the same field of endeavor as the '267 patent, namely, devices for repairing defects within the human heart. Ex. 1002 ¶81. Kuehn, Roth, and Skelton are also reasonably pertinent to a particular problem the '267 inventors were addressing, namely, repairing defects within the heart. *Id*. As analogous art, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VII. SPECIFIC PROPOSED GROUNDS FOR REJECTION

A. Ground 1: Claims 1-9 and 17 Are Unpatentable Under 35 U.S.C. §103(a) as Obvious Over Kuehn in View of Roth and POSITA Knowledge.

Kuehn discloses, or at least suggests to a POSITA, each limitation of claims 1-9 and 17. Furthermore, in view of the knowledge of a POSITA and the tie wires disclosed in Roth, each of those claims would have been obvious as a whole.

1. Kuehn Discloses Clip-Like Device with Opposing Arms for Grasping Leaflets

Kuehn discloses devices for repairing heart valves, including the mitral valve. Ex. 1002 ¶¶75-77. One such device is a clip-like device having two sets of spring-biased arms designed to move closer to each other on either side of a valve leaflet, capturing the leaflets. *Id.* Kuehn discloses delivering its device via a catheter. *Id.*

More specifically, Kuehn's device includes two sets of arms (302, 306 and 304, 308) attached to a central base or hub (332). Ex. 1005, 8:12-30. The arms are loaded into the catheter in a separated position, and they remain separated while in the delivery catheter as shown in Figure 14A:

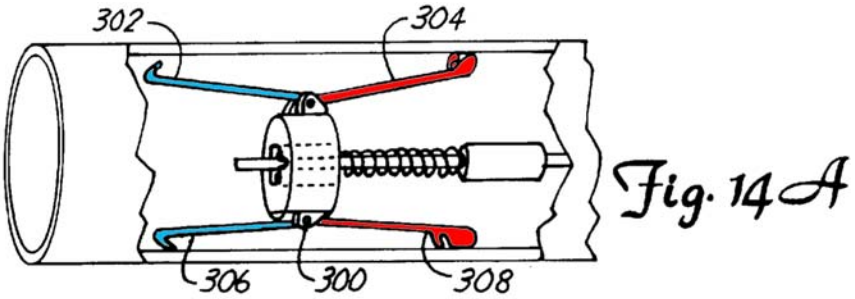


Fig. 14A

Id., Fig. 14A. As the arms emerge from the catheter (126), a spring mechanism actuates the arms and causes them to swing around and engage tissue (i.e., the mitral valve leaflets 122, 124). *Id.*, 8:13-16. Figures 14B and 14C illustrate arm movement caused by this spring actuation feature:

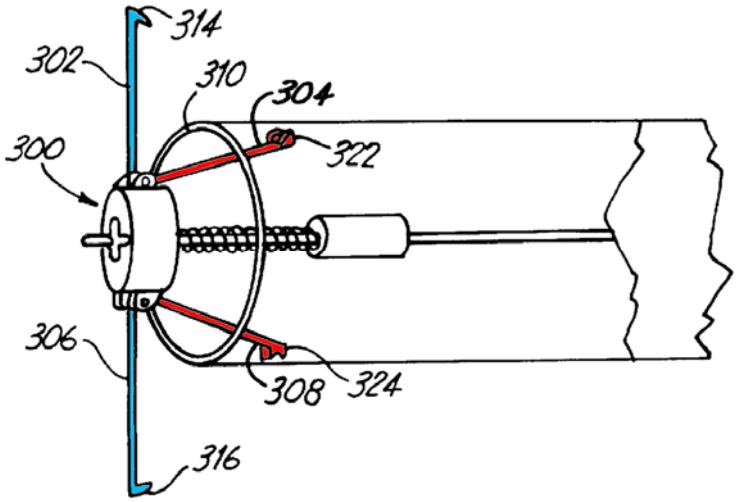


Fig. 14B

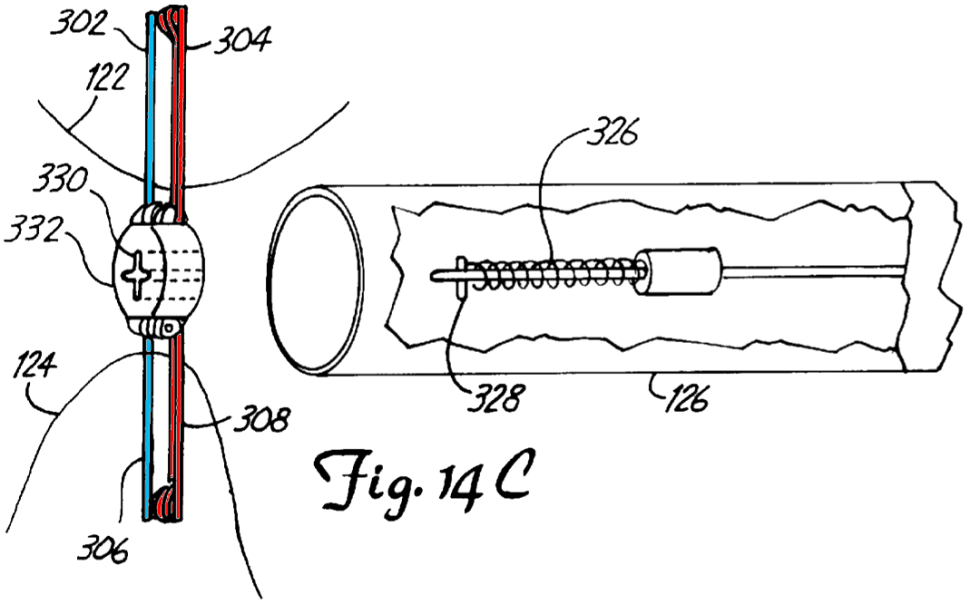


Fig. 14C

Id., Figs. 14B-C. As shown in Figure 14B, during delivery of the device, the central hub (332) is attached to a shaft (326) within the catheter. *Id.* Following implantation, the physician detaches the device from the shaft and withdraws the catheter from the patient. *Id.*, 8:26-28, 13:11-12.

2. Roth Discloses Tie Wires for Controlling Arms

Roth discloses devices for performing less invasive procedures in the heart while the heart is beating. Ex. 1002 ¶¶78-79; Ex. 1006, Abstract. For example, it discloses a device for sealing a hole in the heart to prevent leakage of blood through the hole. *Id., e.g.*, 17:19-51. Roth further discloses using tie wires to control fixation elements to enable repositioning or removing the device. *Id.*, 18:41-48. Roth also discloses that its devices and techniques are useful in a variety of other heart procedures, including repairing the mitral valve. *Id.*, 32:43-48. A person of ordinary skill would have modified Kuehn to include the Roth tie wires to control Kuehn's arms 304, 308, including for removal or repositioning of the device.

3. Claim 1

As explained below, Kuehn in combination with Roth discloses or suggests each element of claim 1.

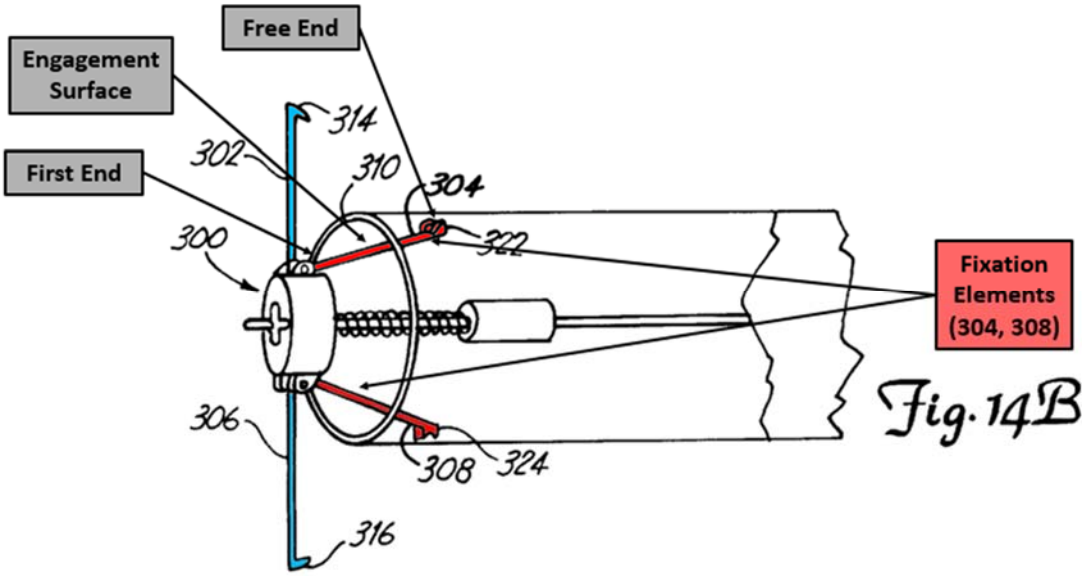
a. Preamble

The preamble of claim 1 recites "[a] fixation device for engaging tissue." Kuehn discloses a "leaflet fastener applicator" for "mitral or tricuspid valve repair." Ex. 1005, Abstract. A POSITA would have understood that the "leaflet fastener applicator" described in Kuehn is a "fixation device for engaging tissue." Ex. 1002 ¶83.

b. Fixation Elements

After the preamble, the body of claim 1 recites "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."

Kuehn discloses a device having a pair of arms 304, 308, which are "fixation elements" that contact and engage the tissue of the mitral leaflets 122, 124. Ex. 1005, 8:12-30, Figs. 14A-C.



Id., Fig. 14B. As shown above, each of the arms 304, 308 (i.e., the fixation elements) 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 (i.e., tissue). Ex. 1002 ¶85. Accordingly, Kuehn discloses, or at least suggests, the "fixation elements" limitation of claim 1.

c. Fixation Elements Movably Coupled Together Such that They Are Moveable (Disclosed by Kuehn Alone)

Claim 1 recites that "the first ends [of the fixation elements are] 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."

Kuehn discloses that the first ends of the fixation elements 304, 308 are both rotatably coupled to a central hub or "base 332." Ex. 1005, 8:12-30, Figs. 14A-C. Thus, the arms are mechanically coupled to each other via the central hub. Ex. 1002 ¶87.

Moreover, the arms are moveable, i.e., "capable of being moved." *See* §V, *supra* (claim construction). 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 ¶¶88-90, Ex. 1005, 8:12-30, Figs. 14A-C.

Kuehn does not disclose any structure that would prevent the arms 304, 308 from being rotated in either direction, and, thus, a POSITA would have understood the arms to be capable of such rotational movement, including movement between a closed position to an inverted position. Ex. 1002 ¶90. Nothing more is required by the functional language in this claim limitation. *See* §V, *supra* (claim

construction). Accordingly, Kuehn discloses or suggests that its fixation elements are movably coupled together, as required by claim 1.

If the Board determines "moveable" requires actual movement, then Petitioners have addressed this alternative in §VII.A.3.e following the section below on "actuation mechanism," which addresses actual movement of the fixation elements.

d. Actuation Mechanism . . . Adapted to Move the Fixation Elements Between the Closed and Inverted Positions

Claim 1 further recites "an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the inverted position."

i. Kuehn's Spring Loaded Actuation Mechanism Moves the Arms from Inverted to Closed

Kuehn discloses this limitation because the Kuehn device includes a spring-loaded actuation mechanism that causes fixation elements 304 and 308 to rotate and move when released from the delivery catheter 126. Ex. 1005, 8:14-16; Ex. 1002 ¶93. Kuehn Figures 14A-C show the arms pivotably arranged at the base 332, which includes the "spring loading feature" coupled to the fixation elements (304, 308). Ex. 1002 ¶94.

A POSITA would have understood that Kuehn's "spring loading feature" is a mechanism within the base 332 that uses spring force to actuate (i.e., rotate or

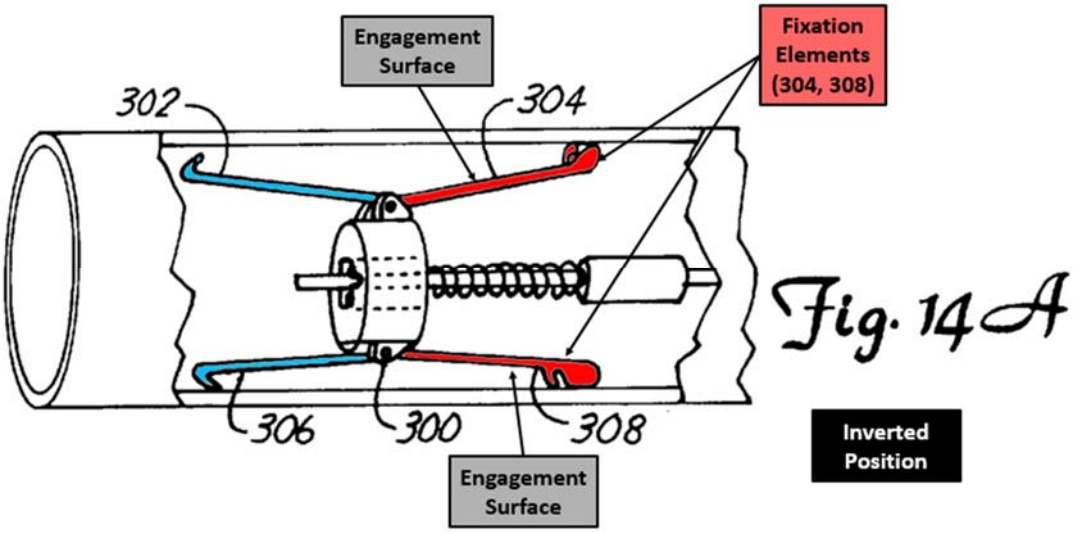
move) the arms toward each other when released from the delivery catheter 126. *Id.* ¶¶93-94. Kuehn discloses that the arms "extend due to the spring loading feature." Ex. 1005, 8:14-16 ("As arms 302, 304, 306, 308 are pushed free of the end 310 of cardiac catheter 126, they extend due to the spring loading feature."). Thus, Kuehn's spring loading feature" is an actuation mechanism adapted to move the fixation elements between positions.[4]

Moreover, the spring-loaded actuation mechanism moves the fixation elements between the closed position and the inverted position. As discussed above regarding claim construction, *see* §V, *supra*, applying the ordinary meaning of "between" to the claim language, the actuation mechanism may move the fixation elements from the closed position to the inverted position or from the

[4] If the Board construes this claim term under §112, ¶6, the structure disclosed by Kuehn is the same as or equivalent to that disclosed by the '267 patent, namely a spring loaded actuation mechanism. Ex. 1002 ¶95; *see* §V.C, *supra*; *Fresenius USA v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1299 (Fed. Cir. 2009) ("[A] challenger who seeks to demonstrate that a means-plus-function limitation was present in the prior art must prove that the corresponding structure--or an equivalent--was present in the prior art.").

inverted position to the closed position, but is not required to do both. Ex. 1002 ¶96.

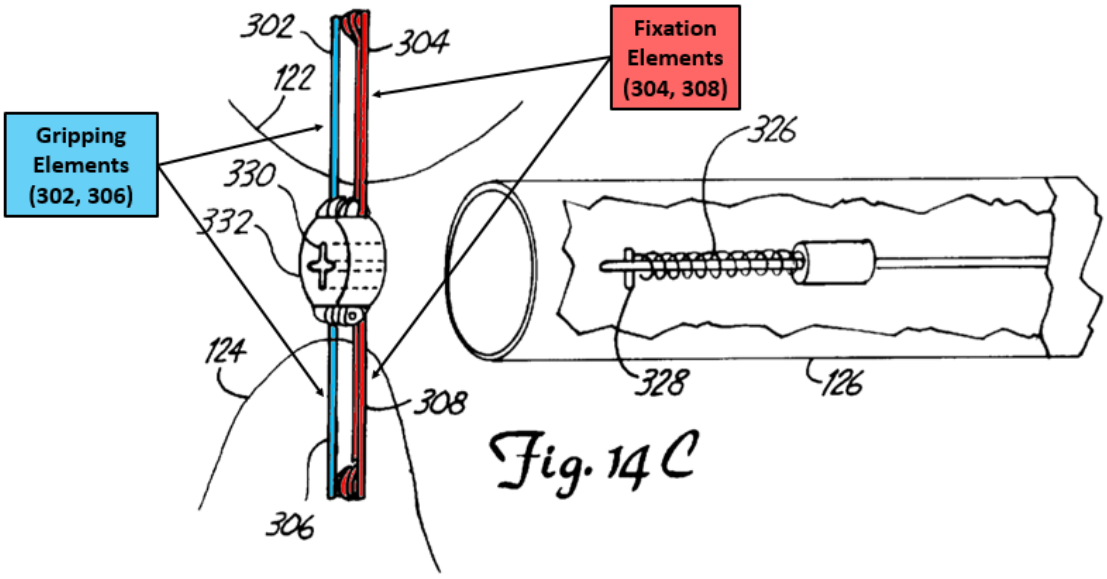
In Kuehn, the spring-loaded actuation mechanism moves the arms from the inverted position in the catheter to the closed position in the mitral valve. *Id.* ¶97. As shown below in Figure 14A, in the catheter, the arms 304, 308 are in an inverted position where their engagement surfaces face away from each other:



Ex. 1005, Fig. 14A. Once the physician moves the Kuehn device out of the catheter, arms 304, 308 are released, and the spring mechanism allows the arms to move to a position where they can "firmly grasp" the leaflets. *Id.*, 8:23-25.

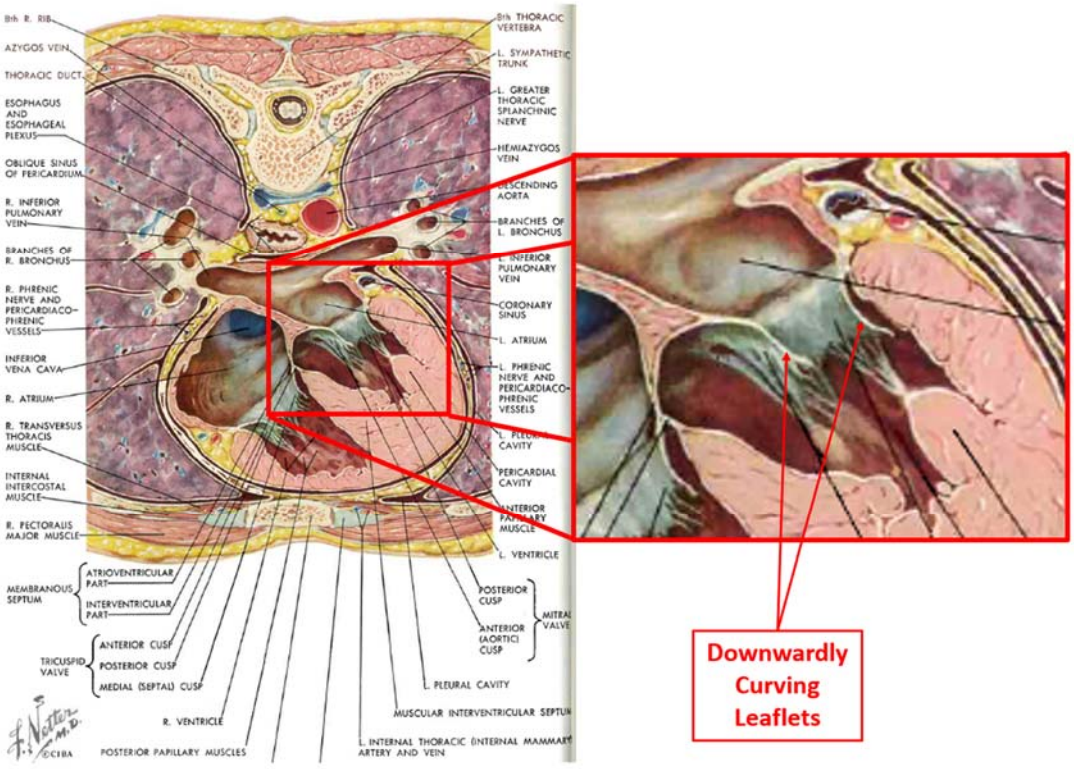
Kuehn discloses that arms 304, 308 (the fixation elements) move to at least the position shown in Figure 14C. In this position, the fixation elements are shown as approximately 180° apart with the mitral leaflets being captured between the

fixation (304, 308) and gripping (302, 306) elements in a generally horizontal plane:



Id., Fig. 14C; Ex. 1002 ¶98.

A POSITA would have been motivated, based on Kuehn's disclosure and their own knowledge, 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 as shown below.



Ex. 1015 at 4; Ex. 1002 ¶99. Figure 1 in the '267 patent also shows the leaflets curving downwardly during systole when the valve is closed:

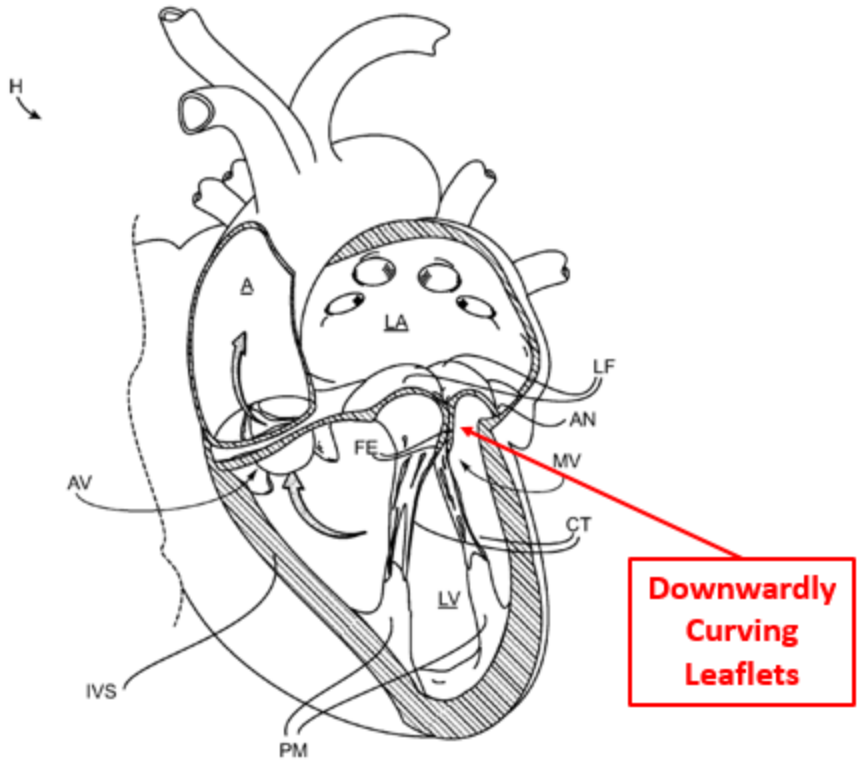
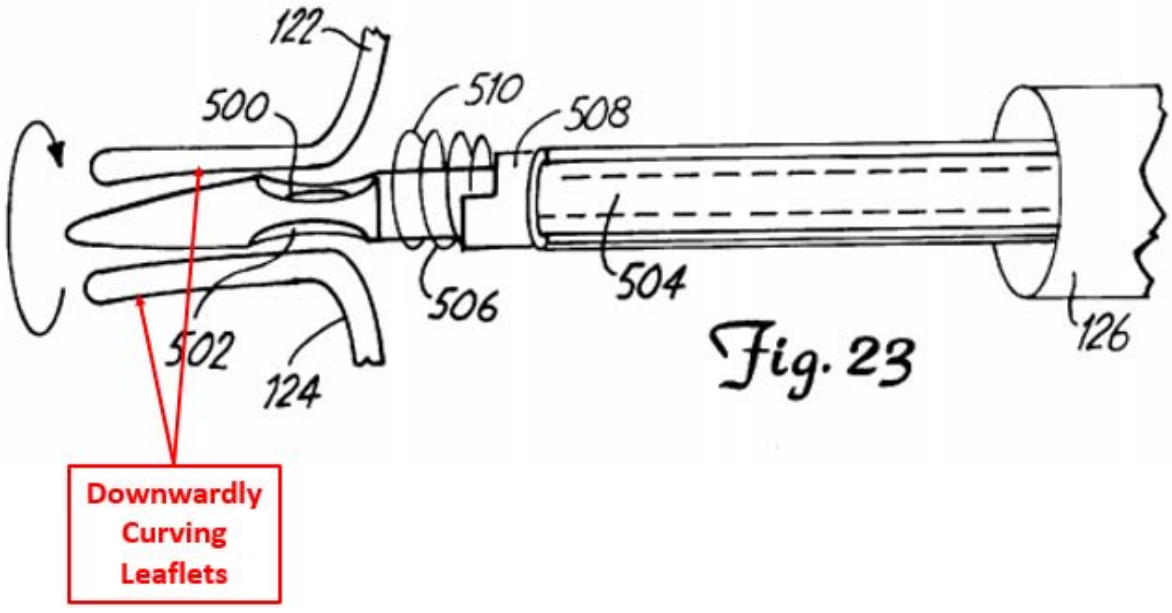


FIG. 1

Ex. 1001, Fig. 1, 12:25-36. Finally, several of Kuehn's figures acknowledge that the leaflets curve downward:



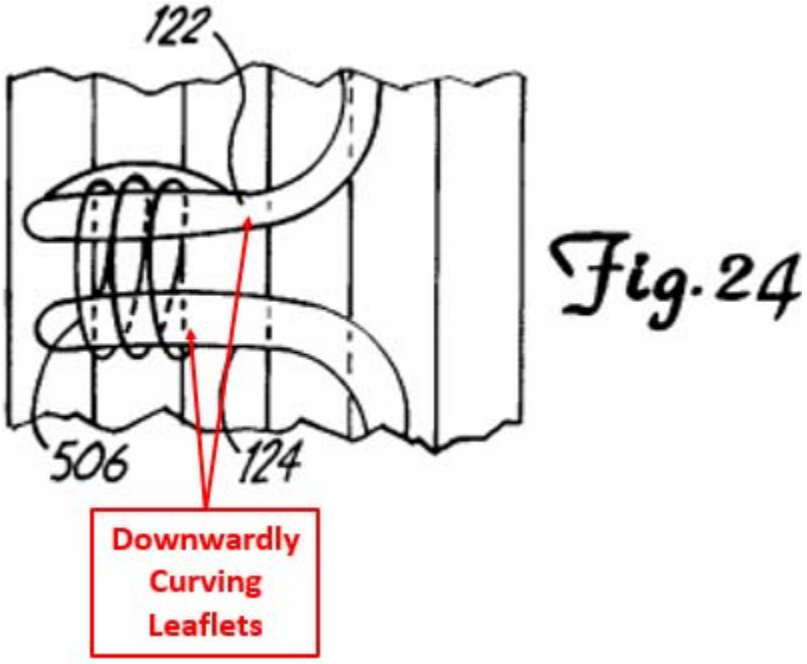


Fig. 24

Ex. 1005, Figs. 23, 24.

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 ¶100. 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 (304, 308) would be closer together and pressed against the ventricular side of the leaflets and, in this position, their engagement surfaces face each other as recited in claim 1. 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 native mitral valve:

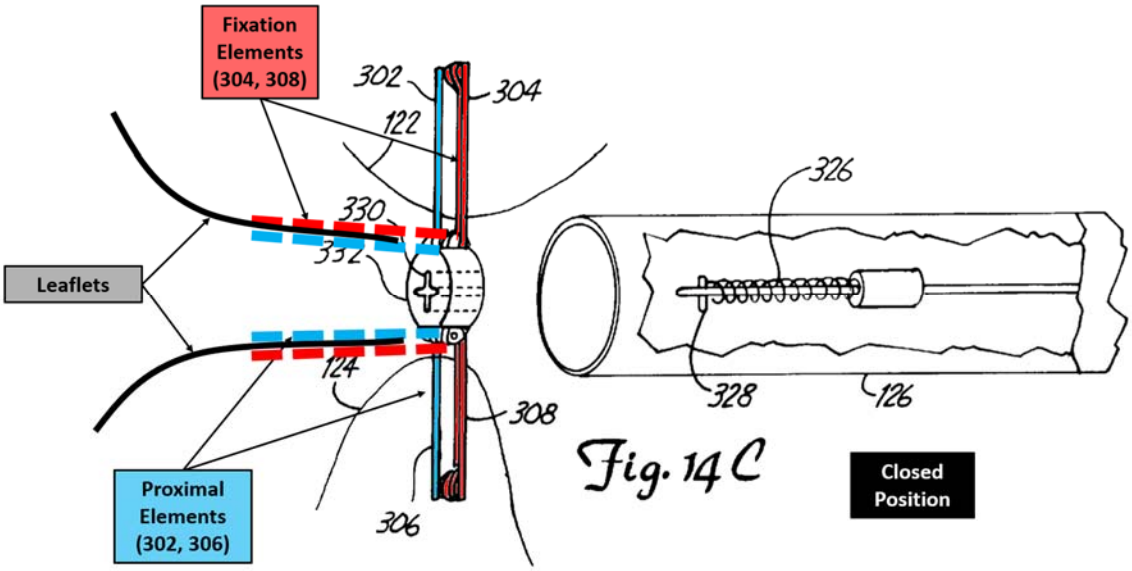


Fig. 14C

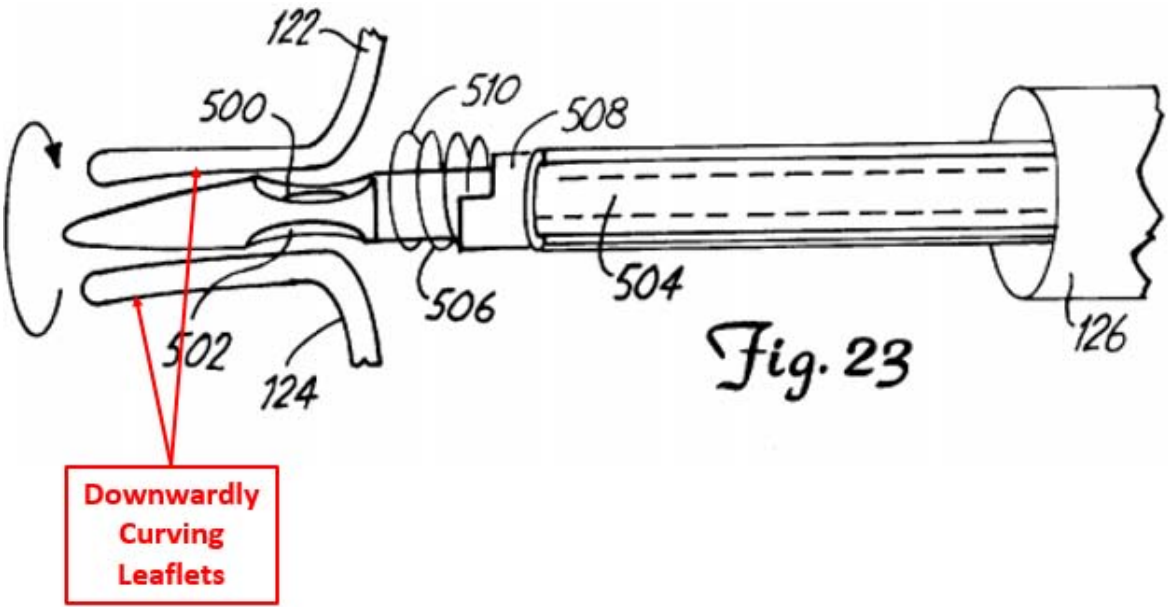
Ex. 1002 ¶100. Thus, the fixation elements would be in a closed position wherein the engagement surfaces face each other. *Id.*

A POSITA would have been motivated to adjust the spring forces in Kuehn's device in this way for several reasons. First, 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. *Id.* ¶101. This would minimize trauma and stress on the leaflets, leading to better patient outcomes and more successful procedures. *Id.*

Second, a POSITA would have understood that Kuehn's device would have been easiest to implant if its arms allowed the native leaflets to maintain a more natural shape. *Id.* As modified, Kuehn's arms would have had an increased

likelihood of capturing both leaflets. *Id.* Capturing the leaflets is essential for a successful procedure, and allowing for an increased likelihood of capturing the leaflets would reduce procedure time and lead to better patient safety and a higher likelihood of a successful outcome. *Id.* ¶102.

Third, motivation exists within Kuehn itself. *See CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1347-48 (Fed. Cir. 2017). Kuehn discloses that the leaflets point downward, into the left ventricle, in their natural configuration:



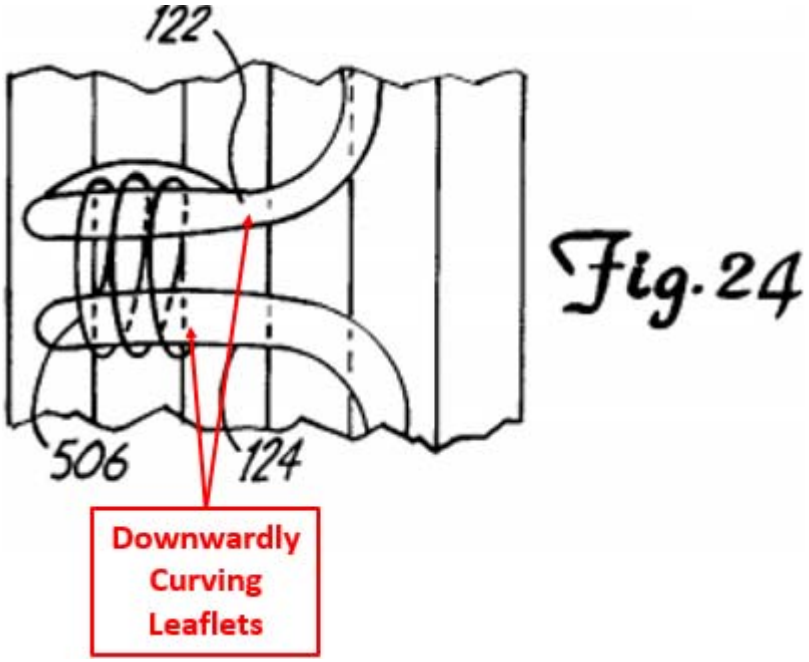


Fig. 24

Ex. 1005, Figs. 23, 24. Furthermore, Kuehn discloses that its arms "extend on one side of the leaflets to grasp leaflets 122, 124." *Id.*, 8:12-30. A POSITA would have understood that the best way to accomplish this would have been to modify the "spring loading feature" such that the deployed arms maintain a more natural shape of the leaflets. Ex. 1002 ¶103.

Fourth, the modification 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 yields predictable results (a version of Kuehn's device that is able to capture the leaflets in a more natural shape). *Id.* ¶104; *KSR*, 550 U.S. at 417.

Fifth, the modification represents a choice from a finite number of identifiable, predictable solutions. Ex. 1002 ¶105; *KSR*, 550 U.S. at 421. Given

Kuehn's device, a POSITA would have had a finite number of choices of how to orient the arms in the final, implanted state. A POSITA would have understood that orienting the arms to match the natural shape of the leaflets is one of those choices and would provide the benefits listed above. Ex. 1002 ¶105.

Finally, a POSITA would have had a reasonable expectation of success in orienting Kuehn's arms as discussed above. *Id.* ¶106. Petitioner's expert is not aware of any reason that Kuehn's arms could not successfully be oriented this way. *Id.* Furthermore, any necessary modification to achieve the desired orientation would be minimal. *Id.* Therefore, a POSITA would have had a reasonable degree of confidence that any modification would be successful. *Id.*

Accordingly, Kuehn discloses, or at least suggests, an actuation mechanism adapted to move the fixation elements from the inverted position to the closed position. *Id.* ¶107.

ii. Roth's Tie Wires Move the Arms from Closed to Inverted

Patent Owner may argue that Kuehn's actuation mechanism does not satisfy the actuation mechanism limitation because, in Patent Owner's view, it does not disclose a mechanism to move the arms the other way, i.e., from the closed position to the inverted position. To the extent that the actuation mechanism must do so, modifying the Kuehn device to include Roth's tie wires would do so. As

explained below, Roth discloses an actuation mechanism that, when combined with Kuehn's spring-loaded actuation mechanism, would move the fixation elements both ways—from the closed position to the inverted position, and back to the closed position. Ex. 1002 ¶108.[5]

Roth discloses a cardiac septal defect closure device having several arms. Ex. 1002 ¶110; Ex. 1006, 17:19-51 (discussing a "defect repair device" with "radially-extending struts 148"), Figs. 10-13B. Roth further discloses, among its benefits, that "[i]n some cases it may [be] desirable to have the capacity to re-collapse [the device] . . . for repositioning or removal from the patient." *Id.*, 18:41-48. To facilitate this, Roth discloses that "tie wires may be provided which are coupled to the inner sides of struts 148 and extend through delivery shaft 134 out of the chest cavity. By tensioning the tie wires, struts 148 may be urged back into a collapsed position" to allow for repositioning or removal of the device. *Id.*

[5] If §112, ¶6 applies to "actuation mechanism," the structure disclosed by Kuehn and Roth is the same as or equivalent to that disclosed by the '267 patent, namely a spring loaded or tie wire-based actuation mechanism. Ex. 1002 ¶109; *see* §V.C, *supra*; *Fresenius*, 582 F.3d at 1299.

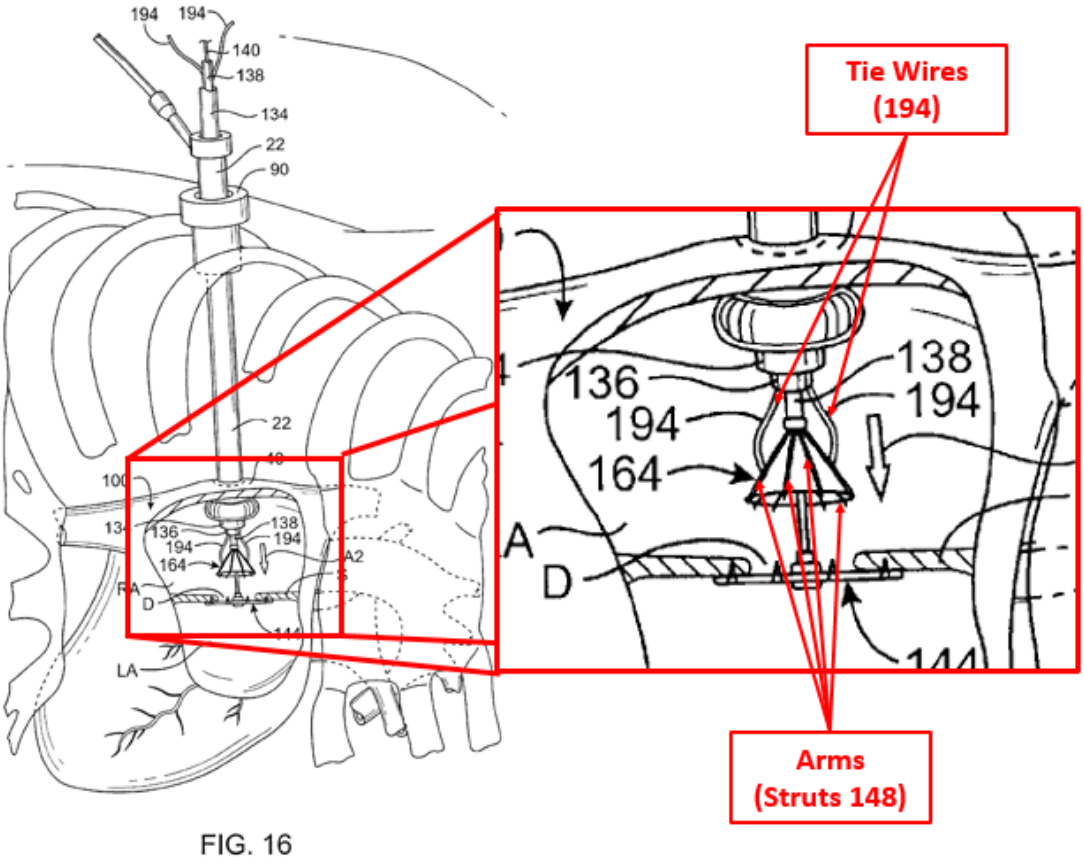


FIG. 16

Id., Fig. 16 (excerpt).

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 in one direction—toward each other—without the ability to control either pair of arms after closure. Ex. 1002 ¶111. A POSITA armed with this knowledge would have been motivated in view of Roth to attach tie wires to Kuehn's fixation elements (304, 308) for several reasons. *Id.*

First, as Roth teaches, tie wires would allow the operator to pull Kuehn's fixation elements (304, 308) away from the gripping elements (302, 306), thereby enabling the operator to reposition or more easily remove the device if it was not properly positioned in the first instance. Ex. 1002 ¶¶112-13. Allowing for repositioning of the arms enhances the ability to capture the leaflets, and allowing for easier removal of the entire device increases patient safety. *Id.*

Second, adding tie wires to Kuehn's device would allow for more granular control of the arms. *Id.* ¶114. In addition to facilitating more accurate positioning generally, granular control would beneficially allow the arms to capture the leaflets during systole, when they are in the best position to be captured, for example. *Id.* The fixation elements could also capture the leaflets in an "open position" and then move to a closed position. *Id.* This would increase the likelihood of a successful deployment of the device, decrease procedure time, and increase patient safety. *Id.*

Third, including tie wires in Kuehn's device would allow for gradual deployment of the arms. *Id.* ¶115. Gradual deployment would prevent potential impact damage to the leaflets from the arms deploying too quickly or with too much force and, thus, including tie wires would help protect the patient. *Id.*

Fourth, the use of tie wires attached to arms to allow for arm control, repositioning, and removal was well known in the art. *Id.* ¶116; *see, e.g.*, Ex. 1018, 4:65-5:9 (discussing a "lasso tether" to retract arms and allow the device to

be repositioned or removed); Ex. 1019, 9:46-58 (discussing "retraction ties 7" attached to struts on the device), Fig. 7.

Fifth, the tie wire modification represents nothing more than the simple addition of one known element (Roth's tie wires for arm repositioning or device removal) to another known element (Kuehn's device) to obtain predictable results (a device for capturing valve leaflets that allows for repositioning and retraction). Ex. 1002 ¶117; *see KSR*, 550 U.S. at 417.

Sixth, the modification represents the use of a known technique (using tie wires for arm repositioning and device removal as disclosed in Roth) to improve a similar device and method (Kuehn's device) in the same way. Ex. 1002 ¶118; *KSR*, 550 U.S. at 417.

Seventh, the modification applies a known technique (using tie wires for arm repositioning and device removal as disclosed in Roth) to a known device and method (Kuehn's device) that is ready for improvement and yields predictable results (a repositionable device that captures valve leaflets and, if necessary, a removable device). Ex. 1002 ¶119; *KSR*, 550 U.S. at 417.

Eighth, Roth expressly discloses that its devices and techniques are useful to repair mitral valves. Ex. 1006, 32:43-48. A POSITA would have been motivated to look to a reference that is useful for mitral valve repair, such as Roth, when

modifying Kuehn's device, which is also used for mitral valve repair. Ex. 1002 ¶120.

Finally, a POSITA would have had a reasonable expectation of success in including Roth's tie wires in Kuehn's device. *Id.* ¶121. Petitioner's expert is not aware of any reason that Roth's tie wires could not be successfully included in Kuehn's device. *Id.* Furthermore, tie wires were well known in the art, as discussed above, and adding them to the Kuehn device would not be a complicated process. Indeed, Roth discloses that its devices and techniques would be useful to repair mitral valves, further providing confidence to a POSITA that the combination would be successful. Ex. 1006, 32:43-48; Ex. 1002 ¶121.

Moreover, other references confirm that nearly identical tie wire systems could be used in the context of a catheter delivery system, like Kuehn. Ex. 1002 ¶122; *see, e.g.*, Ex. 1019, 9:46-58 (discussing use of tie wires in a catheter system). Indeed, the '267 patent itself uses tie wires to control the gripper arms in a catheter delivery system, and does not mention any problems to be overcome or novel solutions to any problem regarding the use of tie wires in a catheter delivery system. *E.g.*, Ex. 1001, 20:65-21:29. Thus, there cannot be any argument that tie wires would not work in a catheter-delivered device. *See Smith & Nephew v. Rea,* 721 F.3d 1371, 1381 (Fed. Cir. 2013) (finding that a patent owner cannot show non-obviousness by arguing that the prior art would have been inoperable, while at

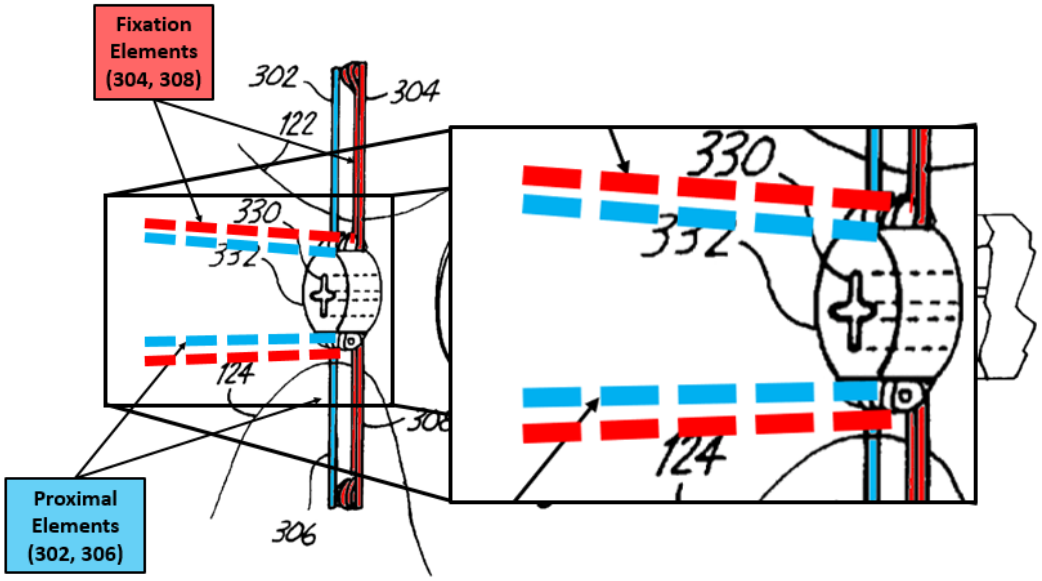
the same time claiming that the alleged invention accomplishes the same result, without disclosing or claiming a novel solution to a problem to be overcome). Therefore, a POSITA would have had a reasonable degree of confidence that the modification would be successful. Ex. 1002 ¶122.

The addition of Roth's tie wires creates an actuation mechanism that allows for controlling movement of the fixation elements from the inverted position to the closed position (via Kuehn's modified spring-loaded actuation mechanism) and from closed to inverted (via tie wires as taught in Roth). *Id.* ¶123. Thus, Kuehn and Roth disclose, or at least suggest, the "actuation mechanism" limitation.

e. Fixation Elements Movably Coupled Together Such that They Are Moveable (Disclosed by Kuehn and Roth)

Returning to the "moveable" limitation addressed above in subsection (c), should actual movement between positions be required, the addition of Roth's tie wires confirms that the arms move and do so in both directions, from the inverted position to the closed position and from closed to inverted. Even if Patent Owner were to argue that the claim requires this type of back-and-forth movement, or movement specifically from a closed position to an inverted position, both are disclosed or suggested by the combination of Kuehn and Roth and would have been obvious to a POSITA for the reasons stated above. Ex. 1002 ¶124.

Moreover, with or without tie wires, a POSITA would have understood that after modifying the spring-loading forces in the Kuehn device, its arms would necessarily rotate between a closed position to an inverted position as the device is being loaded into the catheter. The spring loading feature, as modified by a POSITA to allow the arms to grasp the downwardly sloping leaflets, would have caused the arms to be in a closed position prior to being loaded into the delivery catheter. *Id.* ¶125. Thus, the pre-catheter position of the arms would have looked generally as shown in the following modified Figure 14C of Kuehn:



Id.

In order to insert the modified device into the delivery catheter, an operator necessarily would have had to apply force to move the arms (304, 308) from the closed position to the inverted position. *Id.* ¶126. Even if it was not necessary, it would have been obvious for the operator to do so. *Id.* The operator could apply

this force using the tie wires or simply a finger. *Id.* Once the arms were moved to the inverted position, the modified Kuehn device could be inserted into the catheter, which would hold the arms in the inverted position as shown in Figure 14A. *Id.* Thus, to a POSITA, Kuehn discloses that its fixation elements move between a closed position to an inverted position.

Accordingly, Kuehn and Roth disclose, or at least suggest, this limitation, and even without Roth's tie wires, Kuehn alone discloses or suggests this limitation.

f. Gripping Elements

Claim 1 further recites "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."

Kuehn discloses that its device includes a second pair of arms 302, 306 opposite the arms 304, 308. Ex. 1005, 8:12-30, Figs. 14A-C.

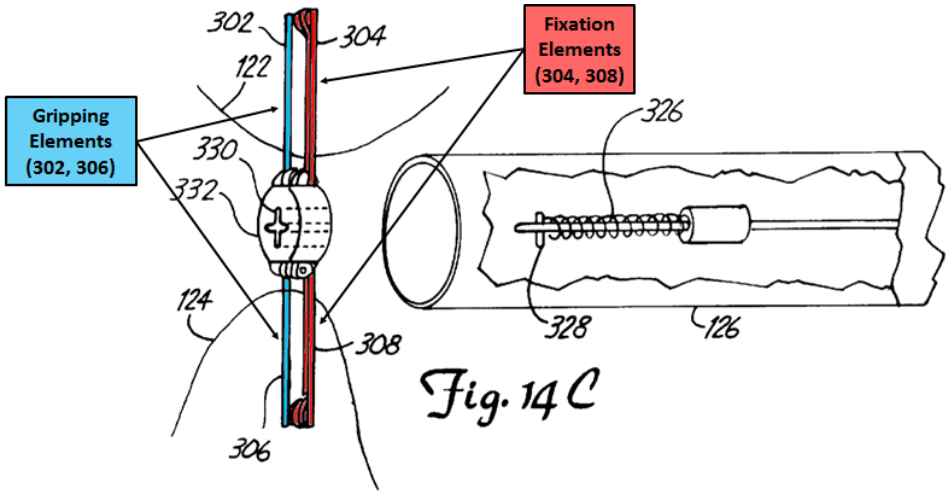
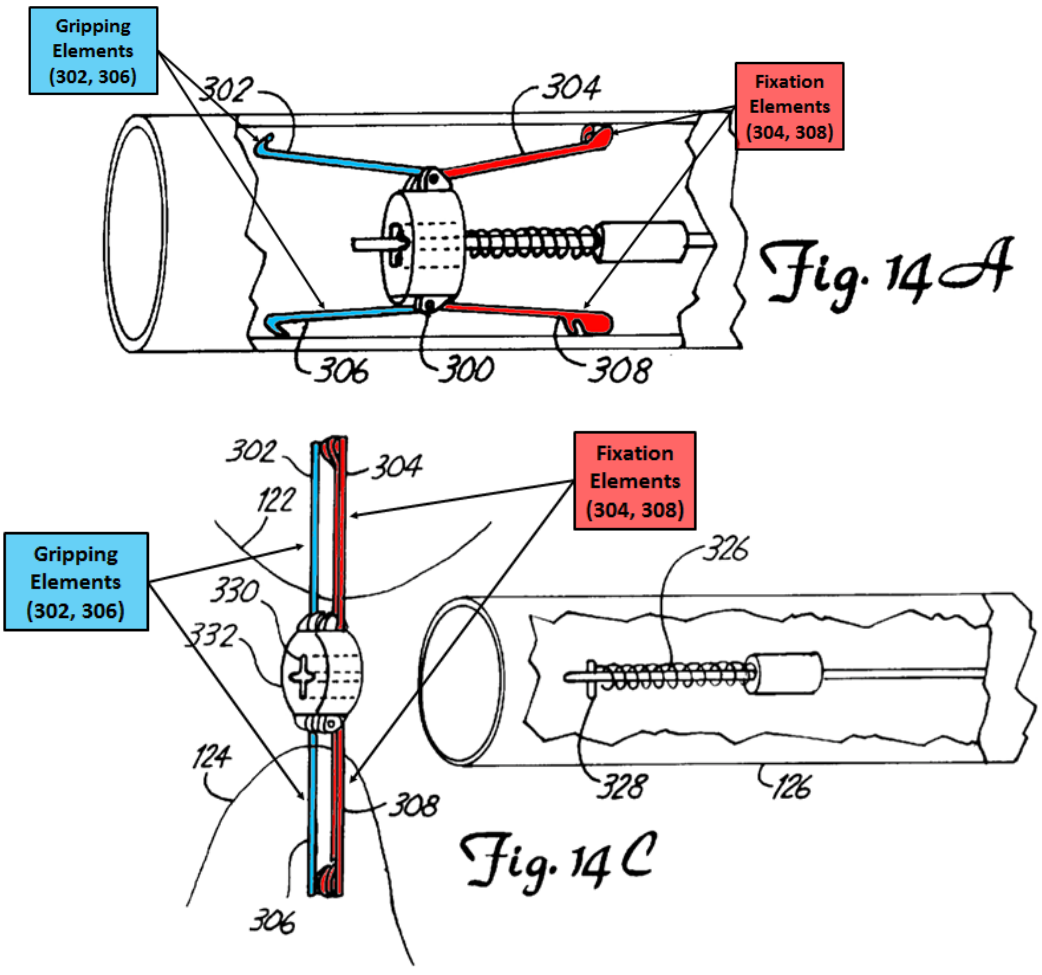


Fig. 14C

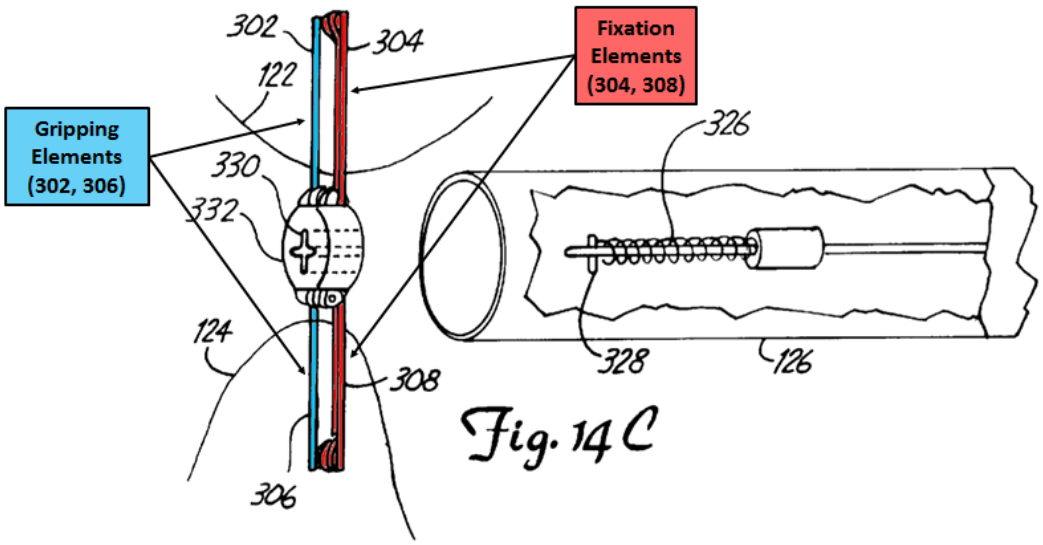
Id., Fig. 14C. As shown in Figure 14C, the arms 302, 306 are gripping elements. Ex. 1002 ¶128.

Kuehn further discloses that the gripping elements (302, 306) are moveable with respect to the fixation elements (304, 308). *Id.* ¶129; Ex. 1005, Figs. 14A-C. For example, Figures 14A and 14C show the gripping elements 302, 306 in different positions relative to the fixation elements 304, 308:



Id., Figs. 14A, C.

Finally, Kuehn discloses that its device captures tissue between gripping elements 302, 306 and fixation elements 304, 308. Ex. 1002 ¶130. Kuehn discloses that "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." Ex. 1005, 8:20-23, Fig. 14C. Kuehn illustrates this capturing of the leaflets between the fixation and gripping elements in Figure 14C:



Id., Fig. 14C. Accordingly, Kuehn discloses, or at least suggests, this limitation.

g. Fixation Elements at Least Partially Concave

Claim 1 further recites that "each fixation element is at least partially concave."

Kuehn discloses that the fixation elements 304, 308 "have clasps 322, 324 that ***engage*** pointed tips 314, 316." Ex. 1005, 8:23-24 (emphasis added), Figs. 14A-C. A POSITA would have understood from this disclosure and Figures 14A-

C that these clasps 322, 324 are concave. Ex. 1002 ¶132. That is, the Kuehn clasps include a curved surface that partially encloses a volume such that a POSITA would have understood that they are concave. *Id.* A POSITA would view the clasps as "cupped," further leading a POSITA to conclude that they are concave. *Id.*; *see* Ex. 1001, 18:9-10 ("the engagement surfaces 50 [of the fixation elements] have a cupped or concave shape to surface area in contact with tissue and to assist in grasping and holding the valve leaflets.").

Furthermore, Kuehn discloses that the clasps 322, 324 engage the pointed tips 314, 316 "such that the arms 302, 304, 306, 308 firmly grasp leaflets 122, 124 therebetween." Ex. 1005, 8:23-25. Based on this disclosure, a POSITA would have understood that at least these clasp portions of the arms are concave. Ex. 1002 ¶132.

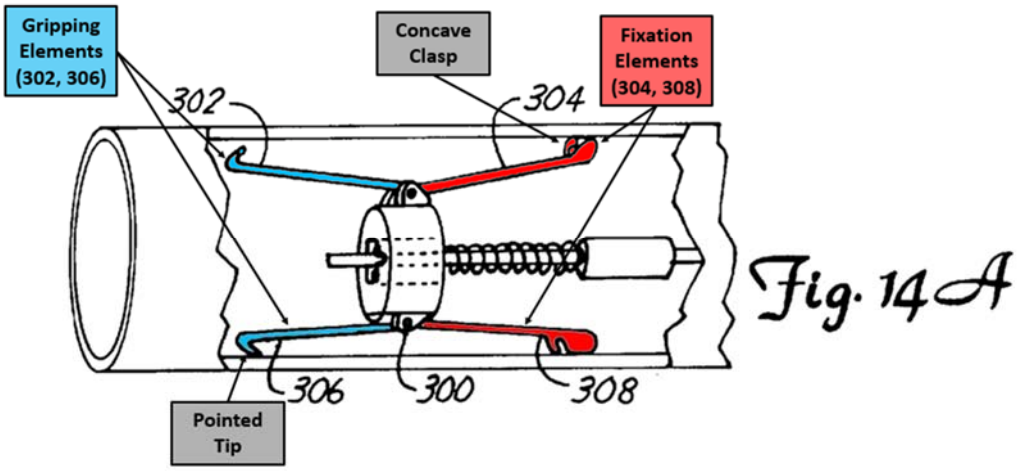


Fig. 14A

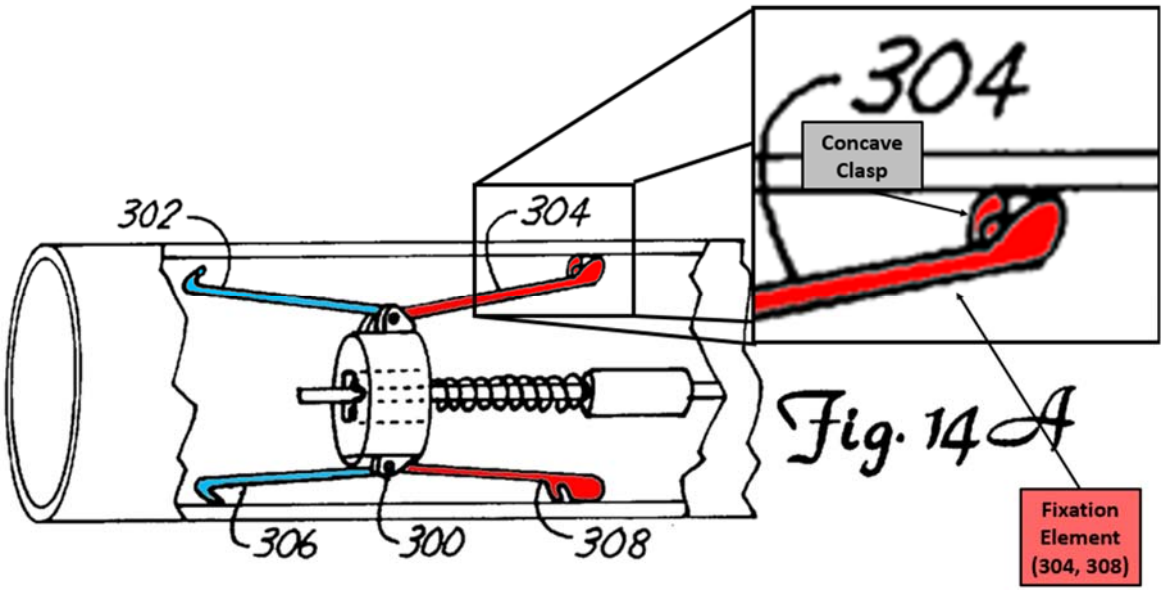


Fig. 14A

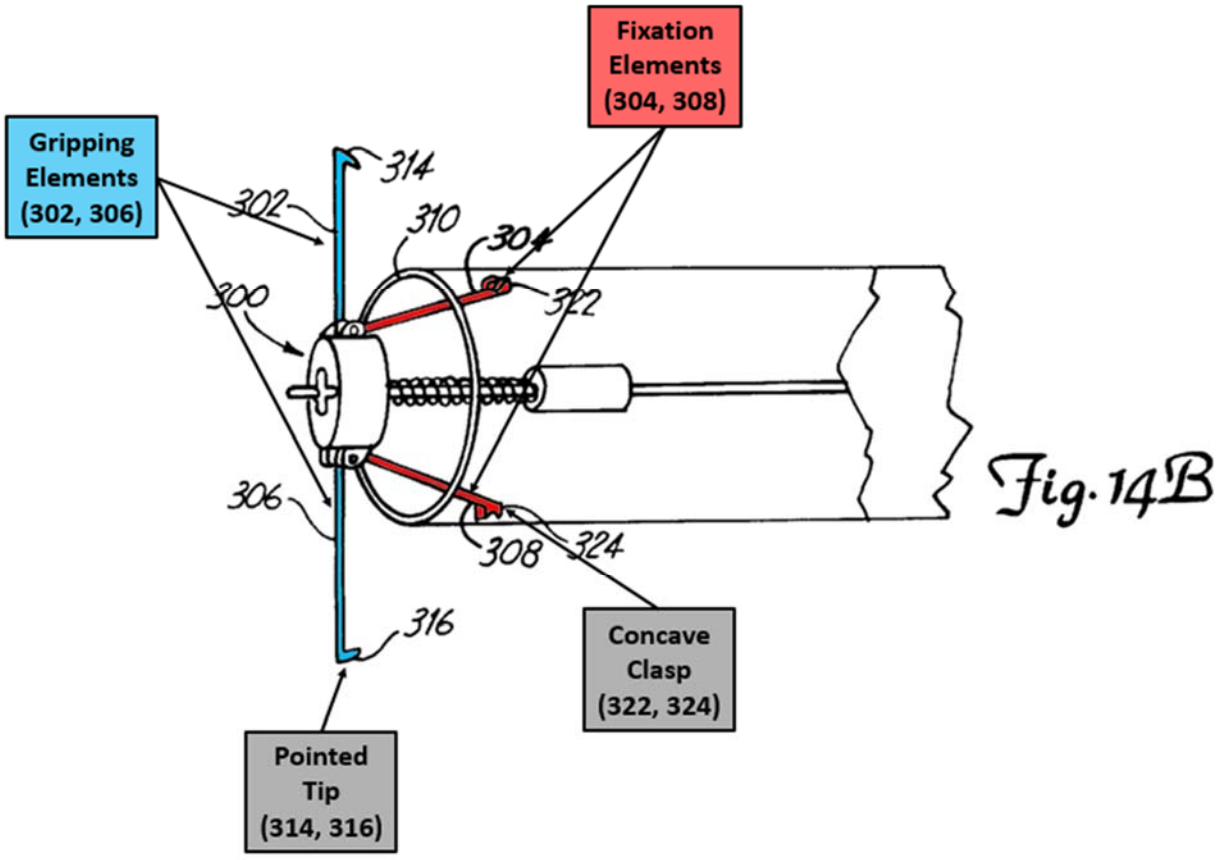


Fig. 14B

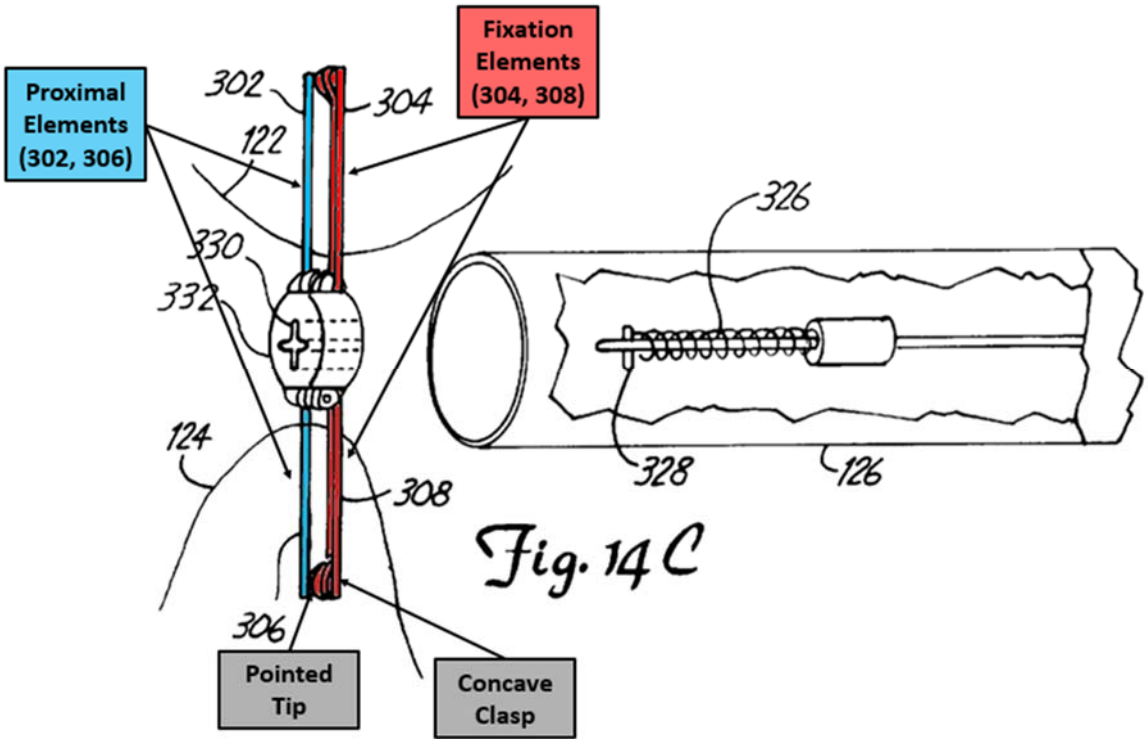


Fig. 14C

Ex. 1005, Figs. 14A-C. Accordingly, Kuehn discloses, or at least suggests, this limitation.

h. Gripping Elements at Least Partially Recessed Within the Fixation Elements

Claim 1 further recites that "each gripping element is at least partially recessed within the fixation element in the deployed configuration."

As discussed above, Kuehn discloses that the gripping elements 302, 306 have "pointed tips 314, 316" that are engaged by clasps on the fixation elements 304, 308. Ex. 1005, 8:23-24, Figs. 14A-C. Figure 14C shows the pointed tips nested within the clasps and the leaflets in between. *Id.* A POSITA would have understood that in the deployed configuration at least the pointed tips of the

gripping elements 302, 306 would be recessed within the clasps of the fixation elements 304, 308 at all angles. Ex. 1002 ¶¶134-35.

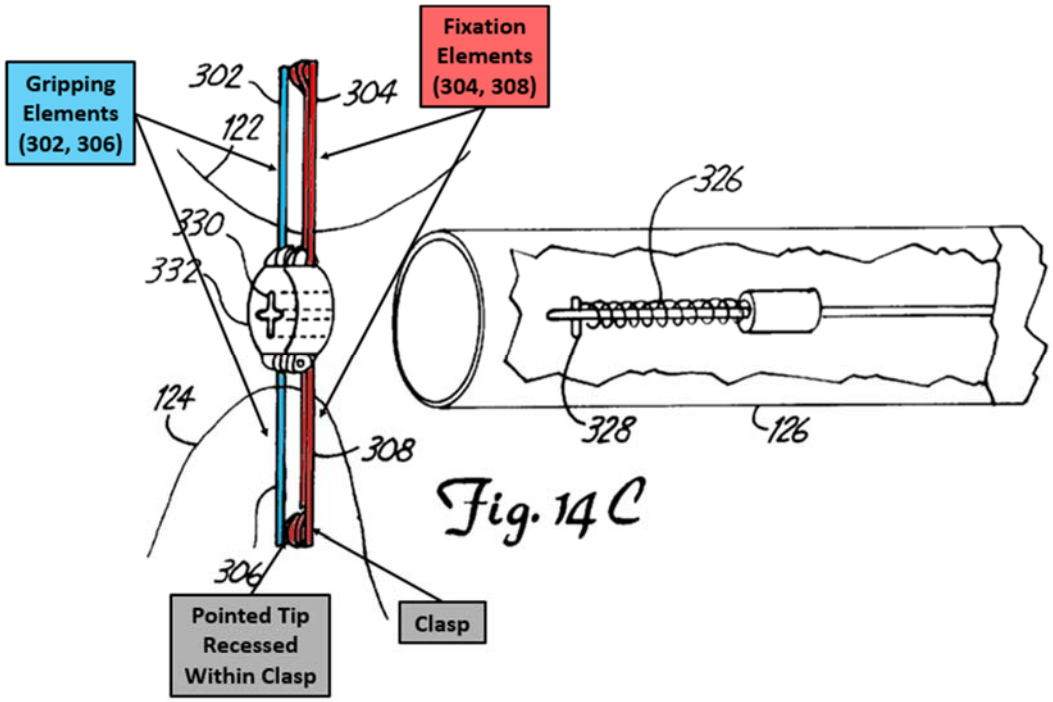


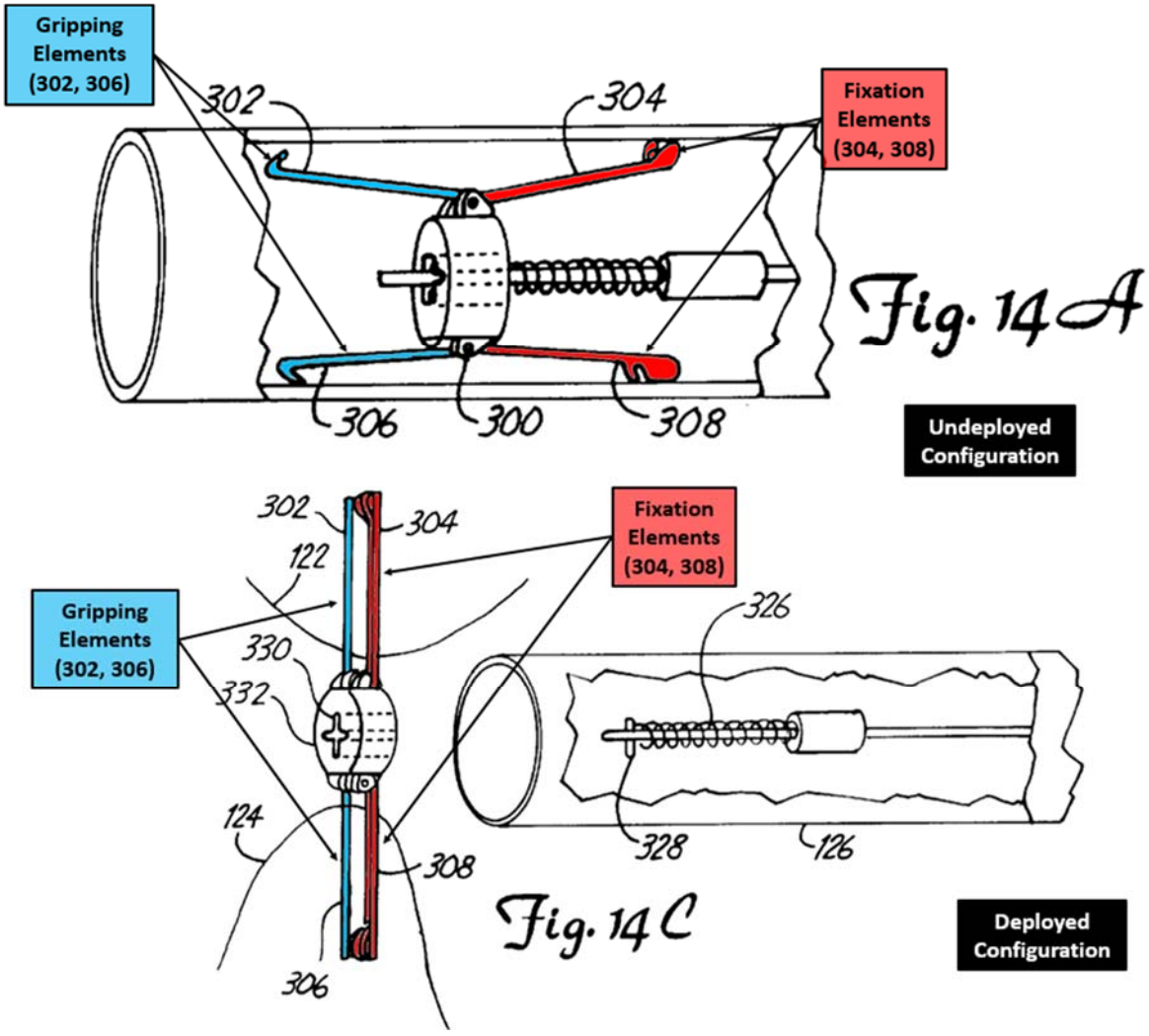
Fig. 14C

Ex. 1005, Fig. 14C. Accordingly, Kuehn discloses, or at least suggests, this limitation.

i. Gripping Elements Moveable Between Undeployed Configuration and Deployed Configuration

Claim 1 finally recites that "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."

Kuehn discloses that gripping elements 302, 306 are moveable (i.e., capable of being moved[6]) from an undeployed configuration (shown in Figure 14A), where they are separated from fixation elements 304, 308), to a deployed configuration (shown in Figure 14C), where they are closer to the fixation elements 304, 308. Ex. 1005, 8:12-30, Figs. 14A-C; Ex. 1002 ¶137.



[6] Petitioners incorporate their arguments regarding the term "moveable" above. *See* §V.A, *supra*.

Ex. 1005, Figs. 14A, C.

In view of the foregoing, Kuehn and Roth disclose, or at least suggest, each limitation of claim 1, and claim 1 would have been obvious as a whole over Kuehn in view of Roth and the knowledge of a POSITA.

4. Claims 2-4: "Open Position"

Claim 2 depends from claim 1 and further recites that "the fixation elements are further moveable to an open position between the closed position and the inverted position." Claim 3 depends from claim 2 and further recites that "in the open position the engagement surface of one fixation element forms an angle of about 5° up to an angle less than about 180° with the engagement surface of the other fixation element." Claim 4 also depends from claim 2 and further recites that "in the open position the engagement surface of one fixation element forms an angle of more than about 90° up to an angle less than about 180° with the engagement surface of the other fixation element."

Kuehn discloses that fixation elements 304, 308 are moveable (i.e., capable of being moved) from the inverted position in the catheter (shown in Figure 14A) to an open position, as required by claim 2. Ex. 1005, 8:12-30, Figs. 14A-C; Ex. 1002 ¶140. After Kuehn deploys, the arms 304, 308 pass through the various angles within the ranges recited in claims 3 and 4 until they reach the leaflets in the mitral valve. Ex. 1002 ¶140. Figure 14C shows the device with the engagement

surface of arm 304 forming an approximately 180° angle with the engagement surface of arm 308:

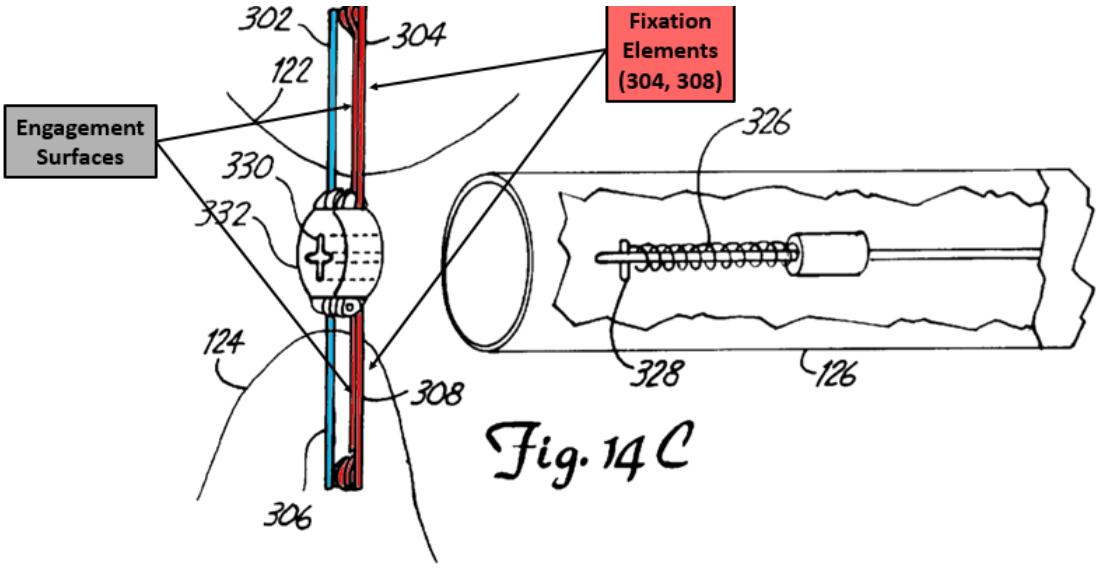
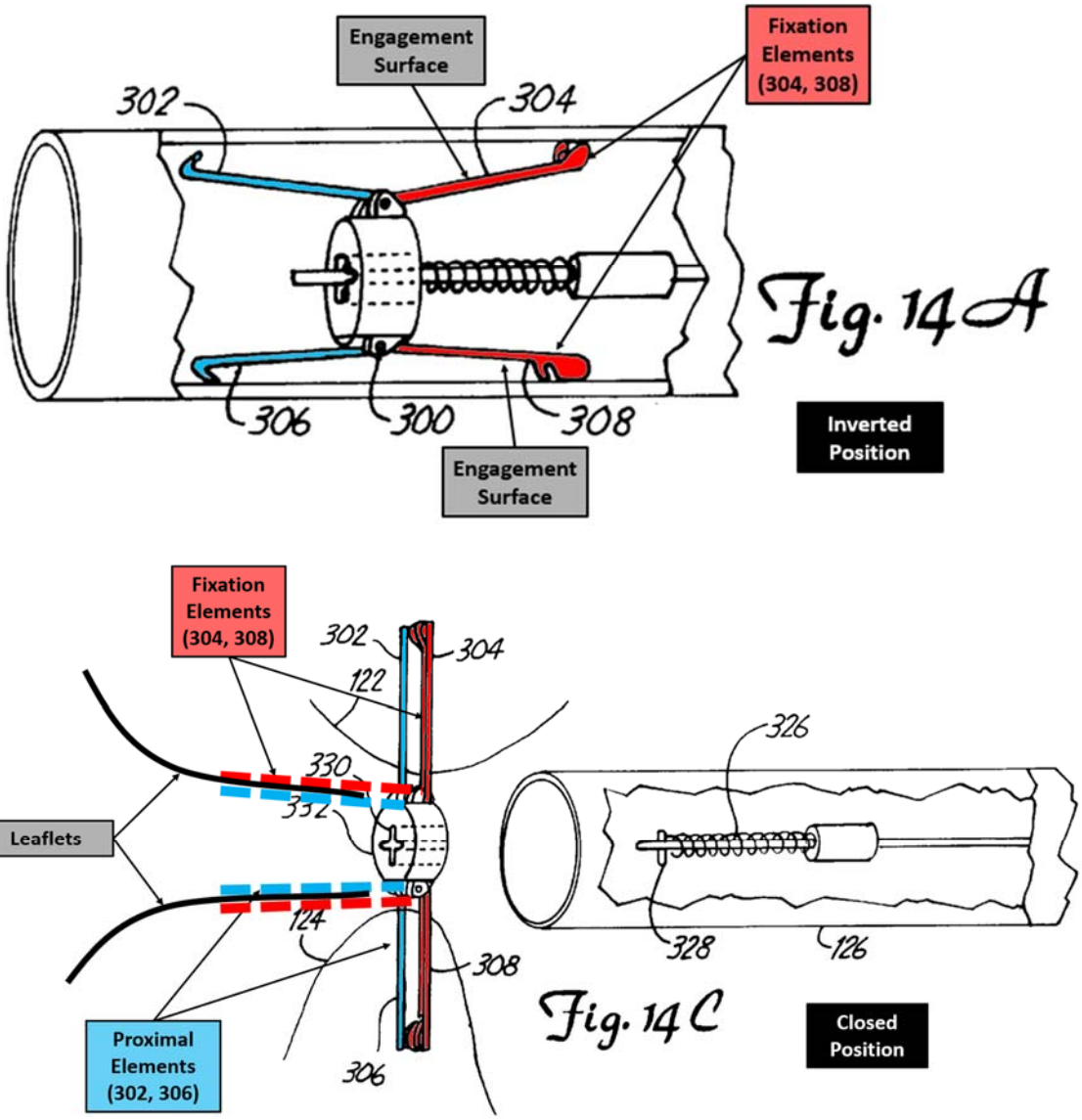


Fig. 14C

Ex. 1005, Fig. 14C; Ex. 1002 ¶140. Importantly, it is the angle between the fixation elements 304, 308 (shown in red) that determines whether the Figure 14A-C device is in the inverted, closed, or open positions, not the angle between the opposing sets of arms (i.e., the blue gripping elements opposed to the red fixation elements). The approximately 180° angle between the fixation elements discloses or suggests the "less than about 180°" angle required by claims 3 and 4, because "about 180°" includes some angle above 180° such that "less than" that angle would include 180°. *See* Ex. 1001, 4:47-50 ("In the open position the engagement surfaces of the distal elements preferably form an angle of up to 180º relative to each other so as to maximize the area in which to capture the valve leaflets or other target tissue.").

Furthermore, the position shown in Figure 14C is between the inverted position shown in Figure 14A and the closed position shown in the annotated Kuehn Figure 14C after the device is modified by a POSITA. Ex. 1002 ¶141.



Ex. 1005, Figs. 14A, C; Ex. 1002 ¶141. Figure 14C is just one example of a position where the fixation elements have an angle between about 5° or 90° and less than about 180°. Indeed, as modified, Kuehn's fixation elements would pass

through many such positions between the inverted position shown in Figure 14A and the closed position shown in the modified Figure 14C above. Ex. 1002 ¶141.

Furthermore, to the extent Patent Owner argues it is required, Kuehn's device as further modified to include Roth's tie wires is able to maintain an "open position," rather than simply pass through it. *Id.* ¶142. A POSITA would have been motivated to modify Kuehn's device using Roth's tie wires for all the reasons discussed above regarding claim 1. *Id.* Furthermore, a POSITA would have been motivated to use the tie wires to allow the Kuehn device to be able to move to and maintain an "open position" in order to aid in capturing the leaflets, for example, as shown in Figure 14C. Ex. 1005, Fig. 14C; Ex. 1002 ¶143. A POSITA would have understood that capturing the leaflets in the position shown in Figure 14C would have advantages, including allowing for easier repositioning of the device using the tie wires. Ex. 1002 ¶143. Through appropriate control of the tie wires, any number of potential "open positions" between the inverted position and closed position could be achieved and maintained. *Id.* A POSITA would have had a reasonable expectation of success for all the reasons discussed above regarding claim 1. *Id.* ¶144.

Accordingly, Kuehn and Roth disclose, or at least suggest, the limitations of claims 2, 3 and 4, and claims 2, 3, and 4 would have been obvious as a whole to a POSITA. *Id.* ¶145.

5. Claim 5

Claim 5 depends from claim 1 and further recites that "the gripping elements have frictional features configured to enhance grip on tissue engaged thereby." The '267 specification discloses that "any suitable frictional accessories may be used, such as prongs, windings, bands, barbs, grooves, channels, bumps, surface roughening, sintering, high-friction pads, coverings, coatings or a combination of these." Ex. 1001, 18:52-62. As discussed above for claim 1, Kuehn discloses that the gripping elements 302, 306 have "pointed tips 314, 316." Ex. 1005, 8:23-24, Figs. 14A-C. A POSITA would have considered Kuehn's "pointed tips" to be frictional features that enhance the grip on the tissue engaged by the gripping elements 302, 306. Ex. 1002 ¶147. For example, a POSITA would have considered Kuehn's "pointed tips" to be at least "prongs" or "barbs." *Id*.

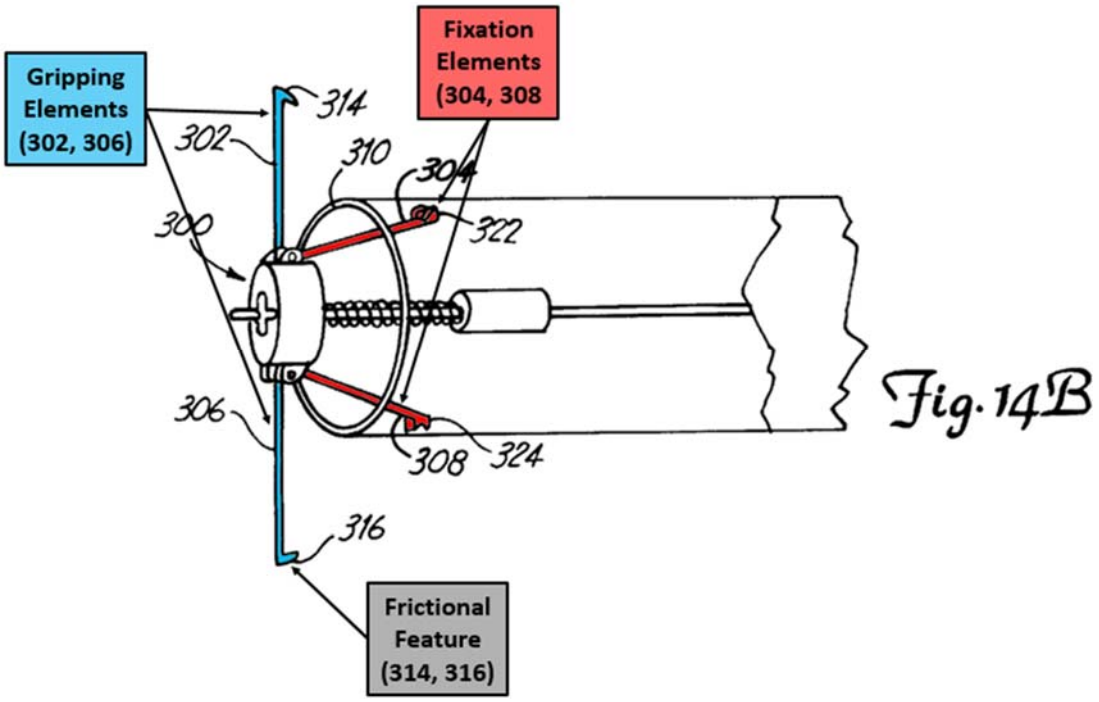


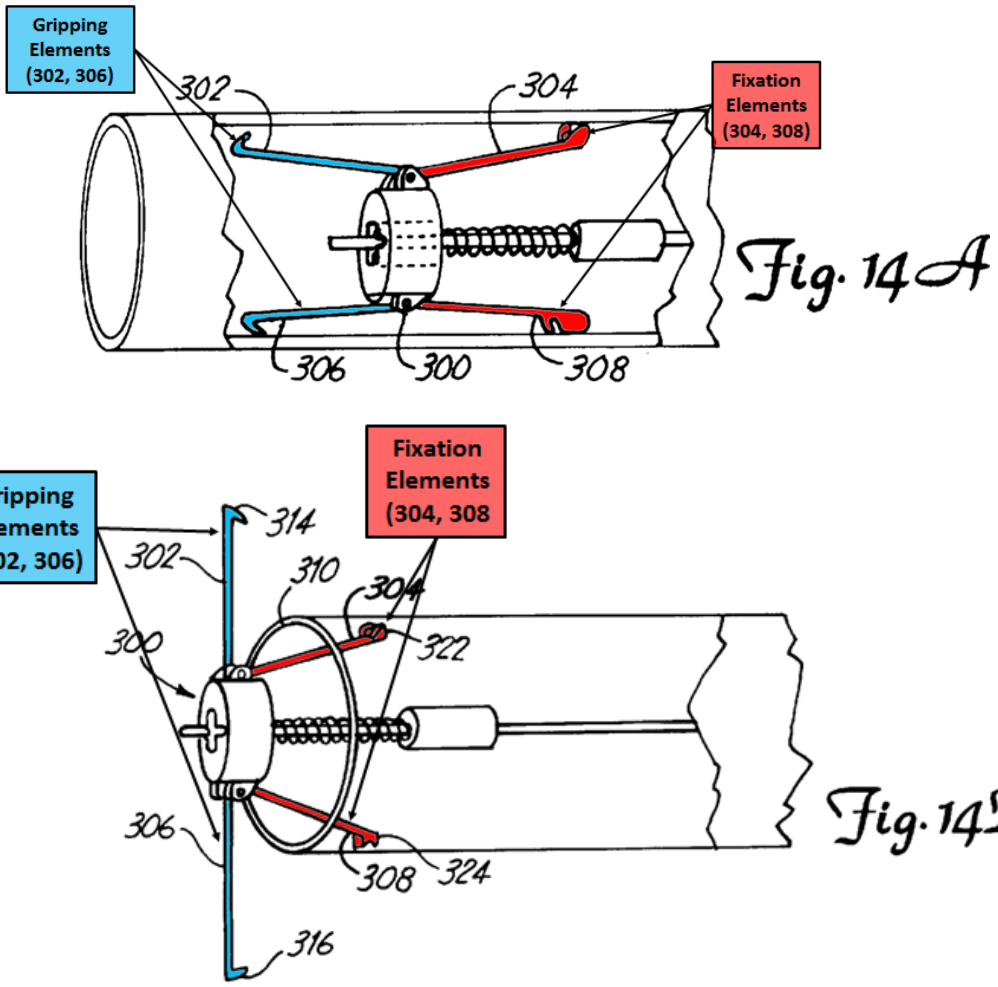
Fig. 14B

Ex. 1005, Fig. 14B. Accordingly, Kuehn and Roth disclose, or at least suggest, the limitations of claim 5, and claim 5 would have been obvious as a whole to a POSITA. Ex. 1002 ¶147.

6. Claim 6

Claim 6 depends from claim 1 and recites that "the gripping elements are movable independently of the fixation elements." Kuehn discloses this limitation because the gripping elements 302, 306 move independently of the fixation elements 304, 308. Ex. 1002 ¶149. For example, Figure 14A shows all four of the arms (302, 306 and 304, 308) stationary inside the delivery catheter. Ex. 1005, Fig. 14A. Then, Figure 14B shows the arms 302, 306 moving outside the delivery

catheter while the arms 304, 308 inside the catheter remain stationary. *Id.*, Figs. 14A-B; Ex. 1002 ¶149.



Ex. 1005, Figs. 14A-B. Accordingly, Kuehn and Roth disclose, or at least suggest, the limitations of claim 6, and claim 6 would have been obvious as a whole to a POSITA. Ex. 1002 ¶149.

7. Claim 7

Claim 7 depends from claim 1 and further recites that "the gripping elements are biased toward the engagement surfaces." Kuehn discloses this limitation

because the "spring loading feature" causes the gripping elements 302, 306 to swing toward fixation elements 304, 308 to grasp tissue therebetween. Ex. 1005, 8:12-30, Figs. 14A-C; Ex. 1002 ¶151. Thus, the pair of arms 302, 306 are biased (by the spring force of the spring loading feature) toward the engagement surfaces of the arms 304, 308, as required by claim 7. Ex. 1002 ¶151. Accordingly, Kuehn and Roth disclose, or at least suggest, the limitations of claim 7, and claim 7 would have been obvious as a whole to a POSITA. *Id.*

8. Claim 8

Claim 8 depends from claim 1 and further recites that "the gripping elements are approximately parallel to each other in the undeployed configuration." Kuehn discloses this limitation because it discloses that the gripping elements 302, 306 are approximately parallel to each other while in the delivery catheter. Ex. 1005, Fig. 14A; Ex. 1002 ¶153.

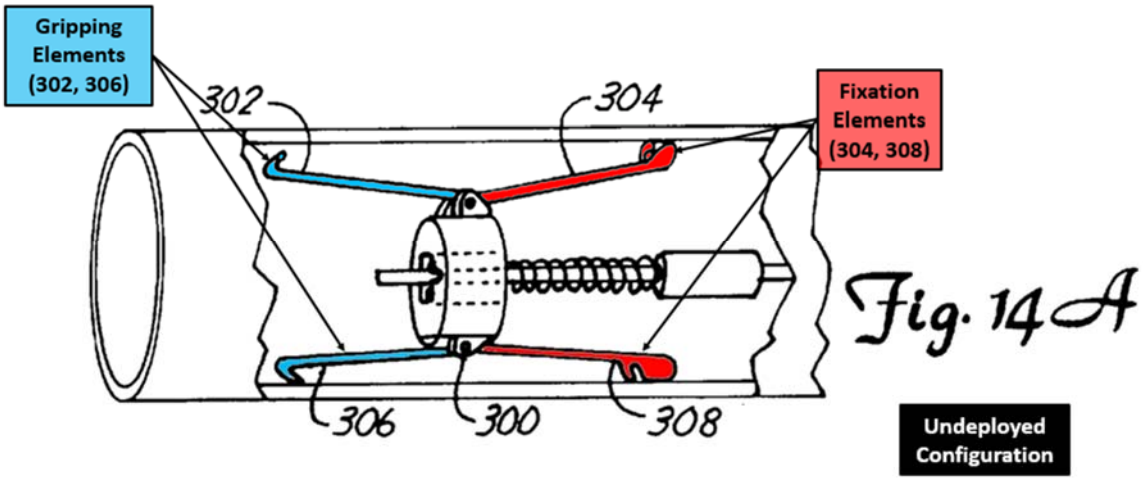


Fig. 14A

Ex. 1005, Fig. 14A. Accordingly, Kuehn and Roth disclose, or at least suggest, the limitations of claim 8, and claim 8 would have been obvious as a whole to a POSITA. Ex. 1002 ¶153.

9. Claim 9

Claim 9 depends from claim 1 and further recites "a coupling member for detachably coupling the fixation device to a delivery device." Kuehn discloses that its fixation device "is released from applicator 326 by rotating knob 328 such that knob 328 passes through passageway 330 within base 332." Ex. 1005, 8:26-28, Figs. 14B-C (showing the device in a coupled and uncoupled configuration). A POSITA would have understood that the "base 332" and the "applicator 326" comprise a coupling member that detachably couples the Kuehn fixation device to a delivery device, i.e., the delivery shaft attached proximally to the applicator 326. Ex. 1002 ¶155.

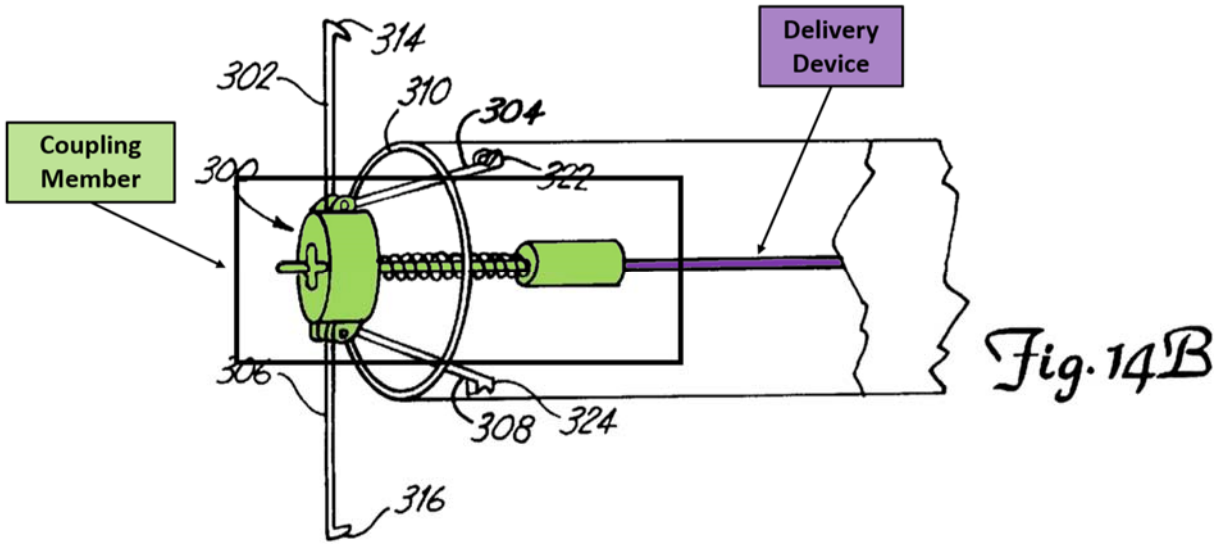


Fig. 14B

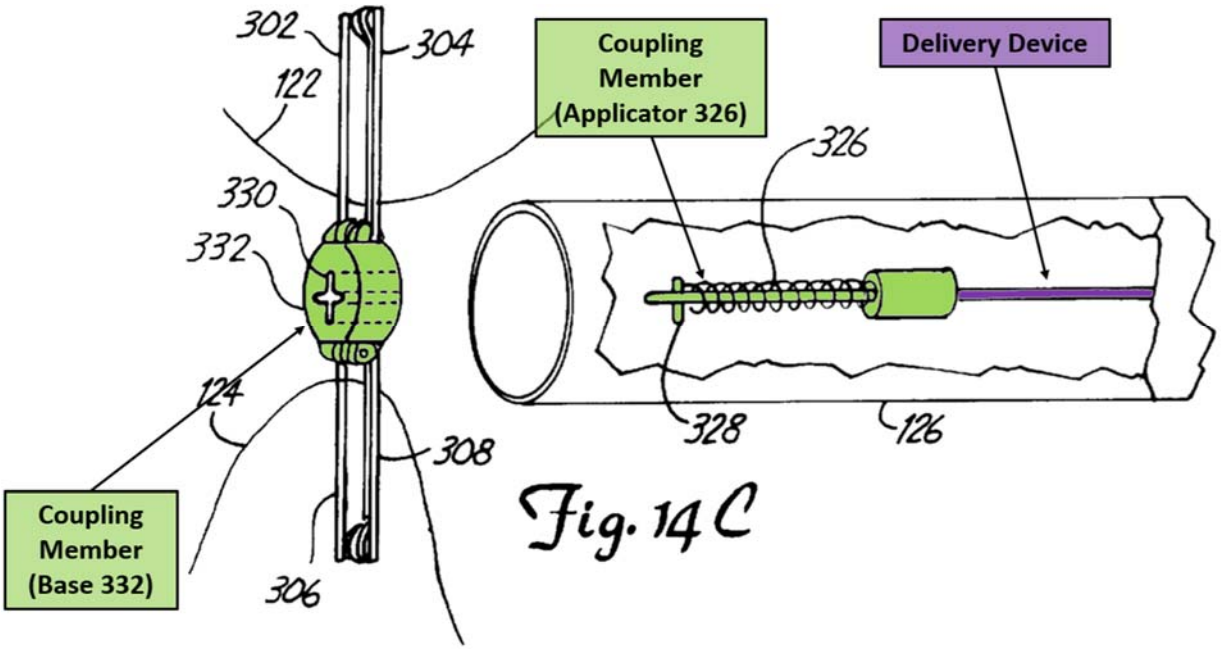


Fig. 14C

Ex. 1005, Figs. 14B-C. Accordingly, Kuehn and Roth disclose, or at least suggest, the limitations of claim 9, and claim 9 would have been obvious as a whole to a POSITA.[7] Ex. 1002 ¶157.

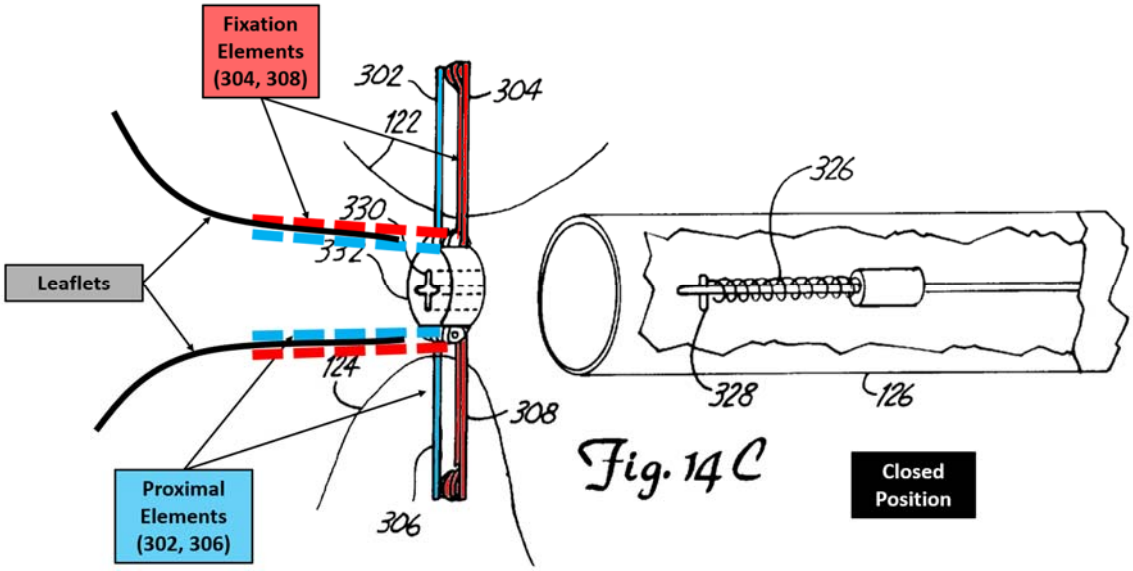
10. Claim 17

Claim 17 depends from claim 1 and further recites: "in the closed position the engagement surface of one fixation element forms an angle of less than

[7] To the extent the Board construes this claim under §112, ¶6, the structure disclosed by Kuehn is the same or equivalent as that disclosed by the '267 patent, namely one or more components that are configured to physically interlock. Ex. 1002 ¶156; *see* §V.D, *supra*.

about 0° up to an angle of about 5° with the engagement surface of the other fixation element."

As discussed above, a POSITA would have understood based on Kuehn's disclosure and their own knowledge that, once implanted, the arms of Kuehn's modified device would take the position shown in the annotated figure below:



Ex. 1002 ¶159. These arm positions result from the balance of forces on the arms, both from the spring-loaded actuation mechanism and from the leaflets. *Id.* A POSITA would have understood that the mitral valve leaflets attain an angle of less than about 0° up to an angle of about 5° with each other. *Id.* ¶160. Due to the balance of forces between the leaflets and the springs, the arms of the modified Kuehn device also obtain such an angle, as shown in the image above. *Id.* Thus, to a POSITA, Kuehn discloses or at least suggests this limitation.

For the foregoing reasons, Kuehn and Roth disclose, or at least suggest, each limitation of claims 1-9 and 17. Thus, these claims would have been obvious as a whole to a POSITA over Kuehn in view of Roth and their own knowledge.

B. Ground 2: Claim 12 Is Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over Kuehn in View of Roth, Skelton, and POSITA Knowledge.

As discussed above, claim 1 is unpatentable as obvious for the reasons stated in Ground 1. Petitioners incorporate the arguments made in Ground 1 as to Kuehn's and Roth's disclosure within this section.[8] Claim 12, which adds a cover to the fixation elements of claim 1, would have been obvious as a whole over Kuehn in view of Roth and Skelton.

1. Skelton

Skelton discloses a "[s]heet materials for cardiovascular and other prosthetic implants" that "promote[s] the formation of natural tissue thereon[.]" Ex. 1007, Abstract. Skelton further discloses that the "elastomeric sheet materials of the invention" allow for "promotion of desirable natural tissue layering upon the sheet material." *Id.*, 4:44-56. Skelton describes the use of the sheet materials, when

[8] *See CRFD*, 876 F.3d at 1346 (holding that the Board should consider arguments from one ground incorporated into other grounds).

stretched over a frame, to create a device to be implanted into the heart. *Id.*, 5:40-6:37; Ex. 1002 ¶¶80, 163.

2. Claim 12

Claim 12 depends from claim 1 and further recites "a covering on the fixation elements adapted for promoting tissue growth."

A POSITA would have been motivated to modify Kuehn's device to cover the fixation elements (304, 308) with the sheet material disclosed in Skelton for several reasons. First, covering the fixation elements would improve the effectiveness of Kuehn's device once implanted. Ex. 1002 ¶164. Promoting tissue growth over the fixation elements would help adhere Kuehn's device to the leaflets and keep the device in place, especially given the stresses imposed by the natural motion of the leaflets. *Id.*

Second, covering the fixation elements would improve the safety of Kuehn's device. *Id.* ¶165. Typically, as a POSITA would have known, foreign objects or devices in the body (such as a device like Kuehn's) cause blood to clot around them. *Id.* Such blood clots, if dislodged, can cause stroke and other health problems for patients. *Id.* A POSITA would have recognized these safety issues and would have known that a covering such as Skelton's that promotes tissue growth would reduce the incidence of clotting and protect patients from health problems such as stroke. *Id.*

Third, coverings to promote tissue growth were well known in the art. *Id.* ¶166; *see, e.g.*, Ex. 1020, 11:13-22 ("A stent according to the invention may also be covered in fabric in order to . . . promote recipient tissue growth in and around the stent once the bioprosthetic valve has been inserted in the recipient. . . . Various fabrics may be used, as is well known by those skilled in the art, including, but not limited to a polyester, such as Dacron®, or a polytetrafluoroethylene, such as Teflon®."); Ex. 1021 at 6 (results "strongly suggest significant advantages" of a fabric-covered heart valve prosthesis).

Fourth, the modification represents nothing more than the simple addition of one known element (a sheet covering to promote tissue growth) to another known element (Kuehn's device) to obtain predictable results (a safer device for fixing valve leaflets having a tissue growth-promoting covering). Ex. 1002 ¶167; *see KSR*, 550 U.S. at 417.

Fifth, the modification represents the use of a known technique (covering a device with a tissue growth-promoting covering) to improve a similar device and method (Kuehn's device) in the same way. Ex. 1002 ¶168; *KSR*, 550 U.S. at 417.

Sixth, the modification applies a known technique (covering a device with tissue growth-promoting sheets) to a known device and method (Kuehn's device) that is ready for improvement and yields predictable results (a safer device for

fixing valve leaflets having a tissue growth-promoting covering). Ex. 1002 ¶169; *KSR*, 550 U.S. at 417.

A POSITA would have had a reasonable expectation of success in including Skelton's covering on Kuehn's device. Ex. 1002 ¶170. Petitioner's expert is not aware of any reason that Skelton's covering could not be successfully included on Kuehn's device. *Id.* Furthermore, coverings were well known in the art as discussed above, and adding them to the Kuehn device would not be a complicated process. Therefore, a POSITA would have had a reasonable degree of confidence that the modification would be successful. *Id.*

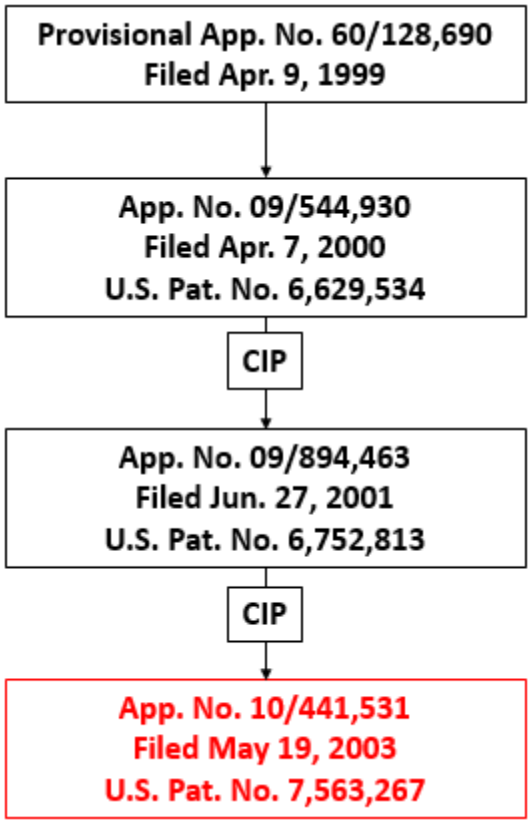
Thus, Skelton discloses or, at a minimum, suggests the additional limitation of claim 12. In view of the above, claim 12 would have been obvious as a whole to a POSITA over Kuehn in view of Roth, Skelton, and their own knowledge. *Id.* ¶171.

VIII. THE '267 PATENT'S EARLIEST EFFECTIVE FILING DATE IS MAY 19, 2003

The challenged claims of the '267 patent are entitled to an effective filing date no earlier than May 19, 2003, their actual filing. "[E]ach application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. §112." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). Therefore, once an application in the chain fails

to provide sufficient written description support, the priority chain to any earlier application is broken.

As discussed in Section IV.D, the '267 patent includes in its purported priority chain two applications and a provisional application:



But each of the preceding applications, including the '267 patent's immediate parent—the '463 application (now the '813 patent)—fails to provide sufficient written description to support the '267 patent claims.

A. Legal Background

1. Burden of Production

As Petitioner, Edwards bears the ultimate burden of proof and the initial burden of production to demonstrate unpatentability. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). But once a petitioner provides invalidating art, the burden of production shifts to the patent owner to demonstrate that (1) the challenged patent is entitled to an earlier priority date, or (2) it can swear behind the prior art reference(s). *Apple, Inc. v. AGIS Software Development, LLC*, IPR2018-00819, Paper 9 at 14 (P.T.A.B. Nov. 7, 2018) ("[T]he burden of production shifts to the patent owner once a petitioner provides invalidating art that predates the filing date of the challenged patent, where the patent-at-issue claims priority through continuations-in-part and the Examiner did not expressly address the priority issue.").

Here, Edwards demonstrates that the references are invalidating prior art. Thus, the burden of production shifts to Patent Owner to come forward with evidence showing (1) the references do not actually invalidate the patent claims, or (2) the references are not prior art because (a) the challenged patent is entitled to an earlier priority date, or (b) Patent Owner reduced the invention to practice prior to the filing date of the references. Patent Owner can do none of the above.

2. Priority to an Earlier-Filed Application

For continuation-in-part applications, priority is determined on a claim-by-claim basis. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1352 (Fed. Cir. 2012). For a claim to be entitled to the benefit of an earlier-filed application, the earlier application must comply with the written description requirement of 35 U.S.C. §112. *See* 35 U.S.C. §120; *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998). Claims whose subject matter is sufficiently disclosed in the priority applications are given the benefit of those applications' earliest filing date; claims with new subject matter are not entitled to those filing dates. *See Paperless Accounting v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 665 (Fed. Cir. 1986).

The relevant inquiry is whether the specification "describe[s] an invention understandable to that skilled artisan and show[s] that the inventor actually invented the invention claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Simply making a claim chart matching features to passages in the specification does not satisfy this requirement. To "isolate and combine aspects from various embodiments in the specifications (including patents incorporated by referenced involving a different [device])" does not demonstrate that the inventor was in possession of the purported invention. *Purdue Pharma L.P. v. Recro Tech., LLC*, 694 Fed. Appx. 794 (Fed. Cir. June 13, 2017). Instead, the written description analysis requires "[t]aking each claim . . . as an integrated

whole rather than as a collection of independent limitations." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

In addition, pointing to an obvious variation of a disclosed embodiment is not enough. "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed." *Lockwood*, 107 F.3d at 1571-72. "One shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed limitations, not that which makes it obvious." *Id.* at 1572 (emphasis in original).

B. The '267 Patent Claims Lack Written Description Support in the Parent

As noted above, the '267 patent's immediate parent is the '463 application, which issued as the '813 patent. As will be explained below, the '463 application does not provide written description support for claim 1 or any of the other challenged claims of the '267 patent. Because each application in the chain leading back to the earlier application must comply with the written description requirement, if the '463 application does not provide written description support, then it is not necessary to analyze the other applications. *See Lockwood*, 107 F.3d at 1571.

The '463 application discloses various embodiments of a device delivered by catheter for repairing the mitral valve. No single embodiment, however,

discloses every limitation of claim 1. Specifically, no embodiment discloses a combination of:

- fixation elements that are moveable between "a closed position . . . to an inverted position,"
- an actuation mechanism "to move the fixation elements between the closed position and the inverted position,"
- a pair of gripping elements . . . 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 "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.".

See generally Ex. 1008; Ex. 1002 ¶¶55-56. While the '463 application may include embodiments that show one of these limitations, it does not disclose an embodiment that includes all of the limitations of claim 1, and thus fails to provide adequate support. *See Purdue*, 694 Fed. Appx. at 794. Because each of the remaining challenged claims depend from claim 1, they suffer from the same defects.

Indeed, the specification and application details of the '267 patent and the '531 application confirm that the '463 application cannot provide sufficient support for the claims of the '267 patent. First, the applicant filed the '531 application as a continuation-in-part application with two new inventors, acknowledging that it was adding and claiming new matter. Ex. 1004; Ex. 1008. Second, applicant added significant new matter in the '531 application. For example, the '531 application includes a nearly entirely different set of figures from the '463 application. *Compare* Ex. 1001 *with* Ex. 1008. The new figures show different embodiments from that disclosed in the '463 application. *Id.*; Ex. 1002 ¶57. As shown in the annotated figures below (Figures 9 and 11B from the '267 patent), the new figures disclose the new subject matter in challenged claim 1:

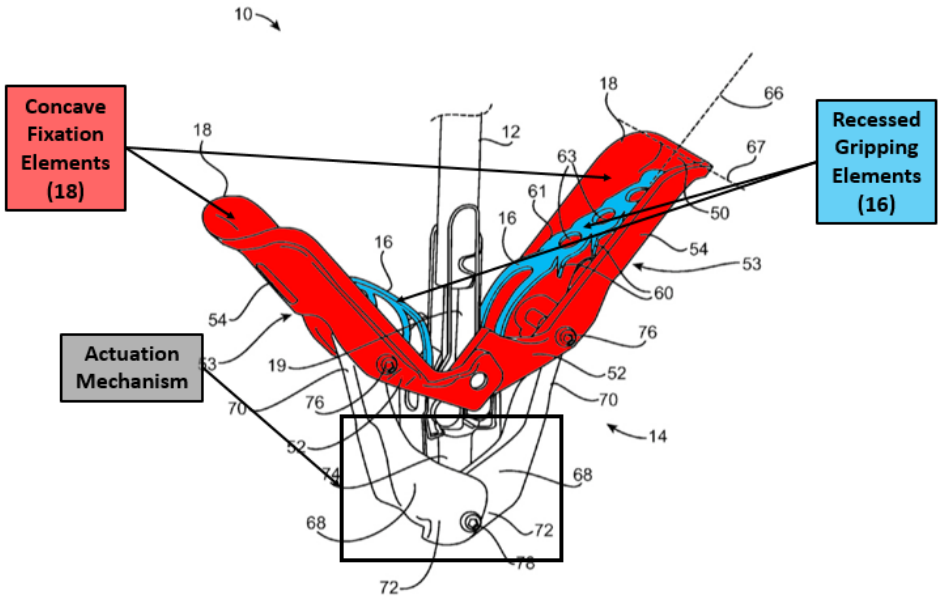


FIG. 9

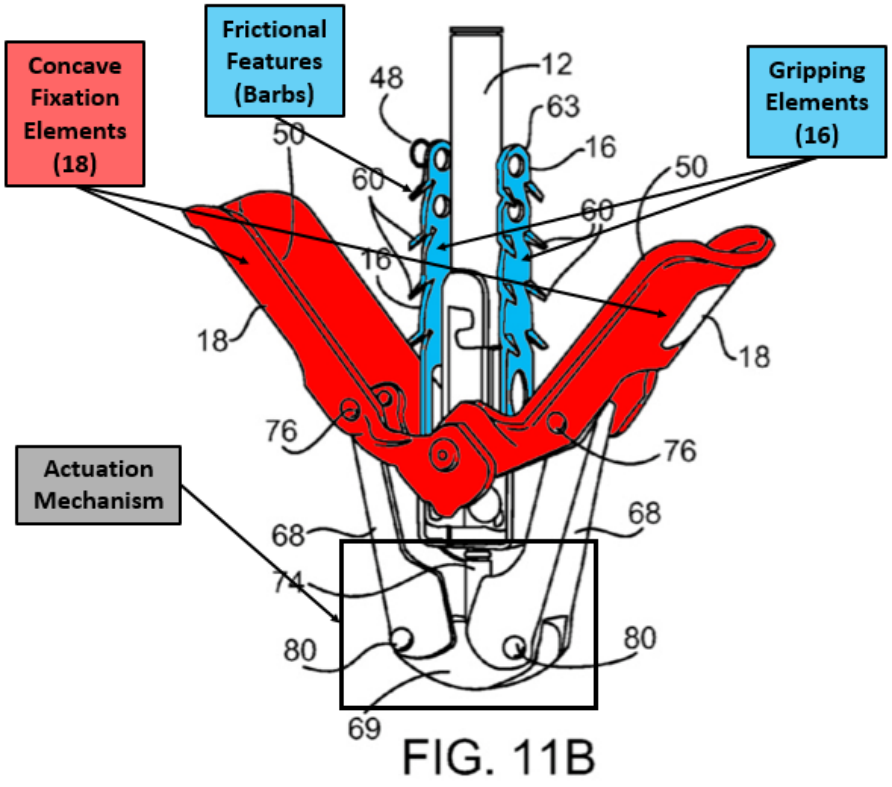


FIG. 11B

Ex. 1001, Figs. 9, 11B. The applicant added new Figures 9 and 11B in the '531 application, because the embodiments disclosed in the '463 application are each missing one or more of the features from those figures. Ex. 1002 ¶57. Accordingly, the addition of these new figures in the '531 application further confirms that the '463 application lacks written description support for the challenged claims.

Therefore, for at least these reasons, the challenged claims of the '267 patent are entitled only to their actual filing date. Thus, the priority date of these claims is May 19, 2003.

IX. SECONDARY CONSIDERATIONS, IF PRESENTED, FAIL TO OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS

Where a strong *prima facie* obviousness showing exists, as here, secondary considerations may not dislodge the obviousness conclusion. *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Furthermore, any assertion of secondary considerations must additionally fail because Patent Owner will be unable to establish a nexus between any secondary consideration and the alleged invention. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.").

In district court litigation, Patent Owner asserted five patents, including the '267 patent, against Edwards. Ex. 1022 at 2. Patent Owner sought a preliminary injunction, and its expert alleged on reply that a device called "MitraClip" made by Patent Owner's licensee had been a commercial success and that this success provided indicia of non-obviousness for the patents remaining in the PI motion. Anticipating that Patent Owner may raise such arguments in this proceeding, Petitioners provide preliminary rebuttal evidence below to show that Patent Owner cannot establish a nexus between the challenged claims and any MitraClip success, or other purported secondary consideration. Petitioners will respond further to any

secondary consideration arguments that Patent Owner raises in this proceeding should Patent Owner do so.

No presumption of a nexus exists between the '267 patent claims and any MitraClip success because Patent Owner alleges numerous patents cover MitraClip and success would be unattributable to any single patent. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299 (Fed. Cir. 2010), reh'g en banc granted, opinion vacated, 374 F. App'x 35 (Fed. Cir. 2010), and opinion reinstated in part, 649 F.3d 1276 (Fed. Cir. 2011) (no presumption of a nexus when patent owner's product embodies multiple patents and success cannot be attributed to a single patent). In addition to the five patents asserted in litigation, Patent Owner's licensee marks MitraClip with 11 other patents. Ex. 1023 at 3.

Moreover, any claimed features appearing in MitraClip were well-known in the art and therefore cannot serve as a basis for MitraClip's commercial success. *Ormco*, 463 F.3d at 1312 ("[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent."). To the extent Patent Owner argues MitraClip's sales are due to fixation and gripping elements that move between positions to engage mitral valve leaflets, those features were already known in the prior art (Kuehn), as explained above. *See* §VII, *supra*. The other features recited in the claims were similarly known. *See id.* In fact, Patent Owner only gained allowance of the '267 patent after amending the claims to require the

nesting feature and to require that the gripping elements are moveable between deployed/undeployed configurations. *See* §IV.B, *supra*. Such well-known and marginal features are not the basis of MitraClip's sales.

Indeed, Patent Owner's own evidence strongly suggests that MitraClip's sales stem from factors unrelated to the '267 patent claims, including MitraClip's exclusive regulatory approval and post-approval marketing. Patent Owner began conducting human trials with MitraClip starting in 2003, and gained FDA approval to market MitraClip in the U.S. in 2013 (European approval was obtained in 2008). Ex. 1022 at 5. Currently, MitraClip is, as Patent Owner asserts, "the only approved transcatheter option for edge-to-edge mitral valve repair" in the U.S. *Id.* at 7. MitraClip has sustained a huge regulatory and commercial head start. But commercial success due to successful clinical trials and sole FDA approval is not an indicator of the patent's non-obviousness. *Ex Parte Allen J. Tower et al.*, No. 2011-008322, 2013 WL 3326014, at *9 (P.T.A.B. May 17, 2013) (FDA approval for Medtronic's method of implanting prosthetic heart valve insufficient to establish nexus to commercial success). *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1331 (Fed. Cir. 2017) (commercial success based on receiving first FDA approval does not overcome fact that drug compositions were already known); *AstraZeneca LP v. Breath Ltd.*, 603 F. App'x 999, 1003 (Fed. Cir. 2015)

(nexus "must be evaluated in terms of what is driving sales, not what is allowing the product to reach the shelf in the first place.").

Even with regulatory approval, however, Patent Owner posits that "MitraClip's success remained in jeopardy unless Abbott could convince physicians to broadly adopt the new procedure." Ex. 1024 at 3. Patent Owner has admitted that "inventing MitraClip" was "not nearly enough to exploit the invention commercially." Ex. 1025 at 2. Abbott, accordingly, "invested enormous resources to demonstrate the benefits of MitraClip" and "spent over a decade" in training and acclimating doctors to MitraClip's procedures. Ex. 1024 at 3; Ex. 1025 at 4 ("So it takes enormous time and resources to build that network for folks comfortable with doing this kind of remote mitral valve repair."). Thus, by Patent Owner's own admission, MitraClip sales were secured with "enormous resources" for marketing and training, not with any feature claimed in the '267 patent.

MitraClip sales are also driven by virtue of being a transcatheter procedure that avoids open-heart surgery. Ex. 1022 at 6-7 ("The minimally invasive nature of the MitraClip obviates the need for open-heart surgery."). Open-heart surgery, as Patent Owner acknowledges, has "significant disadvantages, including significant medical risks and severe surgical trauma." *Id.* at 3. But transcatheter valve procedures were known in the early 2000s and were not invented by Patent Owner. For this reason also, any assertion of an "unmet need" for a "less invasive medical

treatment" for mitral regurgitation must likewise fail. *See id.* at 4. The satisfaction of a generic need is attributable to the transcatheter nature of the MitraClip procedure, not specific features of the challenged claims. Accordingly, there is no "nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

Other secondary considerations, as with commercial success, lack a nexus to the '267 patent claims. For example, in the district court litigation, Patent Owner points to "regulatory and industry praise" for MitraClip. Ex. 1022 at 7-8. But as Patent Owner admits, the praise is related to general "contributions to cardiovascular care," not specific to a claimed MitraClip feature. *Id.* at 7. The New York Times article cited by Patent Owner confirms this, as it describes the results of a recent clinical study that allows for expanded patient populations treatable with MitraClip—the "game changer" is not any claimed feature of MitraClip, but an "impeccably executed" study that found more patients are treatable with MitraClip than originally thought. Ex. 1028.

Thus, any effort by Patent Owner to overcome the strong case of obviousness with alleged secondary considerations must fail, as Patent Owner will be unable to establish a nexus between the '267 patent's claimed features and any such secondary consideration. Should Patent Owner affirmatively raise secondary considerations in a Response, Edwards reserves the right to further address the

issue at that time.

X. CONCLUSION

Edwards has established a reasonable likelihood of prevailing in showing that at least one challenged claim is unpatentable, and therefore requests that the Board order an IPR Trial and, ultimately, cancel all challenged claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 29, 2019

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CERTIFICATE OF TYPE-VOLUME LIMITATIONS UNDER 37 C.F.R. §42.24

Pursuant to 37 C.F.R. §42.24(d), Counsel for Petitioners Edwards Lifesciences Corp. and Edwards Lifesciences LLC hereby certify that the foregoing **PETITION FOR INTER PARTES REVIEW OF CLAIMS 1-9, 12, AND 17 OF U.S. PATENT NO. 7,563,267** complies with the type-volume limitation of 37 C.F.R. §42.24(a)(1). According to Microsoft Office Word 2016's word count, this Petition contains approximately 13,995 words, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 29, 2019

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-9, 12, AND 17 OF U.S. PATENT NO. 7,563,267**and **EXHIBITS 1001-1028** are being served on May 29, 2019 via FedEx Priority Overnight service on counsel of record for U.S. Patent No. 7,563,267 patent owner for **Evalve, Inc.**, as addressed below:

Correspondence Address of Record for U.S. Patent No. 7,563,267 at the U.S. Patent and Trademark Office:

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