

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,

Petitioner,

v.

CARDIOVALVE LTD.,

Patent Owner.

IPR2021-01051

Patent 10,702,385 B2

Before JAMES A. WORTH, RYAN H. FLAX, and SEAN P. O'HANLON,
Administrative Patent Judges.

WORTH, *Administrative Patent Judge.*

DECISION

Granting Institution of *Inter Partes* Review

35 U.S.C. § 314

I. INTRODUCTION

A. *Background and Summary*

On June 4, 2021, Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively, “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–10 (the “challenged

claims”) of U.S. Patent No. 10,702,385 B2 (Ex. 1001, “the ’385 patent”). On September 15, 2021, Cardiovalve Ltd. (“Patent Owner”) filed a notice of its election to waive its preliminary response. Paper 8.

In support of its challenges, Petitioner relies, *inter alia*, on the declaration of Ivan Vesely, Ph.D. Ex. 1003.

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (2018). For the reasons set forth below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that at least one of claims 1–10 would have been unpatentable, and we institute an *inter partes* review of claims 1–10 based on the grounds set forth in the Petition.

B. Real Parties-in-Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC as the real-parties-in-interest. *See* Pet. 110. Patent Owner identifies Cardiovalve Ltd. as the real-party-in-interest. Paper 4, 1.

C. Related Matters

Petitioner identifies as a related proceeding IPR2021-00383 (the -383 IPR). The -383 IPR relates to U.S. Patent No. 10,226,341 (of which the ’385 patent is a continuation). *See* Pet. 111. The Board instituted trial in the -383 IPR on July 20, 2021 (*see* Paper 16 of respective record).

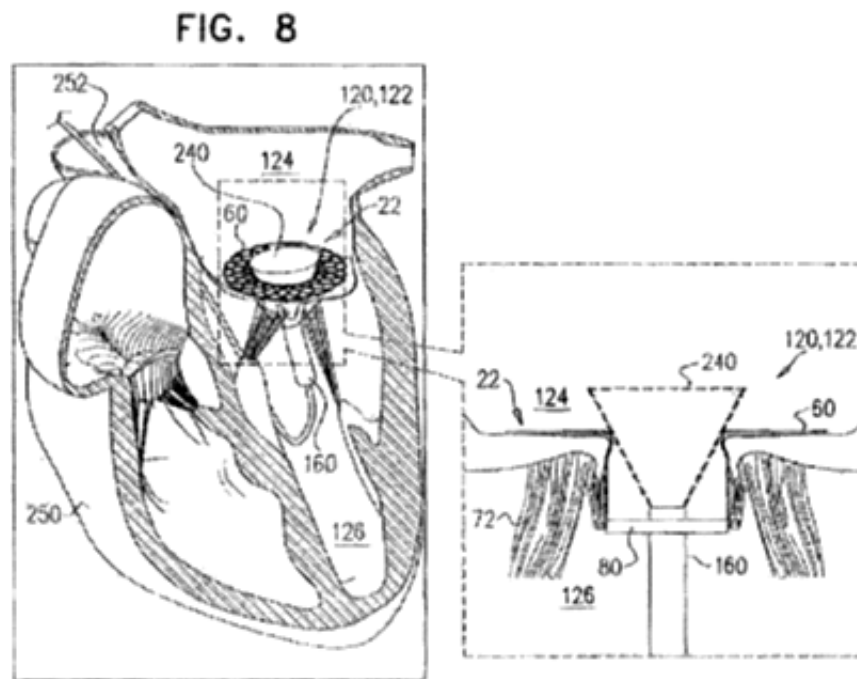
According to Patent Owner, the ’385 patent is related to the following other applications: 16/888,210; 16/881,350; 17/210,183; 17/306,231; 17/355,845; 17/366,711; 17/394,807; 17/397,235; and 17/473,472. Paper 9, 1.

D. The '385 Patent

The '385 patent is titled “Implant for Heart Valve” and “[s]ome applications relate in general to valve replacement” and more specifically to “prosthetic valves for replacement of a cardiac valve.” Ex. 1001, code (54), 1:34–37.¹ According to the '385 patent, ischemic heart disease causes regurgitation of blood through a heart valve by the combination of ischemic dysfunction of the papillary muscles, and the dilatation of the ventricle. *Id.* at 1:41–44. The '385 patent discloses a prosthetic valve support that may be coupled to the valve leaflets to hold the leaflets together to define one or two orifices, and in some applications may be used to facilitate implantation of a prosthetic valve support. *See id.* at 2:18–44.

The '385 patent discloses that, for some applications, the prosthetic valve support is configured to be coupled to the native valve (e.g., to leaflets thereof) without eliminating the check valve functionality by coupling together respective portions of two leaflets, such that (1) the native leaflets define two orifices, and (2) the native valve functions as two (e.g., parallel) check valves. Ex. 1001, 2:18–31. The '385 patent's Figure 8, directed to one embodiment of its disclosed invention, provides some context as to the placement of the prosthetic valve and is reproduced below:

¹ Petitioner asserts that the challenged claims “do not include the annular portion [of the implant described in the Specification] or prosthetic valve.” Pet. 2.



“FIG. 8 is a schematic illustration of a step in the implantation of the prosthetic valve, facilitated by the prosthetic valve support, in accordance with some applications of the invention.” *Id.* at 7:13–16; *see also id.* at 23:49–24:9 (describing the same). Figure 8 shows in its larger image (above-left) a cross-section of a human heart (labeled 250) through the four chambers, including the valves there-between and a prosthetic valve (labeled 240) positioned at the mitral valve (labeled 122). *Id.* The smaller image of Figure 8 (above-right) shows a zoomed-in, cross-sectional view of that prosthetic valve in place and the aforementioned leaflets (flaps of tissue constituting the terminal ends at the center of the valve) extending in a downward direction from the valve’s opening.

The ’385 patent further discloses that, for some applications, it is hypothesized that the use of a two-component implant (i.e., comprising the prosthetic valve support and a separate prosthetic valve) advantageously facilitates delivery of the prosthetic valve via a catheter narrower than 28 Fr

(e.g., by allowing the use of a minimalistic prosthetic valve, such as a prosthetic valve with few or no appendages).² Ex. 1001, 2:32–38.

The prosthetic valve support comprises tissue-engaging elements, such as clips. Ex. 1001, 2:10–11. Typically, but not necessarily, the prosthetic valve support further comprises (1) an upstream support portion, configured to be placed against an upstream surface of the native valve, and shaped to define one of the openings, and (2) a stabilizing element, shaped to define another of the openings. *Id.* at 2:11–16.

Figure 1A of the '385 patent is reproduced below:

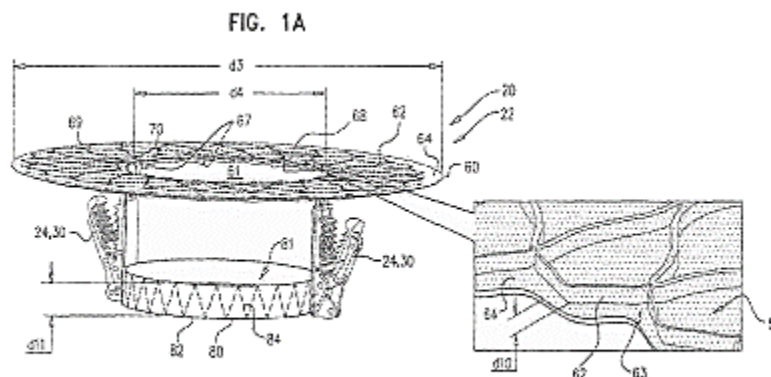


Figure 1A is a schematic illustration of an apparatus, comprising a prosthetic valve support, for facilitating implantation of a prosthetic heart valve at a native heart valve of a subject, in accordance with some applications.

Ex. 1001, 6:53–57. Typically, each tissue-engaging element 24 comprises a clip 30, which typically comprises a plurality of clip arms 32 (e.g., two clips arms, e.g., a first clip arm 32a and a second clip arm 32b), the clip being configured to be coupled to a leaflet of the native valve. *Id.* at 7:35–39.

² “Fr” refers to French units, also called French gauge, and is approximately 0.33 mm.

Figure 1B shows clip 30 in an unlocked configuration, in which an obstructing element 58 (e.g., a restraint) is disposed between rack 51 and engaging element 56, thereby inhibiting (e.g., obstructing) engaging element 56 from engaging rack 51, and thereby facilitating the opening and closing of the clip (i.e., movement between open and closed states thereof). Ex. 1001, 9:30–36. Typically, clip controller 36 facilitates control of the clip by applying a force to clip-controller interface 34, e.g., by transferring an extracorporeally-applied force to the clip-controller interface. *Id.* at 8:39–42.

Figure 6B of the '385 patent is reproduced below:

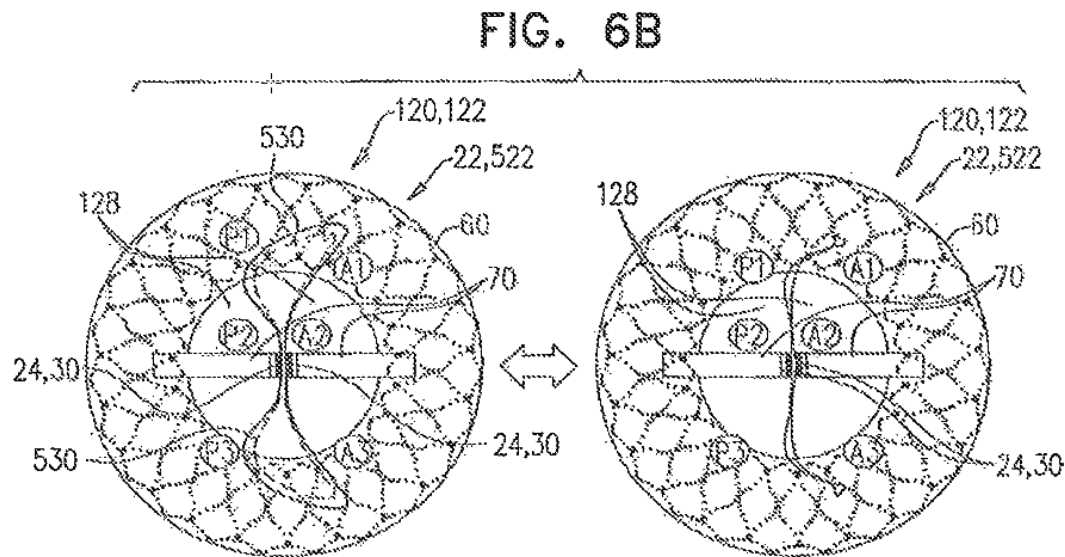


Figure 6B is a schematic illustration of a prosthetic valve support comprising tissue-engaging elements that are couplable to each other, and decouplable from each other, in accordance with some applications. Ex. 1001, 7:6–9. Tissue-engaging elements 24 are coupled to respective portions of leaflets 128 (e.g., scallops A2 and P2 of the anterior and posterior leaflets of the mitral valve, respectively), and to each other, and thereby hold the portions

of the leaflets to which they are coupled close to each other (e.g., together).
See id. at 21:64–22:2.

E. Illustrative Claim

Claim 1, reproduced below, is the sole independent claim challenged in the Petition and is illustrative of the claimed subject matter:

1. A method for use at a native valve of a heart of a subject, the valve including a first leaflet and a second leaflet, the method comprising:

transluminally advancing, to the heart, an implant coupled to a delivery apparatus,

the implant including a first clip and a second clip, the first clip and the second clip fixedly coupled to each other, the first clip including a first-clip arm, and the second clip including a second-clip arm, and

the delivery apparatus including a delivery tube and at least one clip controller disposed within the delivery tube;

advancing the implant out of the delivery tube;

forming the first leaflet and the second leaflet into a double-orifice arrangement by using the implant to couple a middle scallop of the first leaflet to a middle scallop of the second leaflet by, using the clip controller:

opening the first clip by deflecting the first-clip arm;

independently of opening the first clip, opening the second clip by deflecting the second-clip arm;

gripping the first leaflet with the first clip by closing the first clip by deflecting the first-clip arm; and

independently of gripping the first leaflet, gripping the second leaflet with the second clip by closing the second clip by deflecting the second-clip arm;

decoupling the clip controller from the implant; and

withdrawing the delivery apparatus from the subject.

Ex. 1001, 27:13–40.

One of the dependent claims bears mentioning. Claim 5 recites as follows:

The method according to claim 1, wherein:
the first clip further includes a first grip,
the second clip further includes a second grip,
closing the first clip comprises closing the first clip by deflecting
the first clip-arm toward the first grip, and
closing the second clip comprises closing the second clip by
deflecting the **first clip-arm** toward the second grip.

Ex. 1001, 28:3–9 (emphasis added). Petitioner argues that the bolded term is an error and should read “second-clip arm” because the Specification discloses deflecting clip arms toward grips on the same clip as the clip arms and the correction is not subject to reasonable debate. Pet. 53–54 (citing Ex. 1001, 9:9–17, Fig. 1B; *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009)).

For purposes of this proceeding, we understand the bolded “first clip-arm” in the second “closing” limitation of claim 5 as being a clear and inadvertent error, and as being intended to read “second clip-arm” based on the parallelism between the first and second “closing” limitations and in keeping with Figure 1B of the Specification, which shows a unitary clip arm.³ Accordingly, for purposes of this proceeding, we understand claim 5 to read as follows: “5. The method according to claim 1, wherein: the first clip further includes a first grip, the second clip further includes a second

³ A different amendment was made to this claim limitation during prosecution. Ex. 1002, 398 (“closing the second clip comprises closing the second clip by deflecting the first clip-arm toward the ~~first~~ second grip”).

grip, closing the first clip comprises closing the first clip by deflecting the first clip-arm toward the first grip, and closing the second clip comprises closing the second clip by deflecting the ~~first clip-arm~~ second clip-arm toward the second grip.” *See Fitbit, Inc. v. Valencell, Inc.*, 964 F.3d 1112, 1119–20 (Fed. Cir. 2020) (“The Board erred in declining to accept the parties’ uniform position and correct the error that claim 4 depend from claim 3.”); *see also Volkswagen Grp. of Am., Inc. v. Michigan Motor Techs. LLC*, IPR2020-00446, Paper 9 at 12 (PTAB Aug. 25, 2020) (correcting printing error). Patent Owner is invited to comment after institution as to whether it agrees with this preliminary determination.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–10 would have been unpatentable on the following grounds (Pet. 13):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 2, 4–10	102(b)	Goldfarb ’267 ⁴ (Embodiment A) ⁵
1, 2, 4–10	103	Goldfarb ’267 (Embodiment A)
3	103	Goldfarb ’267 (Embodiment A), Goldfarb ’329 ⁶
1, 2, 5, 6, 8	102(b)	Goldfarb ’267 (Embodiment B) ⁷
1, 2, 5, 6, 8	103	Goldfarb ’267 (Embodiment B)
1, 4, 5	103	Goldfarb ’329

⁴ Goldfarb, US 7,563,267 B2, iss. July 21, 2009 (Ex. 1005, “Goldfarb ’267”).

⁵ Petitioner refers to Goldfarb’s ’267 disclosure of a further alternative at Ex. 1005, 27:57–60 as Embodiment A. *See* Pet. 19. We understand the asserted Embodiment A to encompass the description that extends to Ex. 1005, 28:9. *See* Pet. 24–48.

⁶ Goldfarb, US 7,635,329 B2, iss. Dec. 22, 2009 (Ex. 1006, “Goldfarb ’329”).

⁷ Ex. 1005, 17:66–23:29, Figs. 9–16; *see* Pet. 21–22.

II. ANALYSIS

A. *Legal Standards*

A “prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). “A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014).

“[A]nticipation by inherent disclosure is appropriate only when the [single prior art] reference discloses prior art that must *necessarily* include the unstated limitation.” *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) (citation omitted). “Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” *Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (internal quotation marks and citations omitted). Rather, “[t]he inherent result must inevitably result from the disclosed steps.” *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012).

A reference can anticipate a claim even if it “d[oes] not expressly spell out” all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would “at once envisage” the claimed arrangement or combination. *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (citing *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). “[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 50–51 (1966)). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In an *inter partes* review, a petition must identify “with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3) (2018); *see also* 37 C.F.R. § 42.104(b) (2018) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied upon).

B. Level of Ordinary Skill in the Art

Petitioner argues that a person of ordinary skill in the art (POSITA) at the relevant time would have been either: (1) a mechanical or biomedical engineer with at least three years of experience in designing or developing medical devices who would, where necessary or desired, work or consult with others including a physician to develop such a medical device; or (2) an

interventional cardiologist or cardiac surgeon with at least three years of experience developing and/or using medical devices in the heart, and who would, where necessary, work or consult with others including an engineer to develop such a medical device. Pet. 15–16 (citing Ex. 1003 ¶ 32).

On the record at this stage of the proceeding, we adopt Petitioner’s undisputed definition of the ordinarily skilled artisan.

C. Claim Construction

We construe each claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b) (2019). Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

Petitioner requests that we construe the term “clip” to mean “a device that grips or holds.” Pet. 16. Citing dictionary definitions, Petitioner argues that the ordinary meaning of “clip” is “a device, typically flexible or worked by a spring, for holding an object or objects together or in place.” *Id.* (citing Ex. 1009; Ex. 1010). Petitioner argues that the Specification is consistent with the ordinary meaning. *Id.* (citing Ex. 1001, 7:35–39, 9:9–17, 27:27–39).

Given the lack of dispute on this record, and in view of the Specification and the proffered dictionary definitions, for the purposes of this Decision we construe “clip” to mean “a device that grips or holds.” Ex. 1001, 7:35–39, 9:9–17; Ex. 1009; Ex. 1010.

Figure 4 illustrates the position of the fixation device in a desired orientation relative to the leaflets. Ex. 1005, 10:17–18. This is a short-axis view of mitral valve MV from the atrial side, where the proximal elements 16 are shown in solid line and the distal elements 18 are shown in dashed line. *Id.* at 14:28–31. The upstream surfaces may be brought together so as to be in contact with one another or may be held slightly apart, but will preferably be maintained in the vertical orientation in which the upstream surfaces face each other at the point of coaptation. *Id.* at 14:42–46. This simulates the double orifice geometry of a standard surgical bow-tie repair. *Id.* at 14:46–47.

We understand Petitioner relies on the disclosure of Goldfarb '267 at 27:57–28:9 as Embodiment A. *See* Pet. 20, 24–48. Goldfarb '267 describes this unillustrated embodiment as an alternative to the embodiment of Figures 22A and 22B. *See* Ex. 1005, 27:57–58. However, because Embodiment A uses the same numerals as those in Figures 22A and 22B, we understand it to be a variation on Figures 22A and 22B, as argued by Petitioner. *See* 37 C.F.R. § 1.84(p)(4) (“The same part of an invention appearing in more than one view of the drawing must always be designated by the same reference character, and the same reference character must never be used to designate different parts.”); Pet. 30 (citing same). Accordingly, we first review Figures 22A and 22B before reviewing the asserted Embodiment A.

b) Figures 22A and 22B

Figures 22A and 22B of Goldfarb '267 are reproduced below:

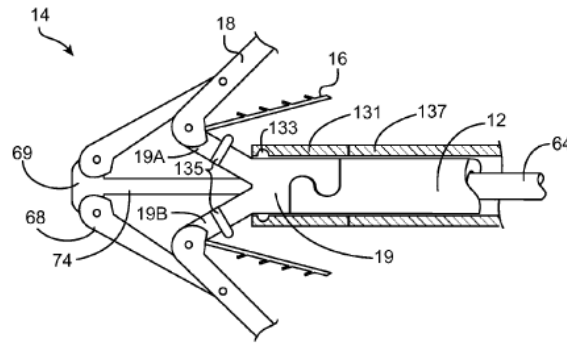


FIG. 22A

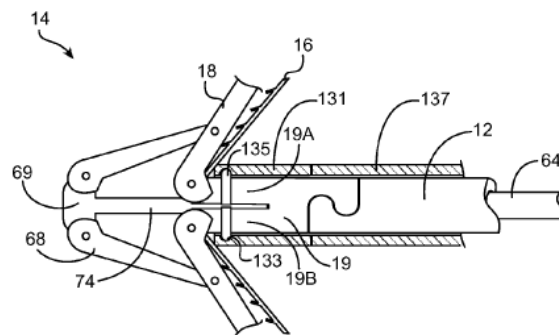


FIG. 22B

Figures 22A and 22B “illustrate a variation of the fixation device to facilitate capture of more widely-separated leaflets or other tissue flaps.” Ex. 1005, 10:40–42. In this embodiment, the proximal and distal elements 16, 18 on each side of the fixation device are movable laterally toward and away from each other to facilitate capture of the leaflets or tissue flaps. *Id.* at 27:6–10. Coupling member 19 is bifurcated into two resilient and flexible branches 19A, 19B which are biased outwardly into the position shown in Figure 22A, but which are movable to the position shown in Figure 22B. *Id.* at 27:10–14. In the alternative, branches 19A, 19B may be more rigid members connected to coupling member 19 by pins or hinges so as to be pivotable toward and away from each other. *Id.* at 27:14–17. Each pair of proximal element 16 and distal element 18 is coupled at their proximal ends to one branch 19A or 19B of the coupling member 19. *See id.* at 27:17–19.

Legs 68 are coupled at their proximal ends to base 69, and therefore stud 74, and at their distal ends to distal elements 18. *Id.* at 27:19–21. Translation of stud 74 distally or proximally relative to coupling member 19 opens or closes distal elements 18. *Id.* at 27:21–24. Collar 131 is slidably disposed over coupling member 19 and has annular groove 133 on its inner wall configured to slide over and frictionally engage detents 135 on branches 19A, 19B. *Id.* at 27:24–27. Sheath 137 is positioned coaxially over shaft 12 and is slideable relative thereto to facilitate pushing collar 131 distally over coupling member 19. *Id.* at 27:27–30.

When the user is ready to capture the target tissue (e.g., valve leaflets), sheath 137 is retracted so that collar 131 slides proximally over coupling member 19. Ex. 1005, 27:35–38. This allows branches 19A, 19B to separate into the position of Figure 22A. *Id.* at 27:38–39. Actuator 64 is pushed distally so as to open distal elements 18. *Id.* at 27:39–40. Tension is maintained on proximal element lines 90 (not shown in Figures 22A–22B) so that proximal elements 16 remain separated from distal elements 18. *Id.* at 27:40–43.⁸ When tissue is positioned between the proximal and distal elements, tension is released on proximal element lines 90 allowing the tissue to be captured between the proximal and distal elements. *Id.* at 27:43–46. Sheath 137 may then be advanced distally so that collar 131 urges branches 19A, 19B back together. *Id.* at 27:46–48. Sheath 137 is advanced until groove 133 in collar 131 slides over detents 135 and is frictionally maintained thereon as shown in Figure 22B. *Id.* at 27:48–50. Sheath 137 may then be retracted from collar 131. *Id.* at 27:50–51. This embodiment

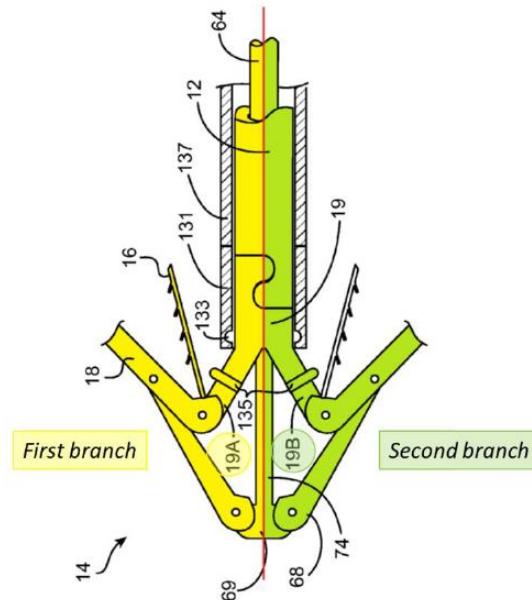
⁸ Proximal element lines 90 are shown in Figures 11A and 13A, annotated versions of which are reproduced below in Section II.G.2.d.

preferably includes a locking mechanism as described elsewhere in Goldfarb '267. *Id.* at 27:53–56.

c) Asserted Embodiment A

Goldfarb '267 discloses that in a further alternative of the embodiment of Figures 22A and 22B, fixation device 14 may be configured to allow for independent actuation of each of the lateral branches 19A, 19B and/or distal elements 18. Ex. 1005, 27:57–60. In an exemplary embodiment, shaft 12 and coupling member 19 may be longitudinally split into two identical halves such that a first branch 19A may be drawn into collar 131 independently of a second branch 19B. *Id.* at 27:60–63. Similarly, actuator shaft 64 may be longitudinally split so that each half can slide independently of the other half, thus allowing one of distal elements 18 to be closed independently of the other distal element 18. *Id.* at 27:64–67. This configuration permits the user to capture one of the valve leaflets between one of the proximal and distal elements 16, 18, then draw the corresponding branch 19A into the collar 131. *Id.* at 27:67–28:3. The fixation device 14 may then be repositioned to capture a second of the valve leaflets between the other proximal and distal elements 16, 18, after which the second branch 19B may be drawn into collar 131 to complete the coaptation. *Id.* at 28:3–7. The closure of distal elements 18 may occur either before or after branches 19A, 19B are drawn into collar 131. *Id.* at 28:7–9.

Petitioner offers the following figure to illustrate Embodiment A:



Petitioner’s figure offered to represent Embodiment A is essentially a reproduction of Figure 22A, rotated counterclockwise, with a red centerline added, with the left side of the diagram colored in yellow and annotated “First branch,” with the numeral 19A highlighted, with the right side of the diagram colored in green and annotated “Second branch,” and with numeral 19B highlighted. See Pet. 20.

2. Analysis of Independent Claim 1

- a) *Preamble: “A method for use at a native heart valve of a heart of a subject, the valve including a first leaflet and a second leaflet”*

Petitioner argues that Goldfarb ’267 discloses devices, systems, and methods “adapted for repair of cardiac valves, and particularly the mitral valve, as a therapy for regurgitation.” Pet. 24 (citing, e.g., Ex. 1005, 3:30–33). Petitioner asserts that the mitral valve has first and second leaflets. *Id.* (citing Ex. 1005, 9:7–11, 12:24–26, Figs. 1, 2A–2B). Petitioner

argues that Embodiment A includes fixation device 14 that performs the claimed method. *Id.* (citing Ex. 1005, 27:6–28:9; Ex. 1003 ¶ 74).

On the record that at this stage of the proceeding, Petitioner has made an adequate showing for the preamble. In particular, Goldfarb '267 discloses that in a particularly preferred embodiment, the devices, systems and methods of the invention are adapted for repair of cardiac valves, and particularly the mitral valve, as a therapy for regurgitation. Ex. 1005, 3:30–33. Goldfarb '267 discloses, in Embodiment A, a method for capturing tissue between proximal 16 and distal elements 18. *See id.* at 27:39–46. Goldfarb '267 discloses that Embodiment A is a variation on the embodiment of Figures 22A and 22B, in which the fixation device is used to facilitate capture of more widely-spaced leaflets or other tissue flaps. *See id.* at 10:41–43, 27:57–58.

b) transluminally advancing, to the heart, an implant coupled to a delivery apparatus

Petitioner argues that fixation device 14 is an implant that the physician leaves behind in a patient and that fixation device 14 is coupled to shaft 12. *See* Pet. 25–26 (citing, e.g., Ex. 1005, 13:26–29, 13:60–64, 27:57–28:9, Figs. 22A–22B; Ex. 1003 ¶ 76). Petitioner asserts that, in Embodiment A, shaft 12 and coupling member 19 are longitudinally split in two identical halves, and the left and right halves of the shaft are part of the claimed delivery apparatus. *Id.* at 26 (citing Ex. 1005, 15:37–53, 27:6–28:9, 27:60–63, Figs. 22A–B; Ex. 1003 ¶ 77).

Petitioner asserts that Embodiment A would include two coupling mechanisms so that branches 19A–19B can be drawn into collar 131 independently, i.e., (1) one between the left half of the shaft and coupling member and (2) one between the right half of the shaft and coupling

member. *See* Pet. 26–27 (citing Ex. 1005, 27:6–30, 27:57–63, Figs. 22A–22B; Ex. 1003 ¶¶ 78–79). Petitioner asserts that Goldfarb ’267 discloses several types of “coupling mechanisms” for coupling the shaft to the coupling member, including interlocking curves and screws. *Id.* at 28 (citing Ex. 1005, 10:19–20, 14:55–15:18, 20:38–46, Figs. 5A–6B, 22A–22B). Petitioner asserts that a person of ordinary skill would have been familiar with these types of mechanisms and expected these mechanisms to work for Embodiment A, just as they work for the embodiments in Figures 9–16 and 22A–22B. *Id.* (citing Ex. 1003 ¶ 79).

Petitioner asserts that Goldfarb ’267 discloses that the “step of advancing may further comprise transluminally positioning the fixation device through a blood vessel into the heart, and may include inserting the fixation device through an interatrial septum of the heart.” Pet. 28 (citing, e.g., Ex. 1005, 3:63–4:2, 8:29–33, 9:20–24) (emphasis omitted). Petitioner argues that Goldfarb ’267 discloses an “interventional system 3” having an “outer guide catheter 1000,” “an inner guide catheter 1020,” and “a delivery catheter 300” to facilitate transluminal advancement of fixation device 14. *Id.* at 28–29 (citing Ex. 52:13–49, Fig. 76).

Petitioner asserts that a person of ordinary skill would have understood that the delivery device of Figure 76 is used to deliver the fixation device of Embodiment A because both Figure 76 and Embodiment A refer to the fixation device as item 14, as does Embodiment A. Pet. 30 (citing 37 C.F.R. § 1.84(p)(4)).

On the record at this stage of the proceeding, Petitioner has made an adequate showing for this limitation. In particular, Goldfarb ’267 discloses shaft 12 and coupling member 19, which are longitudinally split into two identical halves. *See* Ex. 1005, 27:60–60. A person of ordinary skill would

have understood the halves of shaft 12 to be part of the delivery device. *See* Ex. 1003 ¶ 77. Goldfarb '267 also discloses transluminally advancing the fixation device through a blood vessel. *See id.* at 9:20–24.

Further, on this record, we determine that a person of ordinary skill would have envisaged that the device of Embodiment A is transluminally advanced using the apparatus described elsewhere in Goldfarb '267, e.g., because Figure 76 uses a common numbering as the fixation device 14 as Embodiment A. *See Kennametal*, 780 F.3d at 1381; 37 C.F.R. § 1.84(p)(4).

- c) *the implant including a first clip and a second clip, the first clip and the second clip fixedly coupled to each other, the first clip including a first-clip arm, and the second clip including a second-clip arm*

Petitioner argues that left proximal element 16 and left proximal distal element 18 form one clip, and right proximal element 16 and right proximal element 18 form a second clip. *See* Pet. 33–35 (citing Ex. 1005, 27:6–21, Figs. 22A–22B; Ex. 1003 ¶ 91). Petitioner asserts that the clips are coupled to each through at least collar 131, which surrounds the left and right coupling members 19 and prevents the clips from separating. *Id.* at 34 (citing Ex. 1005, 27:17–28:9, Figs. 22A–22B; Ex. 1003 ¶ 90).

On this record, Petitioner has made an adequate showing. In particular, each of the left and right clips is composed of a proximal element 16 and distal element 18. Ex. 1003 ¶ 90. Goldfarb '267 discloses that branches 19A, 19B are drawn into collar 131. *See* Ex. 1005, 28:2–9. This keeps the left and right clips from separating. *See* Ex. 1003 ¶ 90.

- d) *the delivery apparatus including a delivery tube and at least one clip controller disposed within the delivery tube*
 - (1) *delivery tube*

Petitioner asserts that Goldfarb '267 discloses that “the invention provides an interventional system comprising a tubular guide having a proximal end, a distal end and a channel therebetween” Pet. 35–36 (citing Ex. 1005, 7:29–31) (emphasis omitted). Petitioner asserts that the delivery catheter and fixation device are “slidably positioned” within the guide. *Id.* at 36 (citing Ex. 1005, 8:20–25). Petitioner asserts that Figure 76 illustrates the “interventional system 3” (delivery apparatus) having an “outer guide catheter 1000,” “an inner guide catheter 1020,” and “a delivery catheter 300,” where the outer and inner guide are delivery tubes. *Id.* at 36 (citing 52:13–49, Fig. 76; Ex. 1003 ¶¶ 93–94). Petitioner argues that a person of ordinary skill would have understood Goldfarb '267 to disclose delivering Embodiment A through the catheters in Figure 76’s interventional system. *Id.* at 37.

On this record, and as discussed above, Petitioner has made an adequate showing that a person of ordinary skill would have understood that the device of Embodiment A is delivered through the tube described elsewhere in Goldfarb '267. *See* Ex. 1005, 7:29–31, Fig. 76; Ex. 1003 ¶ 94.

- (2) *clip controller*

Petitioner asserts that each half of Embodiment A’s actuator 64 (which is longitudinally split) is a clip controller. Pet. 38 (citing, e.g., Ex. 1005, 27:64–67; Ex. 1003 ¶ 99). Petitioner asserts that the physician pushes or pulls the left half of actuator 64 to open and close the left distal element, and pushes or pulls the right half of the actuator 64 to open and close the right distal element. *Id.* (citing Ex. 1005, 27:39–53, 27:64–28:9,

Figs. 22A–22B). Petitioner asserts that the two halves of actuator 64 are disposed within the other elements of the delivery apparatus, including shaft 12 and the inner and outer guide catheters of the interventional system. *Id.* at 39 (citing Ex. 1005, 27:39–67, 52:13–64, 53:30–34, 8:20–25, Figs. 22A–22B, 76).

On this record, Petitioner has made an adequate showing that, in the embodiment of Figures 22A and 22B of Goldfarb ’267, actuator 64 is a clip controller because it can be pushed distally to open distal elements 18, and in Embodiment A, actuator 64 may be split longitudinally where each half operates independently. *See* Ex. 1005, 27:39–40, 27:63–67. Further, Petitioner has made an adequate showing that the halves of actuator 64 are within shaft 12 (*see* Ex. 1005, Figs. 22A, 22B) and also that fixation device 14 is within outer guide catheter 1000 (*see id.* at Fig. 76). *See* Ex. 1003 ¶ 100 (citing Ex. 1005, 6:53–65, 7:59–64, 8:20–25, 19:43–51, 20:36–38, 24:37–40, 25:64–26:3, 26:45–48, 27:39–67; 32:40–41, 33:60–65, 52:13–64, 53:30–34, Figs. 22A–22B, 76).

e) “*advancing the implant out of the delivery tube*”

Petitioner asserts that fixation device 14 is advanced to the patient’s heart through the outer guide catheter. Pet. 40 (citing Ex. 1005, 52:14–20, 52:40–49, 53:30–34). Petitioner asserts that once the fixation device reaches the end of the outer guide catheter, it is advanced out of the outer guide catheter, as shown in Figure 76 of Goldfarb ’267. *Id.* (citing Ex. 1005, 43:20–44:9, 52:14–20, 52:40–49, 53:30–34, Figs. 63A–63D (describing delivery of the fixation device)).

On this record, Petitioner has made an adequate showing that Goldfarb ’267 discloses advancing fixation device 14 through the delivery

tube, and out of the delivery tube to its target for use in correcting regurgitation. *See* Ex. 1005, 43:62–44:9, Fig. 76.

- f) *“forming the first leaflet and the second leaflet into a double-orifice arrangement by using the implant to couple a middle scallop of the first leaflet to a middle scallop of the second leaflet”*

Petitioner asserts that Figure 4 of Goldfarb '267, reproduced *supra*, shows a first clip coupled to the middle scallop of a first leaflet at the top of the valve and a second clip coupled to a middle scallop of a second leaflet at the bottom of the valve. Pet. 42–43 (citing Ex. 1005, 14:28–54, 3:30–41, 27:31–28:9, Fig. 4; Ex. 1003 ¶¶ 106–108). Petitioner asserts that Goldfarb '267 discloses that this arrangement “simulates the double orifice geometry of a standard surgical bow-tie repair.” Pet. 43 (citing, e.g., Ex. 1005, 14:46–47). Petitioner asserts that a person of ordinary skill would have understood Figure 4 to illustrate Embodiment A because both use number 14 to refer to the fixation device (citing 37 C.F.R. § 1.84(p)(4)) and because Goldfarb '267 discloses, with respect to Embodiment A, that the device can separately capture each leaflet and draw branches 19A–19B into collar 131 “to complete the coaptation.” *Id.* at 43–44 (citing Ex. 1005, 27:67–28:9, Figs. 22A–22B). Pet. 44 (citing Ex. 1003 ¶¶ 109–111).

On this record, Petitioner has made an adequate showing. In particular, Figure 4 of Goldfarb '267 shows the claimed arrangement. Ex. 1005, 14:46–47. On this record, we agree that a person of ordinary skill would have understood that Embodiment A of fixture 14 can be applied to the valve in the configuration shown in Figure 4 because it uses the same numerals and because Embodiment A discloses that the clips can be used for coaptation. *See* 37 C.F.R. § 1.84(p)(4); Ex. 1005, 28:4–7; Ex. 1003 ¶¶ 109–111.

- g) *“by using the clip controller: opening the first clip by deflecting the first-clip arm;
“independently of opening the first clip, opening the second clip by deflecting the second-clip arm”;
“gripping the first leaflet with the first clip by closing the first clip by deflecting the first-clip arm”; and
“independently of gripping the first leaflet, gripping the second leaflet with the second clip by closing the second clip by deflecting the second-clip arm”*

Petitioner asserts, with respect to the embodiment of Figures 22A–22B of Goldfarb ’267, that the physician opens the distal elements by pushing the actuators (half of actuators 64) and closes the distal elements by pulling the actuators. Pet. 47–48 (citing Ex. 1005, 27:39–40, 27:64–28:3, Figs. 22A–B; Ex. 1003 ¶¶ 117–118). Petitioner asserts that Embodiment A of Goldfarb ’267 discloses that the device is “configured to allow for independent actuation of each of the lateral branches 19A, 19B and/or distal elements 18.” *Id.* at 47 (quoting Ex. 1005, 27:57–60).

As discussed below in Section II.G.2., we determine that Petitioner has shown a reasonable likelihood of proving that independent claim 1 is anticipated by Goldfarb ’267 (Embodiment B). As a result, institution of an *inter partes* review is warranted as to all challenged claims on all grounds asserted in the Petition, and the parties will have additional opportunities to address all grounds after institution. We do not take a position at this time and on this record as to whether Embodiment A meets this limitation and we do not take a position more generally as to Petitioner’s asserted ground of anticipation of claim 1 by Goldfarb ’267 (Embodiment A). Nevertheless, we may reach this ground at the time of our final written decision.

The parties are invited to address at trial the sequence of movement of the clip arms, i.e., (1) whether distal element 18 moves to open the clip and to close the clip, (2) whether proximal element 16 also moves to open the clip and to close the clip, and (3) if proximal element 16 moves to close the clip, whether it can still be said that the clip closes “by deflecting” distal element 18, or instead whether the clip is already closed before distal element 18 moves upwards or whether the clip is not yet closed even after distal element 18 moves upwards.⁹

h) “*decoupling the clip controller from the implant; and withdrawing the delivery apparatus from the subject;*”

Petitioner asserts, with respect to the embodiment of Figures 5–16 of Goldfarb ’267, that “the rod 64 and stud 74 may be joined by any mechanism which is releasable to allow the fixation device 14 to be detached from shaft 12.” Pet. 49 (citing Ex. 1005, 14:55–15:31, 20:44–46, Figs. 5A–6B). Petitioner argues that Goldfarb ’267 states that Embodiment A is a variation of the fixation device 14 described previously in the specification, which includes Figures 5–16. *Id.* at 49–50 (citing Ex. 1005, 27:6–7). Petitioner argues that once the physician decouples the fixation device from the delivery apparatus, the physician withdraws the delivery apparatus, including the actuator, from the patient. *Id.* at 50 (citing Ex. 1005, 6:62–65, 13:60–64, 14:55–58, 20:44–46; Ex. 1003 ¶ 122).

⁹ The parties may also address whether the action of proximal element 16 of Goldfarb ’267 (Embodiment A) constitutes an unclaimed step that does not defeat anticipation of claim 1 or instead whether it deprives distal element 18 of causation in the closing of the clip arm. *Compare Smith & Nephew, Inc. v. Ethicon*, 276 F.3d 1304, 1309–10 (Fed. Cir. 2001), with *David Netzer Consulting Engineer LLC v. Shell Oil Co.*, 824 F.3d 989, 996 (Fed. Cir. 2016).

On this record, Petitioner has made an adequate showing for this limitation. In particular, Goldfarb '267 discloses with respect to the embodiment of Figure 4 that once the leaflets are coapted in the desired arrangement, the fixation device 14 is then detached from the shaft 12 and left behind as an implant to hold the leaflets together in the coapted position. *See* Ex. 1005, 14:55–58. For similar reasons as described above, we determine on this record that this disclosure applies to Embodiment A as well, e.g., because the same numbering is used. *See* 37 C.F.R. § 1.84(p)(4).

i) Summary of Claim 1

On the record at this stage of the proceeding, we take no position as to whether Petitioner has demonstrated a reasonable likelihood that claim 1 is anticipated by Goldfarb '267 (Embodiment A).

3. Analysis of Dependent Claims 2 and 4–10

Petitioner argues claims 2 and 4–10 are also anticipated by Goldfarb '267 (Embodiment A). *Pet.* 51–69.

As discussed below in Section II.G.2., we determine that Petitioner has shown a reasonable likelihood of proving that independent claim 1 is anticipated by Goldfarb '267 (Embodiment B). As a result, institution of an *inter partes* review is warranted as to all challenged claims on all grounds asserted in the Petition, and the parties will have additional opportunities to address this ground after institution.

E. Obviousness of Claims 1, 2, and 4–10 over Goldfarb '267 (Embodiment A)

Petitioner argues its assertion that claims 1, 2, and 4–10 would have been obvious over Goldfarb '267 (Embodiment A) together with its assertion that claims 1, 2, and 4–10 are anticipated by Goldfarb '267 (Embodiment A). *See* *Pet.* 23–69. Petitioner also argues for obviousness

based on Petitioner’s assertions, e.g., that the use of Embodiment A with the interventional system in Figure 76 would have been the combination of prior art elements according to known methods to yield predictable results. *See, e.g., id.* at 31–32 (citing *KSR*, 550 U.S. at 417 (2007)), 37, 41). Petitioner also argues that the application of fixation device 14 in the location depicted in Figure 4 would have been based on a finite number of identified predictable locations for implantation. *See id.* at 46 (citing *KSR*, 550 U.S. at 417). Further, Petitioner argues that a person of ordinary skill would have sought to decouple the actuators from the fixation device because the physician cannot leave actuators jutting outside a patient’s body. *Id.* at 50 (citing Ex. 1005, 13:62–64, Ex. 1003 ¶¶ 123–124).

As discussed below in Section II.G.2., we determine that Petitioner has shown a reasonable likelihood of proving that independent claim 1 is anticipated by Goldfarb ’267 (Embodiment B). As a result, institution of an *inter partes* review is warranted as to all challenged claims on all grounds asserted in the Petition, and the parties will have additional opportunities to address this ground after institution.

F. Obviousness of Claim 3 over Goldfarb ’267 (Embodiment A) and Goldfarb ’329

Petitioner argues its assertion that claim 3 would have been obvious over Goldfarb ’267 (Embodiment A) and Goldfarb ’329. Pet. 69–73.

1. Goldfarb ’329

Goldfarb ’329 is titled “Methods and Devices for Tissue Grasping and Assessment” and relates “to methods, devices, and systems for the endovascular, percutaneous or minimally invasive surgical treatment of bodily tissues, such as tissue approximation or valve repair” and more particularly, to “repair of valves of the heart and venous valves.” Ex. 1006,

code (54), 1:30–34. According to Goldfarb '329, the placement of one fixation device near the center of the leaflets of a heart valve simulates the double orifice geometry of a standard surgical bow-tie repair. *Id.* at 10:19–21.

Figure 21A of Goldfarb '329 is reproduced below:

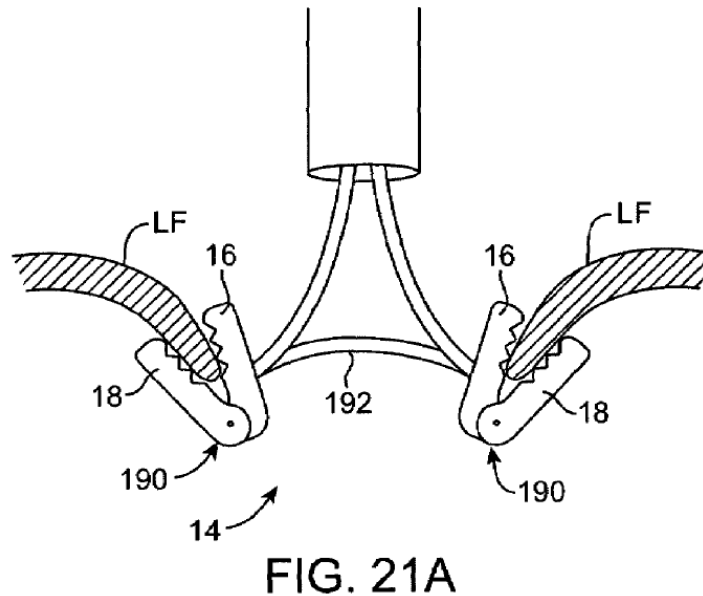


Figure 21A illustrates an embodiment of a device which stabilizes the valve leaflets by reducing upward mobility and flailing of the leaflets. Ex. 1006, 7:16–17. In particular, Figure 21A illustrates an embodiment of fixation device 14 having two single-sided fixation elements 190 joinable by tether 192. *Id.* at 21:58–60. Each single-sided fixation element 190 is comprised of at least proximal element 16 and distal element 18. *Id.* at 21:60–62.

2. Analysis of Dependent Claim 3

As discussed below in Section II.G.2., we determine that Petitioner has shown a reasonable likelihood of proving that independent claim 1 is anticipated by Goldfarb '267 (Embodiment B). As a result, institution of an

inter partes review is warranted as to all challenged claims on all grounds asserted in the Petition, and the parties will have additional opportunities to address this ground after institution.

G. *Anticipation of Claims 1, 2, 5, 6, and 8 by Goldfarb '267 (Embodiment B)*

Petitioner contends that claims 1, 2, 5, 6, and 8 are anticipated by Goldfarb '267 (Embodiment B). Pet. 73–93.

1. *Asserted Embodiment B of Goldfarb '267*

Petitioner identifies the embodiment of Goldfarb '267 at 17:66–23:29 and Figs. 9–16 as Embodiment B. See Pet. 21–22.

Figure 9 of Goldfarb '267 is reproduced below:

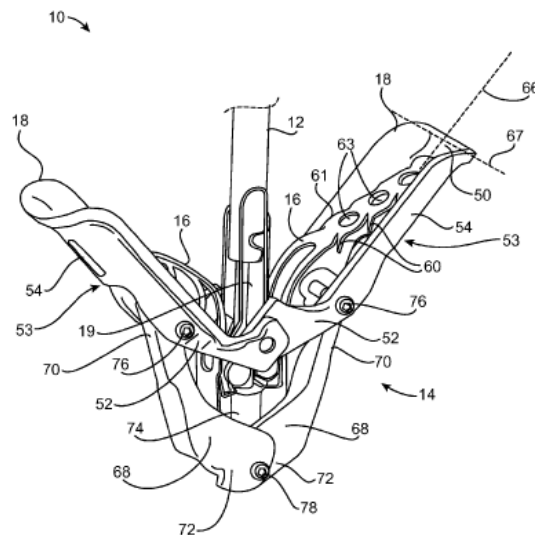


FIG. 9

Figure 9 illustrates another embodiment of the fixation device of Goldfarb '267. Ex. 1005, 10:26–27. Goldfarb '267 further discloses that Figures 10A–10B, 11A–11B, 12A–12B, 13A–13B, and 14–16 (not reproduced here) illustrate embodiments of Figure 9 in various possible

positions. Ex. 1005, 20:11–15; *see* Pet. 21–22 (asserting that these figures relate to the same embodiment).

In Figure 9 above, fixation device 14 is coupled to shaft 12 to form interventional tool 10. Ex. 1005, 17:67–18:1. Distal elements 18 comprise elongate arms 53, each arm having proximal end 52 (rotatably connected to coupling member 19) and free end 54. *Id.* at 18:3–6. Valve leaflets are grasped between distal elements 18 and proximal elements 16. *Id.* at 18:35–36. In some embodiments, the proximal elements 16 are flexible, resilient, and cantilevered from coupling member 19. *Id.* at 18:36–38. The proximal elements are preferably resiliently biased toward the distal elements. *Id.* at 18:38–39. Proximal elements 16 optionally include frictional accessories, frictional features, or grip-enhancing elements to assist in grasping and/or holding the leaflets, such as barbs 60, which are not considered traumatic to the valve. *Id.* at 18:53–58, 19:21–34.

Fixation device 14 also includes actuation mechanism 58. Ex. 1005, 19:35–36. In this embodiment, actuation mechanism 58 comprises two link members or legs 68, each leg 68 having first end 70, which is rotatably joined with one of distal elements 18 at riveted joint 76, and second end 72, which is rotatably joined with stud 74. *Id.* at 19:36–40. In the illustrated embodiment, both legs are pinned to stud 74 by a single rivet but alternatively each leg 68 may be individually attached to stud 74 by a separate rivet or pin. *Id.* at 19:43–46. Stud 74 is joinable with an actuator rod 64 (not shown) which extends through shaft 12 and is axially extendable and retractable to move stud 74 and therefore legs 68 which rotate elements 18 between closed, open, and inverted positions. *Id.* at 19:48–51.

2. *Analysis of Independent Claim 1*

- a) *Preamble: “A method for use at a native heart valve of a heart of a subject, the valve including a first leaflet and a second leaflet”*

Petitioner’s assertions for the preamble in this ground refer, in part, back to its assertions as to the ground of anticipation based on Embodiment A of Goldfarb ’267 (see Pet. 74), and we determine that Petitioner has made an adequate showing for similar reasons. *See supra* Section II.D.2.a.

- b) *transluminally advancing, to the heart, an implant coupled to a delivery apparatus*

Petitioner’s assertions for this limitation in this ground refer, in part, back to its assertions as to the ground of anticipation based on Goldfarb ’267 Embodiment A. *See* Pet. 75–77. In addition, Petitioner asserts that Goldfarb ’267 discloses that the fixation device of Embodiment B is readily passable through catheter 86 and through any structures such as the mitral valve. *See id.* at 77 (citing Ex. 1005, 20:25–33).

On the record at this stage of the proceeding, Petitioner has made an adequate showing. In particular, Goldfarb ’267 discloses that fixation device 14 is readily passable through catheter 86 and the mitral valve. Ex. 1005, 20:30–33.

- c) *the implant including a first clip and a second clip, the first clip and the second clip fixedly coupled to each other, the first clip including a first-clip arm, and the second clip including a second-clip arm*

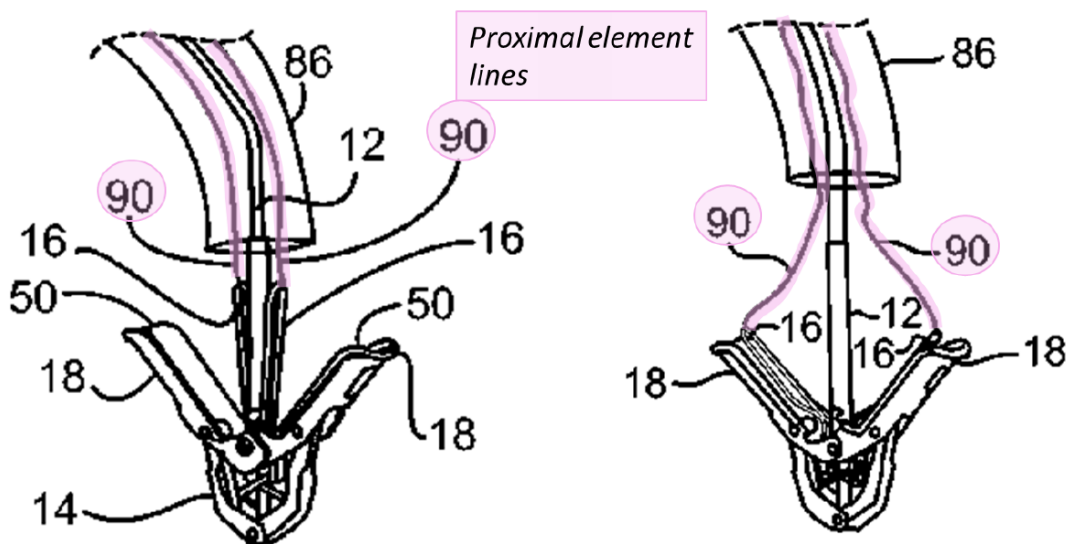
Petitioner argues that the left and right clips of Embodiment B are fixedly coupled to each other. Pet. 78 (citing Ex. 1005, 17:66–18:5, 19:43–51, Figs. 9–11B; Ex. 1003 ¶ 174). Further, for this embodiment, Petitioner identifies left proximal element 16 as a first clip-arm and right

proximal element 16 as a second clip-arm. *See* Pet. 79 (citing Ex. 1003 ¶ 175).

On the record at this stage of the proceeding, Petitioner has made an adequate showing. In particular, Goldfarb '267 discloses that distal elements 18 comprise elongate arms 53, each arm having a proximal end 52 rotatably connected to the coupling member 19. Ex. 1005, 18:3–5. Thus, on this record, the first and second clips are coupled to each other. Further, on this record, left proximal element 16 and right proximal element 16 may be considered a first and second clip-arm. *See* Ex. 1003 ¶ 175.

- d) *the delivery apparatus including a delivery tube and at least one clip controller disposed within the delivery tube*

Petitioner asserts that Goldfarb '267 discloses that, during delivery, the fixation device passes through the catheter. Pet. 79 (citing Ex. 1005, 20:30–34). Petitioner's contentions are illustrated with further reference to the annotated figures below.



Figures 11A and 13A of Goldfarb '267 are annotated by Petitioner to show proximal element lines 90 in color with a label. These figures illustrate embodiments of a fixation device in various possible positions during placement of the device within the body to perform a therapeutic procedure. See Ex. 1005, 10:28–31. Petitioner asserts that these figures show that proximal element lines 90 are disposed within catheter 86. Pet. 81 (citing Ex. 1003 ¶ 179; Ex. 1005, 23:4–12).

On this record, Petitioner has made an adequate showing. In particular, Figures 11A and 13A of Goldfarb '267 show proximal element lines 90 within catheter 86. Ex. 1003 ¶ 179. Goldfarb '267 discloses that proximal elements 16 may be moved inwardly toward shaft 12 by exerting tension on proximal element lines 90 (Ex. 1005, 20:65–21:2, 22:6–10) and proximal elements 16 are lowered by releasing tension on proximal element lines 90 (*id.* at 22:30–33). Thus, on this record, proximal element lines 90 may be considered clip controllers within the meaning of the claim.

e) *“advancing the implant out of the delivery tube”*

Petitioner relies on similar evidence for this limitation as for the “transluminally advancing” limitation. See Pet. 81. In addition, Petitioner relies on an annotated version of Figure 10A, which we reproduce below:

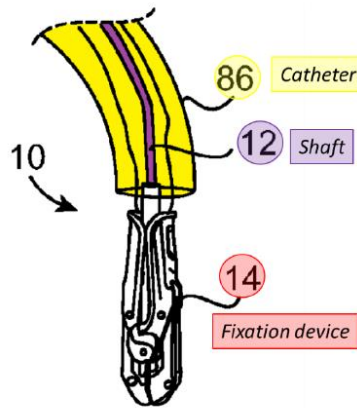


FIG. 10A

Figure 10A of Goldfarb '267 is annotated by Petitioner to show catheter 86 in yellow, shaft 12 in purple, and fixation device 14 in pink, with labels for each. On this record, Petitioner has made an adequate showing that Goldfarb '267 discloses advancing fixation device 14 through catheter 86 and out to its target. See Ex. 1005, 20:30–33, Fig. 10A.

- f) *“forming the first leaflet and the second leaflet into a double-orifice arrangement by using the implant to couple a middle scallop of the first leaflet to a middle scallop of the second leaflet”*

Petitioner's assertions for the preamble in this ground refer, in part, back to its assertions as to the ground of anticipation based on Embodiment A of Goldfarb '267 (see Pet. 82–83), and we determine that Petitioner has made an adequate showing for similar reasons. See *supra* Section II.D.2.f.

- g) *“by using the clip controller: opening the first clip by deflecting the first-clip arm;*
“independently of opening the first clip, opening the second clip by deflecting the second-clip arm”;
“gripping the first leaflet with the first clip by closing the first clip by deflecting the first-clip arm”; and
“independently of gripping the first leaflet, gripping the second leaflet with the second clip by closing the second clip by deflecting the second-clip arm”

Petitioner asserts that to open the clip, the physician applies tension to the proximal element lines 90, which deflects the proximal elements 16 toward the center of the device. Pet. 85 (citing Ex. 1005, 20:66–21:3).

Petitioner asserts that to close the clip, the physician releases tension on the proximal element lines 90, which allows the proximal elements to deflect toward the distal elements. *Id.* (citing Ex. 1005, 22:22–36, 24:46–48, 24:60–25:5.).

On this record, we determine that Petitioner has made an adequate showing, for similar reasons discussed above with respect to the “delivery apparatus” limitation, i.e., Petitioner has made an adequate showing that

proximal elements 16 move to open and close the clip. See Section II.G.2.d.^{10, 11}

- h) “*decoupling the clip controller from the implant; and withdrawing the delivery apparatus from the subject;*”

Petitioner asserts that Goldfarb ’267 discloses that when detachment is desired, one end of each line may be released at the proximal end of the shaft 12 and the other end pulled to draw the free end of the line distally through shaft 12 and through proximal element 16 thereby releasing the fixation device. Pet. 88–89 (citing Ex. 1005, 23:8–12). Petitioner asserts that Goldfarb ’267 discloses that alternatively, proximal element lines 90 may be coupled to the proximal elements 16 by detachable means, including “hooks, snares, clips or breakable couplings.” *Id.* at 89 (citing Ex. 1005, 21:16–23). Petitioner asserts that Goldfarb ’267 discloses that once the

¹⁰ Nevertheless, to the extent that both distal elements 18 and proximal elements 16 move, the considerations discussed above with respect to the ground of anticipation based on Embodiment A may also apply to this ground as well. See Section II.D.2.g. Accordingly, the parties may wish to address at trial the sequence of operation of distal elements 18 and proximal elements 16 in Embodiment B and whether the movement of distal element 18 would deprive proximal element 16 of causation in opening or closing the clip (i.e., because the clip is already open or closed at the time at proximal element 16 moves).

¹¹ The parties may also wish to address whether proximal element 16 is already in an open position at the time fixation device 14 reaches the target valve. See Ex. 1005, Fig. 10A. If so, the parties may wish to address whether the steps of the claimed method must be performed in the order in which they appear in the claim. See *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1345 (Fed. Cir. 2008) (“[A]lthough a method claim necessarily recites the steps of the method in a particular order, as a general rule the claim is not limited to performance of the steps in the order recited, unless the claim explicitly or implicitly requires a specific order. The specification or prosecution history may also require a narrower, order-specific construction of a method claim in some cases.”) (citation omitted).

physician deploys the fixation device, the delivery apparatus, including the proximal element lines 90, are withdrawn from the patient. Pet. 89 (citing, e.g., Ex. 1005, 13:60–64, 14:55–58).

On this record, Petitioner has made an adequate showing. In particular, Embodiment B of Goldfarb '267 discloses that one end of proximal element line 90 may be released at the proximal end of shaft 12 and the other end pulled to draw the free end distally through shaft 12 and through proximal element 16 to release the fixation device. Ex. 1005, 23:8–10. Goldfarb '267 also discloses, elsewhere, that once the leaflets are coapted in the desired arrangement, fixation device 14 is detached from shaft 12 and left behind as an implant to hold the leaflets together in the coapted position. *Id.* at 14:55–58.

i) Summary of Claim 1

On the record at this stage of the proceeding, Petitioner has demonstrated a reasonable likelihood that claim 1 is anticipated by Goldfarb '267, and in particular by its Embodiment B.

3. Claims 2, 5, 6, and 8

As discussed immediately above in Section II.G.2., we determine that Petitioner has shown a reasonable likelihood of proving that independent claim 1 is anticipated by Goldfarb '267 (Embodiment B). As a result, institution of an *inter partes* review is warranted as to all challenged claims on all grounds asserted in the Petition. The parties will have an opportunity to address the dependent claims after institution.

H. Obviousness of Claims 1, 2, 5, 6, and 8 over Goldfarb '267 (Embodiment B)

Petitioner argues its assertion that claims 1, 2, 5, 6, and 8 would have been obvious over Goldfarb '267 (Embodiment B) together with its assertion

that claims 1, 2, 5, 6, and 8 are anticipated by Goldfarb '267 (Embodiment B), and makes certain additional arguments directed to its assertions of obviousness. *See* Pet. 73–93.

Accordingly, we determine that Petitioner has made an adequate showing that claim 1 would have been obvious over Goldfarb '267 (Embodiment B) for similar reasons as for its assertion that claim 1 anticipated by Goldfarb '267 (Embodiment B). *See In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (indicating that anticipation is the epitome of obviousness). Further, as discussed immediately above, the parties will have additional opportunities to address the assertions as to dependent claims 2, 5, 6, and 8 after institution.

I. Obviousness of Claims 1, 4, and 5 over Goldfarb '329

Petitioner contends that claims 1, 4, and 5 would have been obvious over Goldfarb '329. Pet. 93–110.

As set forth above in Section II.G.2., institution of an *inter partes* review is warranted as to all challenged claims on all grounds asserted in the Petition. The parties will have an additional opportunity to address this ground after institution. The parties may wish to address whether Petitioner has adequately shown that, although Goldfarb '329 does not expressly disclose whether fixation elements 190 in Figures 21A–21B are opened and closed independently (Pet. 105), it would have been obvious to independently open and close the clips (*see* Pet. 105–106).

III. CONCLUSION

We conclude, on the present record, that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that at least one of claims 1–10 of the '385 patent would have been unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–10 of the '385 patent is instituted with respect to all grounds set forth in the Petition (*see* Section I.F., *supra*); and

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

IPR2021-01051
Patent 10,702,385 B2

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