

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 JOHN G. NEW, RYAN H. FLAX, and SEAN P. O'HANLON,
Administrative Patent Judges.

NEW, *Administrative Patent Judge*

JUDGMENT
Final Written Decision
Granting Patent Owner's Motion to Amend
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Because we find that Petitioner has failed to establish by a preponderance of the evidence that proposed substitute claims 11–20 of Cardiovalve, LTD’s (“Patent Owner”) non-contingent Motion to Amend (Paper 19) are unpatentable, we GRANT the Motion to Amend.

A. *Procedural History*

On June 4, 2021, Petitioner filed a Petition (Paper 1, “Petition”) seeking *inter partes* review of claims 1–10 of the ’385 Patent. Patent Owner waived filing of a Preliminary Response. (Paper 8). Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review on December 10, 2021, upon all of the challenged claims of the ’385 patent (Paper 10, “Institution Decision” or “Dec.”).

After institution of trial, Patent Owner filed a Motion to Amend pursuant to 37 C.F.R. §42.121 (Paper 15, “Mot. Amend”), to which Petitioner filed an Opposition (Paper 19). In response to Patent Owner’s request (*see* Mot. Amend 1), we issued, on June 24, 2022, Preliminary Guidance (Paper 20) on the Motion to Amend. Petitioner filed a Reply to the Preliminary Guidance (Paper 24, “Reply”), to which Patent Owner filed a Sur-Reply (Paper 28, “Sur-Reply”).

On September 28, 2022, pursuant to an Order from the Board (Paper 32) Patent Owner filed a Revised Supplemental Motion to Amend (“Supp. Mot. Amend.,” Paper 33), correcting certain deficiencies in the original Motion to Amend, and clarifying that the Motion to Amend is non-

contingent.¹ With our authorization, Petitioner filed a Reply to the Supplemental Revised Motion to Amend (“Reply Supp. Mot. Amend.,” Paper 34).

Oral argument was held on September 13, 2022. A transcript of the oral argument is included in the record. (“Hearing Trans.,” Paper 35).

B. Related Proceedings

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).

Patent Owner states that the ’385 patent is related to the following other patent applications: US Appl. Ser Nos. 16/888,210 (allowed August 8, 2022); 16/881,350; 17/210,183 (issued as US 11,291,545 B2 on April 5, 2022); 17/306,231 (issued as US 11,291,546 B2 on April 5, 2022); 17/335,845 (issued as US 11,291,547 B2 on April 5, 2022); 17/366,711 issued as US 11,344,410 B2 on May 11, 2022); 17/394,807 (issued as US

¹ Although Patent Owner did not expressly state the Motion to Amend and Revised Supplemental Motion to Amend were non-contingent, Patent Owner stated, “substitute claims 12–20, which correspond to original claims 2–10, respectfully, ... are modified to change dependencies from canceled claim 1 to substitute claim 11. Patent Owner intends for claims 2–10 to be canceled and replaced with substitute claims 12–20.” Supp. Mot. Amend. 1. Patent Owner thus makes clear its intention that the Motions to Amend (original and revised) are non-contingent and that the original claims are cancelled.

11,369,469 B2 on June 28, 2022); 17/397,235; and 17/473,472 (allowed August 4, 2022). Paper 27, 1–2.

C. The '385 patent (Ex. 1001)

The '385 patent is entitled “Implant for Heart Valve” and notes that “[s]ome [of its] applications relate in general to valve replacement” and more specifically to “prosthetic valves for replacement of a cardiac valve.” Ex. 1001, code (54), col. 1, ll. 34–37.² 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 col. 1, ll. 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. *Id.* at col. 2, ll. 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, col. 2, ll. 18–31. The '385 patent's Figure 8,

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

directed to one embodiment of its disclosed invention, provides some context as to the placement of the prosthetic valve and is reproduced below:

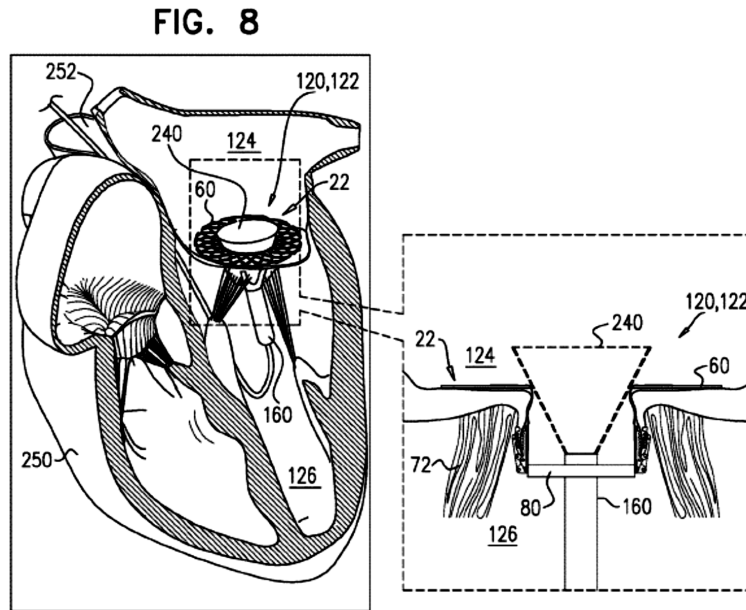


Figure 8 of the '385 patent is a schematic illustration of a step in the implantation of the prosthetic valve, facilitated by the prosthetic valve support

In its larger image (above left), Figure 8 depicts a cross-section of a human heart 250 through the four chambers, including the intervening valves and a prosthetic valve 240 positioned at the mitral valve 122. *See* Ex. 1001 cols. 23–24, ll. 49–9. The smaller image of Figure 8 (above right) shows an enlarged cross-sectional view of the prosthetic valve in place and the leaflets of the mitral valve displaced in an inferior direction from the valve's opening.

The '385 patent further discloses that, for some applications, the use of a two-component implant (i.e., comprising the prosthetic valve support and a separate prosthetic valve) hypothetically could advantageously

to a leaflet of the native valve. Ex. 1001 col. 7, ll. 35–39. Prosthetic valve support 22 comprises a generally annular upstream support portion 60 (e.g., an annular portion), shaped to define an opening 61 (e.g., an aperture) to be placed against an upstream side of the native valve. *Id.* at col. 10, ll. 45–49.

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

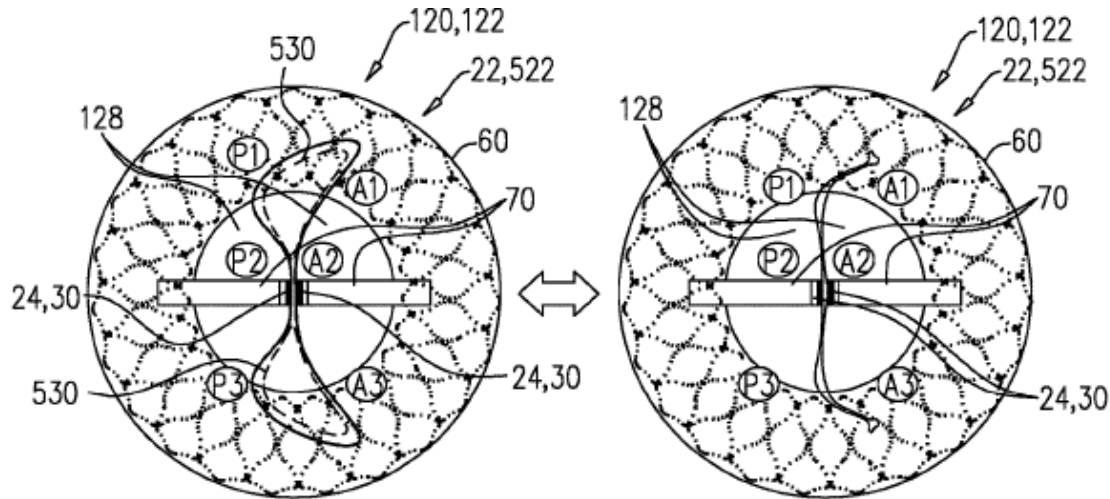


Figure 6B is a schematic illustration of a prosthetic valve support comprising tissue-engaging elements that are couplable to, and decouplable from, each other

As illustrated in Figure 6B, 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 thus hold the portions of the leaflets to which they are coupled in close proximity to each other. *Id.* at cols, 21–22, ll. 64–2.

D. Illustrative Claim

In its Motion to Amend, Patent Owner proposes substitute claim 11 to replace canceled challenged claim 1, the sole independent claim. Mot. Amend. 1; Supp. Mot. Amend 1. Proposed substitute claim 11 is reproduced below, with the limitations added by amendment in *italics*:

11. 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, *and a support portion flexibly coupled to the first and second clips, the support portion having an opening that surrounds a central longitudinal axis of the implant*, 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, *the first-clip arm and the second-clip arm each having an end most displaceable from the central longitudinal axis of the implant*, and

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

the first-clip arm, the second-clip arm, and the support portion being disposed within the delivery tube during the transluminal advancing to the heart;

advancing the implant out of the delivery tube *by advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion 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.

Mot. Amend 2–3.

In its revised Supplemental Revised Motion to Amend, Petitioner adds proposed substitute claims 12–20 to replace challenged claims 2–10, which are modified only to change their dependencies from canceled claim 1 to proposed substitute claim 11. Supp. Mot. Amend. 1.

E. Asserted Grounds of Unpatentability and Asserted Prior Art

Petitioner initially contended that claims 1–10 of the '385 patent are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §	References/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	103	Goldfarb '267 (Embodiment B) ⁷
1, 2, 5, 6, 8	103	Goldfarb '267 (Embodiment B)
1, 4, 5	103	Goldfarb '329

Based upon Petitioner's arguments in its Opposition to Patent Owner's Motion to Amend and its Reply to Patent Owners Supplemental Motion to Amend, it is evident that the first two grounds listed above, challenging claims 1, 2, and 4–10, transfer to new claims 11, 12, and 14–20. Paper 19, 1–25; Reply Supp. Mot. Amend.

Petitioner also relies, *inter alia*, upon the Declaration of Dr. Ivan Vesely. Ex. 1003. We have reviewed the credentials of Dr. Vesely and consider him qualified to provide the opinions for which his testimony has

⁴ Goldfarb et al. (US 7,563,267 B2, July 21, 2009) ("Goldfarb '267") (Ex. 1005).

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

⁶ Goldfarb et al. (US 7,635,329 B2, December 22, 2009) ("Goldfarb '329") Ex. 1006.

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

been submitted. *See id.* ¶¶ 1–9; *see also* Ex. 1004 (Dr. Vesely’s *curriculum vitae*).

F. Level of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would be 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). Patent Owner does not contest Petitioner’s definition.

Having weighed the evidence and Petitioner’s argument, we adopt Petitioner’s definition of a person of ordinary skill in the art as:

(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.

See Pet. 15–16.

II. PATENT OWNER’S MOTION TO AMEND

A. *Introduction*

In its Revised Supplemental Motion to Amend, Patent Owner unambiguously represents that its Motion to Amend is non-contingent and that challenged claims 1–10 are canceled and replaced with substitute claims 11–20. Mot. Amend 1, Supp. Mot. Amend 1. We consequently address the patentability of substitute claims 11–20.

B. *Principles of Law*

In an *inter partes* review, amended claims are not added to a patent as a matter of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). “Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.” *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). Accordingly, we consider whether: (1) the amendment proposes a reasonable number of substitute claims; (2) the proposed claims are supported in the original disclosure (and any earlier filed disclosure for which the benefit of filing date is sought); (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

The Board assesses the patentability of proposed substitute claims “without placing the burden of persuasion on the patent owner” for issues of patentability. *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir.

2017) (en banc); *see also* *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential). Subsequent to the issuance of *Aqua Products*, the Federal Circuit issued a decision in *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027, 1040 (Fed. Cir. 2017) (“*Bosch*”), as well as a follow-up Order amending that decision on rehearing, which confirmed *Aqua Products* insofar as allocating the burden of proof to a petitioner for claims amended by a patent owner (and how to handle a proceeding where the petitioner has ceased participation). *See Bosch Auto. Serv. Sols., LLC v. Iancu*, Order on Petition for Panel Rehearing, No. 2015-1928 (Fed. Cir. 2018).

In accordance with *Aqua Products*, *Bosch*, and *Lectrosonics*, Patent Owner does not bear the burden of persuasion to demonstrate the patentability of the substitute claims presented in the motion to amend. To the contrary, ordinarily, “the petitioner bears the burden of proving that the proposed amended claims are unpatentable by a preponderance of the evidence.” *Bosch*, 878 F.3d at 1040 (as amended on rehearing); *see Lectrosonics*, Paper 15 at 3–4. In determining whether a petitioner has proven unpatentability of the substitute claims, the Board focuses on “arguments and theories raised by the petitioner in its petition or opposition to the motion to amend.” *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 51 (Fed. Cir. 2020).

C. *Analysis*

1. Patent Owner’s Proposed Substitute Claims

Patent Owner proposes changes to claim 1 in substitute independent claim 11. Mot. Amend. 1–3. Proposed substitute claim 11 is reproduced in

Section I.D above. In its Supplemental Revised Motion to Amend, Petitioner adds proposed substitute claims 12–20 to replace challenged claims 2–10, which are modified only to change their dependencies from canceled claim 1 to proposed substitute claim 11. Supp. Mot. Amend. 1.

2. Reasonable Number of Proposed Substitute Claims

We agree with Patent Owner that the proposed substitution of the single proposed substitute claims 11–20 for challenged claims 1–10 meets the requirement for a reasonable number of substitute claims. *See* Mot. Amend 3; Supp. Mot. Amend. 2; 37 C.F.R. § 42.121(a)(3) (establishing a rebuttable presumption that only one substitute claim is needed to replace each challenged claim).

3. Enlargement of Claim Scope

Patent Owner asserts that proposed substitute claims 11–20 do not seek to enlarge the scope of the originally issued claims. Mot. Amend. 3; Supp. Mot. Amend. 2. Patent Owner contends that proposed substitute claim 11 only adds limitations relative to the original claim 1. *Id.* Petitioner does not dispute Patent Owner’s contention that the proposed substitute claims do not seek to enlarge the scope of the claims of the ’385 patent. *See generally* Opp.

Based on the record before us, we agree with Patent Owner, and determine that the proposed substitute claims meet the requirements of 37 C.F.R. § 42.121(a)(2). Proposed substitute claim 11 adds limitations that narrows the scope of the substitute claim. Proposed substitute claims 12–20 are modified only to reflect direct or indirect dependency on proposed substitute claim 11.

4. New Matter/35 U.S.C. § 112 Written Description Support

Patent Owner asserts that the narrowing limitations of proposed substitute claim 11 are supported and enabled by the Specification of US Appl. Ser. No. 16/284,331 (“the ’331 Application”), which issued as the ’385 patent, and particularly points out and distinctly claims the invention. *See* Mot. Amend 4–12; Supp. Mot. Amend 3–5. Because proposed substitute independent claim 11 is the only claim in which any substantive limitations have been amended (excepting dependencies), we perform this analysis only for proposed substitute claim 11. Patent Owner indicates where each limitation receives support in the Specification. Mot. Amend 3–12.

Petitioner does not dispute Patent Owner’s statements and, upon review, we conclude that the proposed substitute claims do not add new matter. We also conclude that the Specification of the ’385 patent provides sufficient written description support and enablement for the limitations of proposed substitute claims 11–20.

5. Responding to a Ground of Unpatentability

Patent Owner asserts that substitute claims 11 is responsive to a ground of unpatentability involved in this proceeding. Mot. Amend. 13–25. (citing 37 C.F.R. § 42.121(a)(2)(i)). Specifically, Patent Owner argues that Petitioner in this proceeding has argued that the asserted prior art anticipates or renders obvious original claims 1–10, which Patent Owner’s Motions seek to amend to distinguish over the asserted prior art. *Id.* Petitioner does not argue otherwise.

We agree with Patent Owner that the substitute claims are responsive to at least one of the asserted grounds of unpatentability. *See* Prelim. Guid. 4; Mot. Amend. 13–25.

6. Patent Owner’s Supplemental Revised Motion to Amend

We next turn to Patent Owner’s Supplemental Revised Motion to Amend. Patent Owner represents that in its original Motion to Amend, claim 11 was submitted as a substitute claim for claim 1, which Patent Owner intends to be canceled and replaced. Supp. Mot. Amend. 1. Patent Owner states that its intention was to maintain dependent claims 2–10 in accord with their original dependency status, albeit now from proposed substitute claim 11 as substituted for claim 1. *Id.* In its Supplemental Revised Motion to Amend, Patent Owner provides (in attached Appendix A) proposed substitute claims 12–20, which correspond to original challenged claims 2–10, respectively, but which are modified only to change dependencies from canceled claim 1 to proposed substitute claim 11, and also canceling claims 2–10. *Id.*

Patent Owner states that it relies on the patentability of proposed substitute claim 11 as set forth in the original Motion to Amend as a basis for patentability for dependent substitute claims 12–20, and that substitute claims 12–20 thus stand or fall with substitute claim 11. Supp. Mot. Amend. 1.

Because Patent Owner agrees that proposed substitute claims 12–20 stand or fall with proposed substitute claim 11, we now address the patentability of proposed substitute claim 11.

7. Patentability of Proposed Substitute Claim 11

Petitioner contests the patentability of proposed substitute claim 11 based on the same Grounds 1 and 2 as presented in the Petition. *See* Opp. 4–25; *see also supra* Section I.E.

a. Overview of Goldfarb '267 and Embodiment A

i. Introduction

Goldfarb '267, entitled “Implant For Heart Valve,” issued on July 21, 2009 and is prior art to the '385 patent. Ex. 1005 codes (54), (45). Goldfarb '267 is directed to “to methods, devices, and systems for the endovascular, percutaneous or minimally invasive surgical treatment of bodily tissues, such as tissue approximation or valve repair.” *Id.* at col. 1, ll. 37–39.

Goldfarb '267 discloses that its invention enables two or more valve leaflets to be joined using an “edge-to-edge” or “bow-tie” technique to reduce regurgitation in a process does not require open-heart surgery through the chest and heart wall as in conventional approaches. Ex. 1005 col. 3, ll. 33–37. Goldfarb '267 discloses that its proximal clip elements are biased outwardly and may be moved inwardly and held against a shaft by the aid of proximal element lines. *Id.* at cols. 20–21, ll. 65–1. Figure 4 of Goldfarb '267 is reproduced below:

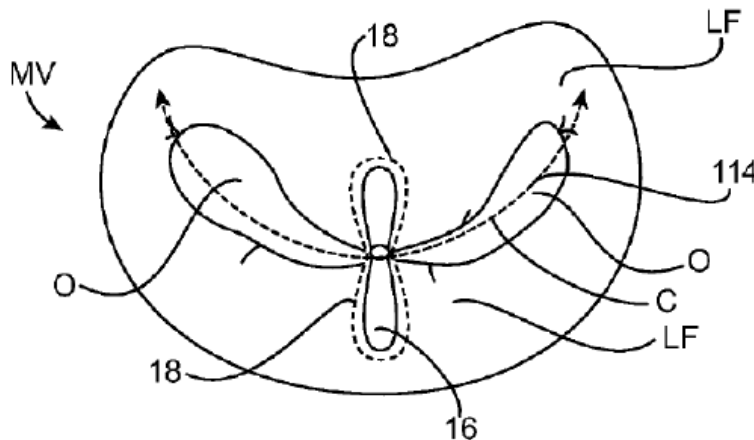


Figure 4 illustrates the position of the fixation device in a desired orientation relative to the leaflets.

Figure 4 depicts a superior-inferior axis view of mitral valve MV, as seen from the atrial side of the valve, in which the proximal elements 16 are shown in solid line and the distal elements 18 (i.e., on the ventricular side) are shown in dashed line. Ex. 1005 col. 14, ll. 28–31. The upstream surfaces⁸ 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 a vertical orientation in which the upstream surfaces face each other at the point of coaptation. *Id.* at col. 14, ll. 42–46. Goldfarb '267 discloses that this positioning simulates the double orifice geometry of a standard surgical bow-tie repair. *Id.* at col. 14, ll. 46–47.

ii. Embodiment A

Petitioner relies on Embodiment A of Goldfarb '267. *See* Pet. 20, 24–48; Opp. 1. Goldfarb '267 describes this embodiment as an alternative to the embodiment depicted in Figures 22A and 22B. *See* Ex. 1005 col. 27, ll. 57–58. The description of Embodiment A, however, uses the same numerical labels as Figures 22A and 22B, and we understand Embodiment A to be a variation on Figures 22A and 22B, as argued by Petitioner. *See* Pet. 30 (citing 37 C.F.R. § 1.84(p)(4) (stating that “[t]he 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

⁸ Blood flows from the atrium to the ventricle on either side of the heart.

must never be used to designate different parts’’)). Figures 22A and 22B of Goldfarb ’267 are reproduced below:

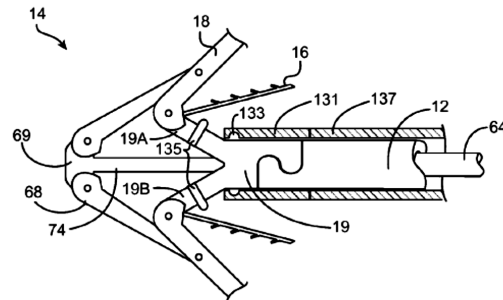


FIG. 22A

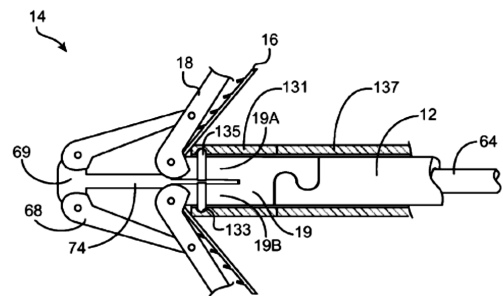


FIG. 22B

Figures 22A and 22B illustrate a variation of the fixation device to facilitate capture of more widely-separated leaflets or other tissue flaps

Figures 22A and 22B illustrate sequential configurations during the operation of (leaflet) fixation device 14, where sheath 137 is advanced distally from a first proximal position, where branches 19A, 19B (supporting clip proximal and distal elements 16, 18 for tissue capture) are entirely outside sheath 137 to a second distal position where they are largely inside sheath 137, which changes the branches’ 19A, 19B orientations. Ex. 1005 col. 27, ll. 6–56. In the embodiment depicted in Figures 22A and 22B, 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 col. 27, ll. 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 col. 27, ll. 10–14.

Alternatively, branches 19A, 19B may be more rigid members connected to coupling member 19 by pins or hinges and can be pivoted toward or away from each other. Ex. 1005 col. 27, ll. 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. *Id.* at col. 27, ll. 17–19.

Legs 68 are coupled at their proximal ends to base 69, which is continuous with stud 74, and at their distal ends to distal elements 18. Ex. 1005 col. 27, ll. 19–21. Movement of stud 74 distally or proximally relative to coupling member 19 opens or closes distal elements 18. *Id.* at col. 27, ll. 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 and 19B. *Id.* at col. 27, ll. 24–27. Sheath 137 is positioned coaxially over shaft 12 and is slidable relative thereto to facilitate pushing collar 131 distally over coupling member 19. *Id.* at col. 27, ll. 27–30.

Goldfarb '267 discloses that, 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, allowing branches 19A, 19B to separate into the position of Figure 22A. Ex. 1005 col. 27, ll. 35–39. Actuator 64 is then pushed distally to open distal elements 18, and 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 col. 27, ll. 39–43.

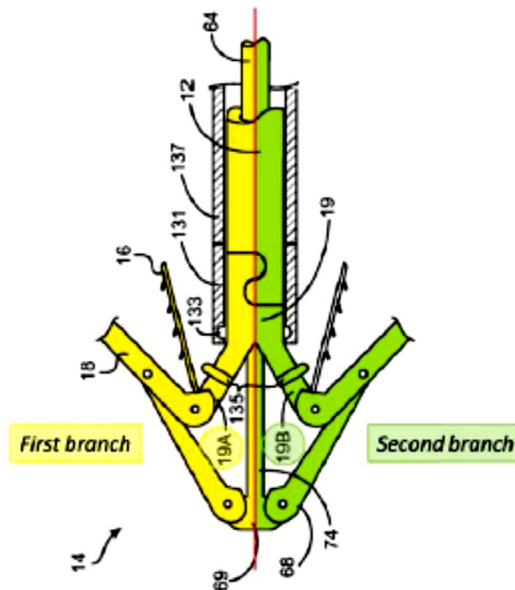
When the target tissue is positioned between the proximal and distal elements 16, 18, tension is released on proximal element lines 90 allowing the tissue to be captured between the proximal and distal elements. *Id.* at col. 27, ll. 43–46. Sheath 137 may then be advanced distally so that collar 131 forces branches 19A, 19B together. *Id.* at col. 27, ll. 46–48. Sheath 137 is advanced until groove 133 in collar 131 slides over the detents 135 and is held by friction in that position, as shown in Figure 22B. *Id.* at col. 27, ll. 48–50. Sheath 137 may then be retracted from collar 131. *Id.* at col. 27, ll. 50–51. Goldfarb '267 discloses that this embodiment preferably includes a locking mechanism (described elsewhere in the reference). *Id.* at col. 27, ll. 53–56.

Embodiment A of Goldfarb '267 is a further alternative embodiment of the embodiment of Figures 22A and 22B. In this embodiment, 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 col. 27, ll. 57–60. For example, 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 col. 27, ll. 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 col. 27, ll. 64–67.

Goldfarb '267 explains that 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 cols. 27–28, ll. 67–3. 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 col. 28, ll. 3–7. The closure of distal elements 18 may occur either before or after branches 19A, 19B are drawn into collar 131. *Id.* at col. 28, ll. 7–9.

Petitioner provides a modified, annotated version of Figure 22A to illustrate its understanding of Embodiment A, which is reproduced below:



Petitioner's modified, annotated Figure 22A purporting to illustrate the invention of Embodiment A of Goldfarb '267

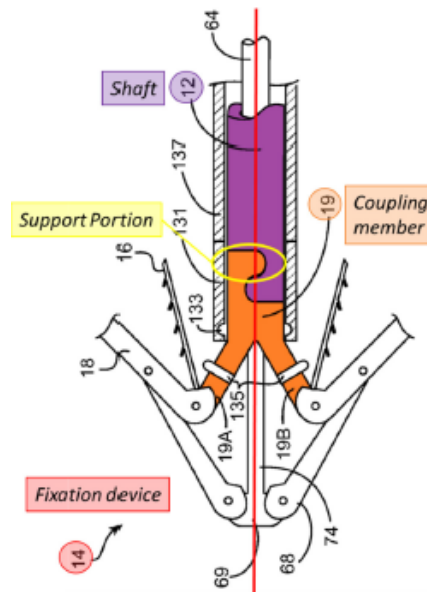
The red centerline added by Petitioner represents the split shaft 12 and coupling member 19 and/or actuator 64, allowing the proximal and distal elements 16, 18 of each half of the device (Petitioner's yellow/green coloring) to be manipulated independently of each other. *See* Pet. 20.

8. Arguments

We address Petitioner’s arguments regarding the proposed substitute claims presented in its Opposition to the Motion to Amend and its Reply to the Preliminary Guidance, as well as Patent Owner’s Sur-Reply. Because we find the added limitations reciting “a support portion flexibly coupled to the first and second clips, the support portion having an opening that surrounds a central longitudinal axis of the implant” and “advancing the implant out of the delivery tube by advancing the end of the [first and] second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube” to be dispositive of patentability issues here, we focus our analysis upon those limitations.

- a. “A support portion flexibly coupled to the first and second clips the support portion having an opening that surrounds a central longitudinal axis of the implant”
 - i. coupling member 19

In its Opposition to the Motion to Amend, Petitioner argues that Embodiment A includes a fixation device 14 (implant) having a coupling member 19. Opp. 4. Petitioner provides another modified, annotated version of Figure 22A of Goldfarb ’267, which is reproduced below:



Petitioner's modified, annotated Figure 22A of Goldfarb '267's
Embodiment A

Petitioner first argues that it is either the “male element” of coupling member 19 (indicated by the yellow oval added by Petitioner), or collar 131, that constitutes the “support portion flexibly coupled to the first and second clips, the support portion having an opening that surrounds a central longitudinal axis of the implant” recited in the amended limitation of proposed claim 11. Opp. 5–11.

Referring to the annotated figure above, Petitioner contends that shaft 12 [purple] and coupling member 19 [orange] interlock at a “joining line” or “mating surface” that permits detachment of the shaft from the coupling member. Opp. 5 (citing Ex. 1005 cols. 14–15, ll. 58–31, Figs. 5A–6B; *id.* at col. 6, ll. 43–57 (describing joining line as a sigmoid curve), col. 13, ll. 60–64 (coupling member allows detachment of the fixation device), col. 15, ll. 58–63 (same); also citing Ex. 2004, 50 (describing joining line)). Petitioner contends that the proximal end of the coupling member 19 comprises a “male element” [yellow oval] that mates with a corresponding “female

element” on the shaft 12. *Id.* (citing Ex. 1005 col. 15, ll. 19–31). It is Petitioner’s position that this identified male element at the proximal end of the coupling member 19 constitutes the “support portion” required by proposed substitute claim 11. *Id.*

By way of example, Petitioner notes that, during delivery, the male element, which Petitioner refers to as the “support portion,” supports the fixation device 14 by bearing its weight. Opp. 6. Furthermore, argues Petitioner, the support portion absorbs the compressive and tensile forces applied to the fixation device during deployment, to hold the fixation device in the correct orientation and prevent the fixation device from prematurely detaching from the shaft. *Id.* (citing Ex. 1005 col. 14, ll. 25–31).

Petitioner argues that the support portion is also flexibly coupled to the first and second clips. Opp. 6. According to Petitioner, Goldfarb ’267 discloses that the coupling member 19 “is bifurcated into two resilient and flexible branches 19A, 19B which are biased outwardly into the position in FIG. 22A, but which are movable to the position shown in FIG. 22B.” *Id.* (citing Ex. 1005, col. 27, ll. 10–14, col. 27, ll. 14–17). Petitioner also notes that Goldfarb ’267 also discloses that “[e]ach of proximal elements 16 and distal elements 18 [i.e., first and second clips [yellow and green in the figure below]] are coupled at their proximal ends to one branch 19A or 19B of the coupling member 19.” *Id.* (citing Ex. 1005 col. 27, ll. 17–29, Figs. 22A–22B).

Petitioner also argues that the support portion also has an opening that surrounds a central longitudinal axis of the implant, as required by claim 11. Referring again to Figure 22A of Goldberg ’267, Petitioner argues the coupling member 19 includes an opening in its center that permits the

actuator rod 64 to extend through the coupling member. Opp. 7 (citing Ex. 2005 col. 24, ll. 37–40, col. 26, ll. 45–48, col. 6, ll. 45–51, Figs. 22A–22B). Petitioner asserts that this opening also extends through the support portion so that the support portion surrounds the central longitudinal axis of the implant. *Id.* at 7–8 (citing, e.g., Ex. 2004, 67).

Petitioner also notes that Goldfarb '267 also discloses that Embodiment A's "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." Opp. 8 (citing Ex. 1005 col. 27, ll. 60–64). In this embodiment, argues Petitioner, the coupling member 19 comprises two identical halves with an opening through the two halves that surrounds a longitudinal axis of the implant to accommodate the actuator rod 64. *Id.* at 8–9 (citing cols. 27–28, ll. 64–90; Ex. 2004, 79–80).

ii. collar 131

Petitioner argues further that collar 131 of Goldfarb '267 is also a support portion, as claimed. Opp. 9. According to Petitioner, Goldfarb '267 discloses that collar 131 is positioned around coupling member 19, such that, when collar 131 is advanced distally or branches 19A, 19B are withdrawn into collar 131, flexible branches 19A and 19B are forced together as collar 131 is advanced distally over detents 135. *Id.* at 9–10 (citing Ex. 1005 col. 27, ll. 46–48, cols. 27–28, ll. 67–9; Ex. 2004, 53–54). Therefore, Petitioner argues, collar 131 supports the branches by holding them together and

resisting their outward bias. *Id.* at 10 (citing Ex. 1005 col. 27, ll. 10–14, 24–30, 48–50, cols. 27–28, ll. 60–9, Fig. 22B).

Petitioner argues further that collar 131 is also flexibly coupled to what are the first and second clips. Opp. 10. Petitioner contends that collar 131 includes groove 133 that mates with detents 135 on the branches 19A, 19B when collar 131 is moved distally. *Id.* (citing col. 27, ll. 48–50, Figs. 22A–22B; Ex. 2004, 82, 83). Therefore, Petitioner contends, collar 131 is coupled to the clips (elements 16, 18) through the branches 19A, 19B and remains behind with the clips after deployment. *Id.* (citing Ex. 1005 col. 27, ll. 46–51, Figs. 22A–22B). Consequently, argues Petitioner, because collar 131 is flexible and engages the detents on the branches, the collar is “flexibly coupled” to the clips. *Id.* at 11.

Petitioner also argues that collar 131 has an opening that surrounds a central longitudinal axis of the implant. Opp. 11. According to Petitioner, collar 131 has a central lumen that allows it to slide over the coupling member 19 and flexible branches 19A and 19B. *Id.* (citing Ex. 1005 col. 27, ll. 35–38, col. 27, ll. 46–50, 60–63, cols. 27–28, ll. 67–9, Figs. 22A–22B).

- b. Advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube
 - i. Petitioner argues that the clip arms are advanced out of the delivery tube before the support portion the coupling member

Petitioner next argues that, because it is the “male element” of Goldfarb ’267’s coupling portion 19 that forms the claimed “support portion flexibly coupled to the first and second clips, the support portion having an opening that surrounds a central longitudinal axis of the implant,” then the

first- and second-clip arms must *necessarily* be advanced out of the delivery before advancing the support portion out of the delivery tube. Opp. 15–25.

Petitioner notes that Embodiment A of Goldfarb '267 is delivered through the delivery tube⁹ “with distal and proximal elements 16, 18 in the closed position.” Opp. 16 (quoting Ex. 1005 col. 27, ll. 31–33; also citing *id.* at col. 20, ll. 11–27, Figs. 10A–10B). Petitioner argues that, Goldfarb '267 discloses that, in the closed position, “the opposed pair of distal elements 18 are positioned so that the engagement surfaces 50 face each other” and the distal elements are generally aligned with the longitudinal axis of the device. *Id.* (quoting Ex. 1005 col. 20, ll. 11–27, Figs. 10A–10B).

To illustrate this point, Petitioner points to the deposition testimony of its expert, Dr. Vesely, who stated that the fixation device “must have the tightest configuration as possible” and that “the clip arms are folded upward to be roughly parallel to the collar and other structures, and the elements 19A and B are pushed together again to be compact.” *Id.* (citing Ex. 2004, 99–100). Petitioner asserts that Goldfarb '267 discloses that when Embodiment A is in the closed position, “[c]ollar 131 is pushed distally against, but not over, detents 135 so that branches 19A, 19B are disposed together and fixation device 14 has a minimal profile.” *Id.* at 16–17 (citing Ex. 1005 col. 27, ll. 31–35).

Petitioner points to Figures 22A and 22B of Goldfarb '267, which depict the fixation device in the open position. Opp. 17. According to Petitioner, Figure 22A illustrates the device in the position in which the

⁹ We note, for the purpose of clarity, that the “delivery tube” recited in the claim is not depicted in any of the illustrations depicted in this Decision.

branches 19A and 19B flex outward, whereas Figure 22B illustrates the fixation device after the proximal and distal elements have captured the leaflets (not shown) and the collar 131 has been advanced distally over the detents. *Id.* (citing Ex. 1005 col. 27, ll. 10–14, cols. 27–28, ll. 6–9, Figs. 22A–22B; Ex. 2004, 101).

Petitioner asserts that the closed, delivery position differs from Figures 22A–22B, because in the closed position “the clip arms are folded upward” and “the elements 19A and B are pushed together again to be compact.” Opp. 17 (quoting Ex. 2004, 99–100; also citing Ex. 1003 ¶ 83). Petitioner’s expert, Dr. Vesely, testified that the pivot points at the bottom of distal elements 18 would be closer to base 69 than in Figure 22B. *Id.* (citing Ex. 2004, 101).

Petitioner notes that the same is true in Figure 22A, where the pivot point at the end of the proximal and distal elements would be located closer to base 69 in the closed position because the branches are pushed together. *Id.* Another annotated version of Figure 22A of Goldfarb ’267, with Petitioner’s markings in this respect, is reproduced below:

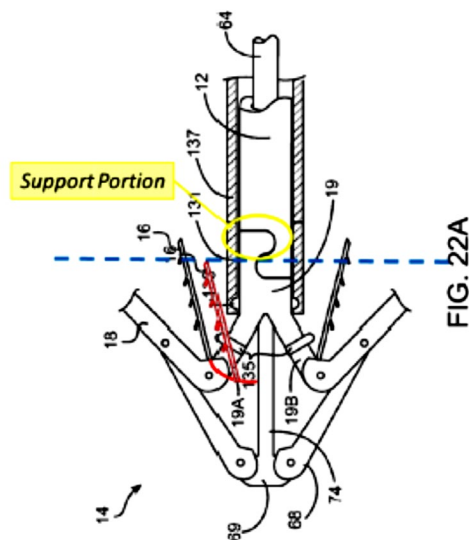
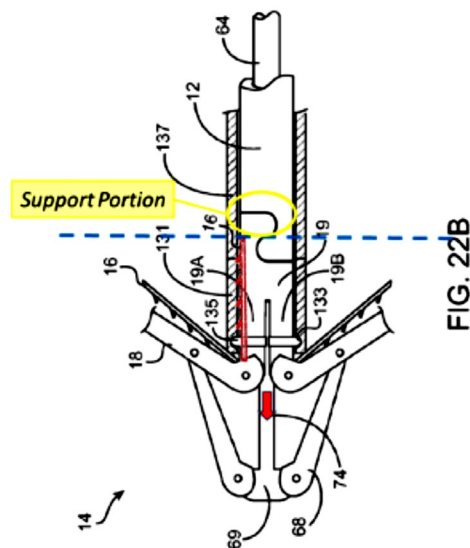


Figure 22A of Goldfarb '267 depicts the fixation device in an open position, and with Petitioner's markings and annotation

Petitioner points to the solid red line, added to Figure 22A above, as illustrating the arc that the proximal element would travel if the branches were pushed together. Opp. 17 (citing Ex. 1003 ¶ 83). Petitioner argues that, because the branches 19A, 19B are fixed to the rest of the coupling member 19, and the proximal element 16 is coupled to the branch 19A, the proximal element 16 must travel along the arced line as the branches are drawn toward each other. *Id.* at 17–18.

Petitioner posits that the consequence is that the free ends of the proximal and distal elements are positioned further distally in the closed, delivery position than in Figure 22A's shown open position. Opp. 18. Petitioner points to the testimony of Dr. Vesely, who stated that base 69 is "closer to the pivot points at the bottom of elements 18." *Id.* (Ex. 2004, 101). Furthermore, Petitioner contends that the red proximal element in Figure 22A above, illustrates the position of the proximal element in the closed, delivery position. *Id.* Petitioner argues that, as illustrated by the dashed (blue) line in the figure above, the free end of the proximal element 16 (or end most displaceable from the central longitudinal axis of the implant) is positioned distal to (or below) the support portion of the coupling member 19 (yellow circle). *Id.* at 18–19. Consequently, argues Petitioner, the free end of the proximal element advances out of the delivery tube before the support portion is advanced out of the delivery tube. *Id.* at 19.

Petitioner next points to Figure 22B as supporting its position. Opp. 19. Petitioner provides another annotated, modified version of Figure 22B in support of this argument, which is reproduced below:



Petitioner's modified, annotated Figure 22B demonstrating the fixation device in the open position with the clips retracted towards each other

According to Petitioner, if the proximal element 16 is pivoted vertically (red proximal element 16), the free end of the element is distal to (or below) what Petitioner calls the Support Portion (yellow circle). Opp. 19. Further, argues Petitioner, in the closed, delivery position, the free end of the proximal element would be even further below the indicated support portion because, as Dr. Vesely testified, the pivot at the end of the proximal and distal elements would be closer to base 69 (i.e., the pivots would move in the direction of the red arrow in the closed, delivery position). *Id.*

Like the proximal elements, argues Petitioner, the free ends of the distal elements (first- and second-clip arms) would also be advanced out of the delivery tube before the alleged support portion is advanced out. Opp. 20. The free ends of the distal elements are not illustrated in Figures 22A–22B (their cut-offs depicted by wavy lines). *Id.* However, Petitioner contends, Goldfarb '267 discloses that the distal elements can have a range

of lengths and engage different amounts of the leaflets. *Id.* (citing, e.g., Ex. 1005 col. 18, ll. 30–32). Petitioner points to Goldfarb '267's several examples of fixation devices, in which the distal elements are roughly equal in length or shorter than the proximal elements. *Id.* (citing, e.g., Ex. 1005 Figs. 11A–11B, Fig. 13A (equal), Fig. 18, Figs. 32–33).

Petitioner also notes that, when asked whether distal element 18 is longer than proximal element 16 in Embodiment A, Dr. Vesely responded: “It can be. It can be roughly the same. It can be slightly longer.” *Id.* (citing Ex. 2004, 46, 45). Petitioner asserts that the evidence thus shows that the distal elements 18 in Embodiment A can have roughly the same length as the proximal elements 16, and that the free ends of the distal elements will also advance out of the delivery tube before the support portion. *Id.* at 20–21.

Furthermore, argues Petitioner, even if the distal elements 18 were slightly longer than the proximal elements 16, the free ends of the distal elements would still be advanced out of the delivery tube before the support portion given the large gap between the free ends of the proximal elements and the support portion. Opp. 21. Petitioner argues that the distal elements would need to be significantly longer than the proximal elements to exit the delivery tube after the support portion begins advancing out. Petitioner contends that Goldfarb '267 does not disclose such large discrepancies between the proximal and distal elements. *Id.*

Alternatively, Petitioner argues, if Embodiment A of Goldfarb '267 does not expressly or inherently disclose this limitation, a person of ordinary skill in the art would have found it obvious to use shorter proximal and distal elements such that the ends of the elements exit the delivery tube before the support portion. Opp. 21 (citing Ex. 1005 col. 18, ll. 30–32). Consequently,

argues Petitioner, the distal elements can range in length from a minimum of 4 mm to longer lengths (e.g., 10 mm). *Id.*

Petitioner contends that a skilled artisan would have been motivated to select the shortest elements possible to limit the amount of material and decrease the overall profile. Opp. 22 (citing Ex. 1003 ¶ 143). Additionally, Petitioner contends that a person of ordinary skill in the art would have had a reasonable expectation of success in using shorter elements in Embodiment A because Goldfarb '267 discloses using short elements that can grab a mere 4 mm of leaflet. *Id.* (citing Ex. 1005 col. 18, ll. 30–32) and the elements in Embodiment A can move laterally to capture the leaflets thereby facilitating shorter elements. *Id.* (citing Ex. 1005 col. 27, ll. 6–10).

- ii. Petitioner argues that the clip arms are advanced out of the delivery tube before the collar is advanced out

Petitioner next argues that the free ends of the distal elements 18 (first- and second-clip arms) are also advanced out of the delivery tube before the collar 131 (support portion) is advanced out of the delivery tube. Opp. 23. According to Petitioner, Goldfarb teaches that, during delivery, the “[c]ollar 131 is pushed distally against, but not over, detents 135 so that branches 19A, 19B are disposed together and fixation device 14 has a minimal profile.” *Id.* (quoting Ex. 1005 col. 27, ll. 31–35). Additionally, asserts Petitioner, the pivot points at the ends of the distal and proximal elements move towards the longitudinal axis of the device and towards base 69, which causes the proximal elements to shift distally. *Id.* (citing Ex. 2004, 101; Ex. 1003 ¶ 83). Therefore, Petitioner argues, the ends of the proximal elements will advance out of the delivery tube before the collar

advances out of the delivery tube. *Id.* Additionally, argues Petitioner, the ends of the distal elements will also advance out of the delivery tube before the collar fully advances out of the delivery tube because the evidence establishes that the proximal and distal elements can be roughly the same length. *Id.* at 23–24.

Alternatively, argues Petitioner, a person of ordinary skill in the art would have found it obvious to use shorter proximal and distal elements such that the ends of the elements exit the delivery tube before the collar for the reasons provided in the preceding section with respect to if the support portion is coupling member 19. Opp. 24; *see supra* Section II.C.8.

9. The Board’s Preliminary Guidance

The Board issued Preliminary Guidance on the Patent Owner’s Motion to Amend on June 24, 2022 (Paper 20, “Prelim. Guid.”). In the Preliminary Guidance, we made the following preliminary construction of the claim term “support portion”:

On this record, and based on the surrounding language of the claim, we understand the “support portion” to include an element in the claimed implant with the elsewhere recited structural features: 1) flexibly coupled to clips, 2) has an opening that surrounds a central longitudinal axis, and 3) disposed within a tube when advanced. ... We encourage the parties to address the claim interpretation of “support portion” in any further briefing, for example, to assist the panel in determining whether the male contour of coupling member 19 of Goldberg ’267 can be considered a “support portion” or whether the entire coupling member 19 is the “support portion.”

Prelim. Guid. 7. With respect to the claim term “advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube

before advancing the support portion out of the delivery tube,” we concluded that:

On this record, we construe “advancing” in the phrase “advancing the support portion out of the delivery tube” in accordance with its plain and ordinary meaning, which we understand to refer to advancing any part of the support portion, rather than the entire support portion. First, we note that the language of the proposed substitute claim uses the term “the end of” to indicate that the whole clip arm is advanced out of the delivery tube, in the phrase “by advancing the end of the first-clip arm and the end of the second clip-arm.” By contrast, there is no term “the end of” in the phrase “before advancing the support portion out of the delivery tube,” which indicates that the entire support portion need not be advanced out.

Id. at 8.

With respect to Petitioner’s arguments in its Opposition to Patent Owner’s Motion to Amend, we found that:

Petitioner has shown a reasonable likelihood that Goldfarb ’267’s coupling member 19 and collar 131 meet structural features of the claimed support portion: being flexibly coupled to the first and second clips and having an opening that surrounds a central longitudinal axis of the implant.... However, ... Petitioner has not adequately explained why the male contour of coupling member 19 would be considered a “support portion,” as claimed, as opposed to the entire coupling member 19.... [I]t is unclear why Petitioner argues that only the male contour of the larger structure is or would have been considered the support portion where the coupling member is one piece.

Prelim. Guid. 12–13. We further acknowledged “Petitioner’s argument that the end of Goldfarb ’267’s distal element 18 is the end of a clip arm that is most displaceable from the central longitudinal axis.” *Id.* at 14 n.7.

However, we refrained from making such a factual finding on the record.

Id.

Finally, we found that:

Petitioner has not shown a reasonable likelihood that Goldfarb '267 teaches advancing the clip-arm ends out of the delivery tube before advancing a support portion out of the delivery tube.

First, Petitioner has not explained why the male element of coupling member 19 alone should be viewed as the support portion, and not the entire coupling member 19....

Second, Petitioner has not shown that the distal element 18 would necessarily precede even the male element of coupling arm 19.

Prelim Guid. 19. We concluded that:

On this record, Petitioner has not met its burden of showing a reasonable likelihood that Goldfarb '267's collar 131 meets the proposed limitations added by amendment. Specifically, Petitioner has not shown a reasonable likelihood that Goldfarb '267 teaches advancing the clip arm ends out of the delivery tube before advancing collar 131 out of the delivery tube.

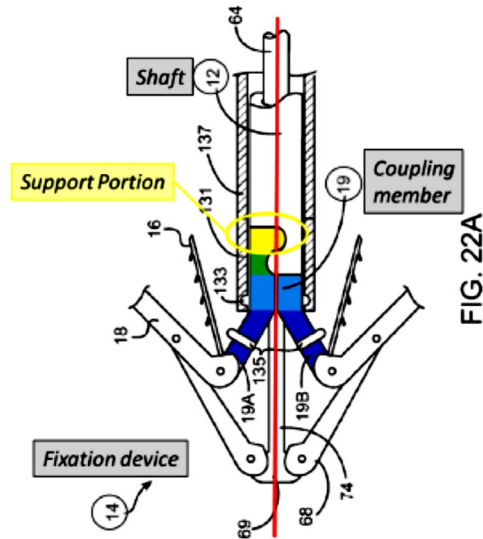
Id. at 21. These preliminary findings help frame and inform Petitioner's Reply and Patent Owner's Sur-Reply to the Preliminary Guidance, and our subsequent analysis.

10. "Support Portion"

a. Arguments

In its Reply to the Preliminary Guidance, Petitioner argues that the male element of the coupling member 19 in Goldfarb '267 (Embodiment A) is a "support portion" under the plain and ordinary meaning of the term. Reply 2 (citing Ex. 1005 col. 15, ll. 19–31). According to Petitioner, the plain and ordinary meaning of "portion" is "a part of a whole." *Id.* (citing, e.g., "Google Dictionary definition of 'portion' provided by Oxford

Languages”).¹⁰ Petitioner asserts that the male element is a “part” of the “whole” fixation device, and is also “part” of the “whole” coupling member 19, which itself is comprised of several different parts that provide unique functions. *Id.* By way of example, Petitioner points to another modified and annotated version of Figure 22A of Goldfarb ’267, reproduced below:



Petitioner’s modified and annotated version of Goldfarb ’267’s
fixation device as shown in Figure 22A

Petitioner contends that, in this figure, the coupling member 19 comprises the male element (yellow) at its proximal end, followed by a female element (green), a cylindrical support (blue), and flexible branches 19A/19B (darker blue). Reply 2–3. According to Petitioner, the male element is a “support” portion because it connects the fixation device to the shaft 12 and: (1) bears the weight of the fixation device during delivery; (2) absorbs and transfers the axial and rotational forces imposed by the shaft 12; and (3) holds the device in the correct orientation. *Id.* at 3 (citing Ex. 1005

¹⁰ Petitioner points to no evidence of record to support this definition.

col. 15, ll. 25–31). Petitioner argues that the remaining portions of the coupling member 19 below (distal to) the male element have different structure and provide different functionality; for example, the cylindrical support (blue) keeps the coupling member centered; branches 19A/19B (purple) flexibly couple to the clips). *Id.*

Petitioner argues that neither proposed substitute claim 11, nor the Specification of the '385 patent requires that the “support portion” be a physically separate part. Reply 3–4. First, Petitioner asserts that the Specification of the '385 patent uses “support portion” consistent with its plain and ordinary meaning. Reply 4. Petitioner contends that, although the Specification does not use “support portion” in isolation, it describes an “upstream support portion 60” as a “portion,” or part, of the larger fixation device. *Id.* (citing e.g., Ex. 1001 col. 2, ll. 11–17, col. 10, ll. 45–58, Fig. 1A). Petitioner contends that the '385 patent consistently uses “portion” to refer to a part of a larger whole. *Id.* (citing e.g., Ex. 1001 col. 4, ll. 31–35). Furthermore, argues Petitioner, the upstream support portion 60 “supports” the tissue-engaging elements and prosthetic valve after implantation by bearing the weight of the elements and holding the elements in position. *Id.* (citing, e.g., Ex. 1001 col. 16, ll. 57–62, col. 17, ll. 16–29).

Second, Petitioner asserts that nothing in claim 11 or the '385 patent specification supports a construction of “support portion” that excludes the male element in Goldfarb '267. Reply 4. According to Petitioner, proposed substitute claim 11 does not specify the location (e.g., upstream) or shape (e.g., annular) of the support portion, unlike other claims in related patents. *Id.* (citing, e.g., *Edwards Lifesciences Corp. v. Cardiovalve Ltd.*, IPR2021-00383, Paper 60 at 11 (PTAB July 18, 2022)). Similarly, argues Petitioner,

neither proposed substitute claim 11 nor the '385 Specification: (1) requires the “support portion” to be a physically separate part from the rest of the device; or (2) precludes the “support portion” from being integral with, or connected to, another part of the device. *Id.* at 5. To the contrary, Petitioner asserts that Patent Owner’s choice of the word “portion” means that the “support portion” is a part of a larger whole. *Id.*

We now turn to Patent Owner’s responsive arguments. Patent Owner responds that Petitioner proposes an artificially broad construction of “support portion” that fails to consider how that term is used in the '385 patent Specification. Sur-Reply 1–2 (citing *Phillips*, 415 F.3d at 1321).

Patent Owner contends that the Specification of the '385 patent discloses the upstream “support portion” 60 as a discrete element of the implant, and not a part of another element. Sur-Reply 2 (citing Ex. 1001, col. 8, ll. 24–30, Fig. 1). Patent Owner asserts that this distinction is made throughout the Specification: for example, in referring to a part of another element, it describes, “at least a portion of clip arms 32 is covered with a padding,” and refers to a “portion (e.g., a middle portion) of each coupling lead,” each clearly referring to a part of another element, not a distinct element of the implant. *Id.* (quoting Ex. 1001 col. 9, ll. 14–16, col. 19, ll. 60–64).

Similarly, argues Patent Owner, the claims of the '385 patent use clear language when differentiating between elements of the implant and discernable portions of elements, for instance, by describing “the end of the first-clip arm.” *Id.* Patent Owner asserts that Petitioner essentially acknowledges this point by arguing that the claim requires the entirety of the support portion to be advanced out of the delivery tube because it does not

recite “portions of the support portion.” *Id.* (quoting Opp. 25). Patent Owner contends that Petitioner’s argument recognizes that, under the proper construction, the entire coupling member 19 constitutes the support portion of the implant—not just its “male element.” *Id.*

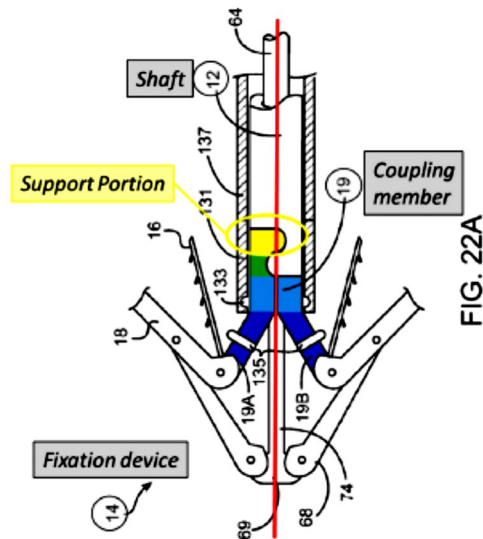
Patent Owner argues further that there is nothing distinct about the male element of coupling member 19. Sur-Reply 2. Patent Owner asserts that Petitioner’s argument that the male element “bears the weight of the fixation device during delivery” only stands because it is part of the entire coupling member 19, which also includes the female element and the cylindrical support. *Id.* at 2–3.

Patent Owner further asserts that proposed substitute claim 11 requires that the “support portion” includes “an opening that surrounds a central longitudinal axis.” Sur-Reply 3. Patent Owner argues that the male element of coupling member 19 does not have “an opening that surrounds a central longitudinal axis.” *Id.* (citing Ex. 1001 col. 22, ll. 7–10, Fig. 6B). According to Patent Owner, the plain and ordinary meaning of “surround” is to be all around, and the Specification of the ’385 patent employs this same plain and ordinary meaning. *Id.* (citing, e.g., Ex. 1001 col. 10, ll. 45–48, Fig. 1A). Patent Owner argues that the male element forms a semicircle and thus does not “surround” a central longitudinal axis of the implant: rather, only the entire coupling member 19 is all around such an axis. *Id.*

b. Analysis

We are not persuaded by Petitioner’s argument that the “support portion” recited in proposed substitute claim 11 is taught by what Petitioner identifies as the “male element” of coupling member 19 of Goldfarb ’267’s

Embodiment A. Petitioner argues that the prior art's coupling member 19 should be dissected into discrete component parts here, when none are necessarily disclosed by the reference itself, such that we should understand the claimed "support portion" to be the "male element" portion of coupling member 19, as indicated in yellow by Petitioner's diagram in the preceding section, reproduced below:



Petitioner argues that we should find only this male element portion of coupling member 19 to be the support portion because it: (1) bears the weight of the fixation device during delivery; (2) absorbs and transfers the axial and rotational forces imposed by the shaft 12; and (3) holds the device in the correct orientation. Reply at 3 (citing Ex. 1005 col. 15, ll. 25–31).

However, coupling member 19 is depicted in Figure 22A and 22B and is described in Goldfarb '267 as plainly a single, unitary structure and, as such, each portion argued as separate elements by Petitioner (i.e., male element (yellow), female element (green), coupling member 19 (blue) and flexible arms 19A and 19B (dark blue)) together form a solid, single component. Thus, *all* of the "elements" described by Petitioner as being

“separate” are in fact a single unit that: (1) bears the weight of the fixation device during delivery; (2) absorbs and transfer the axial and rotational forces imposed by the shaft 12; and (3) holds the device in the correct orientation. Petitioner points to no disclosure of Goldfarb '267 that suggests these elements act independently or separately to perform the functions of the unitary component, nor can we discern any such disclosure.

We therefore find that Petitioner’s argument that only the “male element” portion of coupling member 19 constitutes the “support portion” recited in proposed substitute claim 11 is an arbitrary and unduly restrictive interpretation of the reference’s disclosure. This is particularly true given that Petitioner points to no portion of the male element of coupling member 19 performing a supporting function that is not shared by the other elements of coupling member 19. We conclude that the better understanding of the reference is that the entirety of coupling member 19 (including flexible arms 10A and 19B¹¹) constitutes an analogous support portion, as recited by substitute claim 11, because it provides a unitary structure that performs the supporting functions enumerated by Petitioner.

We also find this understanding of the prior art and the claimed subject matter is correct because substitute claim 11 requires that the support

¹¹ Further support for including flexible arms 19A and 19B as parts of the support portion is supported by the common numerical designation “19” shared with the rest of the coupling member. *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”).

portion has “an opening that surrounds a central longitudinal axis of the implant.” Figures 22A and 22B of Goldfarb ’267, upon which Petitioner principally relies, do not illustrate this configuration in relation to Petitioner’s asserted male element portion of coupling member 19, but we find Figure 49 of Goldfarb ’267, reproduced below, to be instructive:

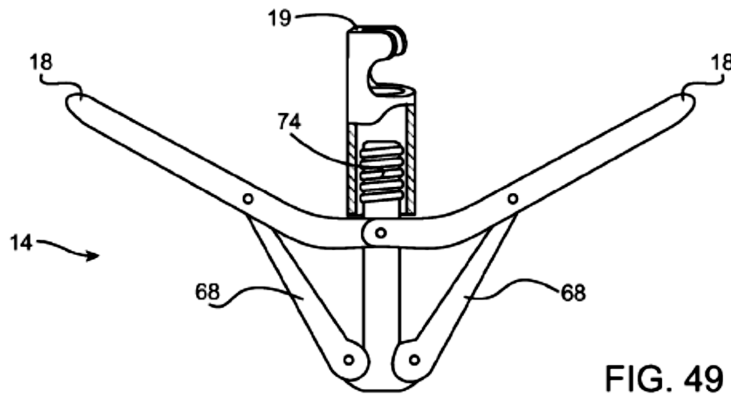
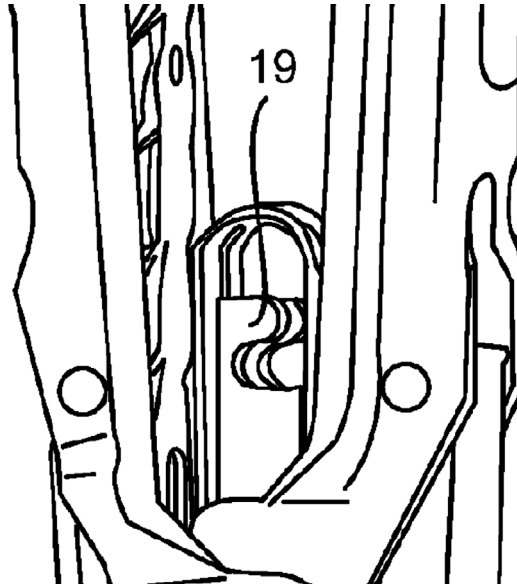


Figure 49 of Goldfarb ’267 depicts another embodiment of the fixation device

In this Figure, the male element portion of coupling member 19¹² does not “surround” the central longitudinal axis of the implant, but rather forms an open “U-shape” around part of the central opening constituting a longitudinal axis. Only the coupling portion 19, considered in its entirety, as depicted in Petitioner’s modified Figure 22A above, surrounds the central opening. This is particularly evident in Figure 49 from the portion of coupling member 19 positioned below what Petitioner terms the “male element.”

¹² See n.11 *supra*.

Figure 16 of Goldfarb '267 similarly indicates that the male element of coupling member 19 does not surround the central longitudinal opening as such is now claimed. A detail of Figure 16 is reproduced below:



Detail of Figure 16 of Goldfarb '267 depicting the male element of coupling member 19

Again, it is evident that the male element of coupling member 19 need not necessarily, and at least in some embodiments, *clearly does not* surround the central longitudinal opening, as required of the “support portion” by proposed substitute claim 11.

Nor does Petitioner point to any express teaching or suggestion of Goldfarb '267 that the male element surrounds the opening around the longitudinal axis of the fixation device. We consequently do not find persuasive Petitioner's argument that the male element of coupling member 19 constitutes the claimed “support portion” of the device, but find, rather, that the claim term properly applies to coupling member 19 as a whole.

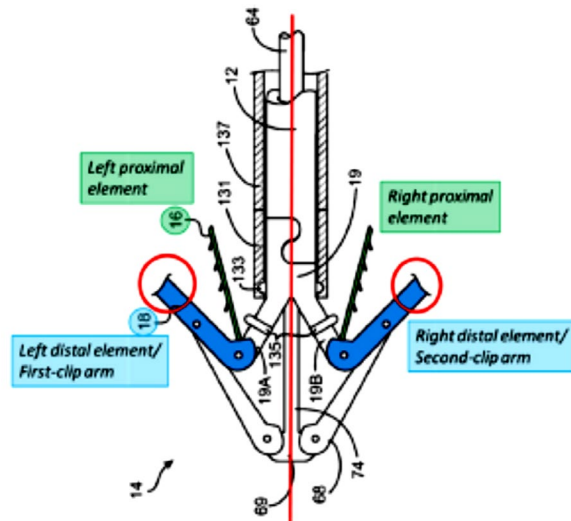
Nor are we persuaded by Petitioner's arguments that collar 131 constitutes a “support portion.” Goldfarb '267 teaches that collar 131 “is

slidably disposed over coupling member 19.” Ex. 1005 col. 27, ll. 24–25. Because coupling portion 19 and collar 131 can freely move with respect to each other (when detents 135 are not engaged with annular groove 133 in collar 131), collar 131 cannot provide the support functions argued by Petitioner above. Furthermore, because collar 131 and coupling member 19 are “slidably disposed,” i.e., move freely with respect to each other, we are not persuaded that collar 131 is “flexibly coupled to the first and second clips,” because moving the slidable collar 131 with respect to coupling member 19 would not exert any mechanical effect on the first and second clips and hence collar 131 and the clips are not “coupled” to each other.

11. “Having an end most displaceable from the central longitudinal axis”

a. Arguments

Petitioner next argues that the left and right distal elements 18 in Goldfarb ’267 should be interpreted as constituting the “first- and second-clip arms.” Reply 5. Petitioner contends that each clip arm has “an end most displaceable from the central longitudinal axis of the implant,” as indicated in Petitioner’s modified Figure 22A reproduced below:



Petitioner's modified, annotated version of Figure 22A of Goldfarb '267 depicting the clips of the fixation device

Petitioner contends that each of the clip arms in Goldfarb '267, whether considering the proximal elements 16 or the distal elements 18, has two ends: (1) an end coupled to the fixation device, and (2) a free end that is “an end most displaceable from the central longitudinal axis of the implant.” Reply 6. Therefore, argues Petitioner, both the proximal and distal elements in Goldfarb '267 satisfy this limitation. *Id.* Furthermore, contends Petitioner, Patent Owner’s Motion to Amend is consistent with this claim interpretation, because Patent Owner acknowledges that both the proximal and distal elements have an “end most displaceable from the central longitudinal axis of the implant” by indicating the ends of both elements in its illustration. *Id.* (citing Mot. Amend. 16).

Petitioner argues that the Board appears to be construing “an end most displaceable” to require a clip arm with an end that is more outwardly displaceable from the central longitudinal axis than any other part of the fixation device, including the free end of another clip arm. Reply 7 (citing Prelim. Guid. 14). However, Petitioner contends, the ’385 patent

Specification does not support this construction, nor do the words of the claim require that the end be “more” outwardly displaceable from everything else. *Id.* By way of example, Petitioner notes that, in all ’385 patent embodiments, the outer circumferential edge of the “upstream support portion 60” is displaced farther from the central longitudinal axis than the free ends of the clips 30. *Id.*

Consequently, Petitioner argues, a clip arm with “an end most displaceable from the central longitudinal axis of the implant” does not mean that the end is the most displaceable point of the entire device but, rather, means that the first- and second-clip arms have “ends” that are the most displaceable part of the first- and second-clip arms from the longitudinal axis. Reply 7–8.

b. Analysis

Proposed substitute claim 11 recites, in relevant part: “the implant including a first clip, [and] a second clip ... the first clip including a first-clip arm, and the second clip including a second-clip arm, the first-clip arm and the second-clip arm *each having an end most displaceable* from the central longitudinal axis of the implant.” Mot. Amend. 2 (emphasis added).

The language of the claim thus contemplates a single clip arm from each of the first and second clips that has an end *most* displaceable from the central longitudinal axis of the device. Figure 22A of Goldfarb ’267 shows, by the wavy line through distal element 18 (i.e., clip arm), that its length is not determinate, whether shorter than, longer than, or the same length as proximal element 16. We interpret the language of proposed substitute claim 11 to refer to either the end of distal element 18 or the end of proximal

element 16 that is displaced furthest from the central longitudinal axis when the clips are expanded upon deployment. *See* Ex. 1001 col. 8, ll. 51–55 (explaining that “[c]lips 30 are typically configured such that movement of clip-controller interface 34 by a first distance d1, moves clip arm 32b by a second distance d2 that is typically more than 1.5 times (e.g., more than 2 times, such as more than 4 times) greater than distance d1).

12. “The ends of the clip arms are advanced out of the tube before the support portion”

a. Arguments

Petitioner disputes the Board’s Preliminary Guidance, which found that the plain and ordinary meaning of “‘advancing’ in the phrase ‘advancing the support portion out of the delivery tube’” referred to “advancing any part of the support portion, rather than the entire support portion.” Reply 8 (citing Prelim Guid. 8). Petitioner argues, to the contrary, that proposed substitute claim 11 merely requires advancing the ends of the clip arms out of the delivery tube “before advancing the support portion out of the delivery tube.” *Id.* According to Petitioner, “the support portion” is most reasonably understood to refer to the whole support portion, not any part of the support portion. *Id.* Petitioner contends that this interpretation is consistent with the Specification of the ’385 patent, which discloses that the clips “typically” engage the leaflets while “at least part” of the support remains in the delivery tube. *Id.* (citing, e.g., Ex. 1001 col. 8, ll. 19–23, col. 14, ll. 53–56). Petitioner contends that the Specification does not disclaim embodiments where the ends of the clip arms exit the delivery tube after part of the support portion (but before the whole support portion). *Id.* at 8–9.

Nevertheless, Petitioner argues, even if we adopt our preliminary construction from our Preliminary Guidance in this final decision, the ends of the proximal and distal elements in Goldfarb '267 (Embodiment A) are advanced out of the delivery tube before any part of the male element.

Reply 9. Petitioner notes that the we preliminarily found that Petitioner had not demonstrated a reasonable likelihood that Goldfarb '267 anticipates this limitation or renders it obvious for two reasons: (1) "Petitioner has not explained why the male element of coupling member 19 alone should be viewed as the support portion, and not the entire coupling member"; and (2) "Petitioner has not shown that the distal element 18 would necessarily precede even the male element of coupling arm 19." *Id.* (quoting Prelim Guid. 19).

Petitioner contends that it has addressed the first issue as discussed in Section II.C.8.a.i above. Reply 9. With respect to the second issue, Petitioner acknowledges that Goldfarb '267 does not illustrate the free ends of the distal elements in Figures 22A–22B. *Id.* However, argues Petitioner, Goldfarb '267 discloses a finite number of options for the distal element length, as compared to the proximal element length: slightly shorter, the same, or slightly longer. *Id.* at 9–10 (comparing Ex. 1005, Figs. 32–33, Figs. 11A–11B, Fig. 16). Furthermore, Petitioner asserts, Goldfarb '267 discloses that the proximal and distal elements must "securely" capture the leaflets. *Id.* at 10 (citing Ex. 1005 col. 5, ll. 58–61). Consequently, Petitioner contends, Goldfarb '267 consistently illustrates similar lengths of the proximal and distal elements to securely capture the leaflets between the elements. *Id.* (citing Ex. 1005 col. 13, ll. 52–56, col. 22, ll. 19–36, cols. 27–28, ll. 67–9). Petitioner contends that a person of ordinary skill in the art

would have understood that significant differences in length between the proximal and distal elements would result in little overlap and would not securely capture the leaflets. *Id.* Therefore, argues Petitioner, considering Goldfarb '267's teachings regarding the need to capture leaflets securely, a skilled artisan would have been motivated to select proximal and distal elements that are similar in length, as confirmed by Petitioner's expert Dr. Vesely, because this configuration was one of a finite number of identified, predictable solutions. *Id.* (citing *KSR*, 550 U.S. at 421; Ex. 2004, 46).

Petitioner repeats that Goldfarb '267's proximal element 16 exits the delivery tube before any part of the male element on the coupling member 19. Reply 10 (citing Opp. 17–21). Petitioner contends that, because Goldfarb '267 teaches that the proximal and distal elements 16, 18 can be the same length, Goldfarb '267 anticipates proposed substitute claim 11. *Id.* at 11. Alternatively, argues Petitioner, a person of ordinary skill in the art would have been motivated, to use a distal element 18 that is the same length as the proximal element 16; the distal element 18 would also exit the delivery tube before any part of the male element. *Id.*

Alternatively, Petitioner argues, even if the ends of the proximal and distal elements illustrated in Figures 22A and 22B would not exit the delivery tube before the male element, Goldfarb '267 discloses that the distal elements can vary in length from a minimum of approximately 4 mm to lengths of 10 mm or more. *Id.* (citing Ex. 1005 col. 18, ll. 30–32).

Petitioner reiterates that Goldfarb '267 (Embodiment A) is particularly well suited for shorter proximal and distal elements (e.g., 4 mm) because the elements “are moveable laterally toward and away from each

other” (due to flexible branches 19A/19B) and, therefore, can securely and reliably capture the leaflets using shorter elements. Reply 11–12 (citing Ex. 1005 col. 27, ll. 6–10). Due to this design feature, Petitioner argues, a person of ordinary skill in the art would have reasonably expected success in using shorter proximal and distal elements with Embodiment A. *Id.*

Petitioner also points to its expert, Dr. Vesely’s, testimony that a skilled artisan would have been motivated to select the shortest elements possible to decrease the amount of metal in the device and decrease the device profile. *Id.* (citing Ex. 1003 ¶ 143). For these reasons, argues Petitioner, a person of ordinary skill in the art would have been motivated to use shorter proximal and distal elements with Embodiment A that would exit the delivery tube before any part of the male element, with a reasonable expectation of success in doing so. *Id.*

Patent Owner points to our Preliminary Guidance where we preliminarily construed “advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube” consistent with the ‘385 patent Specification as requiring that both clip arms must be advanced out of the delivery tube before the support portion begins to be advanced. Sur-Reply 3 (citing Prelim. Guid. 8). Patent Owner disputes Petitioner’s argument that the language of proposed substitute claim 11 requires that the clip arms be advanced out of the delivery tube before the entirety of the support portion. *Id.* at 3–4. Instead, Patent Owner points to our finding that the plain and ordinary meaning of “advancing,” means “to move forward ... toward a terminus or goal” or “to progress forward.” *Id.* at 4 (quoting Prelim. Guid.

8). Patent Owner therefore asserts that “advancing” does not require completion of that goal. *Id.*

Patent Owner also notes that the Board’s construction is consistent with the Specification of the ’385 patent. Sur-Reply 4. By way of example, Patent Owner points to Figures 3B and 3C of the ’385 Specification as showing the “advancing” feature, and depicting the entire prosthetic valve support, including upstream support portion 60, remaining in the delivery tube after the ends of both clip arms have been advanced. *Id.* (citing Ex. 1001, Figs. 3B–3C). Petitioner’s assertion that that “the clips ‘typically’ engage the leaflets while ‘at least part’ of the support remains in the delivery tube” is irrelevant: the pertinent question according to the language of substitute claim 11 is not whether the support portion is advanced out of the delivery tube before the clips engage the leaflets, but rather, whether it is advanced before the clips are advanced out of the delivery tube. *Id.* (quoting Reply at 8). Patent Owner asserts that, under the proper construction, Goldfarb ’267 does not teach or suggest the “advancing” limitation because the ends of its clip arms remain in the delivery tube when the coupling member 19 is advanced, as Petitioner’s expert, Dr. Vesely, admitted. *Id.* (citing Ex. 1004, 104–06).

Finally, Patent Owner argues that Petitioner’s contention that the distal elements of Goldfarb ’267 may be slightly shorter, the same, or slightly longer than the proximal element, and that a person of ordinary skill in the art could modify that length so the distal element end is advanced out of the delivery tube before the support portion, is contradicted by the testimony of its expert, Dr. Vesely. Sur-Reply 4. Patent Owner points to Dr. Vesely’s testimony that, in the Figure 22A and 22B embodiments, the

distal arms are “probably twice as long as pictured” and “roughly the same,” or “slightly longer” than the proximal arms. *Id.* at 4–5 (citing Reply 9–12; Ex. 2004, 44–46). Patent Owner contends that Petitioner’s argument that a person of skill in the art would have been motivated to use shorter distal elements is no more than attorney argument, unsupported by any evidence. *Id.* at 5 (citing *Icon Health and Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017)).

According to Patent Owner, Dr. Vesely’s testimony that “the clip arms are folded upward to be roughly parallel to the collar and other structures,” to have “the tightest configuration possible” during delivery may suggest reducing the width of the distal elements, but not shortening their length. Sur-Reply 5 (citing Ex. 2004, 99–100). Nor, argues Patent Owner, would a skilled artisan expect success with shorter proximal and distal elements: Goldfarb ’267 explains the leaflets must be “securely” captured, and that “capturing” occurs “between” the proximal and distal elements, i.e., based on the length of overlap of these elements. *Id.* (citing Ex. 1005 col. 13, ll. 52–56; col. 22, ll. 19–36, cols. 27–29, ll. 67–9). Patent Owner asserts that no evidence supports an expectation of success that the leaflets will be “securely” captured by shorter proximal and distal elements with less overlap. *Id.*

b. Analysis

As an initial matter, all of Petitioner’s arguments here are predicated upon Petitioner’s “male element” of coupling member 19 alone constituting the claimed support portion. We have explained, in Section II.C.10.b above, why we reject Petitioner’s interpretation, and so Petitioner’s arguments are

not persuasive for this reason alone. Furthermore, we are not persuaded by Petitioner’s argument that the language of proposed substitute claim 11 reciting “advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube” merely requires advancing the ends of the clip arms out of the delivery tube “before advancing the support portion out of the delivery tube.” *See* Reply 8. Petitioner contends that “the support portion” is most reasonably understood to refer to the whole support portion, not any part of the support portion. *Id.*

We disagree. As we explained in our Preliminary Guidance:

[W]e construe “advancing” in the phrase “advancing the support portion out of the delivery tube” in accordance with its plain and ordinary meaning, which we understand to refer to advancing any part of the support portion, rather than the entire support portion. First, we note that the language of the proposed substitute claim uses the term “the end of” to indicate that the whole clip arm is advanced out of the delivery tube, in the phrase “by advancing the end of the first-clip arm and the end of the second clip-arm.” By contrast, there is no term “the end of” in the phrase “before advancing the support portion out of the delivery tube,” which indicates that the entire support portion need not be advanced out.

....

This construction is consistent with the plain and ordinary meaning of “advance” (as understood by an ordinarily skilled artisan) as “to move forward along a course or toward a terminus or goal[;] make or proceed or to progress[;] forward.” *See* Ex. 3001.¹³

¹³ “Advance” *in* WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED (1993). Ex. 3001.

Prelim. Guid. 8. As we further explained, Petitioner’s argument that the claim does not recite “portions of the support portion” is in some sense speculation about the ways in the which the claim could have been written; alternatively the claim could have been written to advance the support portion completely out of the tube, but does not so state as written. *See id.* We further observed that the distinction between including “the end of” in one part of a claim limitation and omitting it for the other part of the same claim limitation is a distinction found in the claim itself. *Id.* (citing, *cf. Schalfly v. Saint Louis Brewery, LLC*, 909 F.3d 420, 425 (Fed. Cir. 2018)). We therefore concluded that proposed substitute claim 11 does not require advancing the end of the support portion out of the tube. *Id.*

Petitioner’s argument is further undermined by its insistence that the “male element” of coupling member 19 constitutes the “support portion” recited in proposed substitute claim 11. We explained in detail in Section II.C.10.b above why we do not find Petitioner’s arguments persuasive in this regard, but rather conclude that the entirety of coupling member 19, including flexible arms 19A and 19B, constitutes the “support portion.” For the reader’s convenience, Figure 22A of Goldfarb ’267 is reproduced again below:

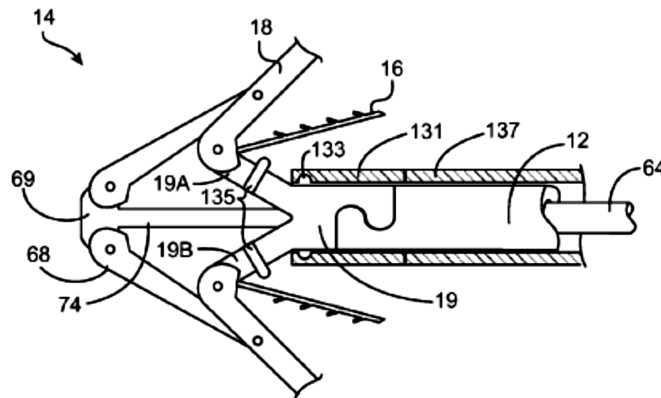


FIG. 22A

Figure 22A of Goldfarb '267 indicates that, regardless of the length of distal element 18 (the actual length is truncated in the illustration), it is apparent that *some* portion of coupling member 19, and at least flexible arms 19A and 19B, would necessarily have emerged from the delivery tube prior to the distal ends of either distal element 18 or proximal element 16. This is not least because flexible arms 19A and 19B (which are part of coupling member 19) are attached to the bases of both proximal and distal elements 16 and 18 and must therefore be advanced from the delivery tube as the clips begin to emerge.

However, the larger problem with Petitioner's argument is that it is largely speculative and based upon Petitioner's interpretation of the Figures of Goldfarb '267. Goldfarb provides no illustration of its Embodiment A within the delivery tube, nor does Petitioner point to any disclosure of Goldfarb '267 that expressly teaches the disputed limitation. Furthermore, the Figures of Goldfarb '267 are not drawn to any defined scale. Lacking any textual support to show that the end of the first-clip arm and the end of the second-clip arm are advanced out of the delivery tube before any portion of the support portion advances out of the delivery tube, Petitioner's reliance

upon Figures 22A and 22B as teaching this limitation is unavailing because it is largely speculative, depending upon what the length of distal element 18 *could* be. *See Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1351 (Fed. Cir. 2013) (holding that “[p]atent drawings [] do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue” (quoting *Hockerson–Halberstadt, Inc. v. Avia Grp. Int’l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000))); *see also In re Wright*, 569 F.2d 1124, 1127 (C.C.P.A.1977) (holding that “[a]bsent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value”).

We conclude that Petitioner’s arguments are insufficient to meet its burden of showing, by a preponderance of the evidence, that Goldfarb ’267 anticipates, or renders obvious, the limitation of proposed substitute claim 11 reciting “advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube” merely requires advancing the ends of the clip arms out of the delivery tube “before advancing the support portion out of the delivery tube.” Moreover, Petitioner’s arguments are not persuasive with respect to proposed substitute dependent claims 12–20 due to their dependence from, and incorporation of, the limitations of proposed substitute claim 11. *See* Supp. Mot. Amend. 1, Reply Supp. Mot. Amend. 1. We therefore conclude that these proposed substitute claims are similarly neither anticipated by, nor obvious over, Goldfarb ’267.

III. CONCLUSION

We GRANT Patent Owner's non-contingent Motion to Amend and Supplemental Motion to Amend, canceling original claims 1–10 and replacing them with substitute claims 11–20.

Additionally, for the foregoing reasons, and after having analyzed the entirety of the record and assigning appropriate weight to the cited supporting evidence, we determine that Petitioner has failed to establish, by a preponderance of the evidence, that proposed substitute claims 11–20 are unpatentable.

In summary:

Motion to Amend Outcome	Claims
Original Claims Cancelled by Amendment	1–10
Substitute Claims: Proposed in the Amendment	11–20
Substitute Claims: Revised Motion to Amend Granted	11–20
Substitute Claims: Revised Motion to Amend Denied	

IV. ORDER

Accordingly, it is

ORDERED that Petitioner's Motion to Amend is GRANTED, claims 1–10 of the '385 patent are canceled and replaced by substitute claims 11–20;

FURTHER ORDERED that Petitioner fails to show by a preponderance of the evidence that claims 11–20 are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 10,702,385 B2

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