

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.

IPR2021-00383
Patent 10,226,341 B2

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

WORTH, *Administrative Patent Judge.*

DECISION

Final Written Decision

Determining All Challenged Claims Unpatentable

Denying Patent Owner's Contingent Motion to Amend

Granting-in-Part and Denying-in-Part Petitioner's Motion to Strike

Denying Patent Owner's Motion to Exclude

35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review that addresses claims 1–3, 5, 6, 8, 11, and 16–21 (the “challenged claims”) of

U.S. Patent No. 10,226,341 B2 (Ex. 1001, “the ’341 patent”). We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that claims 1–3, 5, 6, 8, 11, and 16–21 are unpatentable. We do not reach claims 9, 10, 13, 14, and 15, which Patent Owner has expressly disclaimed. Paper 24, 1 (“PO Resp.”); Paper 53; Ex. 2021. We deny Patent Owner’s contingent motion to amend insofar as we determine that Petitioner has proven, by a preponderance of the evidence, the unpatentability of proposed substitute claims 22 and 23. We further grant-in-part and deny-in-part Petitioner’s motion to strike and we deny Patent Owner’s motion to exclude.

A. Background and Summary

On December 29, 2020, Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively, “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–3, 5, 6, 8–11, and 13–21 of the ’341 patent. On April 23, 2021, Cardiovalve Ltd. (“Patent Owner”) filed a Preliminary Response (Paper 8). With authorization, on May 27, 2021, Petitioner filed a Preliminary Reply addressing (1) Patent Owner’s position that the flaps in Petitioner’s asserted prior art reference Goldfarb ’329¹ would be secured to the annulus based on other prior art references, namely St. Goar,² Liska,³ and Powell;⁴ (2) Patent Owner’s

¹ Goldfarb, US 7,635,329 B2, iss. Dec. 22, 2009 (Ex. 1004, “Goldfarb ’329”).

² St. Goar, US 6,629,534 B1, iss. Oct. 7, 2003 (Ex. 2001, “St. Goar”).

³ Liska, US 2003/0120340 A1, pub. June 26, 2003 (Ex. 2002, “Liska”).

⁴ Powell, US 2006/0229708 A1, pub. Oct. 12, 2006 (Ex. 2003, “Powell”).

implicit construction of the claim term “facilitate” and its application to the cited prior art references; and (3) Patent Owner’s allegation that the “Petition Mischaracterizes Fig. 5 of Goldfarb ’813,” which is another of Petitioner’s asserted prior art references.⁵ See Paper 10; Paper 12. On June 4, 2021, Patent Owner filed a Preliminary Sur-reply thereto. Paper 13.

On July 20, 2021, we instituted an *inter partes* review of claims 1–3, 5, 6, 8–11, and 13–21 of the ’341 patent. Paper 16 (“Dec. Inst.”).

On October 13, 2021, Patent Owner filed a Response to the Petition. PO Resp. Also on October 13, 2021, Patent Owner filed a Contingent Motion to Amend. Paper 23 (“MTA”).

On January 5, 2022, Petitioner filed a Reply to Patent Owner’s Response. Paper 28 (“Pet. Reply”). Also on January 5, 2022, Petitioner filed an Opposition to Patent Owner’s Contingent Motion to Amend. Paper 27 (“MTA Opp.”). Patent Owner did not file a reply to the Opposition to the MTA.

On January 31, 2022, we issued preliminary guidance on Patent Owner’s Motion to Amend. Paper 32.

On February 16, 2022, Patent Owner filed a Sur-reply to Petitioner’s Reply to Patent Owner’s Response and filed a corrected version of this paper on March 4, 2022, which is the paper that we will refer to in this Decision. Paper 37 (“PO Sur-reply”).

On March 7, 2022, Petitioner filed with authorization a Motion to Strike. Paper 39 (“Mot. Strike”). On March 14, Patent Owner filed a response thereto. Paper 42 (“Opp. Mot. Strike”).

⁵ Goldfarb, US 6,752,813 B2, iss. June 22, 2004 (Ex. 1006, “Goldfarb ’813”).

On March 30, 2022, Patent Owner filed a Motion to Exclude. Paper 44 (“Mot. Excl.”). On April 6, 2022, Petitioner filed an opposition (Paper 46, “Opp. Mot. Excl.”), and on April 13, 2022, Patent Owner filed a reply thereto (Paper 47, “Mot. Excl. Reply”).

On April 20, 2022, an oral argument was held in the proceeding, a transcript of which has been entered in the record. Paper 58 (“Tr.”).

On April 25, 2022, Patent Owner filed notice confirming that it disclaimed claims 9, 10, 13, 14, and 15. Paper 53; Exhibit 2021. We do not address these claims in this decision.

On May 16, 2022, we solicited supplemental briefing from the parties on (1) whether Petitioner’s Petition and Reply can and should be understood to argue that a person of ordinary skill would have been presented with a finite number of options with predictable results when executing the optional method of Goldfarb ’329 of leaving flaps 104 behind; (2) whether Petitioner has made similar arguments in its Opposition to Patent Owner’s Contingent Motion to Amend; and (3) if so, whether there would have been a finite number of options with predictable results. *See* Paper 55.

On May 24, 2022, Petitioner filed a supplemental brief in response. Paper 56 (“Pet. Supp. Br.”). On June 1, 2022, Patent Owner filed a supplemental brief in reply. Paper 57 (“PO Supp. Br.”).

In support of its challenges, Petitioner relies, *inter alia*, on the declaration and second declaration of Ivan Vesely, Ph.D. Ex. 1003; 1016. In support of its positions, Patent Owner relies, *inter alia*, on the declaration and second declaration of Michael Sacks, Ph.D. Ex. 2004; Ex. 2014.

B. Real Parties-in-Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC as the real-parties-in-interest. *See* Pet. 104–05. Patent

Owner identifies Cardiovalve Ltd. and Mitraltech Holdings Ltd. as the real-parties-in-interest. Paper 3, 1; *but see* Paper 14, 1 (updated notice solely identifying Cardiovalve Ltd. as the real party-in-interest).

C. Related Matters

According to Patent Owner, the '341 patent is related to the following other patents and applications: 16/888,210; 16/881,350; 17/210,183 (issued as U.S. Patent No. 11,291,545); 17/306,231 (issued as U.S. Patent No. 11,291,546); 17/355,845 (issued as U.S. Patent No. 11,291,547); 17/366,711 (allowed); 17/394,807; 17/397,235; 17/473,472. Paper 45, 1–2; Paper 48, 1–2. Petitioner reports that it is not aware of any other related proceedings. *See* Pet. 105. Although not cited by the parties in this proceeding, there is a related *inter partes* review, i.e., IPR2021-01051, which is also styled *Edwards Lifesciences Corp. and Edwards Lifesciences LLC v. Cardiovalve Ltd.* (trial instituted Dec. 10, 2021).

D. The '341 Patent

The '341 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), 1:31–34.⁶ According to the '341 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 1:38–43. The '341 patent discloses a prosthetic valve support that may be coupled to the valve leaflets (tissue of a heart valve) to hold the leaflets

⁶ Petitioner asserts that the challenged claims “ignore prosthetic valves and recite a different application for valve support,” i.e., using clips on the valve support to hold the leaflet together. Pet. 2. We agree that the claims at issue are directed to the use of clips or tissue-engaging elements.

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 2:15–41.

The '341 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, 2:22–28. The '341 patent's Figure 3B provides some context as to the leaflet coupling and is reproduced below:

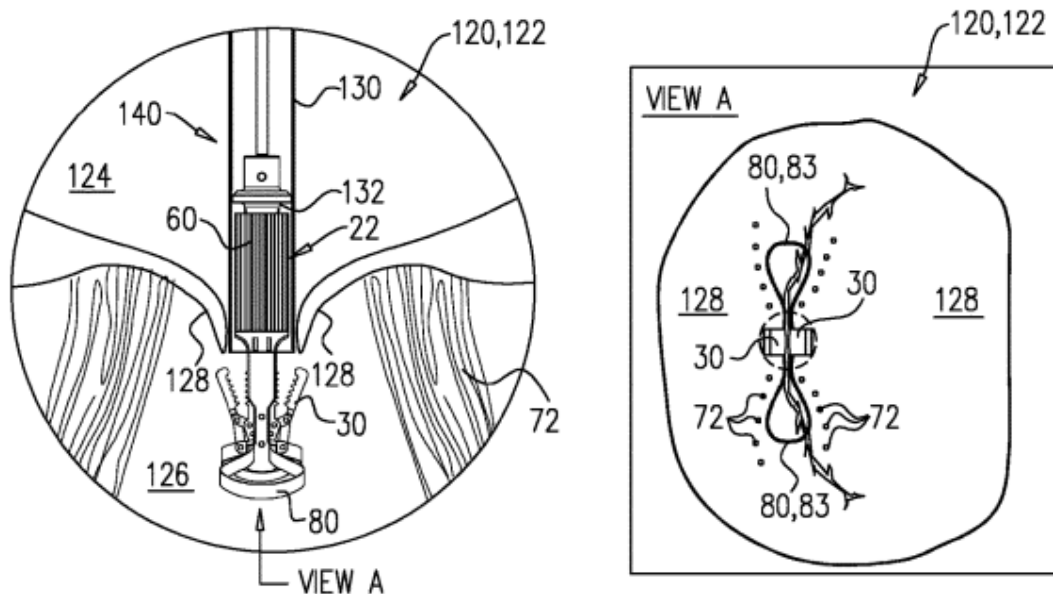


Figure 3B is part of series of schematic illustrations of the delivery and implantation of the prosthetic valve support at the native heart valve of the subject. *See* Ex. 1001, 6:59–61. Prosthetic valve support 22 is advanced out of delivery tube 130 and/or the delivery tube is withdrawn from the prosthetic valve support. *Id.* at 14:14–16. Clips 30 (and/or other tissue-engaging elements) are typically disposed at a downstream portion of prosthetic valve support 22 (e.g., downstream of downstream end 71 of

upstream support portion 60) in the compressed configuration thereof, and are thereby exposed from delivery tube 130. *Id.* at 14:16–21. Stabilizing element 80 is also typically exposed from the delivery tube, and typically forms a generally lemniscate shape, defining two “loops” 83. *Id.* at 14:21–24. Typically, the axis between loops 83 of the lemniscate is generally orthogonal to the axis between clips 30, and may be used to orient prosthetic valve support 22, e.g., such that clips 30 point toward leaflets 128 of the native valve. *Id.* at 14:24–28. Subsequently, prosthetic valve support 60 is moved upstream (e.g., proximally) so as to envelope leaflets 128 between clip arms 32 of each clip 30, and each clip is closed around a leaflet, thereby coupling each clip to a leaflet, e.g., by clamping the leaflet between the clip arms. *See id.* at 14:38–42. Prosthetic valve support 22 is configured to be coupled to the native heart valve so that the native valve functions as a single check valve (e.g., functions in a manner that is generally similar to the natural (e.g., physiological) function of the native valve). *See id.* at 15:55–63.

The ’341 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).⁷ Ex. 1001, 2:29–35.

The prosthetic valve support comprises tissue-engaging elements, such as clips. Ex. 1001, 2:8–9. Typically, but not necessarily, the prosthetic

⁷ “Fr” refers to French units, also called French gauge, and is approximately 0.33 mm.

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 2:9–14.

Figure 1A of the '341 patent is reproduced below:

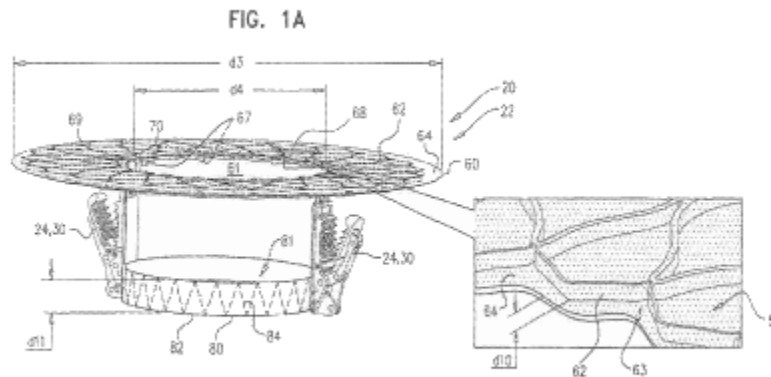


Figure 1A is a schematic illustration of an apparatus, comprising a prosthetic valve support, for facilitating implantation of a prosthetic heart valve at a native heart valve of a subject, in accordance with some applications.

Ex. 1001, 6:51–55. Typically, each tissue-engaging element 24 comprises a clip 30, which typically comprises a plurality of clip arms 32 (e.g., two clip 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 7:33–37.

Prosthetic valve support 22 typically comprises a generally annular upstream support portion 60 (e.g., an annular portion), shaped to define an opening 61 (e.g., an aperture) therethrough, and to be placed against an upstream side of the native valve. *Id.* at 10:43–47.

Figure 1B of the '341 patent is reproduced below:

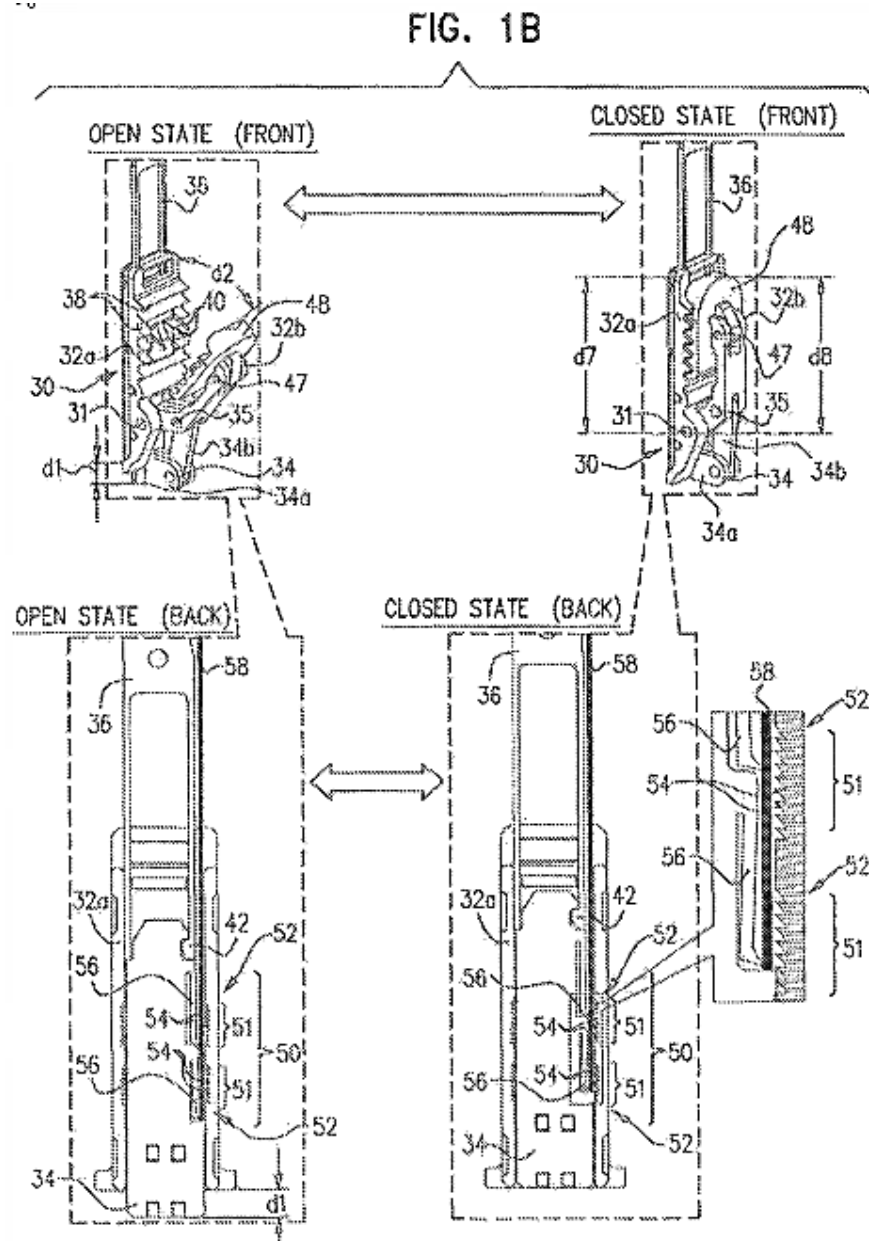


Figure 1B shows clip 30 in an unlocked configuration, in which an obstructing element 58 (e.g., a restraint) is disposed between rack 51 and engaging element 56, thereby inhibiting (e.g., obstructing) engaging element 56 from engaging rack 51, and thereby facilitating the opening and closing of the clip (i.e., movement between open and closed states thereof).

Ex. 1001, 9:29–35. 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 8:38–41.

Figure 6B of the '341 patent is reproduced below:

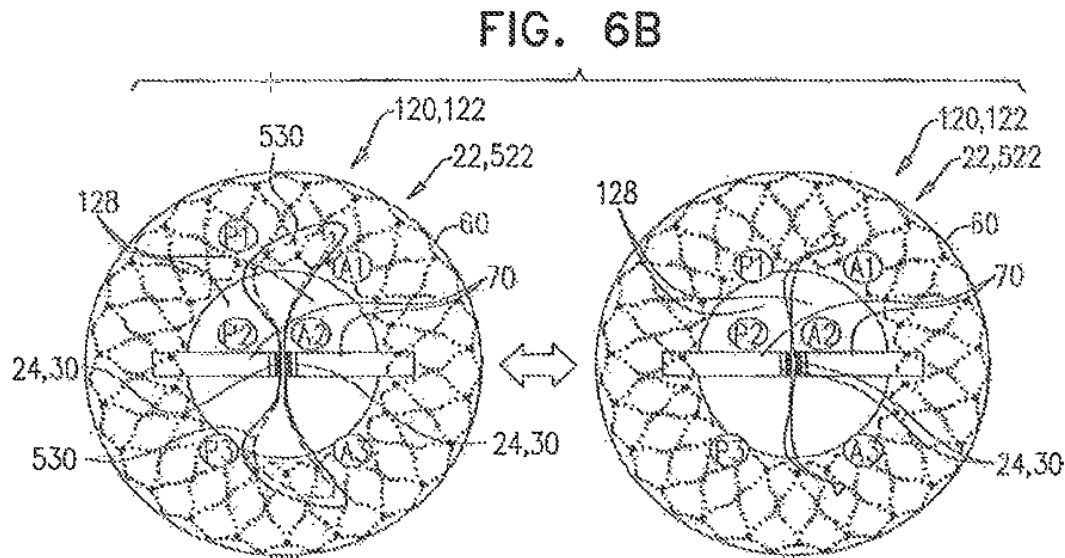


Figure 6B is a schematic illustration of a prosthetic valve support comprising tissue-engaging elements that are couplable to each other, and decouplable from each other, in accordance with some applications. Ex. 1001, 7:4–7. Tissue-engaging elements 24 are coupled to respective portions of leaflets 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. *See id.* at 21:62–67.

E. Illustrative Claim

Claims 1 and 16 are the independent claims challenged in the Petition. Independent claim 9 has been disclaimed, but its dependent claim 11 is still challenged. Claim 1, reproduced below, is illustrative of the subject matter:

1. Apparatus for use at a native valve of a subject, the native valve including at least a first native leaflet and a second native leaflet, the apparatus comprising:

an implant, comprising:

an annular portion, being configured to be placed against an upstream side of the native valve, and having an inner perimeter that defines an opening, and

at least one leaflet clip:

(i) coupled to the annular portion,

(ii) comprising:

at least two clip arms, movable with respect to each other to open and close the clip; and

a clip-controller interface, the clip-controller interface being coupled to at least one of the clip arms, and

(iii) configured:

to be coupled to a portion of the first native leaflet by the clip arms being brought together to close around the first native leaflet,

to be coupled to a portion of the second native leaflet by the clip arms being brought together to close around the second native leaflet, and

to hold together the portion of the first leaflet and the portion of the second leaflet; and

a delivery apparatus, configured to deliver the implant to the native valve, and comprising at least one clip controller, the at least one clip controller being reversibly couplable to the clip-controller interface, and configured to facilitate opening and closing of the clip, and the delivery apparatus being intracorporeally decouplable from the implant.

Ex. 1001, 27:10–41.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–3, 5, 6, 8, 11, and 16–21 would have been unpatentable on the following grounds (*see* Pet. 16–17):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 5, 6, 8, 11, 16–21	103	Goldfarb '329
3	103	Goldfarb '329, Goldfarb '267 ⁸
11	102(b) ⁹	Goldfarb '813
11	103	Goldfarb '813
1–3, 5, 6, 16–18, 21	103	Goldfarb '813, Goldfarb '329
3	103	Goldfarb '813, Goldfarb '329, Goldfarb '267
10	103	Goldfarb '813, Goldfarb '267

⁸ Goldfarb, US 7,563,267 B2, iss. July 21, 2009 (Ex. 1005, “Goldfarb '267”).

⁹ The Petition alleges art qualifying under pre-AIA 35 U.S.C. § 102(b) based on an “earliest claimed priority date” of August 5, 2011. *See* Pet. 17. Patent Owner does not make any contrary representations. The '341 patent was examined under the pre-AIA version of the statute. Ex. 1002, 140. The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103. Because, on this record, the '341 patent was filed before the effective date of the relevant amendment, the pre-AIA versions of §§ 102 and 103 apply. However, our decision would not change regardless of the version of the Patent Act considered.

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). Rather, “[t]he inherent result must inevitably result from the disclosed steps.” *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012).

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) when in evidence, objective evidence of non-obviousness.¹⁰ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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. 18 (citing Ex. 1003 ¶ 32).

Patent Owner does not dispute Petitioner’s definition of the ordinarily skilled artisan. See PO Resp. 16. As we did in our Decision on Institution, we accept Petitioner’s undisputed assertions as factual findings and adopt Petitioner’s proposed definition of a person of ordinary skill. See Dec. Inst. 12; see generally *In re NuVasive*, 841 F.3d 966, 974 (Fed. Cir. 2016).

¹⁰ The parties have not directed us to any such objective evidence in this proceeding.

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) (2020). 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 proposes constructions of the terms “clip” and “facilitate.” Pet. 19; Prelim. Reply 4. Patent Owner agrees with Petitioner’s proposed constructions, and we construe the terms as discussed below. PO Resp. 16. The parties do not request construction of any other terms. *See* Pet. 19; PO Resp. 16. Accordingly, we do not expressly interpret any other claim terms. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (claims are construed only to the extent necessary to resolve a dispute).

I. “clip”

Petitioner requests construction of the term “clip” as “a device that grips or holds.” Pet. 19. Citing a dictionary definition, 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. 1011). Petitioner argues that the Specification, consistent with the ordinary meaning, discloses that its clips are “configured to be coupled to a leaflet of the native valve” and that the clips may have features that “grip the leaflet.” *Id.* (citing Ex. 1001, 7:33–37, 9:8–13).

In the Decision on Institution, we set forth our preliminary construction of “clip” to mean “a device that grips or holds,” in view of the Specification and the proffered dictionary definition. Dec. Inst. 13 (citing Ex. 1001, 7:33–37, 9:8–13; Ex. 1011).

Patent Owner agrees with Petitioner’s proposed construction of “clip.” PO Resp. 16. After considering all evidence and arguments anew, we determine that it is proper to maintain our construction of “clip.”

2. *“facilitate”*

Petitioner argues that Patent Owner implicitly argues that “facilitate” means “induce movement of” or “pulls and pushes,” contrary to the plain meaning of “facilitate,” which Petitioner asserts is “to make easier; help bring about.” Prelim. Reply 3–4 (citing Ex. 1015).

In the Decision on Institution, we set forth our preliminary construction of “facilitate” to mean “to make easier, help bring about,” in view of the proffered dictionary definition and the Specification. Dec. Inst. 14 (citing, e.g., Ex. 1001, 2:66–67, 5:31–33, 8:2–4, 8:30–32, 8:37–40; Ex. 1015).

Patent Owner agrees with Petitioner’s proposed construction of “facilitate.” PO Resp. 16. After considering all evidence and arguments anew, we determine that it is proper to maintain our construction of “facilitate.”

D. Obviousness of Claims 1–3, 5, 6, 8, 11, and 16–21 over Goldfarb ’329

Petitioner contends that claims 1–3, 5, 6, 8, 11, 16–21 are obvious over Goldfarb ’329. Pet. 20–38. Patent Owner disagrees. See PO Resp. 17–36.

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. 1004, 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 10:19–21.¹¹

¹¹ According to Dr. Vesely, to perform a surgical mitral valve repair procedure known as an Alfieri stitch, a surgeon would open the heart and use sutures to attach the free edges of the mitral valve leaflets together, hence the “edge-to-edge” name of the procedure. Ex. 1003 ¶ 42. In certain cases, the surgeon would apply the sutures either at the center of the valve to create two smaller orifices (i.e., the “bow-tie” technique) or on the edge of the valve to reduce the valve’s overall orifice size. *Id.*

Figures 9A and 9B of Goldfarb '329 are reproduced below:

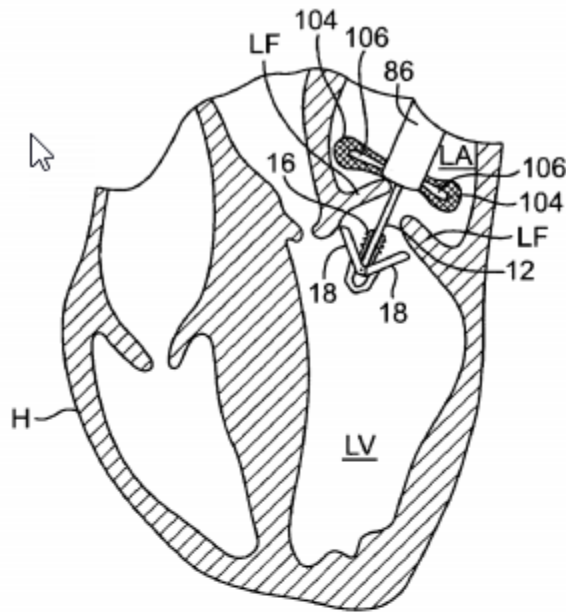


FIG. 9A

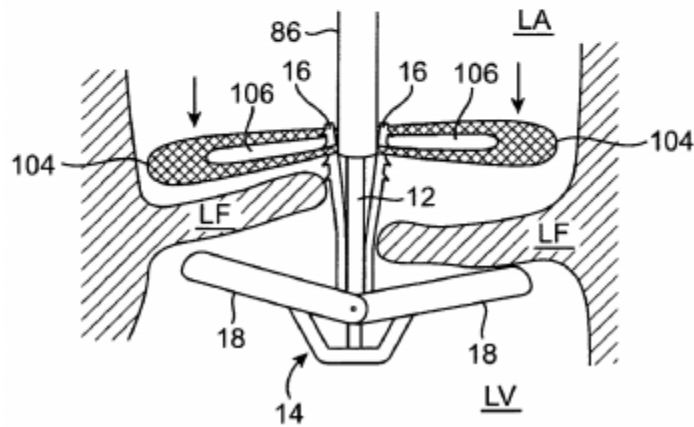


FIG. 9B

Figures 9A and 9B illustrate an embodiment of a device and its use which stabilizes heart valve leaflets by reducing their upward mobility and flailing. Ex. 1004, 6:58–59. As shown in Figure 9A, catheter 86 is advanced into a left atrium LA of a heart H and fixation device 14 is advanced through the

catheter 86 and through mitral valve MV having leaflets LF so that at least a portion of fixation device 14 is positioned within left ventricle LV. *Id.* at 17:22–26. Valve leaflets LF are shown flailing upwards toward the left atrium LA while fixation device 14 is extended into left ventricle LV. *Id.* at 17:26–28. One or more flaps 104 may extend radially outwardly from catheter 86, as shown, and be positioned against the atrial side of leaflets LF. *Id.* at 17:38–40.

As shown in Figure 9B, cutouts 106 of flaps 104 may be sized and positioned to allow proximal elements 16 of fixation device 14 to extend therethrough. *Id.* at 17:44–47. This allows the flaps 104 to be held against the atrial side of the leaflets LF restricting upward motion or flailing of the leaflets LF. *Id.* at 17:47–49. This positions the leaflets LF for optimal grasping between the proximal and distal elements 16, 18. *Id.* at 17:49–50. Once the leaflets have been grasped by elements 16, 18, the flaps 104 may be removed with the catheter 86 or may be left behind to assist in holding the leaflets LF. *Id.* at 17:51–53.

2. *Analysis of Independent Claim 1*

a) *Preamble: Apparatus for use at a native valve of a subject, the native valve including at least a first native leaflet and a second native leaflet*

Petitioner argues that Goldfarb '329 describes devices for grasping and stabilizing the two native mitral valve leaflets to treat mitral regurgitation. Pet. 20 (citing Ex. 1004, code (57); Ex. 1003 ¶ 68).

Patent Owner does not separately dispute Petitioner's contentions as to these recitations. See PO Resp. 18–31. We accept Petitioner's undisputed

“[o]ne or more flaps 104” [purple]. *Id.* (citing Ex. 1004, 17:38–40).

Petitioner asserts that the fixation device is an implant, as recited by the claim. *Id.* (citing Ex. 1003 ¶ 70). Petitioner asserts that Goldfarb ’329 states that flaps 104 may be positioned against the atrial side of the leaflets. *Id.* at 21–22 (citing Ex. 1004, 17:38–53, Fig. 9B).

Petitioner asserts that although Figures 9A and 9B appear to show elliptical flaps, the ’341 patent drawings are schematic and, as such, would not be construed by a person of ordinary skill as showing the exact shapes or proportions of the illustrated elements. Pet. 22–23 (citing *In re Wright*, 569 F.2d 1124, 1127–28 (CCPA 1977)). Petitioner asserts that the specification broadly teaches “the flaps 104 may have any suitable shape” and that “cutouts 106 may be sized and positioned to allow the proximal elements 16 of the fixation device 14 to extend therethrough.” *Id.* at 23 (citing Ex. 1004, 17:43–47). Petitioner argues, based on these teachings, that a person of ordinary skill would have found it obvious to implement annular flaps on the embodiment of Figures 9A and 9B. *Id.* (citing Ex. 1003 ¶ 73).

Patent Owner does not separately dispute Petitioner’s contentions as to these recitations. *See* PO Resp. 18–31.

We determine that Petitioner has shown that Goldfarb ’329 discloses that flaps 104 may be positioned against the atrial side of the leaflets. Ex. 1004, 17:38–53, Fig. 9B; Ex. 1003 ¶ 39 (blood to flow from the left atrium into the left ventricle).

As to the shape of the flaps, we determine that Petitioner has made an adequate showing that Goldfarb ’329 discloses or renders obvious annular flaps. *See* Ex. 1003 ¶¶ 71–76. In particular, Goldfarb ’329 discloses elliptical flaps with cutouts and discloses that flaps 104 may have any suitable shape. Ex. 1004, 17:43–47, Figs. 9A, 9B.

- c) *“implant” comprises “at least one leaflet clip:
(i) coupled to the annular portion”*

(1) *Parties’ Arguments*

(a) *The Petition*

In the Petition, Petitioner argues that Goldfarb ’329 inherently discloses the claim limitation “at least one leaflet clip: (i) coupled to the annular portion,” or, in the alternative, that Goldfarb ’329 renders the limitation obvious. Pet. 24 (citing Ex. 1003 ¶ 79). Petitioner argues that fixation device 14 includes flaps 104 that may be left behind with the fixation device to assist in holding leaflets LF. Pet. 25 (citing Ex. 1004, 17:51–53). Petitioner admits that Goldfarb ’329 does not expressly disclose how the flaps are coupled to the clips of the fixation device if they are left behind, but argues that the flaps must inherently be coupled to the clips for two reasons: (1) the flaps must be coupled to another structure to prevent them from drifting around the heart and (2) the only structure left in the heart after deployment is the fixation device comprised of two clips. *Id.* at 25–26 (citing Ex. 1003 ¶¶ 82–83).

Petitioner’s contentions are illustrated with further reference to the annotated figure below.

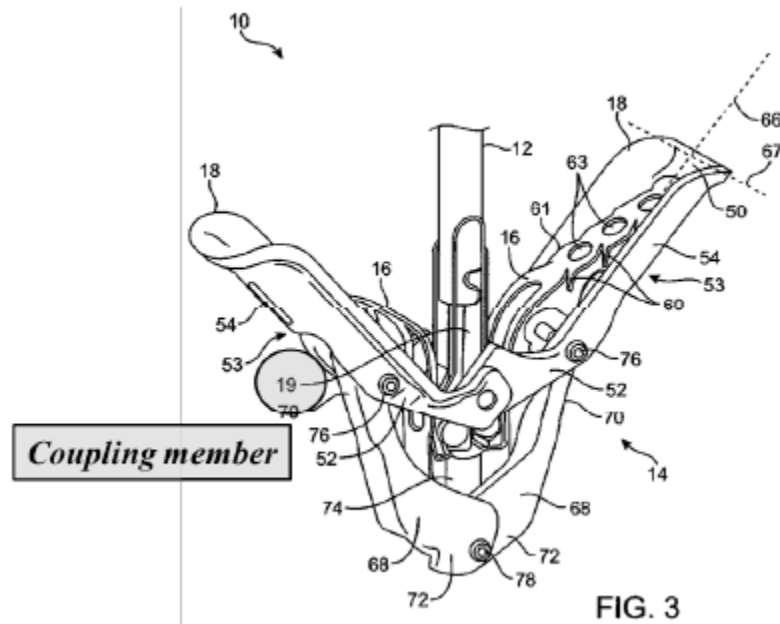


Figure 3 of Goldfarb '329 shows a fixation device and is annotated by Petitioner with a grayscale label for the device's coupling member 19. *See* Pet. 27. Petitioner asserts that the device's flaps could be directly coupled to its clips, or indirectly coupled to the clips through an intermediary portion of the fixation device, such as the coupling member 19 [gray], shown in annotated Figure 3. *Id.* at 26 (citing Ex. 1003 ¶ 83).

Petitioner argues that if the limitation is not inherently present, a person of ordinary skill would have nonetheless found it obvious to couple the flaps to the clips so that the entire apparatus could be detached and “left behind” together. Pet. 27 (citing Ex. 1003 ¶ 84). Petitioner argues that a person of ordinary skill would have been motivated to couple the flaps to the clips to ensure that the flaps remained securely anchored against the atrial side of the leaflets. *Id.* Petitioner argues that the flaps would not interfere with the function of the clips because the flaps have cutouts to accommodate the motion of the proximal elements. *Id.* (citing Ex. 1003 ¶ 84; Ex. 1004, 17:44–47).

Petitioner argues that a person of ordinary skill would have been motivated to couple the flaps to the clips (1) in order to simplify the device, (2) so that the flaps and clips would not require their own deployment (or retrieval mechanism), and (3) so that the physician could simultaneously detach the entire fixation device from the catheter. Pet. 27–28 (citing Ex. 1003 ¶ 85).

(b) *The Patent Owner Response*

Patent Owner responds that Goldfarb '329 never teaches or suggests attaching flaps 104 to the fixation device 14. PO Resp. 17.

Patent Owner also argues that attaching flaps 104 to the fixation device 14 would be counter to the independent movements and functions required of Goldfarb '329's device during the implantation procedure (as depicted in Figures 9A and 9B). PO Resp. 17. Patent Owner argues that doing so would change the basic principles under which Goldfarb '329 was designed to operate. *Id.* at 17–18 (citing *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984); *Microsoft Corp. v. Koninklijke Philips N.V.*, IPR2018-00185, Paper 7 at 12 (PTAB May 22, 2018)). Patent Owner asserts that Goldfarb '329's Figures 9A and 9B illustrate an “embodiment which stabilizes the valve leaflets LF by reducing upward mobility and flailing of the leaflets LF.” *Id.* at 18 (citing Ex. 1004, 17:20–22). Patent Owner argues that the intended function of flaps 104 is to reduce upward mobility of the leaflets prior to capture with distal elements 18 of fixation device 14 (citing Ex. 2004 ¶ 30), and that Figure 9A depicts at least a portion of fixation device 14 is positioned within a left ventricle LV (citing Ex. 1004, 17:22–26). PO Resp. 18. Patent Owner argues that in Figure 9B, flaps 104 are positioned to be held against the atrial side of the leaflets to restrict their upward motion or flailing and that this positions leaflets LF for optimal

grasping between proximal and distal elements 16, 18. *Id.* at 21 (citing Ex. 1004, 17:49–50).

Patent Owner argues that if flaps 104 and proximal/distal elements 16, 18 were coupled together, then they could not serve their respective intended functions to approach the leaflets LF from the left atrium (upstream side) to control flailing and to permit optimal grasping via distal elements 18 from the left ventricle (downstream side). PO Resp. 21 (citing Ex. 1004, 17:35–37, 17:47–53; Ex. 2004 ¶ 28). Patent Owner argues that if flaps 104 were coupled to the fixation device 14, this would be counter to the express disclosure of Goldfarb '329, and would mean that flaps 104 would be positioned with the fixation device in the ventricle, thereby rendering Goldfarb's flaps inoperable for their intended purpose of restricting upward motion or flailing of the leaflets. *Id.* at 22 (citing *Gordon*, 733 F.3d at 902; Ex. 2004 ¶ 30).

Patent Owner acknowledges that Goldfarb '329 also states “[o]nce the leaflets have been grasped, the flaps 104 may be removed with the catheter 86 or may be left behind to assist in holding the leaflets.” PO Resp. 23 (citing Ex. 1004, 17:51–53). Patent Owner states that this disclosure describes a surgeon's options as to whether to leave the flaps 104 behind or remove them following the grasping procedure, and argues that this disclosure forecloses the possibility that flaps 104 are coupled to fixation device 14 because if the flaps are coupled to the fixation device, then they are necessarily being left behind. *Id.*

Patent Owner argues that Dr. Vesely admitted at deposition that he did not study or consider this process by which the device of Goldfarb '329 is implanted in the patient, and appears not to have considered Figure 9A, or at

least not in sufficient detail to understand the figure. PO Resp. 23–25 (citing, e.g., Ex. 2010, 88:22–89:25).

Patent Owner argues that the state of the art prior to Goldfarb '329 provides ample evidence as to how annuloplasty and leaflet stabilizing devices are attached in the left atrium. PO Resp. 26. Patent Owner argues that Powell (Ex. 2003), a patent application including eight inventors common to Goldfarb '329 and filed within a few months after Goldfarb '329, shows how these same inventors attached a prosthetic ring 800 for controlling leaflet “flail” in the left atrium. PO Resp. 26–27. Patent Owner argues that St. Goar (Ex. 2001), which uses a clip 388 to clip leaflets to prevent mitral valve regurgitation, does not rely on a clip to attach an annulus restricting ring 500 to the leaflets, and instead secures the annuloplasty ring 500 to the valve annulus using sutures, staples, or tissue adhesives. *Id.* at 27 (citing Ex. 2004 ¶¶ 32–33). Patent Owner argues that Liska (Ex. 2002) describes a stabilizing element 14 performing the exact same function as Goldfarb '329's flaps 104 (i.e., preventing leaflet prolapse), and teaches attaching the outermost portion of the stabilizing elements 14 to the valve annulus 13 using sutures, staples, tissue adhesives and anchors/clips. *Id.* at 27 (citing Ex. 2004 ¶¶ 34–36). Patent Owner argues that Powell describes implanting prosthetic rings 900 having “flaps” 910 to prevent leaflet “flail” or “prolapse,” and similar to Liska, relies solely on anchors 920 to attach the outermost portion of the ring 900 to the valve annulus. *Id.* at 27–28 (citing Ex. 2004 ¶ 37). Patent Owner argues that common to all of these disclosures is the use of anchors, sutures, clips, staples and tissue adhesives to attach the outermost portions of a separate stabilizing device to the valve annulus of the left atrium as opposed to being coupled to a clip. *Id.* at 27–28 (citing Ex. 2004 ¶¶ 38–40).

Patent Owner argues that Petitioner fails to meet the standard for inherency, which is that the claimed feature necessarily results from the teachings of the reference, or that the flaps must be coupled to the portion of the device left behind. PO Resp. 28–29 (citing *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 960–61 (Fed. Cir. 2014)). Patent Owner argues that Goldfarb ’329 fails to identify any particular method of or location for attaching the flaps 104 so they may be left behind, and certainly fails to describe attaching the flaps 104 to the fixation device 14. PO Resp. 29. Patent Owner also argues that Petitioner’s inherency argument is rebutted by the existence of known techniques (the other art cited by Patent Owner) that shows how a person of ordinary skill would attach flaps 104 to the valve annulus using sutures, staples, tissue adhesives and anchors/clips. *Id.*

Regarding Petitioner’s alternative assertion of obviousness, Patent Owner argues that Petitioner only relies on conclusory statements from the Vesely Declaration and hindsight from the ’341 patent because Goldfarb ’329 provides no direction for a modification that couples the flaps to the clips directly or indirectly. *See* PO Resp. 29–31. Patent Owner argues that Petitioner’s basis for obviousness is unsupported and contradicts Goldfarb ’329 because the modifications would be counter to the express function and purpose of flaps 104 and ignore the knowledge of those skilled in the art that it is not obvious to attach a stabilizing element for leaflet flail to a clip. PO Resp. 31–34 (citing Ex. 2004 ¶ 45). Patent Owner further argues that Petitioner does not provide any rationale to support how the flaps would be coupled to the clips, and how such a coupling would not destroy the intended functions of these devices. *Id.* at 36.

(c) *Petitioner's Reply*

Petitioner replies that the ordinarily skilled artisan would have known that the safest, most practical, and simplest way to leave the flaps behind would have been to couple the flaps to the clips. Pet. Reply 17–18 (citing Ex. 1016 ¶¶ 15–34). Petitioner argues that a person of ordinary skill would have found it obvious to couple the flaps to the clips through coupling member 19 because the coupling member remains behind in the patient and would space the flaps a short distance from the proximal elements as illustrated in Figure 9B. *Id.* at 19 (citing Pet. 25–28; Ex. 1003 ¶¶ 82–85; Ex. 1016 ¶¶ 15–21). Petitioner acknowledges that Patent Owner's argument that Goldfarb '329's flaps cannot be coupled to the clips is based on Figures 9A and 9B, but argues that Figures 9A and 9B reflect only one embodiment. *Id.* at 19. Petitioner replies to Patent Owner's argument that independent movement of the flaps and fixation device precludes the flaps from being coupled to the clips. *Id.* at 21 (citing PO Resp. 18–26). Petitioner disagrees that Goldfarb '329 requires the flaps to move relative to the clips and argues that Figures 9A and 9B are not the only possible configuration. *Id.*

Petitioner also argues that Figure 9B of Goldfarb '329 alone illustrates a configuration where only a portion of the fixation device is positioned within the left ventricle. Pet. Reply 22 (citing Ex. 1004, 17:27–29, Figs. 9A and 9B; Ex. 1017, 45:20–48:15). Petitioner also argues that a person of ordinary skill would have known of two ways to implant the fixation device, as illustrated in Figure 9B, so that the flaps do not move relative to the clips and only a portion of the fixation device is positioned below the left ventricle. *Id.* (citing Ex. 1016 ¶¶ 24–27). First, Petitioner argues that a physician would have opened the distal elements in the left atrium and advanced the fixation device through the mitral valve until the distal

elements are in the left ventricle. *Id.* Second, Petitioner argues that the physician would have positioned the closed fixation device across the mitral valve and the opening of the elements would have deflected or pushed aside the leaflets and caused the elements to rest on the ventricular side of the leaflets. *Id.* (citing Ex. 1016 ¶ 25). Petitioner argues that the configuration of Figure 9B alone would have effectively restricted the leaflets, where Goldfarb '329 states that the cutouts allow flaps 104 to be held against the atrial side of the leaflets LF restricting upward motion or flailing of the leaflets because Goldfarb '329 states this in conjunction with “shown in Figure 9B.” *Id.* at 23 (citing Ex. 1004, 17:44–49).

Petitioner argues that even if Goldfarb '329 required the flaps to move with respect to the clips, a person of ordinary skill would have found it obvious to couple the flaps to a sliding collar or washer that could slide along and move the flaps towards the clips. Pet. Reply 24 (citing Ex. 2010, 160:23–161:19; Ex. 1017, 53:18–56:5). Petitioner argues that Goldfarb '329 incorporates by reference Goldfarb '267 (Ex. 1004, 2:13–18, 8:54–59), which discloses a “collar 131 [that] is slidably disposed over coupling member 19 and has an annular groove 133 on its inner wall configured to slide over and frictionally engage detents 135 on branches 19A, 19B.” *Id.* at 25–26 (citing Ex. 1005, 27:24–27, Fig. 22A). Petitioner argues that the delivery catheter would not have required any modification to push the collar and flaps towards the clips. *Id.* at 27 (citing Ex. 1016 ¶ 32).

Petitioner also argues that the collar could be made of a radiopaque material that would help the physician visualize the collar and determine when it had reached the fixation device. *Id.* at 28 (citing Ex. 1016 ¶ 33). Petitioner argues that the detailed description of this collar for use with similar fixation devices would have given a person of ordinary skill confidence that a

collar/washer would work with Figures 9A and 9B and such collars/washers are simple and predictable. *Id.* (citing Ex. 1016 ¶ 34).

Petitioner argues that Patent Owner's expert testified that the flaps should not be coupled to the mitral valve annulus because the flaps would interfere with the leaflets. Pet. Reply 29 (citing Ex. 1017, 128:16–132:9, 148:5–13, 158:16–22). Petitioner argues that, instead, Patent Owner's expert testified that the flaps should be coupled to the wall of the left atrium. *Id.* Petitioner argues that none of the references cited by Patent Owner disclose devices coupled to the atrial wall and Patent Owner's expert could not identify a single device that existed in August 2011 that could have been used to endovascularly anchor, suture, clip, staple, or adhere the flaps to the atrial wall. *Id.* (citing Ex. 1017, 103:15–106:22, 117:16–118:4, 132:10–135:14, 138:10–21).

Petitioner also argues that (1) Patent Owner's expert confessed that the methods and devices disclosed in Liska and Powell are not relevant to Goldfarb '329 (citing Ex. 1017, 164:18–166:1, 206:1–12); (2) Patent Owner's expert confirmed that none of the devices in St. Goar, Liska, or Powell include leaflet clips or treat mitral regurgitation by holding the leaflets together, as claimed in the '341 patent (citing *id.* at 99:2–100:5, 109:5–110:21, 121:10–123:2); (3) St. Goar, Liska, and Powell describe alternatives to the fixation devices described in Goldfarb '329 (citing Ex. 1016 ¶¶ 37–39); and (4) Liska distinguishes its procedures from the “edge-to-edge” repair technique in Goldfarb '329 (citing Ex. 2002 ¶¶ 7–8, 43). Pet. Reply 29–30.

Petitioner argues that a person of ordinary skill would have been discouraged from coupling flaps to the atrial wall because it would have required additional tools and catheters not disclosed in any reference of

record (citing Ex. 1016 ¶ 43); that Patent Owner has not shown that a required stapler existed in August 2011 (citing Ex. 1016 ¶¶ 41–42; Ex. 1017, 103:14–104:12, 132:10–135:14, 138:10–140:4, 145:5–21); a physician would have had to release the fixation device and withdraw the delivery shaft from the catheter to make room for additional tools (citing Ex. 1016 ¶¶ 43–44; Ex. 1017, 135:10–137:7); and the level of difficulty would have been higher and not recommended (citing Ex. 1017, 146:1–20, 151:18–153:4). Pet. Reply 30–31.

Petitioner asserts that Dr. Vesely understood the purpose of the flaps in Goldfarb '329 was to stabilize the leaflets and testified that he could not recall if his declaration included Figure 9A, but did not testify that he did not consider or understand Figure 9A. Pet. Reply 32–33 (citing, e.g., Ex. 2010, 88:22–89:10, 95:7–11).

(d) Patent Owner's Sur-reply

In its sur-reply, Patent Owner argues that Petitioner has not provided any reference or other information to suggest coupling a leaflet stabilizer to a heart implant, and relies on improper hindsight because the only suggestion to couple a leaflet stabilizer to an implant comes from the '341 patent. PO Sur-reply 1. Patent Owner argues that Goldfarb '329 provides no discussion, even generally, as to how the flaps 104 may be left behind, including how they would be detached from the catheter 86, where the detached flaps would be left behind, or how the flaps would be secured at this unknown location. *Id.* at 3. Patent Owner argues that Petitioner has been unable to provide any evidence suggesting that “leaflet stabilizing” devices can be coupled to a “fixation device” or that such a connection would be technically feasible. *Id.* at 4.

Patent Owner argues that Dr. Sacks did not say that Liska and Powell are not relevant and instead explained that although these references are not using or doing “exactly the same thing,” as Goldfarb ’329, Liska and Powell are still relevant because they show how a POSITA would use these multiple anchoring techniques to attach the flaps 104 of Goldfarb ’329. PO Sur-reply 4–5 (citing Ex. 1017, 164:18–166:1, 206:1–16).

Patent Owner also disagrees with Petitioner’s contention that Dr. Sacks testified that flaps should not be coupled to the mitral valve annulus because they would interfere with the leaflets. PO Sur-reply 5. Patent Owner argues that Dr. Sacks merely testified that flaps could be attached anywhere in the left atrial chamber at a position that does not block a pulmonary artery or vein, and that does not interfere with the operation of the leaflets, and that when portions of the flaps attached to the mitral valve annulus may potentially interfere with the motion of the leaflets, other portions of the atrial wall may be used. *Id.* at 5–6 (citing Ex. 1017, 129:4–12, 131:2–5, 131:14–132:9).

Patent Owner also argues that Petitioner is unable to distinguish Patent Owner’s evidence that it was conventional wisdom to attach leaflet stabilizers within the left atrium. *Id.* at 1.^{13, 14}

¹³ Patent Owner also argues that Petitioner’s own publications and commercial product discussed in Exhibits 2016–2019 show the robustness of anchoring mechanisms in the heart. PO Sur-reply 1, 6–13. However, in addressing Petitioner’s Motion to Strike, we only admit Exhibits 2016 and 2017 for the limited purpose of understanding the deposition transcript and we grant the Motion to Strike Exhibits 2018 and 2019 submitted for the first time with the Sur-reply as violating 37 C.F.R. § 42.23(b). *See infra*, Section III.

¹⁴ Patent Owner argues that Petitioner improperly relies on a new theory of obviousness in its Reply Brief when it relies on collar 131 of Goldfarb ’267

Patent Owner also argues that Goldfarb '267 never teaches using collar 131 to attach ancillary devices to a fixation device and that collar 131 has a different function, i.e., to actuate features branches 19A and 19B between a separated position and contact position. PO Sur-reply 13–14, 16 (citing Ex. 1005, 27:42–52). Patent Owner argues that Petitioner has not shown that collar 131 would be stable for holding flaps 104 and that there is no logical basis to modify collar 131 from its described functionality to a new functionality to attach flaps 104. *Id.* at 17.

Patent Owner argues that at his deposition, Dr. Sacks testified that flaps 104 could be connected to washers so that they may be pushed out and then retracted into the catheter. PO Sur-reply 14–15 (citing Ex. 1017, 55:8–17). Patent Owner emphasizes that Dr. Sacks only testified that a washer could attach the flaps to the catheter but not to the clip, and also only

to attach the flaps, and that Goldfarb '267 had previously only been relied on for dependent claims 3 and 10. PO Sur-reply 13–15 (citing 37 C.F.R. § 42.23(b); *Intelligent Bio-Sys. v. Illumina Cambridge*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016); *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015); *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 705 (Fed. Cir. 2020)). Patent Owner argues that this is a completely new portion of Goldfarb '267 and is not just a new rationale but a new combination. *Id.* at 14. In Section IV *infra*, we determine that Dr. Vesely's testimony is a permissible response to Dr. Sack's testimony, and for the same reason we determine that the corresponding argument in Petitioner's Reply is a permissible response to the Patent Owner Response. *See Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 706 (Fed. Cir. 2020) (“[A]ny ambiguity as to whether Apple raised a new argument on reply is eliminated when we consider whether Apple's reply arguments are responsive to arguments raised in Andrea's Patent Owner Response. As we have regularly held, ‘the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.’”).

testified about a washer and did not testify about a collar. *Id.* at 14–15 (citing Ex. 1017, 58:11–22).

(e) *Petitioner’s Supplemental Brief*

In its Supplemental Brief, Petitioner argues that the Parties have only ever discussed two, finite options for leaving Goldfarb ’329’s flaps behind: (1) coupling the flaps to the clips and (2) leaving the flaps uncoupled from the clips and attaching them to heart tissue. Pet. Supp. Br. 1. Petitioner concedes that the specific phrase “finite number of options” does not appear in Petitioner’s briefs addressing the flaps, but argues that the evidence demonstrates only two possible options. *Id.* (citing *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020)). Petitioner also cites *Intellectual Ventures II* for the holding that the absence of “magic words” for an obviousness argument was immaterial. *Id.* (citing *Intellectual Ventures II LLC v. FedEx Corp.*, No. 2:16-CV00980-JRG, 2019 WL 1434656, at *12 (E.D. Tex. Mar. 29, 2019)).

Petitioner maintains that it does not believe that Patent Owner’s option (i.e., leaving flaps uncoupled from the clips and attaching them to the heart) would yield predictable results. Pet. Supp. Br. 1, 2 (citing Pet. Reply 3, 17). Nevertheless, Petitioner argues that if the Board determines that both options would yield predictable results then at most the evidence shows that a person of ordinary skill would have had two options with predictable results to leave the flaps behind. *Id.* at 1.

Petitioner also points to the testimony of its expert, Dr. Vesely, that one rationale for modifying a reference included “choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.” Pet. Supp. Br. 2 (citing Ex. 1003 ¶¶ 26, 27).

Petitioner states that, in arguing that Goldfarb '329 inherently disclosed the limitation, Petitioner argued in the Petition that a person of ordinary skill in the art would have had one option with predictable results for safely leaving the flaps behind, i.e., coupling the flaps to the clips. Pet. Supp. Br. 2 (citing Pet. 25–27). Petitioner explains that it argued in the Petition that a person of ordinary skill would have found it at least obvious to do so, and also indicated that if the clips were uncoupled they would require their own deployment mechanism, with added complexity. *Id.* at 2–3 (citing Pet. 27–28). Petitioner states that its Reply argued that coupling the flaps to the clips was the “safest, most practical, and simplest way to leave the flaps behind” (citing Pet. Reply 17–18, 24–28, 32) and that it argued that Patent Owner’s proposal was “unpredictable.” *Id.* at 3–4 (citing PO Resp. 3, 17, 28–32).

(f) *Patent Owner’s Supplemental Brief*

In its Supplemental Brief, Patent Owner argues that Petitioner failed to preserve an “obvious to try” ground in its Petition, Reply, or Opposition to Patent Owner’s Motion to Amend. PO Supp. Br. 1. Patent Owner argues that Petitioner consistently argued that if the flaps 104 were left behind, then a person of ordinary skill would necessarily couple them to the fixation device but did not argue that a person of ordinary skill would pursue a finite number of identified, predictable options. *Id.* Patent Owner argues that Petitioner argued that the various procedures presented by Patent Owner were “unpredictable,” and too “dangerous” and “complex” to implement. *Id.* at 1–2 (citing Pet. 3, 9, 17, 30–32; Ex. 2016¹⁵ ¶¶ 17, 40–49) (emphasis

¹⁵ It appears that Patent Owner intended to cite Exhibit 1016 (the Vesely Reply Declaration) instead of Exhibit 2016. *See* PO Supp. Br. 4.

omitted). Patent Owner argues that Petitioner and its expert, Dr. Vesely, characterized the prior art for securing leaflet stabilizing devices to the heart as involving “unpredictable” and “unproven” methods. *Id.* at 4 (emphases omitted).

Patent Owner argues that Petitioner’s reliance on *Uber* is misplaced because in that case, the record included two actual prior art references, one which expressly disclosed “server-side plotting” and one which expressly disclosed “terminal-side plotting,” and thus both options were well known in the art, and were the only two identified, predictable solutions. PO Supp. Br. 4 (citing *Uber*, 957 F.3d at 1339). Patent Owner argues that here Petitioner failed to present any prior art teaching of coupling a leaflet stabilizing element to a fixation device. *Id.* at 4–5.

Patent Owner acknowledges that *KSR* permits an obviousness finding when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions. PO Supp. Br. 5 (citing *KSR*, 398 U.S. at 421). Patent Owner argues that even if Petitioner has preserved an obvious to try argument, *In re Kubin* precludes reliance on the vague phrase “may be left behind” in Goldfarb ’329 as a basis for an “obvious to try” argument. *Id.* (citing *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009)). Patent Owner argues that the Federal Circuit in *Kubin* established it is erroneous to rely on the obvious to try doctrine (1) “where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful” or where what was obvious was (2) “to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *Id.* (citing *Kubin*, 561 F.3d at 1359–60).

Patent Owner argues that the phrase “may be left behind” is devoid of any parameters or direction and that where the prior art suggested leaving behind a stabilizing element, it exclusively suggested coupling that stabilizing element directly to the valve annulus. *See* PO Supp. Br. 5. Patent Owner argues that Petitioner fails to provide any evidence that coupling the flaps to the fixation device of Goldfarb ’329 is “identified” or “predictable.” *Id.* Patent Owner argues that Petitioner presented no evidence that it was known and identifiable to a person of ordinary skill to couple flap 104 to fixation device 14, and a person of ordinary skill would not have done so because there would not be independent movement between the flaps and the fixation device as depicted in Figures 9A and 9B. *See id.* at 6.

Patent Owner argues that the only identified potential solutions in the prior art are Liska and Powell, which teach using sutures, staples, anchors, or clips to attach leaflet stabilizers directly to the mitral valve annulus. PO Supp. Br. 6. Patent Owner also argues that a person of ordinary skill would not be faced with a binary choice but rather with a plethora of options. *Id.* at 6–7.

Finally, Patent Owner argues that collar 131 in Goldfarb ’267 is used as an actuator, a completely different function from an attachment point for attaching structure such as flaps to a fixation device. PO Supp. Br. 7 (citing Ex. 1005, 27:46–48).

(2) *Analysis*

The dispute with regard to this ground arises because Goldfarb ’329 states that it is possible to leave flaps 104 “behind” (Ex. 1004, 17:51–53), but does not explain how flaps 104 would be left behind. Patent Owner’s expert agreed with Petitioner that flaps 104 would have to be attached to

something so that they do not just drift around if they are left behind. *See* Pet. 25–26; Ex. 1017, 69:11–70:8.

In the first instance, we are unpersuaded by Petitioner’s argument that Goldfarb ’329 inherently discloses coupling flaps 104 to fixation device 14. *See* Pet. 25–26. Figures 9A and 9B of Goldfarb ’329 show independent movement between the flaps 104 and fixation device 14. Contrary to Petitioner’s position, Figures 9A and 9B depict a single embodiment. *See* Ex. 1004, 17:20 (“FIGS. 9A-9B illustrate another embodiment”). Thus, it is not necessarily the case that flaps 104 are coupled to fixation device 14 in this embodiment. *Compare* Ex. 1004, Fig. 9B, *with id.* at Fig. 9A.

Petitioner argues that Figures 9A and 9B are schematic (Pet. 23, 26), but we cannot ignore the clear teaching of the drawings. *See In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972). Further, Goldfarb ’329 discloses, with respect to Figure 9A, that “valve leaflets LF *are shown* flailing upwards toward the left atrium LA while the fixation device 14 resides below the valve, within the left ventricle LV.” Ex. 1004, 17:27–29 (emphasis added).

Further, Petitioner did not eliminate the possibility that a person of ordinary skill could have attached the flaps to the heart wall, as Dr. Sacks testified in his deposition. *See* Ex. 1017, 130:9–13.¹⁶

¹⁶ *See infra* discussion in note 17 and accompanying text. We do not decide whether a person of ordinary skill would have been able to attach the flaps to the heart wall; we only decide that Petitioner did not show, for purposes of proving inherency or otherwise, that a person of ordinary skill would not have attached the flaps to the heart wall (*see* Pet. Reply 29; *see also* Pet. 25–26). However, we note the testimony of Dr. Vesely that “[i]f the flaps were uncoupled from the clips, each element (flaps and clips) would require its own deployment (or retrieval) mechanism, thereby increasing the overall complexity of the device.” Ex. 1003 ¶ 43; *see also* Ex. 1016 ¶ 17 (Dr. Vesely opining that no person of ordinary skill would have adopted the

Therefore, we conclude that Goldfarb '329 does not inherently disclose that the flaps are coupled to the clips, as recited by the claim.

However, Petitioner also argues that it would have been obvious to couple flaps 104 to fixation device 14 based on the teaching in the disclosure of Goldfarb '329 that the flaps “may be left behind.” Ex. 1004, 17:52. Even though it is not disclosed in Figures 9A and 9B, this additional statement in Goldfarb '329 may reveal elements of Goldfarb '329's teachings to a person of ordinary skill that are not illustrated in its figures.

Patent Owner relies on its own prior art references (e.g., Liska and Powell) to argue that a person of ordinary skill would have left flaps 104 behind by attaching them to the heart valve annulus, but Petitioner argues that this would have been too complex a procedure for it to have been an option for such an ordinarily skilled artisan. *See* Pet. Reply 17; Pet. Supp. Br. 3. Although Petitioner has successfully cast doubt on Patent Owner's argued procedure for valve repair,¹⁷ Patent Owner does not bear the burden of proof on this issue.

methods of St. Goar, Liska, and Powell or at least not selected them over coupling the flaps to the fixation device, and explaining that the interchanging of catheters would have required additional time and greater risk of complication). Nevertheless, we decide that, even assuming that one option for a person of ordinary skill was to attach the flaps to the heart wall, it would have also been obvious to attach the flaps to the fixation device as a predictable option out of a number of options.

¹⁷ Patent Owner relied on St. Goar, Liska, and Powell for the proposition that material can be anchored, sutured, stapled, or clipped to the mitral valve annulus. PO Resp. 27–28 (citing Ex. 2004 ¶¶ 32–40). However, Patent Owner's own expert testified that the flaps should not be coupled to the mitral valve annulus. Ex. 1017, 128:16–132:9, 148:5–13, 158:16–22. Instead, Patent Owner's expert testified that the flaps should be coupled to the wall of the left atrium. *Id.* Patent Owner's expert also refused to answer

Although Petitioner did not make this argument *in haec verba*, we understand Petitioner essentially to argue that there would have been a finite number of ways to leave the flaps behind (as taught by Goldfarb '329), i.e., to couple the flaps to the clips or to attach the flaps to the heart tissue, with the caveat that Petitioner views the former method as predictable and Petitioner expresses skepticism about this latter method. Petitioner argues that if flaps 104 are left behind, then they must necessarily be coupled to clips 16, 18. Pet. 25–26. Petitioner then proceeds to argue:

If the limitation is not inherent, a POSITA would have found it obvious to couple the flaps to the clips so that the entire apparatus could be detached and “left behind” together. ([Ex. 1003], ¶84.) A POSITA would have been motivated to couple the flaps to the clips to ensure that the flaps remained securely anchored against the atrial side of the leaflets for the reasons explained above. (*Id.*)
...

... *If the flaps were uncoupled from the clips*, the flaps and clips would require their own deployment (or retrieval) mechanism, thereby increasing the complexity of the device. ([Ex. 1003 ¶ 85]). *A POSITA would have been motivated to couple the flaps* so that the physician could simultaneously detach the entire fixation device from the catheter, as this would be the simplest implementation of the system. (*Id.*)

Pet. 27–28 (emphasis added).

In its Reply, Petitioner argues that:

A POSITA would have known of at least two ways to implant the fixation device, as illustrated in Figure 9B, so that the flaps do not move relative to the clips and only a portion of

questions (as beyond the scope of his declaration) as to how a doctor would have held the flaps 104 steady before stapling them. *See id.*, 140:2–11. Patent Owner’s expert also agreed that none of the devices in St. Goar, Liska, or Powell include leaflet clips to treat mitral regurgitation by holding the leaflets together, as claimed in the '341 patent. *See id.*, 100:2–5, 110:14–110:21, 123:16–123:2.

the fixation device is positioned in the left ventricle. (Ex. 1016, ¶¶24-27.) In the first way, the physician opens the distal elements in the left atrium and advances the fixation device through the mitral valve until the distal elements are in the left ventricle. (*Id.*) To pass the fixation device through the valve, the physician rotates the device so that the distal elements are perpendicular to the long edges of the leaflets. (*Id.*) This technique is used to implant the MitraClip and was well known before August 2011. (*Id.*; *see also* Ex. 2007, 2 (describing MitraClip implantation).)

In the second way, the physician positions the closed fixation device across the mitral valve. (Ex. 1016, ¶25.) Due to the shape of the distal elements, opening the elements deflects (or pushes aside) the leaflets and causes the elements to rest on the ventricular side of the leaflets. (*Id.*)

Pet. Reply, 22.

Petitioner argues that a person of ordinary skill in the art would have coupled Goldfarb '329's flaps 104 to clips 16, 18 directly or indirectly via coupling member 19. Pet. 26. Petitioner also argues that a person of ordinary skill would have coupled flaps 104 to collar 131 of Goldfarb '267, which it argues was incorporated by reference into Goldfarb '329. Pet. Reply 25. Petitioner states that: "collars/washers are simple and predictable. ([Ex. 1016 ¶ 34.]) A POSITA would have been familiar with, and used, collars and would have had confidence that they would function as expected. (*Id.*)."

Id. at 28.

Thus, based on the arguments in the Petition and the Reply, we understand Petitioner to argue that a person of ordinary skill would have found it obvious to have coupled the flaps directly to the clips or indirectly via coupling member 19 or collar/washer 131 of Goldfarb '267. Petitioner argues that a person of ordinary skill would have been motivated to do so so that the flaps remained securely anchored against the atrial side of the leaflets. Pet. 27. Petitioner also argues that the use of a collar/washer would

have been predictable. Pet. Reply 28. Therefore, even though Petitioner did not make the argument *in haec verba*, we understand Petitioner to have essentially argued that there would have been a finite number of options with predictable results. To the extent that Petitioner did not cast its argument as such, we understand Petitioner's argument as expressing skepticism that a person of ordinary skill would have left the flaps uncoupled to the clips and, instead, coupled to the heart tissue. Thus, although Petitioner outlined a limited number of options for a person of ordinary skill in its primary briefing, it viewed the option of leaving the flaps uncoupled entirely as not a viable option at all, further viewed coupling the flaps to heart tissue (as argued by Patent Owner) as unproven and unpredictable option, and also viewed coupling the flaps to the clips as a predictable and obvious option. *See, e.g.*, Pet. Supp. Br. 3–4. We determine that Petitioner's wording of its argument was therefore reasonable and does not detract from the fact that, overall, there were a limited number of options, at least one of which Petitioner views as predictable.

Has Petitioner Shown a Finite Number of Predictable Options

We then turn to the merits of whether the modification of Goldfarb '329 to couple the flaps to the clips would have been obvious by reason of there being a finite number of options with predictable results. *See KSR*, 550 at 421 (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.”).

Goldfarb '329 itself describes that once the leaflets have been grasped, the flaps 104 may be removed with the catheter 86 or may be left behind to assist in holding the leaflets LF. Ex. 1004, 17:47–53.

Patent Owner argues that the Federal Circuit in *Kubin* established it is erroneous to rely on the obvious to try doctrine (1) “where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful” or where what was obvious was (2) “to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” PO Supp. Br. 5 (citing *Kubin*, 561 F.3d at 1359–60). However, we do not agree with Patent Owner that there are many possible choices. Rather, Petitioner has argued that a person of ordinary skill would have (1) directly coupled the flaps to the clips, or coupled the flaps (2) to coupling member 19 or (3) to collar 131, and (4) Petitioner disputes Patent Owner’s argument that a person of ordinary skill would have coupled the flaps to the valve annulus. One might even reduce this to two options, i.e., that a person of ordinary skill, if leaving them behind in the heart, would have coupled the flaps (1) to the fixation device or (2) to the heart tissue.

Indeed, the claim recites that the clip is “coupled to the annular portion.” It is undisputed that Goldfarb '329’s flaps constitute or suggest an “annular portion” and it is undisputed that the “coupl[ing]” may occur directly or indirectly. The claim does not differentiate between possible attachment points for the flaps on the fixation device so long as the flaps are coupled to the clips.

We also do not agree with Patent Owner that Goldfarb '329’s disclosure that the flaps may be left behind is simply a suggestion for

experimentation because Goldberg '329 appears to express this teaching as a fact rather than a suggestion for experimentation, and Petitioner's expert indicates that a person of ordinary skill would have "recognized" the options for how to leave the flaps behind. *See* Ex. 1003 ¶ 81; *see also* Ex. 1016 ¶¶ 29–34.

Patent Owner also attempts to distinguish *Uber*, in which there were a finite number of options on the basis that those options were disclosed in prior art references. However, we do not read the *Uber* opinion as limiting the doctrine of a finite number of options to the fact pattern where the options are disclosed in prior art references. The *Uber* opinion states that "[t]he record reflects only two possible methods of achieving this." 957 F.3d at 1339. As in *Uber*, we determine that there are two basic options for leaving the flaps behind, i.e., coupling the flaps to the fixation device or to the heart. The *Uber* opinion also states that "[t]he Supreme Court has 'set forth an expansive and flexible approach' to 'the question of obviousness'" and observes that "[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability" and that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *Id.* at 1338–39 (citing *KSR*, 550 U.S. at 417, 421).

Patent Owner argues that Petitioner fails to provide any evidence that coupling the flaps to the fixation device of Goldfarb '329 is "predictable." PO Supp. Br. 5. However, Dr. Vesely testified that a "person of ordinary skill in the art would have understood that the flaps could be coupled to the clips using well-known and predictable mechanisms common to medical devices, such as pins, hinges, screws, washers, collars, and rods." Ex. 1016 ¶ 21; *see also id.* ¶ 34. Dr. Vesely reasons, with respect to the spacing of the flaps, and also as part of his analysis for reasonable expectation of success,

that flaps have cutouts to accommodate the motion of the proximal elements so that a person of ordinary skill would not have expected the flaps to interfere with the function of the clips. Ex. 1016 ¶ 21 (citing Ex. 1004, 17:44–47).

We determine that, in view of the instruction in Goldfarb ’329, that the flaps may be left behind, a person of ordinary skill would have understood that there were a finite number of options for implementing this, and that it would have been predictable to attach the flaps to coupling member 19 of Goldfarb ’329 or collar 131 of Goldfarb ’267.¹⁸

We determine that a person of ordinary skill would have found it obvious to attach the Goldfarb ’329 flaps to coupling member 19, as one of a finite number of predictable options to “leave the flaps behind,” as described by Goldfarb ’329 in an unillustrated embodiment. Dr. Vesely explains that, contrary to Patent Owner’s contentions, a person of ordinary skill would not have been precluded from attaching the flaps to coupling member 19 even if there were no independent movement between the flaps and the clips. Dr. Vesely explains that a person of ordinary skill would have known of two ways to implant such a device, either (1) by rotating the device as was done with the MitraClip device (citing Ex. 2007), or by opening the distal elements to deflect the leaflets and cause the distal elements to end up on the ventricular side of the device. Ex. 1016 ¶¶ 24–25.¹⁹

¹⁸ Patent Owner does not dispute that Goldfarb ’329 incorporates by reference the pertinent part of Goldfarb ’267, i.e., the embodiment with collar 131. Indeed, Goldfarb ’329 states that it incorporates the application that led to Goldfarb ’267 (i.e., U.S. Application No. 10/441,531) “for all purposes.” Ex. 1004, 2:13–18, 8:54–59; *see* Ex. 1005, code (21).

¹⁹ Although Dr. Vesely states that this is the configuration of Figure 9B of Goldfarb ’329, we understand this to be an unillustrated embodiment, which

Although we do not determine that it is necessary to rely on the embodiment in Goldfarb '267, we determine that a person of ordinary skill would have also had the predictable option of attaching the flaps to collar 131. Although we agree with Patent Owner that this would have added to the function of collar 131, a person of ordinary skill would have done so based on the suggestion in Goldfarb '329 to leave the flaps behind. Using collar 131 as an attachment point for the flaps would have had the benefit of allowing independent movement of the flaps and the clips because it is slidable. *See* Ex. 1016 ¶ 29; *see also id.* ¶¶ 31–33.

We are persuaded by Petitioner that it would have been simpler when leaving the flaps behind in the heart post-procedure, as suggested by Goldfarb '329, to attach the flaps to coupling member 19 or collar 131 rather than to attach the flaps to the heart tissue. *See* Ex. 1016 ¶ 17 (“If the flaps were uncoupled from the clips, each element (flaps and clips) would require its own deployment (or retrieval) mechanism, thereby increasing the overall complexity of the device.”); *see also id.* ¶ 41 (“Even today, there is a paucity of commercially available devices that provide endovascular stapling or suturing. I am aware of suture-based chordal repair techniques, but the procedures are performed through a transapical approach. There are also endoscopic and laparoscopic staplers on the market, but these staplers are not designed for deployment through the patient’s vasculature into the heart, like the fixation devices in Goldfarb '329.”); ¶ 43 (“The process of swapping catheters, removing components, inserting new components, and

may share features with the configuration of Figure 9B of Goldfarb '329, i.e., where only a portion of the fixation device is positioned within the left ventricle. This is because we understand Figure 9B to be part of the same embodiment as Figure 9A of Goldfarb '329. *See* Ex. 1004, 17:20.

repositioning the catheters to find the target site would have discouraged a person of ordinary skill in the art from adopting the procedures advocated by Dr. Sacks.’); ¶ 44 (“The longer the procedures last, the more risk to the patient.”).

We, therefore, determine that a person of ordinary skill would have found it obvious to have attached the flaps to the clips of Goldfarb ’329, via either coupling member 19 or collar 131, as a predictable option when choosing to leave the flaps behind.

d) “at least one leaflet clip ... (ii) comprising: at least two clip arms, movable with respect to each other to open and close the clip; and a clip controller interface, the clip-controller interface being coupled to at least one of the clip arms”

Petitioner argues that each proximal element (16) and its corresponding distal element (18) forms a clip with two clip arms. *See* Pet. 28 (citing Ex. 1003 ¶ 87). Petitioner argues that the proximal elements move with respect to the distal elements to open and close the clips. *Id.* (citing Ex. 1004, 17:29–37). Petitioner argues that Goldfarb ’329 satisfies the “clip-controller interface” limitation in two ways: (1) through a distal clip-controller interface and (2) through a proximal clip-controller interface. *Id.* at 29–33 (citing Ex. 1003 ¶ 88).

Petitioner argues that Goldfarb ’329 discloses that the physician controls distal elements 18 with an actuator rod 64 (“a clip controller”) and an actuation mechanism 58. *Id.* at 29–30 (citing Ex. 1004, 12:53–63). Petitioner argues that actuator rod 64 attaches directly to base 69 of actuation mechanism 58, or to stud 74 connected to base 69. *Id.* at 30 (citing Ex. 1004, 12:56–62). Petitioner argues that pushing or pulling actuator rod

64 causes actuation mechanism 58 to open and close distal elements 18. *Id.* (citing Ex. 1004, 13:1–18, 14:8–26).

Petitioner argues that the physician controls movement of the proximal elements 16 with proximal element lines 90 (where each is a “clip controller”). *Id.* at 32 (citing Ex. 1004, 13:20–24). Petitioner argues that proximal element line 90 may pass through line loop 48 (a “clip–controller interface”) attached to the proximal element. *Id.* at 32 (citing Ex. 1004, 13:24–50). Petitioner argues that Goldfarb ’329 also discloses that the proximal element line could attach to the proximal element by “detachable means” (other “clip-controller interface[s]”) like hooks, snares, clips, or breakable couplings. *Id.* at 32–33 (citing Ex. 1004, 13:37–50.)

Patent Owner does not dispute Petitioner’s contentions as to these recitations. *See* PO Resp. 18–31. We accept Petitioner’s undisputed assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

e) “at least one leaflet clip ... (iii) configured: to be coupled to a portion of the first native leaflet by the clip arms being brought together to close around the first native leaflet, to be coupled to a portion of the second native leaflet by the clip arms being brought together to close around the second native leaflet, and to hold together the portion of the first leaflet and the portion of the second leaflet”

Petitioner argues that Goldfarb ’329 discloses that first and second clips, comprised of a proximal and distal element, hold together portions of the first and second valve leaflets LF. Pet. 33–34 (citing Ex. 1003 ¶ 97).

Patent Owner does not dispute Petitioner’s contentions as to these recitations. *See* PO Resp. 18–31. We accept Petitioner’s undisputed

assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.²⁰

f) “a delivery apparatus, configured to deliver the implant to the native valve, and comprising at least one clip controller, the at least one clip controller being reversibly coupled to the clip-controller interface, and configured to facilitate opening and closing of the clip, and the delivery apparatus being intracorporeally decouplable from the implant”

Petitioner argues that Goldfarb ’329 discloses a delivery apparatus having catheter 86 and shaft 12, where the fixation device 14 is delivered to the valve through the catheter, and “is releasably attached to the shaft 12.” Pet. 35–36 (citing Ex. 1004, 9:14–15; 10:29–33, 12:60–67, 17:51–53). Petitioner asserts that once the fixation device has grasped the leaflets, the delivery apparatus is intracorporeally decoupled from the fixation device. *Id.* at 36 (citing Ex. 1004, 9:14–15, 10:29–33, 12:60–67, 17:51–53; Ex. 1003 ¶ 100). Petitioner asserts, with respect to control of the distal element, that pushing or pulling the actuator rod 64 causes the actuation mechanism 58 to open and close the distal elements 18. *Id.* at 36 (citing Pet. § VII.A.1.d.(1)). Petitioner argues that Goldfarb ’329 discloses that the rod 64 and stud 74 (a part of the actuation mechanism) “may be joined by any mechanism which is releasable to allow the fixation device 14 to be detached from shaft 12.” *Id.* at 37 (citing Ex. 1004, 12:62–67).

Petitioner asserts, with respect to control of the proximal element, that the physician can control movement of the proximal elements 16 with proximal element lines 90. *Id.* (citing Pet. § VII.A.1.d.(2)). Petitioner

²⁰ Because claim 1 recites “at least” one clip, we understand that this limitation may be met by two clips. This is consistent with the Specification of the ’341 patent. *See* Ex. 1001, 21:62–67, Figs. 6A–6B.

asserts that the physician may decouple each proximal element line by releasing one end of the line and pulling it through the catheter, or by applying sufficient tension to break the detachable means. *Id.* at 38 (citing Ex. 1004, 13:19–50.)

Patent Owner does not dispute Petitioner’s contentions as to these recitations. *See* PO Resp. 18–31. We accept Petitioner’s undisputed assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

g) Summary of Claim 1

Based on our analysis as set forth above we determine that Petitioner has established by a preponderance of the evidence that independent claim 1 of the ’341 patent would have been obvious over Goldfarb ’329.

3. Analysis of Dependent Claims 2, 3, 5, 6, 8, and 18–21

Claims 2, 3, 5, 6, 8, and 18–21 depend directly from claim 1. Petitioner argues that Goldfarb ’329 also describes the limitations introduced in each of these respective dependent claims and supports its argument with citations to specific portions of Goldfarb ’329 and testimony from Dr. Vesely. Pet. 39–48, 67–73 (citing, e.g., Ex. 1003 ¶¶ 107–131, 184–199). Other than its arguments over the subject matter of claim 1 incorporated into these dependent claims, which is discussed above, Patent Owner proffers no argument that Goldfarb ’329 fails to describe the limitations of these dependent claims. PO Resp. 18–31 (arguing only alleged failure of Goldfarb ’329 to describe elements of independent claim 1).

Based on our review of Petitioner’s arguments and evidence relating to dependent claims 2, 3, 5, 6, 8, and 18–21, which we adopt as our own (*see In re NuVasive*, 841 F.3d at 974), and our analysis of claim 1 in Section II.D.2. above, we conclude that Petitioner has proven by a preponderance of

evidence that Goldfarb '329 renders obvious dependent claims 2, 3, 5, 6, 8, and 18–21.

4. *Analysis of Claim 11*

Claim 11 depends from independent claim 9. Although claim 9 has been disclaimed, we analyze the limitations of claim 9, which are incorporated into dependent claim 11, as part of our analysis of claim 11.

a) *Preamble: “Apparatus for use at a native heart valve of a subject, the native heart valve including a native annulus and a plurality of native leaflets that provide check valve functionality, the apparatus comprising an implant configured to be transluminally-delivered to the native valve and to be deployed at the native valve, the implant comprising:” [from independent claim 9]*

Petitioner asserts that Goldfarb '329 describes a fixation device 14 that is transluminally-delivered through a catheter 86 for deployment at the mitral valve. Pet. 50 (citing Ex. 1004, 2:54–58, Figs. 9A–9B). Petitioner asserts that the mitral valve has a native annulus, two leaflets, and provides check valve functionality. *Id.* (citing Ex. 1003 ¶ 135).

Patent Owner does not dispute Petitioner's contentions as to these recitations. We accept Petitioner's undisputed assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.²¹

²¹ Regardless of whether the preamble is limiting, Petitioner has shown that the recitation in the preamble is satisfied by the prior art. *See Allen Eng'g Corp.*, 299 F.3d at 1346 (“Generally, the preamble does not limit the claims.”).

b) “one or more tissue-engaging elements, configured to be coupled to the native leaflets, and to couple the implant to the native leaflets without eliminating the check valve functionality, by holding together a portion of one of the native leaflets and a portion of another of the native leaflets such that the one leaflet and the other leaflet become arranged to define two orifices between the one leaflet and the other leaflet, each orifice configured to function as a respective check-valve;” [from independent claim 9]

Petitioner asserts that Goldfarb ’329 discloses a fixation device 14 comprised of two proximal elements 16 and two distal elements 18. Pet. 51 (citing Ex. 1004, 17:29–37). Petitioner asserts that each pair of opposing proximal and distal elements is a “tissue-engaging element.” *Id.* (citing Ex. 1003 ¶ 137). Petitioner asserts that the tissue-engaging elements grasp the leaflets (LF) and couple the fixation device to the leaflets. *Id.* (citing Ex. 1004, 17:29–53).

Petitioner asserts that the tissue-engaging elements hold together portions of the native leaflets such that the leaflets define two openings between the leaflets. Pet. 52 (citing *id.* at 9:66–10:32, Fig. 2A; Ex. 1003 ¶ 138). Petitioner asserts that the fixation device 14 does not eliminate the check valve functionality of the valve. *Id.* Petitioner asserts that each opening O formed by the fixation device continues to function as a check-valve. *Id.*

Patent Owner does not dispute Petitioner’s contentions as to these recitations. We accept Petitioner’s undisputed assertions as factual findings. *See generally NuVasive*, 841 F.3d at 974.

c) “an annular portion, configured to be secured against an upstream side of the native valve by the coupling of the one or more tissue-engaging elements to the native leaflets.” [from independent claim 9]

Petitioner identifies each pair of an opposing proximal element 16 and distal element 18 in Goldfarb ’329 as the recited “tissue-engaging element.” See Pet. 51 (citing Ex. 1003 ¶ 137). Petitioner argues that a person of ordinary skill would have found it obvious to implement annular flaps on the embodiment in Figures 9A–9B for the reasons it argues for claim 1. Pet. 53 (citing *id.* § VII.A.1.b.). Petitioner argues that flaps 104 are secured against an upstream side of the valve by coupling the tissue-engaging elements to the leaflets. Pet. 53 (citing *id.* § VII.A.1.b.). Petitioner asserts that Goldfarb ’329 states that “flaps 104 may extend radially outwardly from the catheter 86, as shown, and be positioned against the atrial side of the leaflets LF.” *Id.* (citing Ex. 1004, 17:38–53, [Fig.] 9B). Petitioner also asserts that flaps 104 may then be left behind with the fixation device “to assist in holding the leaflets.” *Id.* (citing Ex. 1004, 17:51–53).

We determine that Goldfarb ’329 meets this limitation for similar reasons as for the corresponding limitation in claim 1 discussed above, i.e., an “implant” comprises “at least one leaflet clip: (i) coupled to the annular portion.” See Section II.D.2.c., *supra*. We credit the testimony of Dr. Vesely that “a person of ordinary skill in the art would have been motivated to couple the flaps to the clips to ensure that the flaps remained safely and securely anchored against the atrial side of the leaflets.” See Ex. 1016 ¶ 16; Ex. 1003 ¶ 140. This is consistent with Goldfarb ’329, which describes flaps 104 are held against the atrial side of the leaflets for optimal grasping of the leaflets between proximal and distal elements 16, 18, before describing that the leaflets may be left behind. See Ex. 1004, 17:47–53.

d) “wherein the implant comprises one or more flexible connectors, and wherein each tissue-engaging element is flexibly coupled to the annular portion by a respective flexible connector”

Petitioner asserts that the flaps must necessarily be “flexibly coupled” to the clips. Pet. 47 (citing Ex. 1003 ¶ 124) (*referred to by* Pet. 55).

Petitioner asserts that during delivery of the fixation device to the valve, the flaps must be parallel to the catheter so that they fit within the catheter. *Id.*

Petitioner asserts that upon deployment, the flaps must flex or rotate to extend perpendicularly to the catheter. *Id.* (citing Ex. 1004, 17:38–53).

Petitioner asserts that the coupling between the flaps and clips must be flexible for the flaps to move in this way. *Id.* (citing Ex. 1003 ¶ 124).

Patent Owner does not dispute Petitioner’s position. *See generally* PO Resp. We accept Petitioner’s undisputed assertions as factual findings. *See generally* *NuVasive*, 841 F.3d at 974.

e) Summary of Claim 11

We, therefore, determine that Petitioner has established by a preponderance of the evidence that claim 11 of the ’341 patent would have been obvious over Goldfarb ’329.

5. Analysis of Independent Claim 16

Independent claim 16 is directed to a method and recites language and requirements that are substantially similar to the limitations of independent claims 1 and 9, which are apparatus claims. *Compare* Ex. 1001, 28:54–29:26, *with id.* at 27:10–41, 28:1–20. Petitioner’s contentions for claim 16 also are similar to those for claims 1 and 9. *See* Pet. 61–66. Patent Owner does not present arguments in its Response addressing the specific merits of Petitioner’s contentions, separately from Patent Owner’s arguments as to claim 1. *See* PO Resp. 1–67. We determine that Petitioner has established

by a preponderance of the evidence that claim 16 would have been obvious over Goldfarb '329 for the same reasons as for claims 1 and 9.

6. *Analysis of Dependent Claim 17*

Claim 17 depends directly from claim 16. Petitioner argues that Goldfarb '329 also describes the limitations introduced in claim 17, for similar reasons as for claim 9. *See* Pet. 67. Patent Owner proffers no argument that Goldfarb '329 fails to describe the limitations introduced in claim 17. PO Resp. 18–31 (arguing only alleged failure of Goldfarb '329 to describe elements of independent claim 1).

Based on our review of Petitioner's arguments and evidence relating to dependent claim 17, which we adopt as our own (*see NuVasive*, 841 F.3d at 974), and our analysis of claims 9 and 16 in Section II.D.4.–5. above, we conclude that Petitioner has proven by a preponderance of evidence that Goldfarb '329 renders obvious dependent claim 17.

E. *Obviousness of Claim 3 over Goldfarb '329 and Goldfarb '267*²²

Petitioner sets forth argument and evidence for its assertions that dependent claim 3, not addressed in the previous ground, are obvious over Goldfarb '329 and Goldfarb '267. Pet. 40–46, 53–55. Patent Owner does not address the specific merits of Petitioner's contentions as to dependent

²² Petitioner in its listing of asserted grounds of unpatentability casts this ground as obviousness over Goldfarb '329 and Goldfarb '267. Pet. 16. However, in its detailed assertions, claim 3 is under the heading "Grounds 1–2: Obvious In View of Goldfarb '329." The difference might arise from Petitioner's assertion that Goldfarb '329 incorporates Goldfarb '267 by reference, which we determine it does. *See* Ex. 1004, 2:13–18. The difference might also arise because Petitioner has listed only the primary reference in the heading. We would reach the same result under either theory.

claim 3, separate from its arguments as to independent claims 1 and 9. *See* PO Resp. 1–67.

1. Goldfarb '267

Goldfarb '267 (filed as US application 10/441,531, which was expressly incorporated by reference in Goldfarb '329 at 2:16–18) is titled “Fixation Device and Methods for Engaging Tissue” 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.” Ex. 1005, code (54), 1:37–39.²³

Goldfarb '267 discloses that its invention enables two or more valve leaflets to be coapted using an “edge-to-edge” or “bow-tie” technique to reduce regurgitation, yet the process does not require open-heart surgery through the chest and heart wall as in conventional approaches. *Id.* at 3:33–37. 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. *See id.* at 20:65–21:1.

2. Analysis of Dependent Claim 3

Claim 3 depends from claim 1 and further recites “wherein the at least one clip comprises at least a first clip and a second clip, and wherein the second clip is openable and closeable independently of the first clip.” Ex. 1001, 27:44–48.

Petitioner argues, among other things, that Goldfarb '267 discloses that proximal elements 16 are controllable by proximal element lines 90, which may be arranged to “allow the proximal elements to be manipulated

²³ According to Petitioner, Goldfarb '267 discloses many of the same embodiments disclosed in Goldfarb '329. Pet. 43.

independently.” Pet. 44 (citing Ex. 1005, 36:63–37:1, 31:62–32:4, Fig. 54B). Petitioner asserts that Goldfarb ’267 discloses that independent control of each clip allows the physician to grasp a first leaflet, reposition the device, and grasp a second leaflet. *Id.* at 45 (citing Ex. 1005, 31:62–32:4). Petitioner argues that this sequential grasping increases the probability that the physician will securely grasp both leaflets and would have motivated a person of ordinary skill to incorporate independent grasping into Goldfarb ’329. *Id.* (citing Ex. 1003 ¶ 119). Petitioner also argues that Goldfarb ’329 expressly incorporates by reference the application that became Goldfarb ’267. *Id.* at 43 (citing Ex. 1004, 2:16).

Patent Owner does not dispute this limitation, and we adopt Petitioner’s assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974. As above, we determine that Goldfarb ’329 incorporates by reference the application that became Goldfarb ’267. *See* Section II.D.2.c., *supra*. We also determine that a person of ordinary skill would have been motivated to use independent grasping, as taught by Goldfarb ’267, in order to increase the probability that the physician will securely grasp both leaflets. Ex. 1003 ¶ 117.

We, therefore, determine that Petitioner has established that claim 3 would have been obvious over Goldfarb ’329 and Goldfarb ’267.

F. Anticipation of Claim 11 by Goldfarb ’813

Petitioner contends that claim 11 is anticipated by Goldfarb ’813. Pet. 73–85, 96–97. Patent Owner opposes. *See* PO Resp. 66.

1. Goldfarb ’813

Goldfarb ’813 is titled “Methods and Devices for Capturing and Fixing Leaflets in Valve Repair” and relates to medical methods, devices, and systems and more particularly to those for the endovascular or

minimally invasive surgical repair of the valves of the heart, particularly the mitral valve. Ex. 1006, code (54), 1:19–21. Goldfarb '813 discloses methods of accessing a patient's vasculature at a location remote from the heart and advancing an interventional catheter having a capturing device through the vasculature to a location near a cardiac valve to be repaired. Ex. 1006, 3:59–63. The methods may include applying an upward force against a downstream surface of at least one leaflet of the cardiac valve with the capturing device. *Id.* at 3:63–66. Such application of force will reposition at least one leaflet so as to reduce leakage through the valve during ventricular systole. *Id.* at 3:66–4:1.

Goldfarb '813 discloses, in a first aspect, that a distal element of a capturing device protrudes from a shaft of an interventional tool and may be adjusted by retracting or extending the distal element. Ex. 1006, 4:2–16. In a second aspect, flow through the valve may be observed to determine if regurgitation has been inhibited by leaflet repositioning. *Id.* at 4:40–42. In a third aspect, leaflets may be optionally fixed together. *Id.* at 4:50–53. In a fourth aspect, one or more valve leaflets may be atraumatically captured with a capturing device and the captured leaflets may be repositioned independently of each other. *Id.* at 4:61–62. In a fifth aspect, the valve leaflets may be repaired with the use of sutures having attached anchors. *Id.* at 5:16–18.

Figure 21I of Goldfarb '813 is reproduced below:

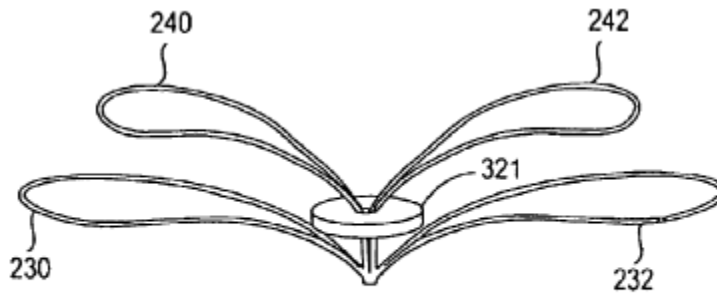


Fig. 21I

Figure 21I illustrates the use of a capture device having a pledget for use as a fixation device. Ex. 1006, 9:30–31. Pledget 321, which is illustrated as a disk-shaped component having a central orifice through which the other elements of the larger device pass, is shown positioned between the proximal elements 240, 242 and distal elements 230, 232 of the device. *Id.* at 19:35–37.

2. *Analysis of Claim 11*

As set forth above with respect to a different ground, claim 11 depends from independent claim 9. Although claim 9 has been disclaimed, as above, we analyze the limitations of claim 9, which are incorporated into dependent claim 11, as part of our analysis of claim 11.

a) *Preamble: “Apparatus for use at a native heart valve of a subject, the native heart valve including a native annulus and a plurality of native leaflets that provide check valve functionality, the apparatus comprising an implant configured to be transluminally-delivered to the native valve and to be deployed at the native valve, the implant comprising”*

Petitioner argues that Goldfarb ’813 discloses an implant that is transluminally-delivered to, and deployed at, a heart valve. Pet. 91–92 (citing Ex. 1003 ¶¶ 242–243).

Patent Owner does not dispute this recitation, and we adopt Petitioner’s assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

b) *“one or more tissue-engaging elements, configured to be coupled to the native leaflets, and to couple the implant to the native leaflets without eliminating the check valve functionality, by holding together a portion of one of the native leaflets and a portion of another of the native leaflets such that the one leaflet and the other leaflet become arranged to define two orifices between the one leaflet and the other leaflet, each orifice configured to function as a respective check-valve”*

Petitioner asserts that Goldfarb ’813 discloses a fixation device having proximal elements 240/242 and distal elements 230/232. Pet. 92 (citing Ex. 1006, 19:35–42). Petitioner asserts that each pair of opposing proximal and distal elements is a tissue-engaging element. *Id.* (citing Ex. 1003 ¶ 245). Petitioner asserts that the fixation device holds together a portion of each valve leaflet thereby arranging the leaflets to define two orifices. *Id.* at 92–93 (citing Ex. 1006, 11:61–12:8, Figs. 5–5A, 21J).

Petitioner’s contentions are illustrated with further reference to the annotated figure from Goldfarb ’813 below.

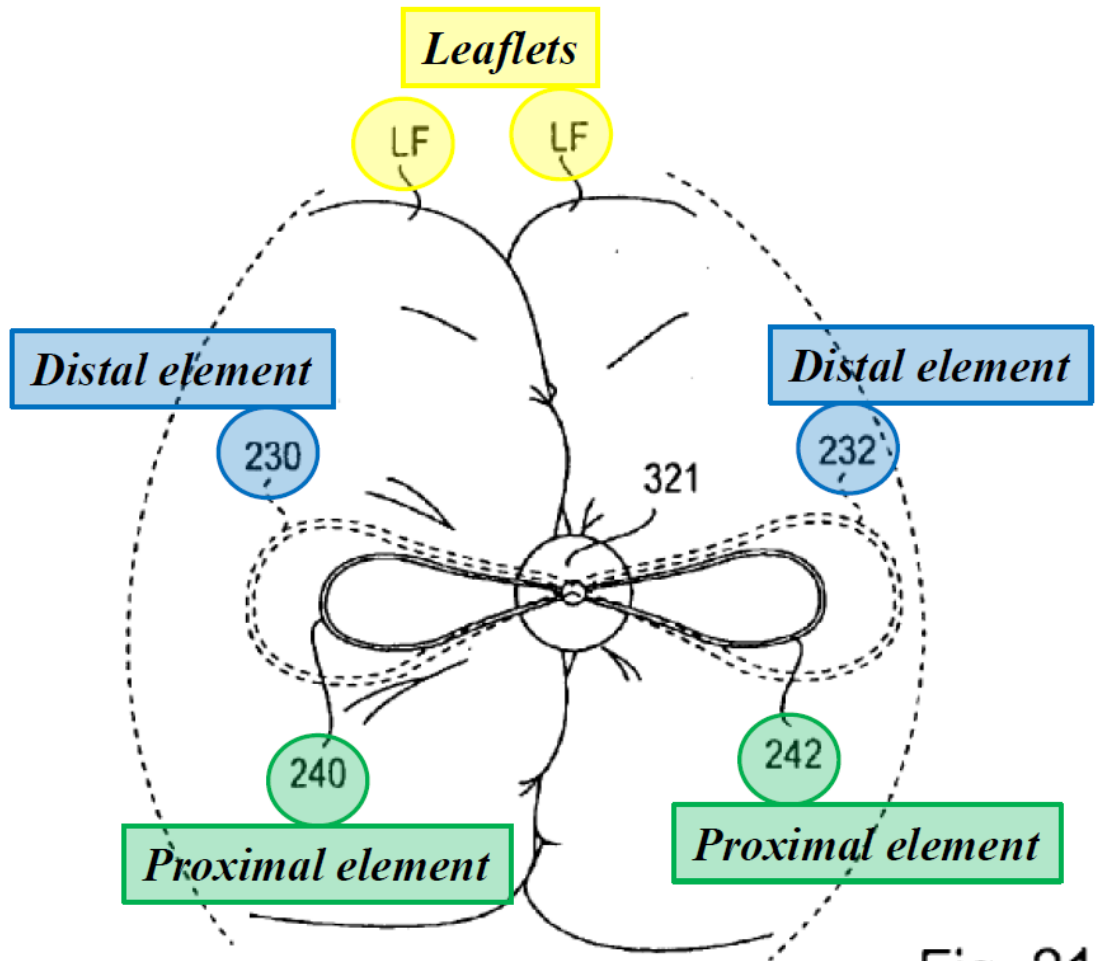


Fig. 21J

Figure 21J of Goldfarb '813 above is annotated by Petitioner with color text boxes and shading to identify the distal (blue) and proximal (green) elements of the device as it is positioned within and on either side of a heart valve. Pet. 93. Petitioner asserts that Figure 21J shows the native valve in the closed state, but argues that when the valve opens, an opening would appear on either side of the fixation device. *Id.* (citing Ex. 1003 ¶ 246).

Petitioner's contentions are illustrated with further reference to the annotated figure from Goldfarb '813 below.

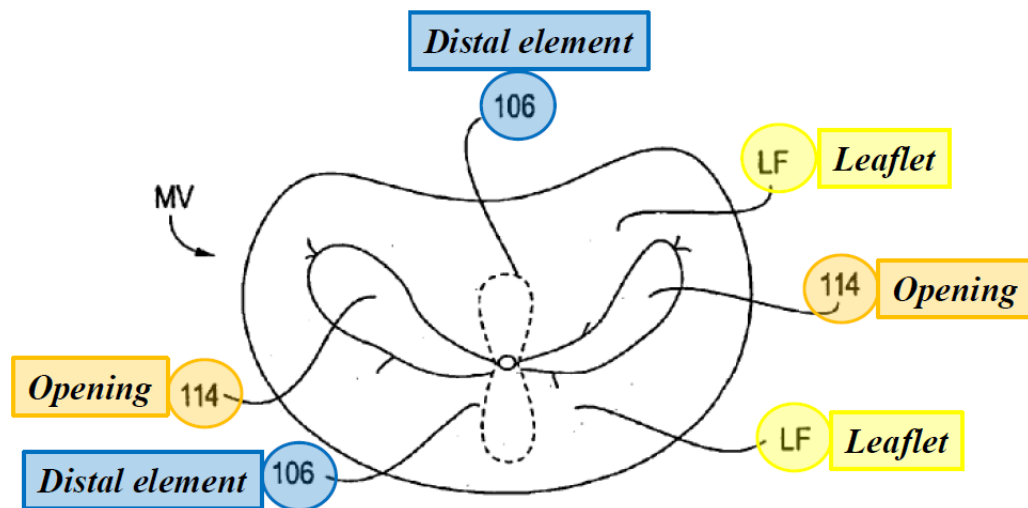


Figure 5 of Goldfarb '813 is annotated by Petitioner with color shading and text boxes to highlight a heart valve fitted with a fixation device. Pet. 94. Petitioner argues, with respect to Figure 5, that Goldfarb '813 discloses that openings 114, labeled orange, on either side of the fixation device and its distal elements 106 (blue) continue to function as check-valves. *Id.* at 93 (citing Ex. 1006, 11:61–12:8). The figure shows two orifices, one on either side of the fixation device.

Patent Owner does not dispute this limitation, and we adopt Petitioner's assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

c) “an annular portion, configured to be secured against an upstream side of the native valve by the coupling of the one or more tissue-engaging elements to the native leaflets”

Petitioner argues that disk 321 is positioned against the atrial sides of the leaflets, which is the upstream side. Pet. 94 (citing Ex. 1006, 37–42 [sic]; Ex. 1003 ¶ 250). Petitioner argues that disk 321 is secured by coupling the tissue-engaging elements to the leaflets. *Id.* (citing Ex. 1003 ¶ 250).

Patent Owner does not dispute this limitation, and we adopt Petitioner's assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

d) “wherein the implant comprises one or more flexible connectors, and wherein each tissue-engaging element is flexibly coupled to the annular portion by a respective flexible connector”

Petitioner refers to its analysis of claim 6, for which it asserts that the proximal and distal elements must flex inward to fit within the catheter and outward to expand upon deployment. Pet. 90 (citing Ex. 1003 ¶ 238) (*referred to in* Pet. 97). Petitioner asserts that in a preferred embodiment, the elements are made from nitinol or shape-memory wire, which are flexible materials. *Id.* (citing Ex. 1006, 14:7–8, 13:60–67, 16:46–48; Ex. 1003 ¶ 238). Petitioner asserts that the proximal element portion extending through the disk (the pledget) opening is a flexible connector that flexibly couples the clips to the disk. *Id.* (citing Ex. 1003 ¶ 238).

Patent Owner argues that the proximal elements 240, 242 extend through a hole in the disk 321 and no flexible connector is present. PO Resp. 67. Patent Owner argues that the claim does not require an annular portion connected to a “flexible clip,” but rather claims the flexible nature of the connection. *Id.* at 66 (*referred to in id.* at 67). Patent Owner argues that while the portion of the clip extending through the disk opening may be flexible, the connection is at best a slidable connection where the portion of the proximal element can move through the hole. *Id.* We have considered Patent Owner's arguments, but are not dissuaded from the conclusion that Petitioner has established anticipation here.

First, we determine that the proximal element portion is a connection because it would prevent the pledget from floating away. *See* Ex. 1006,

Fig. 21I. Dr. Vesely testifies that “[t]he proximal and distal elements are coupled to the disk by a portion of the proximal elements that extend through the opening in the disk.” Ex. 1003 ¶ 238. We find the Court’s opinion in *Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1289–90 (Fed. Cir. 2021), which deals with a different technology, to be nonetheless relevant and informative on this issue. In that case, based on the specification and the prosecution history, the Court held that the claim phrase “internally fixed within” did not exclude gimbaled geophones. *See id.* Here, the term “flexible connector” is even broader than “internally fixed within” because it lacks the concept of being “fixed” and the claim includes the concept of being “flexibly” connected or coupled. Therefore, we determine that the term “flexible connector” does not exclude a threaded coupling.

Second, we determine that the connection is flexible because the proximal and distal elements must flex inward to fit within the catheter and outward to expand upon deployment and because the elements are made from nitinol, which is a flexible material. Ex. 1003 ¶ 238 (citing Ex. 1006, 14:7–8, 13:60–67, 16:46–48).

We, therefore, determine that Petitioner has established that claim 11 of the ’341 patent is anticipated by Goldfarb ’813.

G. Obviousness of Claim 11 over Goldfarb ’813

Petitioner argues its assertion that claim 11 would have been obvious over Goldfarb ’813 together with its assertion that claim 11 is anticipated by Goldfarb ’813. *See* Pet. 91–92, 96–97.

Having found no deficiencies, on this record, in the ground of anticipation by Goldfarb ’813, we determine that Petitioner has established that claim 11 would have been obvious over Goldfarb ’813, for similar

reasons as for the ground based on anticipation. *See In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (indicating that anticipation is the epitome of obviousness). As we noted above, there is no evidence of objective indicia of record that would require a different analysis for this obviousness ground. *See supra* note 10.

H. Obviousness of Claims 1–3, 5, 6, 16–18, and 21 over Goldfarb '813 and Goldfarb '329

Petitioner contends that claims 1–3, 5, 6, 14–18, and 21 would have been obvious over Goldfarb '813. Pet. 74–91, 97–104. Patent Owner opposes. PO Resp. 37–53, 62–65.

1. Analysis of Independent Claim 1

a) Preamble: Apparatus for use at a native valve of a subject, the native valve including at least a first native leaflet and a second native leaflet

Petitioner argues that Goldfarb '813 discloses an apparatus for use at a native valve. Pet. 74 (citing Ex. 1006, 1:18–21; Ex. 1003 ¶¶ 202–203).

Patent Owner does not dispute this limitation, other than to argue that a person of ordinary skill would not have selected Goldfarb '813 as a starting point for an obviousness analysis because other devices were preferred. *See* PO Resp. 37–53. We do not reach this argument because we determine below that independent claim 1 would not have been obvious over Goldfarb '813 and Goldfarb '329 for other reasons.

In any event, we determine that Goldfarb '813 discloses devices for the endovascular or minimally invasive surgical repair of the valves of the heart, particularly the mitral valve. Ex. 1006, 1:18–21.

b) *“an implant” comprising “an annular portion, being configured to be placed against an upstream side of the native valve, and having an inner perimeter that defines an opening”*

Petitioner argues that disk 321 is an annular portion that has an inner perimeter defining an opening at its center through which a portion of the fixation device extends. Pet. 76 (citing Ex. 1003 ¶ 206). Petitioner argues that the disk is placed against an upstream (atrial) side of the native leaflets. *Id.* (citing Ex. 1006, 19:37–42; Ex. 1003 ¶ 206).

Patent Owner does not dispute this limitation, and we adopt Petitioner’s assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

c) *“implant” comprises “at least one leaflet clip: (i) coupled to the annular portion”*

Petitioner argues that proximal and distal elements 240, 242, 230, 232 are coupled to the disk 321 by a portion of the proximal elements that extends through the opening in the disk. Pet. 77–78 (citing Ex. 1003 ¶ 209).

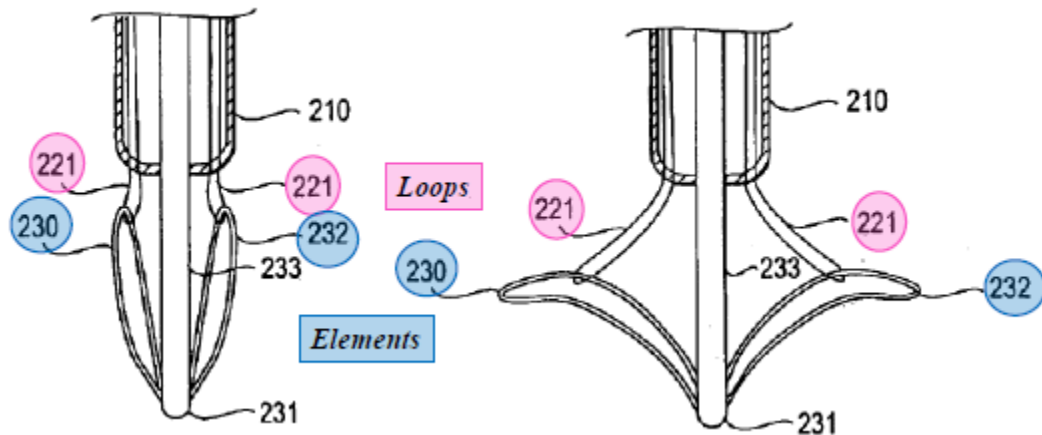
Patent Owner does not dispute this limitation, and we adopt Petitioner’s assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

d) *“at least one leaflet clip ... (ii) comprising: at least two clip arms, movable with respect to each other to open and close the clip; and a clip controller interface, the clip-controller interface being coupled to at least one of the clip arms”*

Petitioner asserts that Goldfarb ’813 in combination with Goldfarb ’329 renders obvious a clip-controller interface coupled to the clip arm. Pet. 78 (citing Ex. 1003 ¶ 210). Petitioner asserts that in some embodiments of Goldfarb ’813, the distal elements are deployed from the catheter to open

the clip, and then the proximal elements are deployed and positioned against the atrial surface to close the clip. *Id.* at 78–79 (citing Ex. 1006, 16:65–17:10, 19:30–42).

Petitioner’s contentions are illustrated with further reference to the annotated figures below.



Figures 16A–16B of Goldfarb ’813, are annotated by Petitioner with color to highlight the loops 221 (in pink) and elements 230, 232 (in blue) of the device, which are shown having the elements in positions collapsed toward (above-left) and extended away (above-right) from the device’s inner shaft 233. Pet. 80.

Petitioner asserts that Goldfarb ’813 also discloses that loops 221 [pink] of any suitable material (e.g., suture, wire) may be threaded through distal elements 230/232 [blue] to control the deployment of the elements. Pet. 79 (citing Ex. 1006, 15:54–16:9). Petitioner asserts that the physician applies tension to the loops to hold the elements in the retracted position against the shaft or releases tension on the loops to extend the elements toward the leaflets. *Id.* Petitioner asserts that a person of ordinary skill would have understood Goldfarb ’813’s disclosure to indicate that features like the loops 221 may be used on proximal elements, like those in Figures

21I–21J because Goldfarb ’813 discloses that proximal elements may have the same features described in relation to distal elements 230, 232. *See id.* at 80 (citing Ex. 1006, 16:46–48, 19:43–50; Ex. 1003 ¶ 213).

Petitioner asserts that it would have been obvious to modify the embodiment in Figures 21I–21J to include loops to control the deployment of the proximal elements and better capture the leaflets. Pet. 80 (citing Ex. 1003 ¶ 213).

Petitioner’s contentions are illustrated with further reference to the annotated figure below.

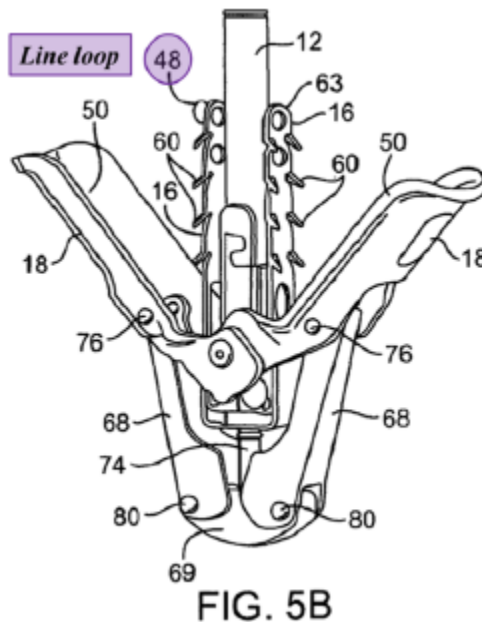


Figure 5B of Goldfarb ’329 above is annotated by Petitioner with color (purple) to highlight feature 48 of the device and to label it “line loop.” Pet. 81.

Petitioner argues that a person of ordinary skill would have found it obvious to implement line loop 48 in Goldfarb ’329 (asserted to be the clip-controller interface) with the embodiments of Goldfarb ’813 in Figures

21I–21J in order to reduce friction as taught by Goldfarb ’329. Pet. 81–82 (citing Ex. 1003 ¶¶ 214–215).

Patent Owner argues that where the proximal elements have a loop shape (similar to Goldfarb ’813), no line loop 48 is used. PO Resp. 56. Rather, Patent Owner argues that proximal element lines 90 merely pass through these loops. *Id.* at 56–57 (citing Ex. 2014 ¶¶ 43–44). Patent Owner points to the disclosure in Goldfarb ’329 that “[w]hen the proximal elements 16 have a loop shape, as shown in FIG. 5A, the line 90 may pass through the loop and double back.” *Id.* at 57 (quoting Ex. 1004, 18:26–37) (emphasis omitted). Patent Owner argues that when the structure of the proximal elements 16 are modified to have an elongated solid shape, as shown in Figure 5B, only then is the line loop 48 added. *Id.* (citing Ex. 2010, 125:9–127:4). Patent Owner also argues that the use of line loops 48 in the embodiment of Figures 16A–C would hinder the movement of loops 221. *See id.* at 58–61.

We agree with Patent Owner that a person of ordinary skill would not have sought to incorporate line loop 48 of Goldfarb ’329 (a clip-controller interface) as an additional feature into the embodiment of 16A–C of Goldfarb ’813’s device because the device already has loops 221. *See* Ex. 1006, 15:60–63, Figs. 16A–C. As Goldfarb ’329 teaches when proximal elements 16 have a loop shape, the line 90 may pass through the loop and double back. Ex. 1004, 13:26–28. Therefore, there is no need for additional loops 48. Rather, such loops would only be needed when it is necessary to reduce friction or when proximal elements 16 are solid or devoid of loops. *See* Ex. 1004, 13:34–37. The embodiment of Goldfarb ’813 has loops and Petitioner has not provided adequate evidence that it would have been necessary to add another loop structure to reduce friction in this situation.

Therefore, Petitioner has not shown that the asserted combination of Goldfarb '813 and Goldfarb '329 would have taught or suggested this limitation.

e) “at least one leaflet clip ... (iii) configured: to be coupled to a portion of the first native leaflet by the clip arms being brought together to close around the first native leaflet, to be coupled to a portion of the second native leaflet by the clip arms being brought together to close around the second native leaflet, and to hold together the portion of the first leaflet and the portion of the second leaflet”

Petitioner argues that Figures 5–5A and 21J demonstrate that the clips of Goldfarb '813 hold together portions of two valve leaflets. *See* Pet. 82–83. Patent Owner does not present arguments addressing the specific merits of Petitioner's contention. *See* PO Resp. 36–65.

Patent Owner does not dispute this limitation, and we adopt Petitioner's assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

f) “a delivery apparatus, configured to deliver the implant to the native valve, and comprising at least one clip controller, the at least one clip controller being reversibly coupled to the clip-controller interface, and configured to facilitate opening and closing of the clip, and the delivery apparatus being intracorporeally decouplable from the implant”

Petitioner relies on a combination of Goldfarb '813 and Goldfarb '329 for this limitation. *See* Pet. 83–84 (citing, e.g., *id.* § VII.B.1.d.). Petitioner asserts that Goldfarb '813 discloses that the interventional catheter may include loops 221 attached to the proximal elements of the fixation device to help control the deployment of the elements. *Id.* at 83–84. Petitioner asserts that loops 221 are clip controllers. *Id.* at 79. Petitioner argues that loops

221 of Goldfarb '813 would be reversibly coupled to line loops 48 disclosed in Goldfarb '329. *Id.* at 84 (citing Ex. 1003 ¶ 220; Pet. § VII.B.1.d.).

Patent Owner counters that loops 221 in Goldfarb '813 and Goldfarb '329 can only facilitate opening—they can pull, but cannot push. *See* PO Resp. 63–65.²⁴ Patent Owner argues that the only members disclosed to counter an “opened” bias in elements 230, 232 are the loops 221, which just effectuate tension and proximal movement. *Id.* Patent Owner argues that when the tension is released, they “hang at any location” and cannot “push” the elements 230, 232. *Id.* Patent Owner argues that these loops 221 are not configured to facilitate “opening” of the clip, but instead they resist opening and provide the sole closing force. *Id.*

We determine that Petitioner has shown that Goldfarb '329 discloses this limitation. Although the clips are biased to extend outwardly and the force exerted on loops 221 is released to allow the clips to so extend, we determine that loops 221 are used by the physician to control the opening and the closing of the clips. *See* Ex. 1003 ¶ 212. Applying our claim construction (*see supra* Section II.C.2), we determine that loops 221 therefore help bring about and facilitate the opening and closing of the clips.

a) Summary of Claim 1

We determine that Petitioner has not established by a preponderance of the evidence that claim 1 of the '341 patent would have been obvious over Goldfarb '813 in view of Goldfarb '329 because we determine that a

²⁴ Patent Owner attempts to incorporate by reference its arguments from its pre-institution Preliminary Response, which we determine to be an improper incorporation by reference, but at the hearing Patent Owner indicated that it did not need to rely on any arguments from its Preliminary Response. *See* Tr. 39:14–21.

person of ordinary skill would not have sought to add loops 48 of Goldfarb '329 to proximal elements 240 of Goldfarb '813.

2. *Analysis of Independent Claim 16*

Independent claim 16 is a method claim that contains language and requirements that are substantially similar to those of independent claim 1, and additionally recites “transluminally advancing an implant to a native heart valve of a subject.” Ex. 1001, 28:55–56.

Petitioner asserts that Goldfarb '813's fixation device is transluminally delivered to the valve through a catheter. Pet. 99 (citing Ex. 1006, 6:26–31). Patent Owner does not present arguments addressing the specific merits of Petitioner's contention for this limitation. *See* PO Resp. 36–65.

However, we determine that Petitioner has not established by a preponderance of the evidence that claim 16 would have been obvious over the asserted combination of Goldfarb '813 and Goldfarb '329 for similar reasons as for claim 1.

3. *Analysis of Dependent Claims 2, 3, 5, 6, 17, 18, and 21*

Claims 2, 3, 5, 6, 17, 18, and 21 each depend from one of claims 1 and 16. Because we determine that Petitioner has not established that claims 1 and 16 would have been obvious over the asserted combination of Goldfarb '813 and Goldfarb '329, we determine that Petitioner has not established by a preponderance of the evidence that claims 2, 3, 5, 6, 17, 18, and 21 would have been obvious over this asserted ground for the same reason.

I. *Obviousness of Claim 3 over Goldfarb '813, Goldfarb '329, and Goldfarb '267*

Petitioner contends that claim 3 would have been obvious over Goldfarb '813, Goldfarb '329, and Goldfarb '267. Pet. 86–88. Petitioner

does not rely on Goldfarb '267 to remedy the identified deficiency in the asserted ground of obviousness over Goldfarb '813 and Goldfarb '329. Because we determine that Petitioner has not established that claim 1 would have been obvious over the asserted combination of Goldfarb '813 and Goldfarb '329, we determine that Petitioner has not established by a preponderance of the evidence that claim 3 would have been obvious over this asserted prior art combination for the same reason.

J. Motion to Amend

Under 35 U.S.C. § 316(d)(1) and 37 C.F.R. § 42.121(a), Patent Owner moves to substitute original claims 1 and 16 with proposed claims 22 and 23. MTA 1.

1. Proposed Substitute Claims

Patent Owner submits the following proposed substitute independent claim 22, which corresponds to original independent claim 1 (with added material underlined):

22. [22.Pre] Apparatus for use at a native valve of a subject, the native valve including at least a first native leaflet and a second native leaflet, the apparatus comprising:

[22.1] an implant, comprising:

[22.2] an annular portion, being configured to be placed against an upstream side of the native valve, and having an inner perimeter that defines an opening, and

[22.3] at least one leaflet clip:

[22.4] (i) coupled to the annular portion,

[22.5] (ii) comprising:

at least two clip arms, movable with respect to each other to open and close the clip; and a clip-controller interface, the

clip-controller interface being coupled to at least one of the clip arms, and

[22.6] (iii) configured:

to be coupled to a portion of the first native leaflet by the clip arms being brought together to close around the first native leaflet,

[22.7] to be coupled to a portion of the second native leaflet by the clip arms being brought together to close around the second native leaflet, and

[22.8] to hold together the portion of the first leaflet and the portion of the second leaflet; and

[22.9] a delivery apparatus, configured to deliver the implant to the native valve, and comprising at least one clip controller, the at least one clip controller being reversibly couplable to the clip-controller interface, and configured to facilitate opening of the clip by the clip controller applying a pushing force to the clip-controller interface to move the at least one of the clip arms in an opening direction, and closing of the clip by the clip controller applying a pulling force to the clip controller interface to move the at least one of the clip arms in a closing direction, and the delivery apparatus being intracorporeally decouplable from the implant.

MTA 25–27 (App’x A) (paragraphing added).

2. *Legal Standard*

In an *inter partes* review, amended claims are not added to a patent as a matter of right; rather, they must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). In reviewing a motion to amend, the Board

assesses the patentability of the proposed substitute claims “without placing the burden of persuasion on the patent owner.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see Lectrosonics, Inc. v. Zaxcom, Inc., Inc.*, Case IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential).

Notwithstanding the foregoing, a patent owner’s proposed substitute claims must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. *Lectrosonics*, Paper 15 at 4–8. In particular, a patent owner must demonstrate: (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 a 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.

3. *Claim Construction*

Neither Patent Owner nor Petitioner proposes that any language in the amendments in the proposed substitute claims needs express construction. *See generally* MTA; MTA Opp. We do not need to construe any claims to resolve the dispute.

4. *Statutory and Regulatory Requirements*

“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*, Paper 15 at 4.

a) Reasonable Number of Substitute Claims

First, we consider whether the Motion to Amend proposes a reasonable number of substitute claims. *See* 35 U.S.C. § 316(d)(1)(B). We apply “a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4–5 (citing 37 C.F.R. § 42.121(a)(3)).

Petitioner does not argue that Patent Owner has proposed an unreasonable number of substitute claims. *See generally* MTA Opp. We find Patent Owner proposes a reasonable number of substitute claims because there is a one-to-one relationship of claims between proposed substitute claims 22 and 23, and original claims 1 and 16.

b) Responsive to a Ground of Unpatentability

Second, we consider whether the proposed substitute claims respond to a ground of unpatentability involved in this trial. *Lectrosonics*, Paper 15 at 5–6.

Patent Owner contends “the substitute claims address and distinguish over the configuration of the loops 221 relied on in Goldfarb ’813,” and that “[n]either Goldfarb ’813 (Ex. 1006) nor Goldfarb ’329 (Ex. 1004) discloses a ‘clip controller’ meeting the recited configuration that includes a clip controller applying a pushing force to open the clip and a pulling force to close the clip, in combination with the ‘annular portion’ feature as recited in substitute claims 22 and 23.” MTA 14–15.

Petitioner argues “Patent Owner failed to *adequately* ‘respond to the ground of unpatentability involved in the trial’” because Patent Owner’s only discussion of Goldfarb ’329 refers to its proximal clip controller and does not address its distal clip controller. *See* MTA Opp. 10 (emphasis added).

Under Rule 42.121, the requirement is for the amendment to be responsive to “a ground of unpatentability.” 37 C.F.R. § 42.121(a)(2)(i). We find Patent Owner has met this requirement. There is no requirement for a response to be “adequate” on a given point or to address every element of the asserted prior art in a ground in order to be responsive.

c) Scope of the Substitute Claims

Third, we consider the scope of the substitute claims, as “[a] motion to amend may not present substitute claims that enlarge the scope of the claims of the challenged patent or introduce new subject matter.” *Lectrosonics*, Paper 15 at 6 (citing 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii)).

(1) Enlarged Claim Scope

“A patent owner may not seek to broaden a challenged claim *in any respect* that enlarges the scope of the claims of the patent, for example, in the name of responding to an alleged ground of unpatentability.” *Lectrosonics*, Paper 15 at 6 (emphasis added). “[A] proposed substitute claim may not remove a feature of the claim in a manner that broadens the scope of the claims of the challenged patent.” *Id.*

Patent Owner contends “substitute claims retain all the features of the corresponding original claims while only adding further limitations.” MTA 2. Petitioner does not argue otherwise. *See generally* MTA Opp. Because no subject matter is removed along with the addition of new limitations, the amendment does not seek to enlarge the scope of the claims.

(2) New Matter

New matter is any addition to the claims without support in the original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . the new claim[] . . . must find support in the original

specification.”). The test for adequate written description support is “whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Patent Owner appears to have identified adequate written description support for the proposed substitute claims. *See* MTA 3–14. Petitioner argues that “the original disclosure does not support at least the proposed amendment in claims 22 and 23 requiring the clip controller to facilitate ‘closing of the clip by the clip controller applying a pulling force to the clip-controller interface to move the at least one of the clip arms in a closing direction.’” MTA Opp. 23 (emphasis omitted). Specifically, Petitioner argues that “while the clip-controller interface moves in response to force, the patent does not explain how the force is applied, and does not disclose that the clip controller opens the clip by ‘applying a pushing force’ and closes the clip by ‘applying a pulling force.’” *Id.* (emphasis omitted).

The ’069 Application²⁵ discloses “applying a force,” which “facilitate[s] control” of “opening and closing.” *See* Ex. 2012, 11:28–12:2 (*cited at* MTA 7, 12) (“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”). Figure 1B of the ’069 Application is reproduced below:

²⁵ U.S. Application No. 15/197,069 (Ex. 2012, “the ’069 Application”), which issued as the ’341 patent (*see* Ex. 1001, code (21)).

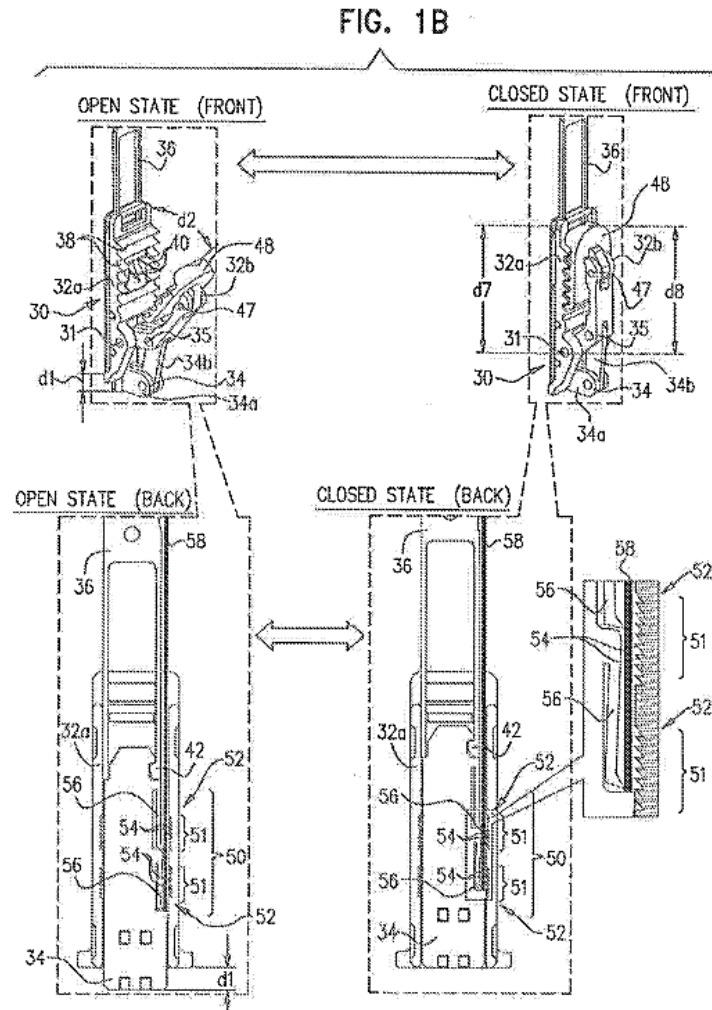


Figure 1B is a schematic illustration of an apparatus of the '069 Application. *See* Ex. 2012, 9:16–18. In Figure 1B, clip controller 36 appears to be extended further in the closed state than in the open state, when comparing the “front” views with each other and comparing the “back” views with each other. *See id.* at Fig. 1B. On this record, we determine that it is inherent in Figure 1B and the above-cited portion of the Specification that the clip controller is pulled to transition from the open state to the closed state and is pushed to transition from the closed state to the open state. *See, e.g., Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy’s Labs. Inc.*, 923 F.3d 1368, 1382–83 (Fed. Cir. 2019) (under a

narrow set of circumstances, written description requirement may be satisfied without an explicit disclosure if the claimed features are necessarily inherent in what is expressly described).²⁶ The application of force in the '069 Application, in view of Figure 1B, provides written description support for opening of the clip by the clip controller applying a pushing force and closing the clip by applying a pulling force, as recited in the substitute claims.

Thus, Patent Owner has shown by referencing *inter alia* Figure 1B and 11:28–12:2 of the '069 Application (*see* Ex. 2012), that there is adequate written description support for proposed substitute claims 22 and 23.

5. *Burden on Petitioner to Prove Unpatentability of Proposed Substitute Claims 22 and 23*

Petitioner has the burden of persuasion as to the alleged unpatentability of proposed substitute claims 22 and 23. *See* Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board, 85 Fed. Reg. 82,923, 82,924, 82,935 (Dec. 21, 2020) (codified at 37 C.F.R. 42.121(d)(2)) (stating that “[a] petitioner bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable” as to any motion to amend filed on or after January 20, 2021).

²⁶ We observe that Petitioner argues that Patent Owner has not alleged that the '341 patent inherently discloses the term “pulling.” Opp. 24. Even if Patent Owner did not make such an argument, the record supports a conclusion that the claimed pulling/pushing features are inherently present from the disclosures.

*a) Asserted Obviousness of Proposed Substitute
Claims 22 and 23 Over Goldfarb '329 Alone or Further
in Combination with Goldfarb '267*

Petitioner contends that proposed substitute claims 22 and 23 would have been obvious over Goldfarb '329 alone or further in combination with Goldfarb '267. MTA Opp. 4–22.

(1) Proposed Substitute Claim 22

(a) Elements 22.Pre and 22.1–22.8

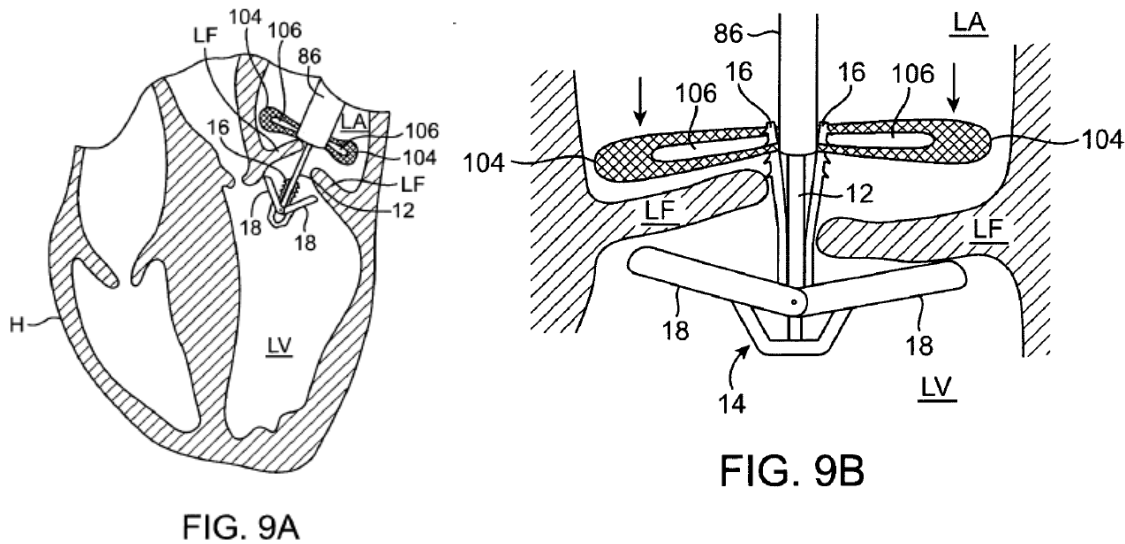
We have already evaluated the claim language maintained from the preamble and elements 22.1–22.8 of original claim 1. We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Goldfarb '329 alone or further in combination with Goldfarb '267 discloses these aspects. Patent Owner does not present arguments for this claim language.

(b) Element 22.9

Element 22.9 employs some claim language maintained from original claim 1 and some additional language. Element 22.9 maintains the language from the original claim of “a delivery apparatus, configured to deliver the implant to the native valve, and comprising at least one clip controller, the at least one clip controller being reversibly couplable to the clip-controller interface, and configured to facilitate opening” and “closing of the clip” and “the delivery apparatus being intracorporeally decouplable from the implant.” MTA 26–27. However, Element 22.9 adds language to the proposed substitute claim that the clip is configured to facilitate opening “of the clip by the clip controller applying a pushing force to the clip-controller interface to move the at least one of the clip arms in an opening direction,” and closing of the clip “by the clip controller applying a pulling force to the

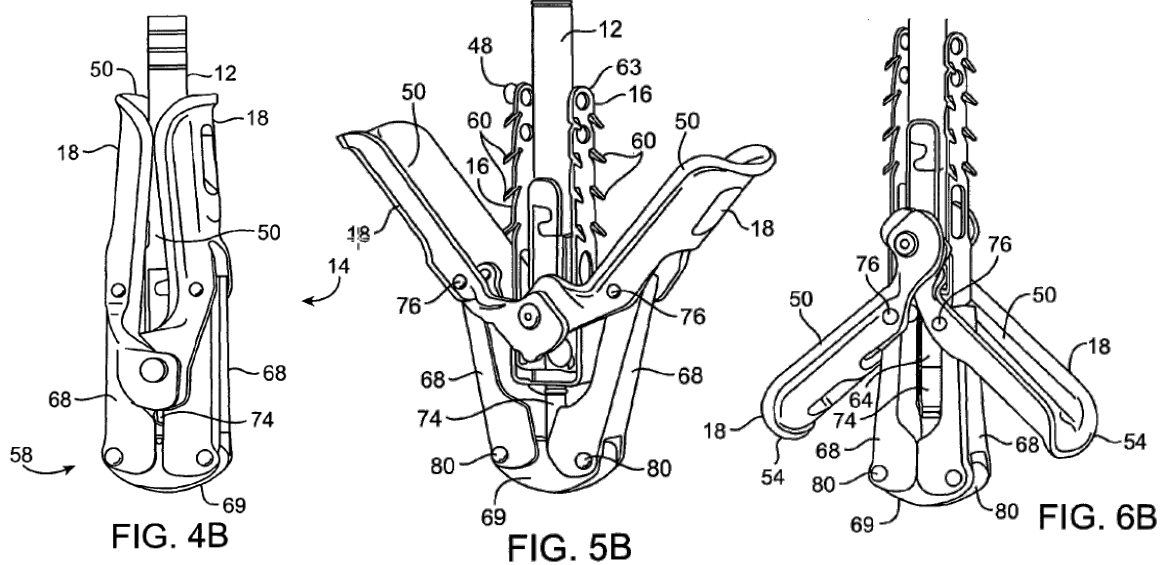
clip controller interface to move the at least one of the clip arms in a closing direction.” *Id.*

Figures 9A and 9B of Goldfarb '329 are reproduced below.



Figures 9A and 9B show distal element 18 and proximal element 16, as well as flaps 104. *See* Ex. 1004, 17:20–40. Petitioner contends that element 16 and 18 correspond to the claimed clip, and flap 104 corresponds to the claimed “annular portion.” *See* MTA Opp. 12.

For the new limitations, Petitioner contends that Figures 4B, 5B, and 6B of Goldfarb '329 disclose the claimed features. MTA Opp. 5–10. Figures 4B, 5B, and 6B are reproduced below.



Figures 4B, 5B, and 6B show distal elements 18 and actuator rod 64. Ex. 1004, 12:32–58. Figure 4B shows the device in a closed position. *Id.* at 12:41–43. Figure 5B shows the device in an open position. *Id.* at 13:1–4. Figure 6B shows the device in an “inverted” position. *Id.* at 14:10–11.

Petitioner argues that Goldfarb ’329 discloses that “the physician may use the actuator rod 64 (clip controller) to apply a pushing force to the actuation mechanism 58 (clip-controller interface) to move the distal elements in an opening direction.” MTA Opp. 6 (citing Ex. 1003 ¶¶ 88, 100; Pet. 30; Ex. 1016 ¶ 61). Petitioner argues that its understanding of the operation of the device of Goldfarb ’329 is confirmed by Goldfarb ’267, which discloses identical embodiments. MTA Opp. 9 (citing Ex. 1005, 23:19–22). Patent Owner did not address these arguments in its motion to amend and did not file a reply to Petitioner’s opposition.

We find Goldfarb ’329 teaches that pushing and pulling on its disclosed rod 64 opens and closes the clip by “applying a pushing force to the clip-controller interface to move the at least one of the clip arms in an opening direction,” and “applying a pulling force to the clip-controller

interface to move the at least one of the clip arms in a closing direction,” as recited in proposed substitute claims 22 and 23. See Ex. 1004, 12:2–6, 13:1–7; Ex. 1016 ¶¶ 62–63. In particular, Goldfarb ’329 discloses that the distal elements are rotated outwards in the open position and that “[d]istal advancement of the stud 74 relative to coupling member 19 by action of the actuator rod 64 applies force to the distal elements 18 which begin to rotate around joints 76 due to freedom of movement in this direction.” Ex. 1004, 13:1–7. Goldfarb ’329 also discloses that the actuator rod “is axially extendable and retractable to move the stud” to “rotate the distal elements 18 between closed, open and inverted positions.” Ex. 1004, 12:2–6; Ex. 1003 ¶¶ 88, 100; *see also* Pet. 8–9. We determine that a person of ordinary skill would understand from Goldfarb ’329 that pushing actuator rod 64 would open the clips and pulling actuator rod 329 would close the clips. *See* Ex. 1003 ¶ 88 (citing Ex. 1004, 13:1–18, 14:8–26).²⁷

(2) *Conclusion as to
Proposed Substitute Claim 22*

For the reasons set forth above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that proposed substitute claim 22 would have been obvious over Goldfarb ’329 alone (which incorporates Goldfarb ’267) or further in view of Goldfarb ’267.

a) *Proposed Substitute Claim 23*

Proposed substitute claim 23 contains additional language that is substantially similar to that of proposed substitute claim 22. *Compare* MTA

²⁷ Although we need not rely on it, we determine that Goldfarb ’267 also discloses a “push-to-open, pull-to-close mechanism.” *See* Ex. 1005, 23:19–22. As noted above, we determine that Goldfarb ’329 incorporates Goldfarb ’267 in its entirety. *See* Section II.D.2.c., *supra*.

29, *with id.* at 26–27. Petitioner argues the unpatentability of proposed substitute claim 23 together with that of proposed substitute claim 22. *See* MTA Opp. 2.

We determine that Petitioner has established by a preponderance of the evidence that proposed substitute claim 23 would have been obvious over Goldfarb ’329 alone or further in view of Goldfarb ’267 for the same reasons as for proposed substitute claim 22 and independent claim 16.

III. PETITIONER’S MOTION TO STRIKE

The party moving to strike bears the burden of proving that it is entitled to the relief requested. *See* 37 C.F.R. § 42.20(c).

Petitioner moves to strike Patent Owner’s Exhibits 2016–2019, which were filed with Patent Owner’s Sur-reply, and to strike the portions of the Sur-reply that contain substantive arguments about Exhibits 2016–2019. Mot. Strike 1.

Petitioner points to 37 C.F.R. § 42.23(b), which states: “A sur-reply may only respond to arguments in the corresponding reply and may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.” Mot. Strike 1–2 (citing 37 C.F.R. § 42.23(b)). Petitioner also points to the Board’s Consolidated Trial Practice Guide (Nov. 2019) (“CTPG”) ²⁸ for the same proposition. *Id.* at 2 (citing CTPG 73–74).

Petitioner acknowledges Patent Owner’s argument that Board precedent permits the submission of new evidence with a sur-reply if the exhibits were introduced during a deposition and are “for the purpose of

²⁸ Available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=>.

testing the witness's testimony.” Mot. Strike 3 (citing Ex. 1018, 11). Petitioner counters that Patent Owner conceded that Exhibits 2018 and 2019 were not introduced during Dr. Vesely's deposition. *Id.* Petitioner argues that, therefore, these exhibits would not fall under this alleged exception to the Rules. *Id.* at 3–4. Petitioner also argues that the Board's decision in *Ascend Performance Materials Operations LLC v. Samsung SDI Co.*, IPR2020-00349, Paper 53 at 12–13 (PTAB July 15, 2021) never mentioned the governing Trial Rule, 37 C.F.R. § 42.23(b), or the relevant portion of the CTPG, pages 73–74, raised by Petitioner in this motion, or provide other authority in support. *Id.* at 4. Petitioner further argues that in *Ascend Performance*, the petitioner had erred by not bringing a motion to strike, which is not the case here. *Id.* Petitioner also argues that Petitioner will suffer prejudice if Exhibits 2016–2019 and the accompanying portions of the Sur-reply are not stricken because the untimely submission of this evidence has deprived Petitioner of the opportunity to fully address this evidence. *Id.* at 5.

Patent Owner responds that in *Ascend Performance*, the Board interpreted Rule 42.23(b), noting that not any exhibit made of record during a deposition may be submitted with a sur-reply, but “if exhibits are introduced during deposition for the purpose of testing the witness' testimony, a party should be able to submit those exhibits with the transcript, so the Board has the full context available in order to evaluate the testimony.” Opp. Mot. Strike 1.

Patent Owner argues that Exhibits 2016 and 2017 were presented at the deposition. Opp. Mot. Strike 2–3. Patent Owner argues that Exhibits 2018 and 2019 were not introduced at the deposition, but are relevant to the cross-examination of Dr. Vesely, i.e., as context for purposes of evaluating

Dr. Vesely's testimony, as they highlight Dr. Vesely's failure to discuss the Cardioband product with Petitioner.²⁹ *Id.* at 3–4.

There is no controlling Board precedent on point.³⁰ Nevertheless, this panel will allow the exhibits used during cross-examination to be submitted, but only for the limited purpose of allowing the Board to understand the context of the cross-examination. We determine that this is consistent with 37 C.F.R. § 42.23(b) because the exhibits are not being admitted as substantive evidence. Further, 37 C.F.R. § 42.23(b) allows the submission of a deposition transcript, and allowing exhibits to be used in this manner merely allows them to be used as an adjunct to reading and understanding the deposition transcript. We, therefore, deny the motion to strike as to Exhibits 2016 and 2017 and the portions of the Sur-reply related thereto, which were used as exhibits in cross examination during the deposition. In our view, Petitioner is not prejudiced because Dr. Vesely had an opportunity to respond to the exhibits during his deposition. Nevertheless, we grant the motion to strike as to Exhibits 2018 and Exhibit 2019 which were not used

²⁹ Patent Owner asserts that “Dr. Vesely testified that he knew [Petitioner] purchased Valtech’s Cardioband System.” Opp. Mot. Strike 4.

³⁰ The Board’s final written decision in *Ascend Performance Operations LLC v. Samsung SDI Co.*, IPR2020-00349, Paper 53 (PTAB July 15, 2021) (non-precedential) was vacated by the Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office based on a petition for Director review which had petitioned on other grounds. *See id.*, Order, Paper 57 (Nov. 1, 2021). Other Board decisions have interpreted 37 C.F.R. § 23(b) more strictly than suggested here. *See Netflix v. Divx*, IPR2020-00511, Paper 46 at 52–55 (PTAB Aug. 13, 2021) (panel found § 42.23(b) to be a blanket rule and that the interest of justice did not weigh in favor of including exhibits raised during the deposition on the basis of providing context where the declarant testified they had not seen them before).

at the deposition, and the portions of the Sur-reply related thereto. Even if, as Patent Owner argues, Exhibits 2018 and 2019 would be helpful to understand the deposition testimony, Patent Owner had an opportunity to show them to the deponent and did not do so.

IV. PATENT OWNER'S MOTION TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.20(c), 42.62(a).

Patent Owner moves to exclude a number of exhibits for various reasons. *See* Mot. Excl. 1–15. In particular, Patent Owner argues that certain evidence represents a new theory of unpatentability not presented in the Petition or Dr. Vesely's First Declaration and that certain evidence is not based on underlying facts and data. *See id.*

Petitioner responds that the proper course for Patent Owner to raise its argument regarding alleged new evidence as a motion to strike, which requires obtaining prior authorization from the Board. Opp. Mot. Excl. 2 (citing CTPG 80; *Unified Patents LLC v. MobilePay LLC*, IPR2019-00466, Paper 36 at 10 n.4 (PTAB July 29, 2020)). We do not deny this aspect of the motion to exclude as improper on the basis that it could have been filed as a motion to strike and instead proceed to analyze the substance of the motion. *See Celltrion, Inc. v. Genentech, Inc.*, IPR2017-01139, Paper 68 at 27 (PTAB Oct. 3, 2018) (treating a motion to exclude as a motion to strike).

Alleged Impermissible New Evidence:

Paragraph 21 of Dr. Vesely's Second Declaration

Paragraphs 29–34 of Dr. Vesely's Second Declaration (and Figure 22A of Goldfarb '267)

Paragraphs 23–26 of Dr. Vesely's Second Declaration

Patent Owner argues that paragraph 21 of Dr. Vesely's Second Declaration presents a belated theory including new evidence describing how a person of ordinary skill could have allegedly attached flaps to a clip using pins, hinges, screws, washer, collars and rods because none of this was presented in the original Petition or in Dr. Vesely's First Declaration. Mot. Excl. 3.

Petitioner argues that nothing in Dr. Vesely's Second Declaration constitutes evidence or argument that exceeds the proper scope of a reply under 37 C.F.R. § 42.23(b). Opp. Mot. Excl. 4. Petitioner argues that Dr. Vesely's Second Declaration does not rely on any evidence or reference that was not previously of record in this proceeding. *Id.* at 5. For paragraph 21 of the Second Declaration, Petitioner argues that Dr. Vesely explained that a person of ordinary skill would have reasonably expected success in coupling the flaps to the clip because such coupling could be accomplished using common, well-known mechanisms such as pins, hinges, screws, washers, collars, and rods, and that this was additional detail on how to secure flaps to clips. Opp. Mot. Excl. 5 (citing Ex. 1016 ¶ 21).

We agree with Petitioner that a proper reply may provide additional detail as to whether a person of ordinary skill would have a reasonable expectation of success in combining the teachings of the prior art. *See Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (reply may document the knowledge that skilled artisans would bring to bear

in reading the prior art identified as producing obviousness); *see also* *Chamberlain Grp., Inc. v. One World Techs., Inc.*, 944 F.3d 919, 925 (Fed. Cir. 2019) (“Parties are not barred from elaborating on their arguments on issues previously raised.”). Accordingly, we deny this aspect of the motion.

Patent Owner argues that in paragraphs 29–34, and particularly in paragraphs 31 and 33–34, Dr. Vesely proffers new rationales in a new direction for modifying FIGS. 9A–9B by using the teachings of Goldfarb ’267. Mot. Excl. 4–5. Patent Owner argues that in paragraphs 23–26, Dr. Vesely presents a new methodology for implanting fixation device 14. *Id.* at 5–6. Patent Owner argues that when the rationale for unpatentability is changed by the Petitioner based on new evidence, this exceeds the permissive scope of a reply under 37 C.F.R. §42.23(b). *Id.* at 2–3 (citing *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016); CTPG 74). Patent Owner also suggests that even where the Board does not exclude evidence, it may determine that there is “impermissible new argument” that exceeds the proper scope of a reply. *See* Mot. Excl. Reply 2 (citing *Apple Inc. v. Parus Holding, Inc.*, IPR2020-00686, Paper 37 at 41–42 (PTAB Sept. 9, 2021)).

For paragraphs 23–26 and 29–34 of the Second Declaration, Petitioner argues that Dr. Vesely was responding to Dr. Sack’s testimony that Figures 9A–9B require independent movement of flaps 104 with respect to fixation device 14, in showing ways to implant the device that do not require independent movement of the clips or a way to achieve independent movement of the clips by using a sliding collar. Opp. Mot. Strike 6–7 (citing Ex. 2004 ¶¶ 27–30). Petitioner argues that this was within the proper scope of a response. *Id.* at 7 (citing 37 C.F.R. § 42.23(b); *Masterimage 3D, Inc. v. RealD Inc.*, IPR2015-00040, Paper 85 at 72 (PTAB Apr. 14, 2016)).

Petitioner argues that Patent Owner had ample opportunity to cross-examine Dr. Vesely on his testimony in paragraphs 21, 23–26, and 29–34 and to respond to his opinions therein. Opp. Mot. Strike 7–8 (citing *Belden Inc. v. Berk-Tek, LLC*, 805 F.3d 1064, 1080–82 (Fed. Cir. 2015); *Samsung Elecs. Co. Ltd. v. Affinity Labs of Texas, LLC*, IPR2014-01181, Paper 36 at 63 (PTAB Jan. 28, 2016)).

We agree with Petitioner that the testimony regarding how to implant a fixation device with the flap coupled to coupling portion 19 was responsive to the testimony of Dr. Sacks that Figures 9A–9B required independent movement of the flaps and the fixation device. *See Belden Inc.*, 805 F.3d at 1081–82 (“Rebuttal evidence is supposed to be limited to that which is responsive to the adversary’s evidence: ‘the traditional principle [is] that evidence offered to rebut must accomplish the function of rebuttal; ‘to explain, repel, counteract, or disprove the evidence of the adverse party.’”).

It is a closer case when analyzing Dr. Vesely’s testimony that a person of ordinary skill could have coupled the flaps to collar 131 of Goldfarb ’267 because Dr. Vesely is arguably relying on an additional reference. However, Goldfarb ’267 was already of record and was incorporated by reference into Goldfarb ’329, which means reliance on the latter necessarily implicates consideration of the former, to a degree. Ex. 1005; *see* Section II.D.2.c., *supra*. Therefore, we find Petitioner was not relying on new evidence. Further, even if Petitioner was relying on an additional portion of Goldfarb ’267, we determine that Dr. Vesely was merely responding to Dr. Sack’s argument and explaining that even if Figures 9A and 9B required independent movement of the flaps and the clips, the flaps could still be attached to the clips in this manner. *See Belden Inc.*, 805 F.3d at 1081–82;

Apple Inc. v. Andrea Elecs. Corp., 949 F.3d 697, 706 (Fed. Cir. 2020) (citing *Anacor*, 889 F.3d at 1380–81) (the petitioner in an *inter partes* review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner). Accordingly, we deny these aspects of the motion.

For similar reasons, we determine that Petitioner’s Reply Brief is responsive to the Patent Owner Response.

Alleged Failure to Provide Underlying Facts or Data:

Paragraphs 24–25 of Dr. Vesely’s Second Declaration

Paragraphs 29–34 of Dr. Vesely’s Second Declaration

Paragraphs 44–50 of Dr. Vesely’s Second Declaration

Patent Owner argues that in paragraphs 24–25, Dr. Vesely fails to provide facts or data to support these allegedly known “two ways to implant the fixation device” so that the flaps do not move relative to the clips. Mot. Excl. 7–8.

Petitioner responds that Patent Owner’s motion acknowledges that Dr. Vesely relies on Exhibit 2007 and Goldfarb ’329. Opp. Mot. Excl. 9 (citing Mot. Excl. 8). We agree with Petitioner that Dr. Vesely’s testimony is supported by Exhibit 2007 and Goldfarb ’329. *See* Ex. 1016 ¶¶ 24–25. Accordingly, we deny this aspect of the motion.

Patent Owner argues that in paragraphs 29–34, Dr. Vesely fails to provide a scintilla of data as to why a person of ordinary skill would have found it obvious to attach the flaps to the clips as alleged and states for Goldfarb ’267 that collar 131 functions as an actuator and is not used to attach any element. Mot. Excl. 9 (citing Ex. 1005, 27:31–56); *see also id.* at 10–13.

Petitioner argues that paragraphs 29–34 of Dr. Vesely’s Second Declaration rely on the teachings of Goldfarb ’329 and Goldfarb ’267 to support Dr. Vesely’s opinions. Opp. Mot. Excl. 10. We deny this aspect of the motion. Where, as here, the decision is by an administrative agency, rather than a jury, there is a diminished concern that such exhibits would be prejudicial. *See Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) (sitting as a non-jury tribunal, the Board may assign appropriate weight to evidence presented) (citing *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941)). The panel may consider the support for the opinions in question in according them the appropriate weight.

Patent Owner argues that in paragraph 44, Dr. Vesely fails to provide any factual evidence or data to support his opinion that time is the primary driver of whether a particular method for surgery would be selected. Mot. Excl. 13.

Patent Owner argues that in paragraphs 45–49, Dr. Vesely provides no underlying facts for his opinion that a person of ordinary skill would not have attached anchors or staples to the heart wall or mitral valve annulus, and that Dr. Vesely’s opinion was contrary to St. Goar, Liska, and Powell. Mot. Excl. 13–16. Patent Owner argues that the PTAB Trial Practice Guide requires the underlying facts and data supporting expert testimony be disclosed. *Id.* at 6–7 (citing CTPG 40–41).

Petitioner argues that the motion reflects Patent Owner’s disagreement on the merits and that Dr. Vesely provides the facts on which he reaches his conclusion. *See* Opp. Mot. Excl. 11–15. We determine that this goes to weight rather than admissibility. *See Corning*, Paper 66 at 19. Accordingly, we deny this aspect of the motion.

V. CONCLUSION³¹

We conclude that Petitioner has established by a preponderance of the evidence that claims 1–3, 5, 6, 8, 11, and 16–21 of the '341 patent would have been unpatentable.

Claims	35 U.S.C. §	References/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 5, 6, 8, 11, 16–21	103	Goldfarb '329	1–3, 5, 6, 8, 11, 16–21	
3	103	Goldfarb '329, Goldfarb '267	3	
11	102	Goldfarb '813	11	
11	103	Goldfarb '813	11	
1–3, 5, 6, 16–18, 21	103	Goldfarb '813, Goldfarb '329		1–3, 5, 6, 16– 18, 21
3	103	Goldfarb '813, Goldfarb '329, Goldfarb '267		3
Overall Outcome			1–3, 5, 6, 8, 11, 16–21	

Motion to Amend Outcome	Claim
Original Claims Cancelled by Amendment	

³¹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

Motion to Amend Outcome	Claim
Substitute Claims Proposed in the Amendment	22, 23
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	22, 23
Substitute Claims: Not Reached	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has proved by a preponderance of the evidence that claims 1–3, 5, 6, 8, 11, and 16–21 of the '341 patent are unpatentable;

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;

FURTHER ORDERED that Patent Owner's Motion to Amend is *denied*;

FURTHER ORDERED that Petitioner's Motion to Strike is *granted-in-part* and *denied-in-part*; and

FURTHER ORDERED that Patent Owner's Motion to Exclude is *denied*.

IPR2021-00383
Patent 10,226,341 B2

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