NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

EDWARDS LIFESCIENCES CORPORATION,
EDWARDS LIFESCIENCES LLC,
Appellants

v.

CARDIOVALVE LTD.,
Appellee

2023-1515

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2021-01051.

Decided: June 9, 2025

JOSHUA STOWELL, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA, argued for appellants. Also represented by BRIAN C. BARNES, CRAIG S. SUMMERS.

SARA TONNIES HORTON, Willkie Farr & Gallagher LLP, Chicago, IL, argued for appellee. Also represented by DEVON WESLEY EDWARDS, New York, NY; DAVID PHILLIP EMERY, WILLIAM MANDIR, Sughrue Mion, PLLC, Washington, DC.

Before MOORE, *Chief Judge*, HUGHES and CUNNINGHAM, *Circuit Judges*.

CUNNINGHAM, *Circuit Judge*.

Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, "Edwards") appeal from a final written decision of the Patent Trial and Appeal Board in an *inter partes* review of U.S. Patent No. 10,702,385. In the final written decision, the Board granted Cardiovalve Ltd.'s ("Cardiovalve") non-contingent Motion to Amend and Supplemental Motion to Amend, canceling original claims 1–10 and replacing those claims with substitute claims 11–20 and concluded that Edwards failed to show that claims 11–20 are unpatentable. *Edwards Lifesciences Corp. v. Cardiovalve Ltd.*, No. IPR2021-01051, Paper 36 at 58–59 (P.T.A.B. Dec. 6, 2022) ("*Decision*").[1] For the reasons below, we *affirm*.

I. BACKGROUND

Cardiovalve owns the '385 patent, which is titled "Implant for Heart Valve." '385 patent; *see also Decision* at 2. The '385 patent is generally directed to methods of using "a prosthetic valve support" that facilitates "minimally invasive (e.g., transcatheter and/or transluminal) implantation of a prosthetic valve at a native valve of a subject." '385 patent col. 1 ll. 56–59; *see id.* col. 27 l. 14 to col. 28 l. 59.

On June 4, 2021, Edwards petitioned for *inter partes* review of claims 1–10 of the '385 patent. *Decision* at 2; J.A. 209. Edwards asserted six grounds of unpatentability,

[1] Citations in this opinion are to the version of the Board's decision in the Joint Appendix. *See* J.A. 1–60.

including that Goldfarb[2] anticipated or rendered obvious claims 1–2 and 4–10 of the '385 patent and that the combination of Goldfarb and Goldfarb '329[3] rendered claim 3 obvious. *Decision* at 9–10; J.A. 229. Edwards's unpatentability arguments rely on an embodiment of Goldfarb, which the parties and the Board refer to as "Embodiment A." *Decision* at 10, 16–22; J.A. 229.

Embodiment A is an embodiment of Goldfarb in which a "fixation device" (depicted in Fig. 22A–22B below as element 14) has "distal and proximal elements" (elements 18 and 16 respectively) on each side of the fixation device that can move towards each other to capture tissue flaps and "lateral branches" (elements 19A, 19B) and/or the distal elements (element 18) that can move independently of each other.[4] J.A. 1380 at col 27. ll. 6–10, 57–60.

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[2] U.S. Patent No. 7,563,267 (filed May 19, 2003; issued July 21, 2009), J.A. 1294–396 ("Goldfarb").

[3] U.S. Patent No. 7,635,329 (filed Sep. 27, 2005; issued Dec. 22, 2009) ("Goldfarb '329"). '329 patent; *see Decision* at 10 n.6.

[4] Goldfarb "does not contain a picture of Embodiment A." J.A. 236. The parties agree that the "description of Figures 22A–22B largely still applies to Embodiment A, as evidenced by the use of the same reference numerals to identify the common features across the embodiments." J.A. 236 (citing J.A. 1380 col. 27 l. 6 to col. 28 l. 9); Appellee's Br. 14; *see also Decision* at 18–19.

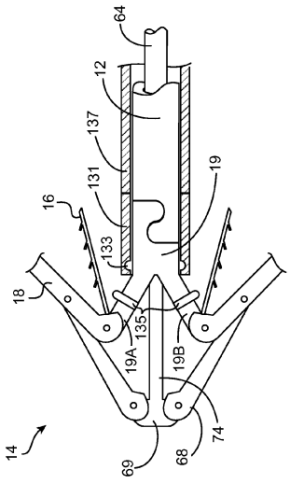


FIG. 22A

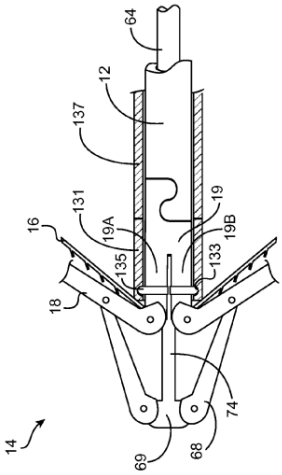


FIG. 22B

J.A. 1312 (rotated); *see also Decision* at 19. As shown in Figures 22A–22B, fixation device 14 includes coupling member 19, which "is bifurcated into two resilient and flexible branches 19A, 19B" which can move from the position shown in Fig. 22A to the one shown in Fig. 22B. J.A. 1380 col. 27 ll. 10–14. Fixation device 14 also includes a "collar 131" that is positioned around coupling member 19. *Id.* col. 27 ll. 24–27 ("A collar 131 is slidably disposed over coupling member 19"); *see also id.* col. 27 ll. 46–48.

Goldfarb describes male and female elements of coupling member 19. Specifically, "fixation device 14 is coupled to the shaft 12 by a coupling mechanism." J.A. 1373 col. 14 ll. 58–61. One embodiment of the coupling mechanism includes "an upper shaft 20 and a detachable lower shaft 22 which are interlocked at a joining line or mating surface 24." J.A. 1373 col. 14 ll. 61–63. As depicted below, mating surface 24, J.A. 1302, Fig. 5A, can be a "sigmoid curve defining a male element and female element" on the upper shaft of coupling member 19 which "interlock respectively with corresponding female and male elements" on the lower shaft. J.A. 1374 col. 15 ll. 19–23.

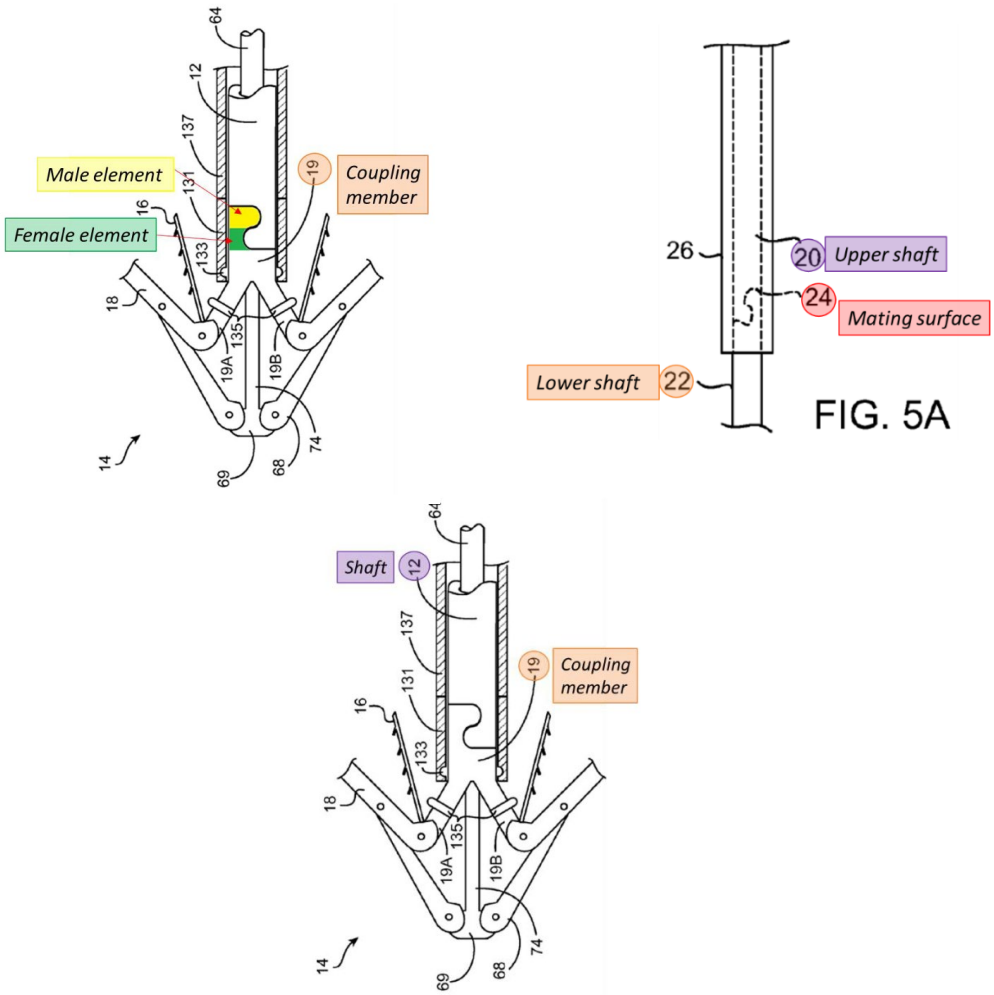


FIG. 5A

Appellant's Br. 14, 16 (rotating and annotating J.A. 1312); *see also id.* at 15 (annotating J.A. 1302).

On December 10, 2021, the Board instituted *inter partes* review. *Decision* at 2. On March 7, 2022, Cardiovalve filed a Motion to Amend pursuant to 37 C.F.R. § 42.121. *Id.*; J.A. 390; J.A. 101. On September 28, 2022, Cardiovalve filed a Revised Supplemental Motion to Amend to "correct[ ] certain deficiencies in the original Motion to Amend" and to "clarify[ ] that the Motion to Amend is non-contingent." *Decision* at 2–3 & n.1. The

Supplemental Motion to Amend (1) canceled original claims 1–10; (2) substituted independent claim 11 for original claim 1; and (3) changed the dependency of claims 1–10 from canceled claim 1 to substitute claim 11, resulting in substitute dependent claims 12–20. *Decision* at 3 n.1, 9.

Substitute claim 11 recites:

> 11. A method for use at a native valve of a heart of a subject, the valve including a first leaflet and a second leaflet, the method comprising:
>
> transluminally advancing, to the heart, an implant coupled to a delivery apparatus,
>
> the implant including a first clip*,* a second clip, *and a support portion flexibly coupled to the first and second clips, the support portion having an opening that surrounds a central longitudinal axis of the implant*, the first clip and the second clip fixedly coupled to each other, the first clip including a first-clip arm, and the second clip including a second-clip arm*, the first-clip arm and the second-clip arm each having an end most displaceable from the central longitudinal axis of the implant*, and
>
> the delivery apparatus including a delivery tube and at least one clip controller disposed within the delivery tube*,*
>
> *the first-clip arm, the second-clip arm, and the support portion being disposed within the delivery tube during the transluminal advancing to the heart*;

> advancing the implant out of the delivery tube *by advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube*;
>
> forming the first leaflet and the second leaflet into a double-orifice arrangement by using the implant to couple a middle scallop of the first leaflet to a middle scallop of the second leaflet by, using the clip controller:
>
> > opening the first clip by deflecting the first-clip arm;
> >
> > independently of opening the first clip, opening the second clip by deflecting the second-clip arm;
> >
> > gripping the first leaflet with the first clip by closing the first clip by deflecting the first-clip arm; and
> >
> > independently of gripping the first leaflet, gripping the second leaflet with the second clip by closing the second clip by deflecting the second-clip arm;
>
> decoupling the clip controller from the implant; and
>
> withdrawing the delivery apparatus from the subject.

J.A. 395–96 (emphasis added for limitations added by amendment and deletions incorporated); *Decision* at 7–9.

Two limitations from substitute claim 11 are at issue in this appeal: (1) "a support portion flexibly coupled to the first and second clips, the support portion having an

opening that surrounds a central longitudinal axis of the implant" (the "support portion" limitation); and (2) "advancing the implant out of the delivery tube by advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube" (the "advancing" limitation).

On December 6, 2022, the Board granted the Motion to Amend filed by Cardiovalve because Edwards failed to show by a preponderance of the evidence that the proposed substitute claims were unpatentable. *Decision* at 1–2. The Board focused its analysis on the unpatentability of substitute claim 11 based on Goldfarb. *See id.* at 10, 16–18 (acknowledging that Edwards had agreed "that substitute claims 12–20 thus stand or fall with substitute claim 11"); J.A. 433.

Edwards timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II. STANDARD OF REVIEW

"We review the Board's legal conclusions de novo and its fact findings for substantial evidence." *Game & Tech. Co. v. Wargaming Grp. Ltd.*, 942 F.3d 1343, 1348 (Fed. Cir. 2019). "Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1343 (Fed. Cir. 2020) (internal quotation marks and citation omitted).

"Anticipation is a question of fact as is the question of what a reference teaches." *In re NTP, Inc.*, 654 F.3d 1279, 1297 (Fed. Cir. 2011). "We review the Board's legal determination of obviousness de novo and its factual findings for substantial evidence." *Outdry Techs. Corp. v. Geox S.p.A.*, 859 F.3d 1364, 1367 (Fed. Cir. 2017). "We review claim construction de novo and any subsidiary factual findings based on extrinsic evidence for substantial evidence."

Apple Inc. v. MPH Techs. Oy, 28 F.4th 254, 259 (Fed. Cir. 2022).

III. DISCUSSION

In its briefing on appeal, Edwards argued that the Board erred by (1) adopting an implicit construction of "support portion" that excluded the male element portion of the coupling member, Appellant's Br. 34, 39–51; (2) finding that Goldfarb's male element does not have an opening that "surrounds" the central longitudinal axis of the fixation device, *id.* at 35, 51–57; (3) finding that Goldfarb does not disclose or render obvious the "advancing" limitation, i.e., that the ends of the clip arms are advanced out of the delivery tube before the support portion, *id.* at 36, 57–60; (4) finding that Goldfarb's collar does not satisfy the "support portion" limitation, *id.* at 36, 60–66; and (5) misconstruing "advancing" and "having an end most displaceable," *id.* at 36, 66–72. However, at oral argument, Edwards asserted only "three independent bases for remand," namely that the Board (1) misconstrued support portion to require a unitary structure; (2) erred in finding that "collar" is not a support portion; and (3) erred in its construction of the "advancing" limitation and in concluding that the limitation was not disclosed by teachings of the references asserted. Oral Arg. 1:00–2:41, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1515_10082024.mp3; *see also id.* at 7:43–8:38. We address each of these three arguments in turn.

A.

Edwards argues that the Board erred by adopting an implicit construction of "support portion" that excludes the male element of the coupling member of Goldfarb. Appellant's Br. 39. Cardiovalve responds that this is not a claim construction issue—instead, Cardiovalve argues the Board's refusal to deem the male element of the coupling member as a support portion was a factual finding that rested on its interpretation of Goldfarb, not the

interpretation of the claims of the '385 patent. Appellee's Br. 49. We agree with Cardiovalve.

The Board made a factual finding that the male element of the coupling member alone does not constitute a support portion. The Board held that Goldfarb's coupling member is "plainly a single, unitary structure." *Decision* at 41. The Board considered Edwards's argument that the male element portion of the coupling member is "the support portion because it: (1) bears the weight of the fixation device during delivery; (2) absorbs and transfers the axial and rotational forces imposed by the shaft 12; and (3) holds the device in the correct orientation." *Id.* The Board found that all the "elements" that Edwards described as being separate—the male and female elements of the coupling member, the coupling member, and flexible arms 19A and 19B—"*together* form a solid, single component." *Id.* (emphasis added). Accordingly, the Board concluded that the entirety of the coupling member, i.e., "*all* of the[se] 'elements'" perform the required functions of a "support portion." *Id.* at 41–42 (emphasis in original). The Board further noted that Edwards "points to no disclosure of Goldfarb . . . that suggests these elements act independently or separately to perform the functions of the unitary component, nor can we discern any such disclosure." *Id.* at 42. Thus, the Board concluded that Edwards's argument was "an arbitrary and unduly restrictive interpretation of [Goldfarb's] disclosure." *Id.*

In sum, the Board's analysis was not directed towards "discern[ing] the meaning of a particular term" in substitute claim 11. *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1319 (Fed. Cir. 2013). Therefore, the Board engaged in fact finding rather than implicit claim construction. We further agree that the portions of Goldfarb relied on by the Board provide substantial evidence to support its conclusion. We also conclude that the Board did not err in finding that the male element of the coupling member is not a support portion.

B.

Next, we address Edwards's argument that the Board erred in finding that Goldfarb's collar is not a support portion. Appellant's Br. 60. Substitute claim 11 requires "advancing . . . an implant . . . including . . . *a support portion flexibly coupled to the first and second clips*." J.A. 395 (emphasis added). Thus, the plain language of substitute claim 11 requires a support portion that is coupled to the first and second clips when the implant is advanced. We agree with Cardiovalve that substantial evidence supports the Board's finding that Goldfarb's collar does not constitute the claimed support portion. Appellee's Br. 60–63.

The Board explained why Goldfarb's collar does not satisfy the claim limitation for support portion. The Board stated that Goldfarb teaches that the collar "is slidably disposed over" the coupling member. *Decision* at 44–45 (quoting J.A. 1380 col. 27 ll. 24–27). The Board reasoned that because the collar and coupling member can freely move with respect to each other, Goldfarb's collar "cannot provide the support functions" required of a support portion. *Decision* at 45. Additionally, the Board explained that because moving the slidable collar with respect to the coupling member "would not exert any mechanical effect on the first and second clips," then it follows that the "collar . . . and the clips are not 'coupled' to each other." *Id.*

We agree with the Board's reasoning and conclude that substantial evidence supports its determination that the collar does not constitute the claimed support portion in substitute claim 11. Edwards argues that "the Board ignored that the collar and clips are slidably disposed only temporarily" and that "[o]nce the collar engages the detents on the coupling member, the components are permanently coupled." Appellant's Br. 33; *see also id.* at 61–62 (arguing that once the groove 133 on collar 131 engage with detents 135, "collar 131 is permanently coupled to the clips . . . through the branches 19A, 19B and remains

behind with the clips after deployment of the fixation device, as shown in Figure 22B."). Even if we accept that the collar may eventually be permanently coupled to the clips, Edwards's argument fails because the collar is not coupled to the clips at the time of delivery of the implant, as required by the claim language. As the Board recognized, Edwards agreed that Embodiment A of Goldfarb is "delivered through the delivery tube 'with distal and proximal elements 16, 18 in the closed position.'" *Decision* at 28 (quoting J.A. 448). Goldfarb provides that, in this closed position, the collar is "pushed distally against, *but not over*, detents 135 so that branches 19A, 19B are disposed together and fixation device 14 has a minimal profile." J.A. 1380 col. 27 ll. 31–35 (emphasis added). In other words, the collar is not coupled to the detents, and therefore not coupled to the clips, during delivery of the implant.

In sum, substantial evidence supports the Board's determination that Goldfarb discloses that the collar is not coupled to the clips at the time of delivery of the implant as substitute claim 11 requires. Therefore, we conclude that the Board did not err in determining that Goldfarb's collar does not constitute a support portion.

C.

Edwards argues that the Board erred in (1) construing the "advancing" limitation, Appellant's Br. 66–69; and (2) finding that Goldfarb does not disclose and render obvious the "advancing" limitation. *Id.* at 57–60. We address each argument in turn.

i.

Edwards argues that the Board improperly construed "'advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube' to 'require the ends of the clips to precede ***any part*** of the support portion, not the entire support portion, when advanced.'"

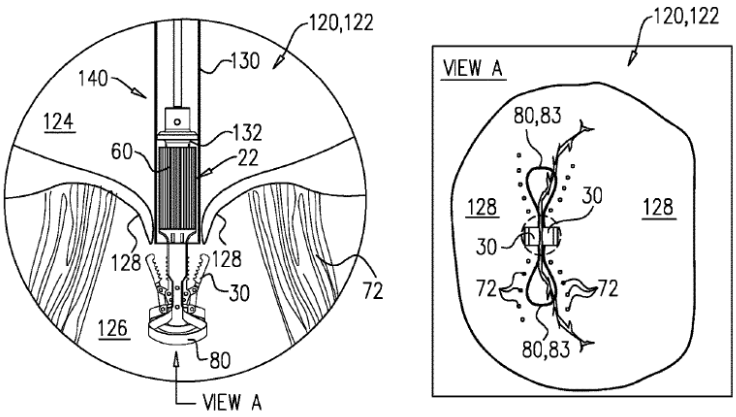
Appellant's Br. 67 (emphasis in original) (quoting J.A. 480). Specifically, Edwards argues that the proper construction requires reading the "support portion" to refer to the entire support portion, rather than "any part" of the support portion. *Id.* Cardiovalve counters that, under the plain and ordinary meaning of "advancing," the object being advanced must only "begin[ ] to emerge from the delivery tube" and need not "come fully out towards the native heart valve." Appellee's Br. 29. We agree with Cardiovalve.

"Claim terms are generally given their plain and ordinary meaning, which is the meaning one of ordinary skill in the art would ascribe to a term when read in the context of the claim, specification, and prosecution history." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (en banc)). As always, "[w]e start with the claim language." *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1360 (Fed. Cir. 2015).

The claim language indicates that the support portion must only be partially advanced out of the delivery tube. As the Board explained, "the language of the proposed substitute claim uses the term 'the end of' to indicate that the whole clip arm is advanced out of the delivery tube, in the phrase 'by advancing the end of the first-clip arm and the end of the second clip-arm.'" *Decision* at 54 (quoting J.A. 467). By contrast, the phrase "before advancing the support portion out of the delivery tube" does not include the phrase "the end of." *Id.* (quoting J.A. 467). We agree with the Board that this claim language indicates that the entire support portion need not be advanced out of the delivery tube.

The specification also supports this interpretation. Figure 3B in the specification provides an example of the prosthetic valve support 22 being "advanced out of delivery tube 130." '385 patent col. 14 ll. 15–17. Specifically, Figure 3B shows that the clip arms emerge in their entirety, while the prosthetic valve support 22, which includes the support portion 60, is only partially out of the delivery tube.

FIG. 3B



'385 patent Fig. 3B; *see id.* col. 14 ll. 15–23. This disclosure indicates that "advancing" an object "out of the delivery tube" requires only partial emergence of that object. *See* '385 patent col. 14 ll. 15–23. Accordingly, the Board correctly determined that "advancing the support portion out of the delivery tube" refers to "advancing any part of the support portion, rather than the entire support portion." *Decision* at 54 (quoting J.A. 467).

In sum, we conclude that the Board did not err in its construction of the "advancing" limitation.

ii.

Edwards also argues that the Board erred in finding that Goldfarb does not disclose or render obvious the "advancing" limitation. Appellant's Br. 57. Cardiovalve responds that, under the Board's construction of "advancing," the coupling member and the collar cannot meet the "advancing" limitation. Appellee's Br. 36–37. We agree with Cardiovalve that the coupling member does not meet the limitation of "advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube" as construed by the Board. [5]

The Board found that Edwards failed to meet its burden of showing that Goldfarb anticipates or renders obvious the "advancing" limitation. *Decision* at 57. The Board based its conclusion on Figure 22A of Goldfarb, which indicates that, regardless of the length of distal element 18, "*some* portion of coupling member 19, and at least flexible arms 19A and 19B, would necessarily have emerged from the delivery tube prior to the distal ends of either distal element 18 or proximal element 16." *Id.* at 56 (emphasis in original). The Board reasoned that "flexible arms 19A and 19B (which are part of coupling member 19) are attached to the bases of both proximal and distal elements 16 and 18 and must therefore be advanced from the delivery tube as the clips begin to emerge." *Id.*; *see* J.A. 1380 col. 27 ll. 17–19 ("Each of proximal elements 16 and distal elements 18

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[5] Because we find that the Board did not err in finding that the collar does not constitute a support portion, we need not address Edwards's argument that the Board failed to address the support functions provided by the collar. For the same reason, we do not separately address the parties' arguments regarding whether the collar meets the "advancing" limitation.

are coupled at their proximal ends to one branch 19A or 19B of the coupling member 19.").

Substantial evidence supports the Board's findings. Edwards argues that a skilled artisan "would have found it obvious to adjust the length of the proximal and/or distal elements so that they exited the delivery tube before the male element." Appellant's Br. 58; *see* J.A. 50–51. The Board explained that "the problem with [Edwards's] argument is that it is largely speculative and based upon [Edwards's] interpretation of the Figures of Goldfarb." *Decision* at 56. Edwards did not provide an illustration of Embodiment A within the delivery tube or identify any disclosure of Goldfarb that taught the "advancing" limitation or draw the figures of Goldfarb to "any defined scale." *Id.* The Board therefore found that Edwards's arguments that Figures 22A and 22B of Goldfarb taught the "advancing" limitation were "unavailing" and "largely speculative" in that they "depend[ed] upon what the length of distal element 18 *could* be." *Id.* at 56–57 (emphasis in original). We see no error in the Board's determination that Goldfarb does not disclose or render obvious the "advancing" limitation.

IV. CONCLUSION

We have considered Edwards's remaining arguments and find them unpersuasive. For the above reasons, we *affirm*.

AFFIRMED