

NOTE: This disposition is nonprecedential.

**United States Court of Appeals  
for the Federal Circuit**

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**CARDIOVALVE LTD.,**  
*Appellant*

v.

**EDWARDS LIFESCIENCES CORPORATION,  
EDWARDS LIFESCIENCES LLC,**  
*Appellees*

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2022-2230

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Appeal from the United States Patent and Trademark  
Office, Patent Trial and Appeal Board in No. IPR2021-  
00383.

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Decided: March 21, 2024

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SARA TONNIES HORTON, Willkie Farr & Gallagher LLP,  
Chicago, IL, argued for appellant. Also represented by  
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2 CARDIOVALVE LTD. v. EDWARDS LIFESCIENCES CORPORATION

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Before TARANTO, CHEN, and STOLL, *Circuit Judges*.

TARANTO, *Circuit Judge*.

Cardiovalve Ltd. owns U.S. Patent No. 10,226,341, titled “Implant for Heart Valve.” Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, Edwards) successfully petitioned the Patent and Trademark Office (PTO) to institute an inter partes review of claims 1–3, 5, 6, 8–11, and 13–21 of the ’341 patent under 35 U.S.C. §§ 311–19. After review, the PTO’s Patent Trial and Appeal Board determined in relevant part that all of the challenged claims were unpatentable for obviousness over U.S. Patent No. 7,635,329 (Goldfarb). *Edwards Lifesciences Corp. v. Cardiovalve Ltd.*, No. IPR2021-00383, 2022 WL 2812478, at \*40 (P.T.A.B. July 18, 2022) (*Board Decision*). Cardiovalve appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A). We affirm.

## I

The ’341 patent describes, with a particular focus on heart valves, “a prosthetic valve support . . . for facilitating minimally invasive (e.g., transcatheter and/or transluminal) implantation of a prosthetic valve at a native valve of a subject.” ’341 patent, col. 1, lines 53–56; *see also id.*, col. 1, lines 31–34. Independent claim 1, which the parties agree is representative, recites:

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

## 4 CARDIOVALVE LTD. v. EDWARDS LIFESCIENCES CORPORATION

closing of the clip, and the delivery apparatus being intracorporeally decouplable from the implant.

*Id.*, col. 27, lines 10–41 (emphases added).

Goldfarb discloses, in one of its embodiments, a device for stabilizing heart valve leaflets. Goldfarb, col. 17, lines 20–22. Figure 9B of Goldfarb illustrates this device, which is being inserted from above, so that upper is proximal and lower is distal from the inserter's perspective:

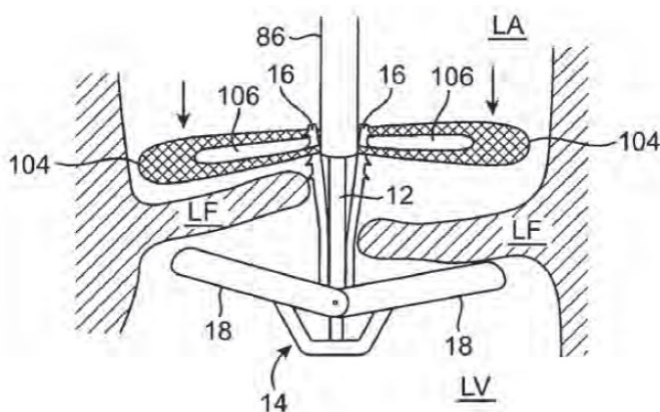


FIG. 9B

*Id.*, fig.9B. The disclosed fixation device, 14, includes two proximal elements, 16, and two distal elements, 18, configured such that a proximal and distal element pair, when brought together, form a clip that grasps a heart valve leaflet, LF, from the top and bottom. *Id.*, col. 17, lines 29–37. The fixation device also includes flaps, 104, which restrict upward motion of the leaflets to better enable the proximal and distal elements to grasp the leaflets. *Id.*, col. 17, lines 38–50. Additionally, Goldfarb discloses that “[o]nce the leaflets have been grasped, the flaps . . . may be removed . . . or *may be left behind* to assist in holding the leaflets.” *Id.*, col. 17, lines 51–53 (emphasis added).

CARDIOVALVE LTD. v. EDWARDS LIFESCIENCES CORPORATION 5

Cardiovalve does not dispute that Goldfarb discloses every limitation of the claims of the '341 patent other than the requirement that the implant comprise “at least one leaflet clip” “coupled to the annular portion.” Further, Cardiovalve accepts that each of Goldfarb’s pairs of proximal and distal elements constitutes a “leaflet clip,” that each of Goldfarb’s flaps constitutes or contains an “annular portion,” and that any direct or indirect attachment of Goldfarb’s proximal and distal elements to Goldfarb’s flaps is a “coupl[ing].” See Cardiovalve Opening Br. at 32–33, 38–47; see also *Board Decision*, at \*18. The Board found that Goldfarb makes the disputed claim element obvious, *id.*, at \*16–20, and concluded that Edwards had established obviousness, *id.*, at \*21.

## II

On appeal, Cardiovalve’s only challenge is that the Board erred in determining that Edwards had shown that it would have been obvious to a relevant artisan to attach, either directly or indirectly, Goldfarb’s flaps to its proximal and distal elements. We reject this challenge.

“Obviousness is a question of law based on underlying findings of fact.” *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). We decide obviousness de novo but review for substantial-evidence support the Board’s subsidiary fact findings, including the presence or absence of a motivation to combine or modify teachings in the prior art, the presence or absence of a reasonable expectation of success, and the predictability of results from known methods. See *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1363 (Fed. Cir. 2018); *In re Stepan Co.*, 868 F.3d 1342, 1345–46 (Fed. Cir. 2017); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016); *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1341 (Fed. Cir. 2010).

The Board here invoked the passage in the Supreme Court’s opinion in *KSR International Co. v. Teleflex Inc.* that addresses proof of obviousness through a

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