NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

CARDIOVALVE LTD.,
Appellant

v.

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,
Appellees

2022-2230

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

Decided: March 21, 2024

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

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

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

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:

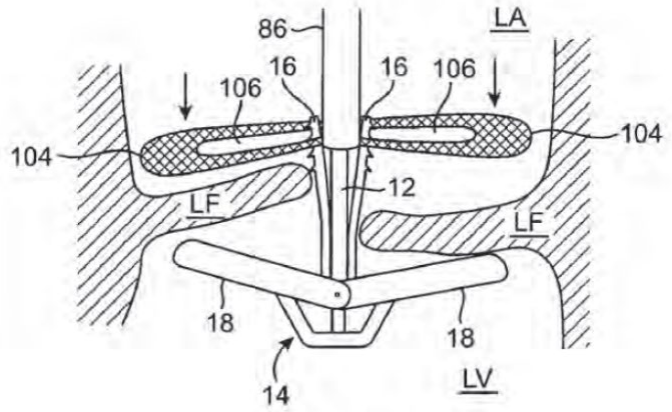

FIG. 9B

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 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

determination that a "combination" would have been "obvious to try." 550 U.S. 398, 421 (2007); *Board Decision*, at *17–19. The pertinent passage from *KSR* reads:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a [relevant artisan] 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.

KSR, 550 U.S. at 421. We conclude that the Board's findings made under this paragraph have substantial-evidence support and that its determination of obviousness is not legally erroneous.

Relying on Goldfarb's statement that the flaps "may be left behind," Goldfarb, col. 17, lines 51–53, the Board found that the flaps may be left behind, and it is not disputed that leaving the flaps behind would necessitate that they be attached to something fixed. *Board Decision,* at *18. We read the Board's opinion also to find, and Cardiovalve does not dispute, that Goldfarb's flaps, if left behind, must be attached either "(1) to the fixation device [implant] or (2) to the heart tissue." *Board Decision*, at *18; *see id.,* at *15 (reciting Cardiovalve's argument for heart-tissue fixation); Cardiovalve Opening Br. at 38–47. Whether or not the heart-tissue option might itself be divided into two types of tissue (heart wall, and heart-valve annulus), the result, the Board determined, was that a relevant artisan would know of a "finite number of predictable options." *Board Decision,* at *19; *see id.,* at *18–20; *id.,* at *16 n.16 ("[W]e decide that, even assuming that one option for a [relevant artisan] 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."). In fact, the Board added, it was actually simpler to attach the flaps to the implant device (in particular, though perhaps not only, to a "coupling member" 19 shown in Goldfarb)—which *is* attaching them to the clips indirectly. *Id.*, at *18–19; *see also id.,* at *23 (making that finding in the context of Claim 11, which raises the same issue).

The Board's findings are supported by substantial evidence. Edwards's expert explained with concrete reasoning why a relevant artisan would know to attach the flaps to the implant device and why such attachment would be expected to succeed. *See* J.A. 1163–68 ¶¶ 77–83, 1637–41 ¶¶ 15–21, 1644–46 ¶¶ 24–27, 1648–51 ¶¶ 31–34, 1656–63 ¶¶ 40–50. On appeal, Cardiovalve has concededly not challenged the Board's finding of the relevant expectation of success. Oral Arg. at 35:53–36:03.

Cardiovalve criticizes the Board's invocation of the obvious-to-try passage from *KSR,* but we find the criticisms unpersuasive. *See Board Decision*, at *17–18. First, Cardiovalve argues that there was no "*finite number* of identified, predictable solutions," *KSR*, 550 U.S. at 421 (emphasis added); Cardiovalve Opening Br. at 33–36, because there are too many possibilities. The Board properly determined otherwise. The claims require coupling a leaflet clip to an annular portion, undisputedly allow indirect coupling, and are indifferent to where on the device or with what specific means the connection between an annular portion and the device is made. '341 patent, col. 27, lines 13–19. The record readily supports placing possibly relevant heart tissue into two categories—the valve annulus and wall tissue. *See* J.A. 2099–105 ¶¶ 32–45, 2627–28 ¶¶ 20–23, 1816–20; *see also* U.S. Patent No. 6,629,534 (St. Goar), U.S. Patent Application Publication No. 2003/0120340 (Liska), U.S. Patent Application Publication No. 2006/0229708 (Powell); *Board Decision*, at *18. And as already noted, there was ample evidence for why a relevant artisan would have found it at least "simpler" to

use the implant for the attachment. *See Board Decision*, at *19; J.A. 1656–63 ¶¶ 40–50, 1816–20. The device-attachment option would have been obvious, as the Board found, whether or not there were a small number of other options that were also obvious.

Second, Cardiovalve argues that, in order to be a "known option[]" within the obvious-to-try passage of *KSR*, 550 U.S. at 421, the option at issue must have been expressed in prior art documents. Cardiovalve Opening Br. at 36–38. That proposed document requirement is nowhere articulated in *KSR*, and adopting it would be inconsistent with the Supreme Court's rejection in *KSR* of a rigid demand for the steps in an obviousness analysis to be proved by prior-art documents, to the exclusion of the knowledge and skill of the relevant artisan. *See KSR*, 550 U.S. at 418–22, 427. Nor, contrary to Cardiovalve's assertions, does our precedent require such a documentary basis. The fact that we relied on documents in the two cases Cardiovalve highlights, *Uber Technologies* and *Bayer*, does not mean that a documentary basis is required. *Uber Technologies, Inc. v. X One, Inc.*, 957 F.3d 1334, 1339–40 (Fed. Cir. 2020); *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, 575 F.3d 1341, 1350 (Fed. Cir. 2009).

Third, Cardiovalve makes the procedural argument that the Board's invocation of *KSR*'s obvious-to-try paragraph impermissibly injected a new theory different from the one raised by the petition. Cardiovalve Opening Br. at 48–54; *see Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1001–02, 1008 (Fed. Cir. 2023). We reject this argument for setting aside the Board's decision.

The Board's obvious-to-try analysis did not change the prior art, or the embodiments in the prior art, relied on. Edwards argued from the beginning that a relevant artisan would have found it obvious to attach Goldfarb's flaps to its fixation device (and therefore indirectly to its proximal and distal elements), because the flaps, if left behind, had to be

attached somewhere and this was an obvious location. *Compare* J.A. 174 ("[A] [relevant artisan] would have found it obvious to couple the flaps to the [proximal and distal elements] so that the entire apparatus could be detached and 'left behind' together."), *with Board Decision*, at *20 ("[A] [relevant artisan] would have found it obvious to have attached the flaps to the [proximal and distal elements] of [Goldfarb] . . . as a predictable option when choosing to leave the flaps behind."). Edwards's expert cited in his original declaration to such a method of attachment—via coupling member 19 shown in figure 3 of Goldfarb. J.A. 1166 ¶ 81; *see* Goldfarb, fig.3. In response, Cardiovalve pointed to another solution to the attachment problem, namely, attachment to heart tissue (valve annulus or wall), and urged that a relevant artisan would have used that solution. *See Board Decision*, at *15, *16 (discussing Cardiovalve submissions). In its obvious-to-try analysis, the Board then said that it need not find that the solution argued for by Edwards was the only obvious one, because it was enough that, even if Cardiovalve's submissions about alternative attachment locations were to be accepted, the Edwards-urged solution was *an* obvious one among two or three a relevant artisan would have known.

It is the essential point of the *KSR* passage relied on by the Board that, when a relevant artisan would have recognized a problem, a consideration of whether only a small number of solutions existed is a natural part of an evaluation of whether a patent-claimed solution would have been obvious. The Board's undertaking such consideration here was therefore a legitimate exercise of its duty to evaluate whether Edwards was right or wrong about the position Edwards consistently maintained—that attachment to the implant would have been obvious. All the Board did was to credit that position even on the assumption that Cardiovalve was right that a relevant artisan would have found one or two alternatives obvious as well. *See Board Decision*, at *16 n.16 (quoted *supra*). And Cardiovalve was

given an ample opportunity, through supplemental briefing, to address this proposed conclusion before the Board eventually adopted it. J.A. 871, 885.

In these circumstances, we see no procedural error on the Board's part in using the obvious-to-try paragraph of *KSR* as it did. We note that Cardiovalve does not meaningfully challenge that use as incomplete for want of additional analysis, after finding the preconditions laid out in that paragraph met, to move from the conclusion that the at-issue solution "likely" was or "might" have been obvious, *KSR*, 550 U.S. at 421, to a determination that it actually would have been obvious. In this regard, it is notable that the Board actually found reasons for a relevant artisan to choose the Edwards-urged solution over the alternative(s)—at the least, greater simplicity. *Board Decision*, at *19, *23. In light of that factual finding, together with the unchallenged factual finding of predictability, moreover, it may well be that we could affirm the obviousness conclusion even apart from the obvious-to-try analysis. We need not so decide, however, because we are not persuaded that there is reversible error in the Board's analysis.

III

We have considered Cardiovalve's additional arguments and find them unpersuasive. For the foregoing reasons, we affirm the Board's decision.

AFFIRMED