United States Court of Appeals for the Federal Circuit

AORTIC INNOVATIONS LLC,
Plaintiff-Appellant

v.

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, EDWARDS LIFESCIENCES (U.S.), INC.,
Defendants-Appellees

2024-1145

Appeal from the United States District Court for the District of Delaware in No. 1:21-cv-01377-JPM, Judge Jon P. McCalla.

Decided: October 27, 2025

JOHN BRUCE CAMPBELL, McKool Smith, P.C., Austin, TX, argued for plaintiff-appellant. Also represented by GEOFFREY SMITH, JOEL LANCE THOLLANDER.

MARK ANDREW PERRY, Weil, Gotshal & Manges LLP, Washington, DC, argued for defendants-appellees. Also represented by BRIAN C. BARNES, CHRISTY G. LEA, JOSHUA STOWELL, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA; BRIAN CHRISTOPHER HORNE, Los Angeles, CA.

Before PROST, REYNA, and CHEN, *Circuit Judges*.

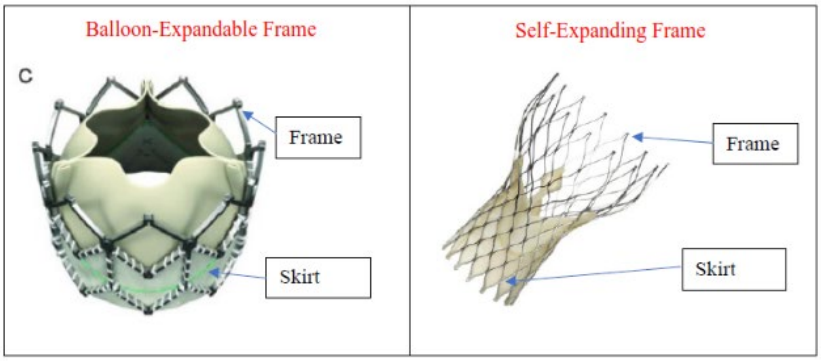
REYNA, *Circuit Judge*.

This appeal concerns devices for transcatheter aortic valve replacement, a procedure in which a prosthetic heart valve replaces a diseased aortic valve. Aortic Innovations LLC appeals from a stipulated judgment of non-infringement of four asserted patents from the U.S. District Court for the District of Delaware. Aortic argues that the district court's construction of "outer frame," on which the stipulated judgment of non-infringement was based, was erroneous. We agree with the district court's construction and affirm the judgment as to three of the asserted patents at issue. As to the fourth asserted patent, we dismiss the appeal for lack of jurisdiction.

BACKGROUND

I.

It was known in the art that a transcatheter aortic valve replacement device collapses down to a narrow diameter and is delivered to the site of the patient's diseased aortic valve via a delivery catheter. Once at the site, the device is removed from the catheter sheath and expanded in one of the following two ways, anchoring the device in place. First, it can expand via a balloon-expandable frame. This is a frame that requires a balloon inflating at the center of the device to expand from the collapsed state to the deployed state. Second, it can expand via a self-expanding frame, which expands due to its shape-memory material that springs back to an expanded shape after being released from the delivery catheter. The two types of frames are displayed below:



J.A. 3680.[1]

II.

Appellant Aortic Innovations LLC ("Aortic") owns the four asserted patents in this case, which are U.S. Patent Nos. 10,881,538 ("'538 patent"), 10,966,846 ("'846 patent"), 10,987,236 ("'236 patent"), and 11,129,735 ("'735 patent") (collectively, the "Asserted Patents"). The Asserted Patents derive from the same predecessor application and claim priority to the same provisional applications. J.A. 41–42. They also share a common specification.

The specification discloses two types of devices.[2] The first is an "endograft device" for endovascular repair of ascending aortic aneurysms, directed primarily to treatment of aortic diseases. J.A. 173, 2:53–55; J.A. 175, 6:36–49. The second is a "transcatheter valve." J.A. 174, 3:61–62. The claims of the Asserted Patents are directed to the transcatheter valve. J.A. 183; J.A. 150; J.A. 118; J.A. 85–86. According to the summary section of the specification, a "transcatheter valve" "includes a frame component having a balloon-expandable frame extending distally

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[1] Appellee included the red text displayed in the image above. *See* Response Br. 13.

[2] For the remainder of this opinion, we cite to the specification of the '735 patent when discussing the Asserted Patents' common specification.

from a proximal end of the frame component and a self-expanding frame secured to the balloon-expandable frame." J.A. 174, 3:61–65.

On appeal, the parties dispute the construction of the claim term "outer frame" in claim 1 of the '735 patent. This claim recites:

> 1. An endovascular transcatheter valve assembly comprising:
>
> an *outer frame*,
>
> wherein the *outer frame* is formed from a metallic material and defines an open cell configuration
>
> wherein the *outer frame* includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof,
>
> wherein the *outer frame* is formed by a plurality of struts that adjoin each other at the inflow end to form apices:
>
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the *outer frame* for providing sealing to the prosthetic heart valve,
>
> wherein the *outer frame* is secured to the inner graft covering by stitching a proximal portion of the *outer frame*;
>
> an outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows of cells formed in the *outer frame*,

> wherein the outer seal is formed of outwardly extending fibers positioned externally to the *outer frame*,
>
> wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,
>
> wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient
>
> wherein an end of the apices of the *outer frame* that are most proximal are covered by the outer seal and the graft covering,
>
> wherein the end of the most proximal apices of the *outer frame* extends more proximally than a proximal end of the outer seal.

J.A. 183, 21:17–22:11 (emphases added).

The specification discloses two categories of embodiments. It first discloses "serial-frame" embodiments, where a self-expanding frame and balloon-expandable frame attach at a meeting point, meaning there is no outer or inner frame but rather one serial frame. *See* J.A. 180, 15:23–16:14. The specification also discloses "dual-frame" embodiments, where an inner frame sits within the outer one. J.A. 181, 17:47–61.

Turning to the dual-frame embodiments, the specification provides for a dual-frame transcatheter valve, as illustrated in Figure 20 displayed below:

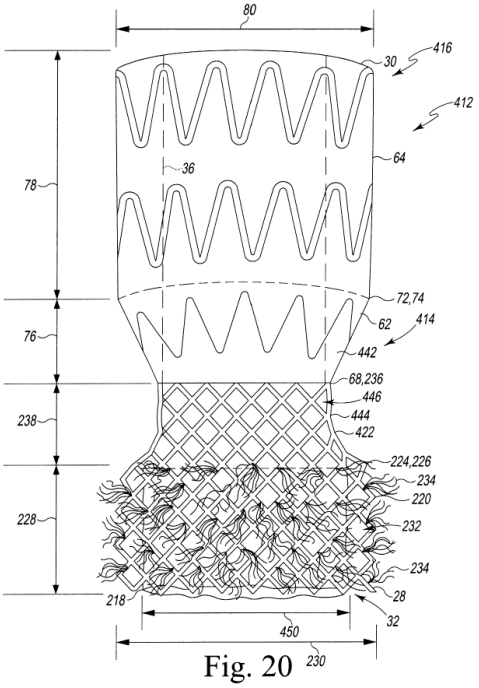

Fig. 20

J.A. 170; *see also* J.A. 182, 19:19–22.

When discussing Figure 20, the specification refers to structure 416 as an "outer frame" several times. J.A. 181, 17:64–67 ("It should be appreciated that in other embodiments the outer frame 416 may be formed from a polymeric material."); J.A. 181, 18:3–4, 18:22–23, 18:35; J.A. 182, 19:19, 19:36, 19:39, 19:41. It also refers to structure 416 as a "self-expanding frame" or a "self-expanding outer frame" several times. J.A. 181, 17:58–61 ("The dual-frame 414 includes a self-expanding outer frame 416 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 416 and houses the valve 32."); *see also* J.A. 181, 17:61–62, 18:43–44, 18:53–54, 18:66–67.

The specification also provides for a dual-frame endograft device, as illustrated in Figure 9 displayed below:

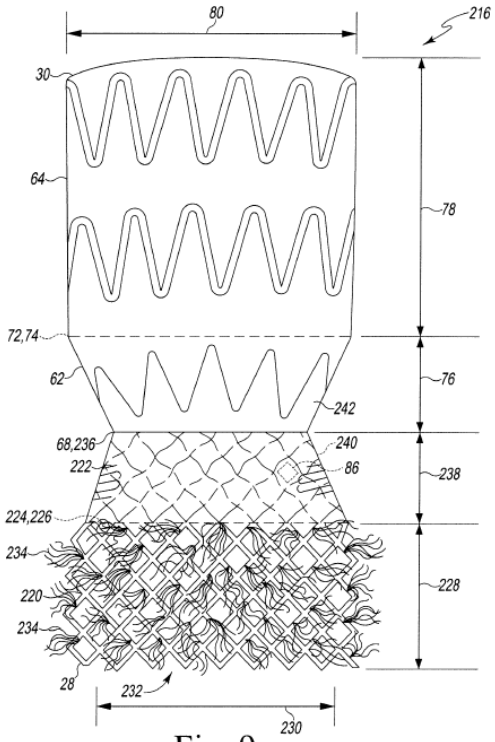

Fig. 9

When discussing Figure 9, the specification refers to structure 216 as an "outer frame" several times. *See, e.g.*, J.A. 178, 12:20–23 ("The outer frame 216 includes an elongated proximal section 220 . . . ."). It also refers to structure 216 as a "self-expanding frame" or "self-expanding outer frame" several times. *See, e.g.*, J.A. 178, 12:14–18 ("Referring now to FIG. 9, the self-expanding outer frame 216 has a generally hourglass shape . . . ."); J.A. 178, 12:64–67 ("The outwardly tapered middle section 62 of the self-expanding frame 216 has . . . .").

III.

Aortic sued appellees Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences

(U.S.), Inc. (collectively, "Edwards") in the U.S. District Court for the District of Delaware. J.A. 194. Aortic alleged that Edwards' SAPIEN 3 Ultra valve, a single, balloon-expandable frame, infringed Aortic's Asserted Patents.

Edwards then filed petitions for inter partes review before the Patent Trial and Appeal Board ("Board"). J.A. 1830. The Board instituted review as to three of the Asserted Patents, denying institution only as to the '735 patent. Edwards then moved the district court to stay the litigation, which the district court did except for the '735 patent.

Before the district court, the parties disputed the meaning of the term "outer frame" in claim 1 of the '735 patent. Aortic argued that this term should be given its plain and ordinary meaning. Edwards argued that "outer frame" should be construed as "[a] self-expanding frame having a generally hourglass shape that is positioned outside the inner frame." J.A. 3619.

The district court determined that the patentee acted as his own lexicographer and redefined the term "outer frame" to be "a self-expanding frame." J.A. 14; J.A. 19–20; J.A. 40.[3] The district court grounded this redefinition on the point that the terms "outer frame," "self-expanding frame," and "self-expanding outer frame" interchangeably refer to the same structure in two embodiments, i.e., structures 216 and 416. J.A. 19–20. The district court also clarified that its construction of "outer frame" in claim 1 of the

[3] The district court rejected Edwards' argument that an "outer frame" also has a "generally hourglass shape." J.A. 20–21. No party challenges this determination on appeal.

'735 patent applied to each of the Asserted Patents. J.A. 39.[4]

The district court also concluded that the patentee, acting as a lexicographer, redefined "inner frame" of claim 1 as a "balloon-expandable frame" by using these terms interchangeably. J.A. 22–24. No party disputes this construction on appeal.

Following claim construction, the parties jointly stipulated to non-infringement of the Asserted Patents because Edwards' accused product does not have a self-expanding frame. J.A. 2. The district court lifted the stay as to the '846, '538, and '236 patents and entered a final judgment of non-infringement as to the Asserted Patents. J.A. 2.

Aortic appeals the judgment of non-infringement, challenging the district court's construction of "outer frame." J.A. 2.

JURISDICTION

We have jurisdiction under 28 U.S.C. § 1295(a)(1) as to Aortic's appeal of the judgment concerning the '735, '846, '236 patents. We dismiss Aortic's appeal as to the '538 patent for lack of subject matter jurisdiction. On December 1, 2023, the U.S. Patent and Trademark Office issued a certificate cancelling the asserted claims of the '538 patent. Thus, there is no actual case or controversy between the parties concerning the '538 patent, mooting Aortic's appeal as to this patent. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013).

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[4] The district court determined that there was no clear disavowal made in the specification of outer frames that are not self-expanding. J.A. 17–18.

STANDARD OF REVIEW

We review a district court's claim construction and its interpretations of intrinsic evidence de novo. *Apple Inc. v. Wi-LAN Inc.*, 25 F.4th 960, 967 (Fed. Cir. 2022). We review any subsidiary fact findings based on extrinsic evidence for clear error. *Id.*

DISCUSSION

I.

The parties dispute the construction of "outer frame" in claim 1 of the '735 patent. Aortic argues that the claim term "outer frame" should be given its plain and ordinary meaning of "positioned outside," a meaning that is "readily apparent" to the parties and to the court. Appellant Br. 26. Aortic also argues that the specification does not support a determination that "outer" is interchangeable with "self-expanding," which are two separate and distinct concepts. Appellant Br. 24–41, 32–36. Thus, Aortic argues, the district court erroneously read out "outer" and read in a "self-expanding" limitation. *See* Appellant Br. 42–52. For the following reasons, we agree with the district court's construction that the "outer frame" is a "self-expanding frame."[5] We affirm the judgment of non-infringement.

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[5] At oral argument, the parties discussed an alternative construction as a "self-expanding outer frame," a construction which would not affect the stipulation to a judgment of non-infringement. *See* Oral Arg. at 18:37–58, 19:30–35, 20:16–20, 28:28–50, *available at* https://www.cafc.uscourts.gov/oral-arguments/24-1145_06022025.mp3. We see little difference between a "self-expanding outer frame" and a "self-expanding frame" for purposes of this claim construction. We, however, leave untouched the district court's construction, which parallels

The claims define the metes and bounds of the patentee's invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee clearly redefines the term (lexicography) or disavows claim scope (claim disavowal). *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). The standard for these two exceptions is exacting. *Id.* at 1366.

To act as his own lexicographer, "a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." *Id.* at 1365 (citation modified). Thus, the patentee's written description of the invention is relevant and controlling "insofar as it provides *clear lexicography* . . . [.]" *Id.* at 1366 (citation modified) (emphasis in original).

An explicit redefinition is not required for a patentee to act as a lexicographer. "[T]he specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) (citation modified). But "implied redefinition must be so clear" that a skilled artisan would understand "that it equates to an explicit one." *Thorner*, 669 F.3d at 1368 (citation modified). "Simply referring to two terms as alternatives or disclosing embodiments that all use the term[s] the same way is not sufficient to redefine a claim term." *Id.*

A patent's consistent and clear interchangeable use of two terms can result in a definition equating the two terms. *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009); *Wasica Fin. GmbH v. Cont'l Auto.*

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the district court's construction of claim 1's "inner frame" as a "balloon-expandable frame."

Sys., Inc., 853 F.3d 1272, 1282 n.6 (Fed. Cir. 2017) (highlighting interchangeable use within the claims and within the written description); *Bid for Position, LLC v. AOL, LLC*, 601 F.3d 1311, 1317–18 (Fed. Cir. 2010) (highlighting interchangeable use within a claim and within certain embodiments); *Bell Atl.*, 262 F.3d at 1274–75 (highlighting interchangeable use within the written description and within the prosecution history); *Tate Access Floors, Inc. v. Maxcess Techs., Inc.*, 222 F.3d 958, 968 (Fed. Cir. 2000) (highlighting interchangeable use throughout the abstract and summary of invention).

For example, in *Edwards*, the "specification consistently use[d] the words 'graft' and 'intraluminal graft' interchangeably." *Edwards*, 582 F.3d at 1329. Specifically, the court noted the interchangeable use of the claimed term "graft" and the narrowed term "intraluminal graft" in the disclosure of the invention of U.S. Patent 6,582,458 at 1:57–59 and in the "preferred embodiment" at columns 5 and 6. *Id.* The court then concluded that the interchangeable use of the two terms was "akin to a definition equating the two." *Id.*

Here, a skilled artisan would understand that the claimed term "outer frame" is a "self-expanding frame." First, when discussing structure 416 in the dual-frame transcatheter valve embodiment and structure 216 in the dual-frame endograft device embodiment, the specification refers to these structures as an "outer frame," a "self-expanding frame," and a "self-expanding outer frame" several times. J.A. 178, 12:20–23, 12:14–18, 12:64–67; J.A. 181, 17:65–67, 17:58–62, 18:3–4, 18:22–23, 18:35, 18:43–44, 18:53–54, 18:66–67; J.A. 182, 19:19, 19:36, 19:39, 19:41. Thus, this disclosure clearly indicates that structures 216 and 416 are outer frames that must self-expand.

Second, beyond the discussion of structures 416 and 216, the specification consistently indicates that claim 1's "outer frame" is a "self-expanding frame." The summary

section of the specification provides that "[a]ccording to another aspect [of the disclosure], a transcatheter valve is disclosed." J.A. 174, 3:61–62. It then says that "[t]he transcatheter valve includes a frame component having a balloon-expandable frame . . . and a self-expanding frame secured to the balloon expandable frame." J.A. 174, 3:62–65. In the paragraphs immediately following this statement, the specification notes that "[i]n some embodiments," other features may be present, but it never limits the presence of a self-expanding frame to only "some embodiments." *See* J.A. 174, 4:5–35. The contrast in the language indicates that a transcatheter valve must have a self-expanding frame and a balloon-expanding frame, whether it be configured as a serial-frame or a dual-frame.[6] Claim 1 is undisputedly directed to a dual-frame transcatheter valve, i.e., a device with an inner frame that sits within the outer frame. *See* J.A. 183, 21:16–41. Given that the district court construed claim 1's "inner frame" to be balloon-expandable, a construction no party disputes on appeal, then claim 1's "outer frame" must be self-expanding.

This conclusion, that a transcatheter valve must have a balloon-expandable frame and a self-expanding frame, is supported by the dual-frame embodiments. When discussing structures 216 and 416, the specification notes several times that "in other embodiments," these self-expanding structures (216/416) may have different features, such as being covered by a hydrogel. *See* J.A. 181, 18:14–16; J.A. 181, 18:29–31. However, the specification never indicates

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[6] Contrary to Aortic's position, we do not read this disclosure as limited to a serial-frame transcatheter valve. Reply Br. 17–18. There is no indication from this disclosure that it excludes dual-frame transcatheter valves and includes only serial-frame transcatheter valves. To the contrary, it broadly states that a "transcatheter valve is disclosed." J.A. 174, 3:61–62.

that the self-expanding nature of structures 216 and 416 is absent or modified in other embodiments. Thus, the specification clearly and consistently conveys that the self-expanding nature of structures 216 and 416 is present in all embodiments of those devices. *See GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370 (Fed. Cir. 2016) ("[W]hen a patent repeatedly and consistently characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization." (citation modified)).

In sum, a skilled artisan, when reading the patent, would understand that the "very character of the invention [of a transcatheter valve] requires the [self-expanding] limitation be a part of every embodiment." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003). Thus, the district court correctly construed the claim term "outer frame" as a "self-expanding frame."

II.

Aortic alternatively argues that Edwards should be judicially estopped from arguing that the claim term "outer frame" should be construed as having a meaning other than its plain and ordinary one. According to Aortic, Edwards argued before the Board that "outer frame" carried its plain and ordinary meaning but argued to the district court that "outer frame" only means a "self-expanding frame." Appellant Br. 53–55. Thus, according to Aortic, Edwards should be judicially estopped here from arguing the latter position. *Id.*

Edwards responds, and we agree, that Aortic forfeited its judicial estoppel argument by not raising it before the district court.

Aortic's responsive claim construction brief at the district court noted the position Edwards took at the Board and maintained that "Edwards should not be heard to argue differently here." J.A. 5050. However, that brief did

not otherwise develop any argument for application of judicial estoppel. Further, at the claim construction hearing, after Edwards's counsel preemptively addressed the prospect of an estoppel-based argument on this issue and observed that "Aortic hasn't argued or cited any law" that would support estoppel, *see* J.A. 6500, Aortic's counsel responded: "I think there's some confusion, it seems, as to the point here. *The propriety of taking different positions in front of different forums, I'll leave for the* [*c*]*ourt . . . .* [*T*]*he point here is that we know what the plain and ordinary meaning is*." J.A. 6511–12 (emphasis added). Under these circumstances, we deem Aortic's judicial-estoppel argument as not having been raised before the district court and thus forfeited in this appeal.

"We have regularly stated and applied the important principle that a position not presented in the tribunal under review will not be considered on appeal in the absence of exceptional circumstances." *In re Google Tech. Holdings LLC*, 980 F.3d 858, 863 (Fed. Cir. 2020). Here, we see no exceptional circumstances that would justify departing from that principle. We therefore do not consider Aortic's judicial estoppel argument.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the reasons discussed, we affirm the district court's judgment as to the '735, '846, '236 patents and dismiss the appeal for lack of jurisdiction as to the '538 patent.

AFFIRMED-IN-PART AND DISMISSED-IN-PART

COSTS

Costs to Edwards.