United States Court of Appeals for the Federal Circuit

ST. JUDE MEDICAL, LLC,
Appellant

v.

SNYDERS HEART VALVE LLC,
Cross-Appellant

UNITED STATES,
Intervenor

2019-2108, 2019-2109, 2019-2140

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2018-00105, IPR2018-00106.

Decided: October 15, 2020

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for appellant. Also represented by HANNAH LAUREN BEDARD, JASON M. WILCOX; BRYAN SCOTT HALES, KRISTINA NICOLE HENDRICKS, Chicago, IL.

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Houston, TX.

MELISSA N. PATTERSON, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, for intervenor. Also represented by COURTNEY DIXON.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.

TARANTO, *Circuit Judge*.

Snyders Heart Valve LLC owns U.S. Patent No. 6,540,782, which describes and claims an artificial heart valve and a system for inserting the valve. In October 2017, St. Jude Medical, LLC filed two petitions with the United States Patent and Trademark Office, under 35 U.S.C. §§ 311–19, seeking inter partes reviews of claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent (the challenged claims) by the Office's Patent Trial and Appeal Board. The Board, as delegee of the Director of the Office, 37 C.F.R. §§ 42.4, 42.108, instituted two reviews, each addressing all the challenged claims.

In IPR2018-00105 (IPR-105), the Board ultimately ruled that St. Jude had failed to establish unpatentability of any of the challenged claims. Specifically, the Board rejected St. Jude's contention that all the challenged claims were anticipated by the Leonhardt patent and would have been obvious over Leonhardt plus either the Anderson patent or the Johnson and Imachi patents. *St. Jude Medical, LLC v. Snyders Heart Valve LLC*, IPR2018-00105, 2019 WL 1975348 (P.T.A.B. May 2, 2019) (*IPR-105 Decision*). In IPR2018-00106 (IPR-106), the Board found claims 1, 2, 6, and 8 anticipated by the Bessler patent, but it rejected St. Jude's contentions as to all other claims. Specifically, it ruled that St. Jude had not proved, as to all but claims 1, 2, 6, and 8, anticipation by Bessler or obviousness over Bessler combined with either Anderson or Johnson and Imachi. *St. Jude Medical, LLC v. Snyders Heart Valve*

LLC, IPR2018-00106, 2019 WL 1975349 (P.T.A.B. May 2, 2019) (*IPR-106 Decision*).

St. Jude appeals on a subset of the challenges it presented to the Board. For IPR-105, it argues that the Board erroneously rejected the contention that Leonhardt anticipated claims 1, 2, 4–8, and 28, the alleged error being the Board's application of the construction of the claim term "band." For IPR-106, St. Jude argues that the Board erroneously rejected the contention that Bessler anticipated claim 28, the alleged error being the Board's finding a failure of proof that Bessler meets claim 28's "manipulator" limitation. St. Jude also argues, for IPR-106, that the Board erred in rejecting St. Jude's challenge to most of the claims at issue (all but claims 17, 27, and 30) for obviousness over Bessler plus Johnson and Imachi. Snyders cross-appeals in IPR-106, arguing that the Board committed several errors in finding claims 1, 2, 6, and 8 anticipated by Bessler.

We affirm the Board's decision in IPR-105. We reverse the Board's finding in IPR-106 that Bessler anticipated claims 1, 2, 6, and 8. We need not reach St. Jude's anticipation argument as to claim 28, and we affirm the Board's obviousness rejection in IPR-106.

I

A

Human hearts have four chambers and four valves that regulate blood flow as the heart expands and contracts. '782 patent, col. 1, lines 13–18. According to the '782 patent, if a valve becomes damaged or diseased so as to compromise healthy opening and closing, blood may flow backwards through the valve and blood pressure may drop dangerously. *Id.*, col. 1, lines 18–24. Although a damaged valve may be replaced with an artificial one, such replacement traditionally required invasive procedures, like open-heart surgery. *Id.*, col. 1, lines 25–32. Even after artificial

valves were developed that could be installed via catheter without open-heart surgery, the specification states, such prior-art valves still involved risk-presenting surgical removal of the damaged native valve before inserting the new artificial one. *Id.*, col. 1, lines 32–42.

The '782 patent, titled "Artificial Heart Valve," issued in April 2003 to Dr. Robert Snyders. It describes an artificial heart valve that can be installed via catheter without invasive surgery and "without removing the damaged native heart valve." *Id.*, col. 2, lines 23–30. The artificial heart valve has three main components: a valve element, a frame, and a band. *Id.*, col. 10, lines 22–60. The '782 patent also discloses a system for installing the artificial valve using an instrument that consists of a holder, a manipulator, and an ejector. *Id.*, col. 3, lines 30–44.

Independent claim 1 of the '782 patent recites an artificial valve as follows:

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream and the downstream region and a central portion located between the plurality of peripheral anchors.
>
> a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; and
>
> a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame

> and adjacent the band, said valve element having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

Id., col. 10, lines 22–60. Claims 2–9 depend, directly or indirectly, on claim 1 and therefore incorporate all of claim 1's limitations.

Independent claim 28 recites a "combination" of the artificial valve recited in claim 1—set forth in claim 28 using the language of claim 1 but adding the restriction that the "frame [is] collapsible to a configuration having a maximum width less than about 18 mm"—and "an instrument for inserting the artificial valve between the upstream region and the downstream region," the latter further specified as follows:

> an instrument including
>
> a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration;
>
> an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region; and
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> an ejector mounted in the hollow interior of the holder for ejecting the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

Id., col. 13, line 66, through col. 14, line 56. None of the issues before us require consideration of claim language outside claims 1 and 28.

The key prior art in IPR-105 is U.S. Patent No. 5,957,949 (Leonhardt). Leonhardt discloses an artificial valve that is installed via catheter to replace damaged valves in the heart or esophagus. '949 patent, col. 1, lines 4–8. It has three main components: a biological valve, a valve stent, and graft material. *Id.*, col. 4, lines 14–16; *id.*, Fig. 4. The graft material is made of "thin-walled biocompatible, flexible and expandable, low-porosity woven fabric" and is "arranged to surround [the] stent." *Id.*, col. 5, lines 53–55, 62–64.

The key prior art in IPR-106 is U.S. Patent No. 5,855,601 (Bessler). Bessler discloses an artificial heart valve and a method and device for installing that valve. '601 patent, col. 2, lines 55–67. The artificial heart valve may be compressed or expanded, and the installed unit includes a rigid stent member and a flexible valve member with a cuff portion. *Id.*, col. 3, lines 48–57. The system for installing the valve includes a catheter with the valve at the distal end and a pusher member to release the valve when the desired implant site is reached. *Id.*, col. 4, line

53, through col. 5, line 12. "Alternatively, or in combination [with the described system], the heart valve could be positioned over a guidewire." *Id.*, col. 5, lines 13–14.

In IPR-106, St. Jude also relied on two other patents in its argument for obviousness in combination with Bessler. U.S. Patent No. 4,339,831 (Johnson) discloses an artificial heart valve with a durable and flexible membrane. '831 patent, col. 4, lines 49–68. U.S. Patent No. 5,413,599 (Imachi) discloses a medical valve apparatus that is not the subject of substantial discussion in this court. '599 patent, Abstract.

B

St. Jude filed petitions for inter partes reviews of the '782 patent in October 2017. J.A. 312, 2870. In IPR-105, St. Jude cited Leonhardt as its primary reference, arguing that Leonhardt anticipated claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent. J.A. 322. In IPR-106, St. Jude argued that the same claims were anticipated by Bessler, as well as unpatentable for obviousness over Bessler, Johnson, and Imachi. J.A. 2881.[1]

In IPR-105, the Board rejected St. Jude's argument that Leonhardt anticipated the '782 patent. *IPR-105 Decision*, at *7–14. In the respect relevant on appeal, the Board essentially adopted St. Jude's proposed claim construction of "band": The Board's construction was "a structure generally in the shape of a closed strip or ring," which slightly broadened St. Jude's language by replacing St. Jude's "circular" with "closed" (thereby including ovals, for example). *Id.* at *5–6. But the Board found that St. Jude did not

[1] In IPR-105, St. Jude, besides arguing anticipation, presented obviousness arguments, which the Board rejected and are not at issue on appeal. In IPR-106, St. Jude presented one obviousness combination not mentioned in text, which the Board rejected and is not at issue on appeal.

prove that Leonhardt disclosed a "band" under that construction because what St. Jude alleged was the "band" in Leonhardt covered the entire length of the frame, like a "sleeve," and was therefore not a "strip" or "ring." *Id.* at *8–9.[2]

In IPR-106, the Board determined that St. Jude had proved by a preponderance of the evidence that Bessler anticipated claims 1, 2, 6, and 8 of the '782 patent. *IPR-106 Decision* at *8–12. For claim 28, the Board determined that St. Jude did not prove that Bessler discloses the "manipulator" required by the claim, thus defeating St. Jude's anticipation contention as to that claim. *Id.* at *14. Finally, the Board rejected all of St. Jude's obviousness arguments. *Id.* at *15–20.

St. Jude filed a timely notice of appeal for both IPRs on July 1, 2019. J.A. 238–40; 35 U.S.C. §§ 141(c), 319; 37 C.F.R. § 90.3(a)(1). Snyders filed a timely cross-appeal for IPR-106 on July 10, 2019. J.A. 248–50. We have jurisdiction under 28 U.S.C. § 1295(a) and 35 U.S.C. §§ 141(c), 319.

II

We review the Board's final written decision under the Administrative Procedure Act, "hold[ing] unlawful and set[ting] aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law . . . [or] unsupported by substantial evidence." 5 U.S.C. § 706; *Dickson v. Zurko*, 527 U.S. 150, 164 (1999). Anticipation is a question of fact, with the Board's determination of what is taught in the

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[2] The Board and the parties have followed the patent's use of the word "length," *see* '782 patent, col. 9, lines 24–28; *id.*, Fig. 6, to describe what, for material forming a closed loop, would ordinarily be described as the "width" of the material (as opposed to its thickness or its linear extent if cut and laid out straight).

prior art at issue reviewed for substantial evidence. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068 (Fed. Cir. 2017); *In re Gleave*, 560 F.3d 1331, 1334–35 (Fed. Cir. 2009). For obviousness, the ultimate determination is a legal one reviewed de novo, but underlying factual determinations are reviewed for substantial-evidence support. *Personal Web Techs., LLC v. Apple, Inc.*, 917 F.3d 1376, 1381 (Fed. Cir. 2019). The Board's claim constructions, here under the "broadest reasonable interpretation" standard, are determinations of law reviewed de novo where based on intrinsic evidence, with any Board findings about facts extrinsic to the patent record reviewed for substantial-evidence support. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–27 (2015); *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1367 (Fed. Cir. 2017); *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 751 (Fed. Cir. 2016).[3] "Substantial evidence review asks 'whether a reasonable fact finder could have arrived at the agency's decision' and requires examination of the 'record as a whole, taking into account evidence that both justifies and detracts from an agency's decision.'" *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016) (quoting *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2001)).

A

The sole issue on appeal for IPR-105 is whether the Board erred in rejecting St. Jude's argument that Leonhardt anticipated claims 1, 2, 4–8, and 28. The sole alleged error is the Board's rejection of St. Jude's contention that Leonhardt discloses a "band"—a requirement of claim 1

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[3] Because the petitions in IPR-105 and IPR-106 were filed in 2017, claim construction here is subject to the "broadest reasonable interpretation" standard. *Celgene Corp. v. Peter*, 931 F.3d 1342, 1349 n.8 (Fed. Cir. 2019).

(and therefore of dependent claims 2 and 4–8) and claim 28. If Leonhardt does not disclose a "band," it does not anticipate these claims. We affirm the Board's determination that Leonhardt does not disclose a band and therefore affirm the Board's decision in IPR-105.

The Board determined that Leonhardt's graft material—the component in Leonhardt that St. Jude argued was the required "band"—did not meet the band limitation. St. Jude challenges that determination on the ground that, in making it, the Board failed "to apply its own construction, and instead appl[ied] a narrower implicit construction" of "band." St. Jude Opening Br. at 28. We disagree.[4]

In the respect relevant on appeal, the Board adopted as the governing claim construction for "band" the proposal that St. Jude itself advanced, except for making one small change that broadened, rather than narrowed, St. Jude's proposal. St. Jude proposed that "band" be construed to mean "'[a] structure generally in the shape of a circular strip or ring; a band can be integrated with the frame.'" *IPR-105 Decision* at *5. Relying on a district court's analysis in related litigation, the Board rejected the "can be integrated with the frame" portion of St. Jude's proposal, and St. Jude does not dispute that conclusion. *Id.* at *5–6. As to the rest, the Board concluded that "circular" was too limiting, as it might exclude oval shapes, so it substituted "closed" to arrive at its construction: "a structure generally in the shape of a closed strip or ring." *Id.* St. Jude

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[4] Snyders also argues that—even if Leonhardt's graft material constitutes a band—we should affirm the Board's decision on the alternative grounds that (1) the graft material does not limit spacing between peripheral anchors and (2) Leonhardt does not disclose a valve element attached to the central portion of the frame. Snyders Response Br. at 34–35. We need not and do not reach those issues.

expressly accepts that construction. St. Jude Opening Br. at 21 ("St. Jude agrees with this construction—it is entirely consistent with the claim language itself and the specification's description of a band.").

The Board later concluded that the Leonhardt graft material does not qualify, because, like a sleeve, it extends in width (or "length," in the patent's language) over the entire structure it wraps around. *IPR-105 Decision* at *8–9. In reaching this conclusion, the Board relied on the terms "strip" and "ring"—which came from and are accepted by St. Jude. *Id.* ("graft material 24 cannot be considered a strip or ring"). St. Jude's argument is that this conclusion changed the claim construction. But the Board in fact expressly relied on the now-accepted claim construction.

St. Jude's argument that the Board must have changed the construction is meritless. St. Jude argues that no width restriction can be part of the ordinary skilled artisan's understanding of the term "band"—that no matter how wide (or "long," in the patent's terms) is the material making a loop around a structure (here, the frame), it necessarily counts as a "band." In support, St. Jude quotes a dictionary definition of "band" ("[a] thin strip of flexible material used to encircle or bind one object or to hold a number of objects together") and contends that the specification "explicitly disclaims any restriction on the length of a band." St. Jude Opening Br. at 30–31.

One problem with these contentions is that they are flawed on their own terms. The dictionary definition does not exclude *any* width constraint from being part of the relevant understanding. Indeed, "thin strip" in the quoted definition suggests the possibility of such a constraint, as do the words "strip or stripe" and "narrow strip" in the immediately succeeding definitions in the same dictionary entry for "band." American Heritage Dictionary of the English Language 143 (3d ed. 1992). And the specification material cited by St. Jude goes no further than showing

that the specification does not affirmatively specify any particular limit on a band's width ("length," in the patent's terms). *See* '782 patent, col. 9, lines 24–28 (reciting examples of certain "lengths" and adding that a band "may have other lengths"). The specification does not "explicitly disclaim[] any restriction on the length of a band." St. Jude Opening Br. at 31.

The more fundamental problem with St. Jude's basis for its argument, however, is that it simply does not address the terms "strip" and "ring," which St. Jude itself proposed and now accepts as the defining terms of the claim construction. The relied-on dictionary definitions and specification passages address "band" but not "strip" or "ring." St. Jude has offered nothing at all to indicate that "strip" and "ring" cannot have any width ("length," in the patent's terms) constraint in the relevant skilled artisan's understanding. If St. Jude wanted to argue that "band" precludes any such constraint, it should have proposed a claim construction that did so. It did not. The adopted claim construction therefore governs, and St. Jude has no persuasive argument that all width constraints are alien to the key terms of that construction, "strip" and "ring." Nor has St. Jude made any argument that, if some width constraint is within a skilled artisan's understanding of "strip" or "ring," the Board lacked substantial evidence to find that the full-length sleeve-like covering of Leonhardt does not qualify.

We therefore reject St. Jude's challenge to the decision in IPR-105.

B

Both parties challenge aspects of the Board's decision in IPR-106. We begin by addressing the challenge presented by Snyders, in its cross-appeal, to the Board's finding that Bessler anticipated claims 1, 2, 6, and 8. We then address St. Jude's argument that the Board erred in not finding claim 28 anticipated. Lastly, we address St. Jude's obviousness challenge.

1

In its cross-appeal, Snyders alleges three errors underlying the Board's finding that Bessler anticipated claim 1 and dependent claims 2, 6, and 8. It argues that the Board's construction of the claim 1 limitation concerning how the frame is "sized and shaped" is incorrect because it covers frames sized and shaped for installation with the native valve removed, rather than only with the troubled native valve remaining in place. Snyders also challenges the Board's construction of claim 1's "attached" limitation, arguing that the limitation must be construed to exclude indirect methods of attaching the valve element and the frame. Finally, Snyders argues that the Board incorrectly found that the cuff in Bessler satisfies the claim 1 requirement that the band "limit[] spacing" between adjacent frame anchors.

We agree with Snyders that the Board erred in construing the "sized and shaped" limitation and that Bessler therefore does not anticipate claims 1, 2, 6, and 8. We do not reach the other cross-appeal arguments.

In finding that Bessler anticipated claims 1, 2, 6, and 8, one of the limitations the Board found satisfied by Bessler is the claim 1 limitation requiring a "frame sized and shaped for insertion between the upstream region and the downstream region." *IPR-106 Decision* at *8–9. The Board determined that "[t]he claim language does not require the frame be sized and shaped for insertion into a damaged heart valve," but "only that the frame is sized and shaped for insertion *in a position* between the upstream region and the downstream region." *Id.* at *9. For that reason, the Board, without disputing the express assertion by Snyders that Bessler requires removal of the native valve for installation of the replacement valve, found that Bessler's valve satisfies the limitation. *Id.*

Claim 1 of the '782 patent recites an "artificial heart valve for repairing a damaged heart valve having a

plurality of cusps, separating an upstream region from a downstream region . . . comprising . . . a flexibly resilient frame sized and shaped for insertion between the upstream region and downstream region." '782 patent, col. 10, lines 22–27. The language provides some support for the reading advanced by Snyders in preference to the Board's construction. The requirement that the frame be "sized and shaped" a certain way suggests a focus on how the frame is fitted to the surrounding material (which depends on whether the native valve remains), a focus that goes beyond mere linear "position" between two regions, *IPR-106 Decision* at *9. The claim's reference to "repairing a damaged heart valve," without any reference to removal, suggests that the native valve remains. So too does the claim's reference to the damaged heart valve "having a plurality of cusps," which appears superfluous if claim 1 is interpreted to include embodiments where the damaged valve and its cusps are removed. *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) ("It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous."); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim.").

We turn to the '782 patent's specification, which we conclude resolves the interpretive question in this case under the standard requiring the "broadest reasonable interpretation in light of the specification." 37 C.F.R. § 42.100(b) (2016); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (explaining that the specification "is the single best guide to the meaning of a disputed term"). The specification states that "the frame is *sized and shaped for insertion between the plurality of cusps C of the damaged heart valve* in a position between an upstream region and a downstream region." '782 patent, col. 5, lines 48–51 (emphasis added). That language indicates that "sized and shaped" is not meant to refer only

to placement in a position between the upstream and downstream regions, but also to fitting between the cusps of the intact native valve.

Moreover, the specification stresses that the artificial heart valve it discloses can be inserted without removing the native valve and that this is an improvement on the prior art. *See* '782 patent, col. 1, lines 37–42 ("[M]any [previous] valves also require the damaged native heart valve to be removed prior to implanting the artificial valve."); *id.*, col. 1, lines 40–42 ("Removing the native valve increases the risk that a portion of the valve will migrate through the body and block vessels downstream from the heart."); *id.*, col. 2, lines 21–25 ("Among the several objects and features of the present invention may be noted the provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve . . . ."). Of particular note, the specification expressly describes Bessler as presenting problems that the Snyders invention overcomes, stating that the procedure disclosed in Bessler is too invasive because it "includes excision, vacuum *removal of the native valve*, cardiopulmonary bypass and backflushing of the coronary arterial tree." *Id.*, col. 2, lines 14–20 (emphasis added).

The specification passages, including its specific description of overcoming deficiencies in Bessler, go beyond stating a general preference for leaving the native valve intact. Those passages make it unreasonable to read the "sized and shaped for insertion" claim language as covering an artificial valve fitted for the space left after removing the native valve.

This conclusion precludes anticipation by Bessler on the record of IPR-106. Before the Board, in responding to the argument by Snyders on this claim limitation, St. Jude relied only on its claim-construction argument that the '782 claims cover the situation of a removed native valve; it did not dispute the express assertion by Snyders that Bessler

"'requires *removal* of the native heart valve.'" *IPR-106 Decision* at *9 (quoting Patent Owner's Response at 17–18); J.A. 3289–90 (Reply to Patent Owner's Response at 3–4).[5] St. Jude therefore has not preserved any argument that Bessler taught a non-removal alternative that satisfied the "sized and shaped" limitation. *See Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1329 (Fed. Cir. 2017); *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012).

Because we reject St. Jude's (and the Board's) claim construction, we conclude that Bessler does not meet this limitation and therefore cannot anticipate claims 1, 2, 6, and 8. *See Biscotti*, 878 F.3d at 1069 ("[A] prior art reference must provide every element of the claimed invention arranged as in the claim in order to anticipate."). Accordingly, we hold that claims 1, 2, 6, and 8 are not anticipated by Bessler, and we reverse the Board's contrary determination.

2

St. Jude's first contention in its appeal in IPR-106 is that the Board committed substantive and procedural errors when it found claim 28 not anticipated by Bessler because St. Jude did not prove that Bessler discloses the "manipulator" required by claim 28. We need not and do not reach this challenge. Claim 28 contains exactly the same "sized and shaped" limitation for the valve as does claim 1, requiring a valve meeting that limitation (among others) in combination with an instrument used to install the valve. '782 patent, col. 13, line 66, through col. 14, line

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[5] In its briefing in this court, St. Jude appears to suggest at one place that, before the Board, it responded to the "sized and shaped" contention of Snyders by arguing that Bessler does not require native-valve removal. *See* St. Jude Response & Reply Br. at 40–41. Its citations to the record do not support the suggestion.

56. Because we hold that Snyders is correct that Bessler does not meet the "sized and shaped" limitation, Bessler cannot anticipate claim 28 regardless of whether it meets the additional requirement of a "manipulator" component relating to the insertion instrument.

3

St. Jude's second contention in its appeal in IPR-106 challenges the Board's conclusion that St. Jude failed to prove that claims 1, 2, 4–8, 10–13, 18, 19, 21, 22, 25, 26, 28, and 29 of the '782 patent would have been obvious over Bessler, Johnson, and Imachi. We reject this challenge.

The Board agreed with St. Jude that a relevant skilled artisan would have been motivated to combine Bessler and Johnson, given that Johnson disclosed a more durable valve than Bessler's valve, while Bessler disclosed a stent that could be installed via catheter (not open-heart surgery). *IPR-106 Decision* at *18. But the Board found that St. Jude failed to prove that a relevant artisan would have made the particular combination St. Jude proposed—retaining the "cuff" from Bessler (but not its valve) to provide the "band" required by the claims at issue. *Id.* at *19.[6] The Board found that Bessler's cuff is "an integral portion of the valve member" and that its purpose is "attaching the valve to the stent." *Id.* It therefore concluded that St. Jude had not shown why a relevant artisan "when replacing Bessler's valve with Johnson's valve would remove the leaflet portion of B[e]ssler's valve but retain the cuff portion." *Id.*

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[6] Before the Board, St. Jude proposed an alternative combination that would use a feature of Johnson (not the cuff of Bessler) as the claim-required band, but the Board rejected that alternative, *IPR-106 Decision* at *19, and St. Jude does not challenge that rejection on appeal.

The Board's determination on this point—whether a skilled artisan would be motivated to make the proposed combination to arrive at the claimed invention—is a factual one that we review for substantial-evidence support. *See Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1359 (Fed. Cir. 2017). It was St. Jude's burden to support its assertion by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376–77 (Fed. Cir. 2016). We conclude that the Board did not lack substantial-evidence support in finding a failure of proof by St. Jude.

As the Board noted, Bessler describes its cuff as extending from the periphery of the circular and leaflet portions of its valve, and attaching to the stent to hold the valve and stent together. '601 patent, col. 5, lines 15–25, 38–42. In St. Jude's proposed combination of Johnson and Bessler, however, the leaflet portion of Bessler's valve would be removed in favor of Johnson's valve, while retaining the cuff portion of Bessler's valve. Pet. for Inter Partes Review at 68, J.A. 2946. The Board explained, however, that "the cuff is an integral portion of the valve member," that "the purpose of the cuff portion [is] for attaching the valve to the stent," and that, "[o]nce the leaflet portion of Bessler's valve is removed, the cuff serves no purpose." *IPR-106 Decision* at *19. The Board found no "adequate[]" or "persua[sive]" explanation by St. Jude for why a relevant artisan would keep the "integral" cuff portion while replacing the leaflet portion to which it is attached. *Id.*

The relevant portion of St. Jude's petition offers no meaningful explanation for this proposal. Pet. for Inter Partes Review at 55–56, J.A. 2933–34. The relevant portion of the petition cites five paragraphs from the declaration of St. Jude's expert, Dr. Lakshmi Prasad Dasi, *id.* (citing Dasi Declaration ¶¶ 66–70, J.A. 3677–79), but those paragraphs merely characterize Bessler, without addressing the specific question of separating the leaflets from the cuff for purposes of a combination with Johnson. St. Jude

now points to two additional paragraphs of the Dasi declaration, J.A. 3696–98 (¶¶ 109, 111)—which themselves describe how the contemplated combination would function, rather than specifically address the question of motivation to make the specific combination—but those paragraphs are not cited in the relevant portion of the petition or in any other submission to the Board on this point that St. Jude identifies. St. Jude has not demonstrated the unreasonableness of the Board's determination that St. Jude did not adequately or persuasively establish the motivation to make the particular combination it proposed in arguing obviousness. We therefore affirm the Board's obviousness determination in IPR-106.[7]

III

The Board's decision in IPR-105 is affirmed. The Board's decision in IPR-106 is reversed as to claims 1, 2, 6, and 8 but otherwise affirmed.

Costs awarded to Snyders.

AFFIRMED IN PART, REVERSED IN PART

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[7] As an alternative ground for affirming the Board's obviousness finding, Snyders challenges the Board's determination that a relevant artisan would be motivated to combine Bessler, Johnson, and Imachi. Snyders Response Br. at 45. We need not reach that argument.