

NOTE: This disposition is nonprecedential.

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

SNYDERS HEART VALVE LLC,
Appellant

v.

ST. JUDE MEDICAL, LLC,
Appellee

UNITED STATES,
Intervenor

2019-2111

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2018-00107.

Decided: October 5, 2021

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

This is the second time we have considered this appeal. We previously vacated and remanded the *inter partes* review (“IPR”) at issue in this appeal for rehearing by the Patent Trial and Appeal Board (“Board”) pursuant to our opinion in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). *Snyders Heart Valve LLC v. St. Jude Med., LLC*, 825 F. App’x 888 (Fed. Cir. 2020), *cert. granted, judgment vacated sub nom. Iancu v. Fall Line Pats.*, No. 20-853, 2021 WL 2637823 (U.S. June 28, 2021). In that opinion, we reached only Snyders Heart Valve LLC’s (“Snyders”) arguments under the Appointments Clause. We did not address the merits of the Board’s decision. The United States of America, which intervened in the appeal, sought certiorari to challenge our remand. After its decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021), the Supreme Court vacated and remanded the matter to us for reconsideration in light of its decision. *Iancu*, 2021 WL 2637823. On remand, Snyders waives its Appointments Clause challenge and asks that we address its appeal on the merits. We do so and *reverse* the Board’s determination that the challenged claims are unpatentable because that finding rests on an erroneous claim construction.

I. BACKGROUND

In October 2016, Snyders sued St. Jude Medical, LLC (“St. Jude”) in the Eastern District of Texas. It alleged that St. Jude had infringed two patents directed to “artificial heart valves for repairing damaged heart valves”: U.S. Patent No. 6,540,782 and U.S. Patent No. 6,821,297. ’782 patent, col. 1 ll. 15–16; ’297 patent, col. 1 ll. 15–16. In October 2017, St. Jude filed four IPR petitions challenging claims of the two patents.

At issue in this appeal is IPR2018-00107 (“IPR-107”), in which St. Jude challenged claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 of the ’297 patent. The key prior art in this appeal 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 ll. 55–67.

In its final written decision in IPR-107, the Board found all challenged claims of the ’297 patent unpatentable as either anticipated by Bessler or obvious over Bessler in combination with other prior art references. *St. Jude Med., LLC v. Snyders Heart Valve LLC*, IPR2018-00107, 2019 WL 1978347 (P.T.A.B. May 2, 2019). Snyders appealed to this court. In its appeal, it raised, *inter alia*, an Appointments Clause challenge and challenges to the Board’s final written decision on the merits. We vacated the Board’s decision and remanded for a new hearing in compliance with this court’s decision in *Arthrex*. The United States petitioned the Supreme Court for a writ of certiorari. After the Supreme Court devised a new remedy for the Appointments Clause violation in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021), it granted the United States’ petition, vacated, and remanded to this court for further consideration in light of its *Arthrex* decision.

In other cases where we have received similar remands from the Supreme Court, we have remanded to the Patent Office for the Director to review the Board’s decision. But, in this case, all parties agree that Snyders has waived its

Appointments Clause challenge and that remand to the Patent Office for Director review is not proper. Snyders argues that we should reverse the Board's unpatentability decision on the merits in light of our intervening decision reversing portions of the Board's decision in one of the '782 patent IPR proceedings. St. Jude contends that reversal is not appropriate and that we should, instead, remand to the Board for reconsideration in light of our intervening decision concerning the '782 patent.

We agree with Snyders' argument and find that, on this record, reversal is the appropriate course of action. For the same reasons that we reversed the Board's unpatentability decisions as to claims 1, 2, 6, and 8 in the '782 patent IPR proceedings, we reverse the Board's unpatentability decisions as to claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 of the '297 patent.

The '782 Patent IPR Proceedings

In IPR2018-00106 ("IPR-106"), the Board ruled that St. Jude had shown by a preponderance of the evidence that claims 1, 2, 6, and 8 of the '782 patent were unpatentable but had failed to establish unpatentability of all other challenged claims. *St. Jude Med., LLC v. Snyders Heart Valve LLC*, IPR2018-00106, 2019 WL 1975349 (P.T.A.B. May 2, 2019). St. Jude appealed some of the Board's findings and Snyders cross-appealed the Board's unpatentability findings as to claims 1, 2, 6, and 8. We affirmed the Board's findings that certain claims were not shown unpatentable but reversed the Board's finding that claims 1, 2, 6, and 8 are unpatentable. *St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232 (Fed. Cir. 2020). Our opinion as to claims 1, 2, 6, and 8 focused on the limitation "a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region," and, particularly, the "sized and shaped" requirement. We held that the Board erred in construing the "sized and shaped" limitation of '782 patent claim 1. *Id.* at 1240. We

reversed the Board's finding that Bessler anticipated claims 1, 2, 6, and 8 because it was based on the Board's erroneous construction of the "sized and shaped" limitation and because St. Jude had not preserved any argument that Bessler disclosed the "sized and shaped" limitation as properly construed. *Id.* at 1242.

The Board did not expressly construe the "sized and shaped" limitation in IPR-106. But, in finding that Bessler anticipated claims 1, 2, 6, and 8, it 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." *St. Jude*, 2019 WL 1975349 at *9. The Board rejected Snyders' argument that Bessler could not read on the limitation because Bessler's valve is inserted in a "much larger space left following the excision and removal of a damaged heart valve." *Id.* Thus, the Board concluded, Bessler satisfied the claim 1 limitation of a "frame sized and shaped for insertion between the upstream region and the downstream region." *Id.* at *9.

On appeal, Snyders argued that the Board's construction was incorrect because it covers frames sized and shaped for installation with the native valve removed, rather than only with the native valve in place. We agreed.

We found support for Snyders' construction in the language of the '782 claims and written description. 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 the downstream region." '782 patent, col. 10 ll. 22–27. We found that "[t]he 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[.]” *St. Jude*, 977 F.3d at 1240. We also found that the Board’s construction would render claim 1’s reference to the damaged heart valve “having a plurality of cusps” superfluous because it would include instances where the damaged heart valve and its cusps are removed. *Id.* at 1240–41.

We then found evidence in the ’782 specification that “resolves the interpretive question” under the applicable broadest reasonable interpretation standard.¹ *Id.* The ’782 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 ll. 48–51 (emphasis added). We found that this 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.” *St. Jude*, 977 F.3d at 1241. The specification also stresses that the claimed artificial heart valve can be inserted without removing the native valve—an improvement over prior art heart valves. *See* ’782 patent, col. 1 ll. 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 ll. 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 ll. 21–25 (“Among the several objects and features of the present invention may be noted the

¹ Challenged claims in IPR petitions filed prior to November 13, 2018 are construed under the broadest reasonable interpretation standard. 37 C.F.R. § 42.100(b) (2016); *St. Jude*, 977 F.3d at 1238 n.3. IPR-106 and IPR-107 were both filed in 2017, so the broadest reasonable interpretation standard applies.

provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve . . .”). Finally, the specification states that the Bessler heart valve poses problems which the claimed valve overcomes because the procedure disclosed in Bessler includes invasive “excision, vacuum *removal of the native valve*, cardiopulmonary bypass and backflushing of the coronary arterial tree.” *Id.*, col. 2 ll. 14–20 (emphasis added). We concluded that these specification passages “make it unreasonable to read the ‘sized and shaped for insertion’ claim language as covering an artificial valve fitted for the place left after removing the native valve.” *St. Jude*, 977 F.3d at 1241.

II. DISCUSSION

A. Similarities Between the ’782 and ’297 Patents

St. Jude asks that we remand IPR-107 to the Board rather than outright reverse the Board’s unpatentability finding because of differences between the ’782 and ’297 patents. We disagree. The claims and written descriptions in the two patents are the same in all relevant respects. Thus, our claim construction holding concerning the ’782 patent’s “sized and shaped” limitation forecloses a different construction for the “sized and shaped” limitation in the ’297 patent.

All challenged claims of the ’297 patent, like claims 1, 2, 6, and 8 of the ’782 patent, require 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 the downstream region.” *Compare* ’782 patent, col. 10 ll. 22–27, *with* ’297 patent col. 19 ll. 11–16.

The two patents have similar, but not identical, written descriptions. But all portions of the ’782 written description which we found “resolve[] the interpretive question” of

the proper construction of the “sized and shaped” limitation appear in the ’297 patent’s written description. *Compare* ’782 patent, col. 5 ll. 48–51, *with* ’297 patent, col. 6 ll. 30–32 (“[T]he frame 20 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.”); *compare* ’782 patent, col. 1 ll. 37–42, *with* ’297 patent, col. 1 ll. 41–43 (“[M]any [previous] valves also require the damaged native heart valve to be removed prior to implanting the artificial valve.”); *compare* ’782 patent, col. 1 ll. 40–42, *with* ’297 patent, col. 1 ll. 43–46 (“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.”); *compare* ’782 patent, col. 2 ll. 21–25, *with* ’297 patent, col. 2 ll. 26–29 (“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”); *compare* ’782 patent, col. 2 ll. 14–20, *with* ’297 patent, col. 2 ll. 20–23 (“The Bessler procedure includes excision, vacuum removal of the native valve, cardiopulmonary bypass and backflushing of the coronary arterial tree.”).

Based on these similarities between the ’782 and ’297 patents, we hold that, in the ’297 patent, just as in the ’782 patent, it is “unreasonable to read the ‘sized and shaped for insertion’ claim language as covering an artificial valve fitted for the place left after removing the native valve.” *See St. Jude*, 977 F.3d at 1241.

B. Similarities Between IPR-106 and IPR-107

St. Jude asks that we remand IPR-107 to the Board rather than reverse the Board’s unpatentability finding because of differences between IPR-106 and IPR-107. St. Jude avers that, in IPR-107, unlike in IPR-106, it argued that it would have been obvious to reduce Bessler’s size and that a second reference, U.S. Patent No. 4,339,831

(“Johnson”), taught the “sized and shaped” limitation. St. Jude argues that the Board has not yet addressed those arguments and that it should be given the opportunity to do so. We disagree. We have reviewed St. Jude’s filings in IPR-107, and, just as we found in our review of IPR-106, “St. Jude relied only on its claim-construction argument that the [] 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.’” *See St. Jude*, 977 F.3d at 1241 (quoting *St. Jude*, 2019 WL 1975349 at *9). Thus, here, as there, “St. Jude therefore has not preserved any argument that Bessler taught a non-removal alternative that satisfied the ‘sized and shaped’ limitation.” *See id.* at 1241–42.

The two purportedly different invalidity arguments St. Jude identifies are unhelpful to its cause. These arguments are either based on the rejected claim construction or are directed to limitations other than the “sized and shaped” limitation.

Although St. Jude submits that it presented a theory of obviousness over Bessler, review of the record reveals that St. Jude’s only obviousness theories involving Bessler are directed to limitations other than the “sized and shaped” limitation. St. Jude never argued that it would be obvious to modify Bessler to fit within a native valve rather than to replace a native valve. In its petition, in a section about the obviousness of all challenged claims over Bessler, but not directed to any specific limitations, St. Jude stated: “In this case, given Bessler’s use of the same types of components, organized and operating in the same way as claimed, and in view of the breadth of these claims, minor modifications to the stent and the [flexible valve element] as Defined to achieve predictable improvements is the application of routine engineering, characteristic of obviousness; nothing more.” Petition at 49, *St. Jude Med., LLC v. Snyders Heart Valve LLC*, IPR2018-00107, Paper No. 3. St. Jude went on to address other limitations specifically

but did not address the “sized and shaped” limitation or whether Bessler could be modified for implantation without removal of the native valve. *Id.* In its Petitioner’s Reply, St. Jude merely reiterated those vague arguments. Petitioner’s Reply to Patent Owner’s Response at 11–12, *St. Jude Med., LLC v. Snyders Heart Valve LLC*, IPR2018-00107, Paper No. 38. In its Petitioner’s Reply, St. Jude also asserted that a skilled artisan would have been motivated to combine the Bessler valve with aspects of a valve disclosed by Johnson, despite Snyders’ argument that such a combination would create a valve that was too large for transluminal² delivery. *Id.* at 16. St. Jude argued that a skilled artisan would know that “achieving collapsibility to a desired size was a matter of routine engineering.” *Id.* But this argument was not directed to the “sized and shaped” limitation. It was directed to a separate limitation—claim 37’s requirement of an included “vascular catheter.” St. Jude never argued that a skilled artisan would modify Bessler to meet the “sized and shaped” limitation as properly construed.

Similarly, St. Jude submits that it cited Johnson for the “sized and shaped” limitation, but review of the record reveals that St. Jude’s only unpatentability theory involving Johnson is an obviousness combination with Bessler in which St. Jude proposed inserting the valve structure of Johnson into the outer tubular structure of Bessler. Petition at 56, *St. Jude*, IPR2018-00107. In this proposed combination, the tubular structure of Bessler, which is “sized and shaped” to replace the native valve rather than sit within the native valve, “performs its known function of holding the entire structure within the anatomy.” *Id.* Thus, St. Jude’s arguments regarding Johnson incorporate

² “Transluminal” refers to passing through a lumen of a blood vessel (i.e., vasculature). Petition at 37, *St. Jude*, IPR2018-00107.

the error of its arguments regarding Bessler—they fail to meet the “sized and shaped” limitation as properly construed. That St. Jude’s invalidity theory incorporating Johnson suffers from the same flaw as its theories involving Bessler is confirmed by an argument St. Jude made in its Petitioner’s Reply: “The Bessler and Johnson frames are both individually sized and shaped for insertion in the native valve annulus, as would be the combination.” Petitioner’s Reply to Patent Owner’s Response at 17, *St. Jude*, IPR2018-00107. St. Jude never argued that Johnson met the “sized and shaped” limitation as properly construed.

III. CONCLUSION

We conclude that, as in *St. Jude*, 977 F.3d at 1242, our rejection of the Board’s claim construction of “sized and shaped for insertion” precludes an unpatentability finding as to the challenged claims of the ’297 patent. St. Jude relied only on its now rejected claim construction argument before the Board. It never disputed Snyders’ assertion that Bessler requires removal of the native valve before insertion of its valve. Thus, St. Jude has not preserved any argument on which it might prevail. Accordingly, we *reverse* the Board’s unpatentability finding with respect to claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 of the ’297 patent.

REVERSED