NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BOSTON SCIENTIFIC SCIMED, INC.,
Appellant

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR ITELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2018-2004

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2017-00060.

SEALED OPINION ISSUED: April 27, 2020
PUBLIC OPINION ISSUED: May 6, 2020*

MATTHEW WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, argued for appellant. Also represented

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* This opinion was originally filed under seal and has been unsealed in full.

by EDWARD HAN, JENNIFER SKLENAR, MARC A. COHN.

KAKOLI CAPRIHAN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by SARAH E. CRAVEN, THOMAS W. KRAUSE, ROBERT J. MCMANUS.

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

WALLACH, *Circuit Judge*.

Petitioners Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG (collectively, "Edwards") sought inter partes review ("IPR") of claims 1–4 ("the Challenged Claims") of Appellant Boston Scientific SciMed, Inc.'s ("Boston Scientific") U.S. Patent No. 8,992,608 ("the '608 patent"). The U.S. Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") instituted review and issued a final written decision finding, inter alia, that the Challenged Claims are unpatentable as obvious. *See Edwards Lifesciences Corp. v. Bos. Sci. SciMed, Inc.*, No. IPR2017-00060, 2018 WL 1508704, at *1 (P.T.A.B. Mar. 23, 2018).

Boston Scientific appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A). We affirm.

BACKGROUND

I. The '608 Patent

Entitled "Everting Heart Valve," the '608 patent "provides methods and [an] apparatus for endovascularly replacing a patient's heart valve." '608 patent, Abstract. Valve replacement is "used to repair or replace diseased heart valves." *Id.* col. 1 ll. 23–24. It is a treatment option for "stenosis" (i.e., "a narrowing of the native heart valve") and for "when the native valve leaks or regurgitates." *Id.* col. 1 ll. 29–31. During endovascular aortic valve replacement, a transcatheter heart valve ("THV") is inserted

endovascularly and then "deployed across the native diseased valve," with "the replacement valve [positioned] in place of the native valve." *Id.* col. 1 ll. 56–60. While endovascular "replacement of the aortic heart valve" is a less "invasive surgery," *id.* col. 1 ll. 53–55; *see* J.A. 6759–61, it still presents the "risk of paravalvular leakage or regurgitation around" the deployed THV, *id.* col. 12 ll. 19–21. Because the "surface of the native valve leaflets . . . is irregular," the "interface . . . between leaflets . . . and [a THV's] anchor . . . may comprise gaps where blood . . .may seep through," resulting in "a risk of blood clot formation or insufficient blood flow." *Id.* col. 12 ll. 23–27; *see id.* Fig. 13.

The '608 patent discloses a THV apparatus that includes "a replacement valve and an expandable and retrievable anchor." *Id.* col. 1 ll. 17–19. The apparatus is "configured for endovascular delivery to the vicinity of the heart valve" with "at least a portion of the replacement valve . . . configured to evert about the anchor during endovascular deployment," *id.* col. 2 ll. 46–49, the anchor having "a lip region and a skirt region," *id.* col. 2 l. 59, "wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve," *id.* col. 2 ll. 62–64. To address the risk of paravalvular leakage, the '608 patent discloses a "fabric seal," that "[w]hen deployed," "bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets . . . , particularly when the pockets are filled with blood in response to backflow blood pressure." *Id.* col. 14 ll. 24–28; *see* Figs. 33, 34. "This arrangement" is meant to "create[] a seal around the replacement valve." *Id.* col. 14 ll. 28–29.

Independent claim 1 of the '608 patent is representative and recites:

A system for replacing a heart valve, comprising:

> an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end;
>
> *a replacement valve commissure support element attached to the expandable anchor*;
>
> a commissure portion of a replacement valve leaflet attached to the commissure support element; and
>
> *a fabric seal* at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration, the fabric seal having an undeployed state and a deployed state, *wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets*;
>
> wherein a distal end of the replacement valve leaflet is attached to the fabric seal and when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, *the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue*.

Id. col. 22 ll. 22–42 (emphases added).

II. The Relevant Prior Art

A. Spenser

Entitled "Implantable Prosthetic Valve," WIPO International Publication No. WO 03/047468 A1 ("Spenser") relates to "a valve prosthesis for cardiac implantation or for implantation in other body ducts." J.A. 1589. Spenser discloses "a valve prosthesis device suitable for [percutaneous]

implantation in body ducts," that includes "a support stent, comprised of a deployable construction" with "a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material," such as polyurethane ("PU") and polyethylene terephthalate fabric ("PET"), "attached to the [stent's] support beams providing collapsible slack portions of the conduit at the outlet." J.A. 1591–92; *see* J.A. 1590 (defining "percutaneously" as "inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the desired location via a large blood vessel such as the femoral artery"). Spenser teaches that "[t]o prevent leakage from the [valve] inlet[,] it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present [a] rolled-up sleeve-like portion," that is, a fabric cuff, "at the inlet." J.A. 1609; *see* J.A. 1613 (providing for use of "PU leaflets and PET tubular construction" for its valve).

B. Elliot

Entitled "Implantable Prosthesis with Displaceab[l]e Skirt," U.S. Application Publication No. 2003/0236567 ("Elliot") relates to "tubular prostheses, including, but not limited to, endovascular grafts and stent[ ]grafts, for maintaining patency of blood vessels and treating aneurysms (e.g., aortic aneurysms), and tubular conduits for maintaining patency in other bodily passageways." J.A. 1710. Elliot discloses an "implantable prosthesis" with "a radially expandable tubular body and at least one skirt extending therefrom." J.A. 1702. The prosthesis "is positioned to bypass the aneurysm . . . being in contiguous contact with the healthy portions of the aorta." J.A. 1710. The prosthesis has "at least one skirt . . . (which may be formed in various geometric configurations)" such that its "peripheral edge . . . is free and displaceable to a greater diameter than the diameter of the tubular body[.]" J.A. 1712; *see* J.A. 1704 (Figs. 2a, 2b), 1705 (Figs. 3b, 3c), 1707 (Figs. 5b, 5d), 1708 (Fig. 7). The skirt may "be displaced to contact, and form a seal with a surrounding wall," "respond[ing] to"

"[i]rregularities and/or wall displacement . . . [to] minimize[e] endoleaks about the prosthesis." J.A. 1712.

Elliot teaches that, once the prosthesis is in position, the skirt or skirts on the prosthesis may inhibit certain "failures in the form of endoleaks," in particular, "leaks between the vascular prosthesis and the vessel wall." J.A. 1710. Elliot explains that such endoleaks may be caused by the "continual expansion of [part of] the aneurysm" or by an imperfect fit between the "circular prosthe[sis]" and the "non-circular aortic lumens" due to "irregular vessel formation and/or [the] calcified topography of the [aortic] lumen[.]" J.A. 1710. Elliot teaches that its "skirt may be used to inhibit [such] endoleaks upon its selective displacement in response to irregular aortic shaping and/or aneurysm neck expansion." J.A. 1710. "The skirt may actively inhibit [such] endoleaks by forming a physical barrier against flow between the tubular body and the aortic wall" and "may passively inhibit [such] endoleak formation by sufficiently restricting blood flow to allow coagulation and clot formation" that may also "act as a barrier against endoleakage." J.A. 1710.

DISCUSSION

I. Standard of Review and Legal Standard

"We review the PTAB's factual findings for substantial evidence and its legal conclusions de novo." *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015) (citation omitted). "Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence." *In re NuVasive, Inc.*, 842 F.3d 1376, 1379–80 (Fed. Cir. 2016) (internal quotation marks and citation omitted). "It is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (internal quotation marks and citation omitted). "If two inconsistent conclusions may reasonably be drawn from the evidence in record, the PTAB's decision to favor one conclusion over the other is the epitome of a

decision that must be sustained upon review for substantial evidence." *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1356 (Fed. Cir. 2018) (internal quotation marks, alterations, and citation omitted).

A patent claim is invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art [('PHOSITA')] to which said subject matter pertains." 35 U.S.C. § 103(a) (2006).[1] Obviousness "is a question of law based on underlying findings of fact." *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Those underlying findings of fact include (1) "the scope and content of the prior art," (2) "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) objective indicia of non-obviousness, such "as commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966). "A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (citation omitted).

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[1] Congress amended 35 U.S.C. § 103 when it enacted the Leahy-Smith America Invents Act ("AIA"). Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011). However, because the application that led to the '608 patent never contained (1) a claim having an effective filing date on or after March 16, 2013, or (2) a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application that ever contained such a claim, the pre-AIA § 103 applies. J.A. 79; *see* AIA, § 3(n)(1), 125 Stat. at 293.

In assessing the prior art, the PTAB "consider[s] whether a PHOSITA would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so." *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (internal quotation marks, alterations, and citation omitted). Motivation to combine "may be found explicitly or implicitly in market forces; design incentives; the interrelated teachings of multiple patents; any need or problem known in the field of endeavor at the time of invention and addressed by the patent; and the background knowledge, creativity, and common sense of the [PHOSITA]." *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013) (internal quotation marks and citations omitted). Expectation of success "need only be reasonable, not absolute." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (citations omitted). The petitioner bears "the burden of proving a proposition of unpatentability by a preponderance of the evidence" in an IPR. 35 U.S.C. § 316(e).

In assessing objective indicia of non-obviousness, the PTAB considers whether the evidence presented has "a 'nexus' to the [patent's] claims." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (citation omitted). "[T]here must be a legally and factually sufficient connection between the evidence and the patented invention" for the evidence "to be accorded substantial weight in the obviousness analysis[.]" *Id.* (internal quotation marks and citation omitted). "[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (internal quotation marks and citations omitted). The patent owner "bears the burden of showing that a nexus exists." *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). Further, the

patent owner "bears the burden of production with respect to evidence of secondary considerations of non[-]obviousness." *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018) (citation omitted).

II. The PTAB Properly Concluded that the Challenged Claims Were Obvious over the Asserted Prior Art

The PTAB, "[h]aving consider each of the *Graham* factors individually," weighed those factors "collectively," and determined that "[t]he scope and content of the prior art . . . heavily favor[ed] [Edwards'] contention that [the Challenged Claims] would have been obvious over Spenser[] in combination with . . . Elliot," and that, even if Boston Scientific had "shown the requisite nexus between [its] alleged objective indicia of non[-]obviousness and the [C]hallenged [C]laims," which it had not, its "objective evidence of non[-]obviousness . . . provide[d] only either very little or limited support for [the] non[-]obviousness of the [C]hallenged [C]laims." *Edwards Lifesciences*, 2018 WL 1508704, at *32. The PTAB, accordingly, concluded that Edwards "ha[d] demonstrated . . . that the subject matter of the [Challenged Claims] would have been obvious over the combination[] of . . . Spenser and Elliot[.]" *Id.* at *33. On appeal, Boston Scientific argues that: (1) the PTAB's motivation to combine and reasonable expectation of success analysis was "contrary to law and unsupported by substantial evidence," Appellant's Br. 46 (capitalization normalized and emphasis omitted); and, (2) the PTAB "inexplicably dismissed" Boston Scientific's evidence of nexus, *id.* at 68, and its "consideration of [Boston Scientific's] objective indicia of non-obviousness was inadequate," *id.* at 62 (capitalization normalized and emphasis omitted). We disagree with Boston Scientific.

A. Substantial Evidence Supports the PTAB's Finding that a PHOSITA Would Have Been Motivated to

Combine Spenser and Elliot with a Reasonable Expectation of Success

The PTAB found that, in combination, Spenser and Elliot "teach every limitation of [the Challenged Claims]." *Edwards Lifesciences,* 2018 WL 1508704, at *10. In particular, the PTAB found that Spenser discloses a THV with a "fabric seal," *id.* at *13; *see id.* at *10, Elliot discloses a stent graft with a "fabric seal with flaps," *id.* at *13, and, together, they teach a THV with "a fabric seal 'adapted to prevent blood from flowing between the fabric seal and heart tissue,' as recited by [independent] claim 1" of the '608 patent, *id.* The PTAB found that a PHOSITA would have been motivated to combine Spenser's THV and Elliot's fabric seal to better address "the problem of paravalvular leakage" in THV, *id.* at *28, with a reasonable expectation of success, given "the proven capabilities of sealing" shown by such "fabric seals in the stent graft context." *Id.* at *29. Boston Scientific argues that the PTAB's motivation to combine and reasonable expectation of success analyses relied on "hindsight," Appellant's Br. 48, "failed to identify evidence that would have led a P[H]OSITA" to combine Spenser with Elliot, *id.* at 56 (capitalization normalized and emphasis omitted), and improperly "shifted the burden of proof to" Boston Scientific, *id.* at 54. We disagree with Boston Scientific.

Substantial evidence supports the PTAB's finding that a PHOSITA would have been motivated to combine Spenser's THV with Elliot's fabric seal with flaps. Paravalvular leakage was a well-known problem in prosthetic valves prior the 2004 priority date of the '608 patent. J.A. 1905 (U.S. Patent No. 3,365,728, issued in 1968, disclosing an aortic valve prosthesis with an "upholstered" seal to prevent "leakage between the valve and the tissue"); J.A. 3766 (a medical textbook, published in 1994, explaining that "[t]he designer of any percutaneously placed [prosthetic] valve will need to consider" and "minimize," inter alia, "perivalvular leak"); *see also* J.A. 3247–48 (Boston

Scientific's Expert Deposition) (agreeing that the problem of "paravalvular leaks" was "known from the use of surgical valves" and the "percutaneous valve implants that had occurred by the date of [the '608] patent").[2] Similarly, endoleaks were a well-known problem in stent grafts. J.A. 1953–54 (medical text, published in 1990, discussing a stent graft made of "woven [fabric]" with a "[frictional] sealing cuff," noting that the "primary technical complications" were "[e]ndoleaks resulting from an incomplete seal"); *see* J.A. 1751–52 (Edwards' Expert Declaration) (explaining that "stent designers and physicians . . . recognized the risk of . . . 'endoleaks'" in stent grafts prior to the priority date of the '608 patent). Both problems were addressed by the prior art with varying degrees of success. For example, for THVs, Spenser teaches use of a fabric cuff to prevent paravalvular leakage. J.A. 1609–10 (teaching use of a fabric cuff "[t]o prevent leakage" in a THV); *see* J.A. 1820

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[2] Boston Scientific asserts that the PTAB "did not conduct its inquiry from the perspective of a P[H]OSITA" because the PTAB "credited [Edwards' Expert] testimony above the testimony of [Boston Scientific's Experts]," when Edwards' Expert "ha[d] no relevant experience in [transcatheter or] surgical valve replacement, or [stent grafts]" and Boston Scientific's Experts did. Appellant's Br. 50. This argument is misplaced. Boston Scientific has not sought to exclude Edwards' expert testimony. *See id.* at 50–54; J.A. 940 (PTAB Hearing Transcript) (Boston Scientific's counsel stating that they "have not moved to exclude [Edwards' Expert] on lack of qualification."). Rather, Boston Scientific seeks for us to reassess expert credibility. *See* J.A. 940 (PTAB Hearing Transcript) (Boston Scientific's counsel agreeing its argument "goes to the weight of the testimony"). We decline to do so. *See Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) ("We defer to the [PTAB's] findings concerning the credibility of expert witnesses.").

(Edwards' Expert Declaration) (explaining that Spenser's THV is "anchored into place upon expansion" with "the fabric seal . . . conform[ing] to the surrounding tissue"); J.A. 3345 (Boston Scientific's Expert Deposition) (agreeing that "Spenser's cuff will prevent" paravalvular leakage "depend[ing] upon the degree of calcification" in the heart tissue). For stent grafts, Elliot teaches use of a "fabric skirt" that forms flaps to better conform to "irregular" or "calcified" vessel walls. J.A. 1710–11; *see* J.A. 1808 (Edwards' Expert Declaration) (explaining that Elliot's "fabric skirt . . . forms flaps and pockets that prevent [paravalvular leaks]").

"[F]rom the earliest disclosures of [THV] . . . it was well known to look to stent graft technology in forming external covers on THVs," J.A. 1814, with various early THV patents suggesting "the interchangeability of stent graft and prosthetic heart valve technology," J.A. 1769; *see, e.g.*, J.A. 1984 (U.S. Patent No. 5,411,552, issued in 1995, disclosing a transcatheter "valve prosthesis, preferably a cardiac valve prosthesis"); J.A. 2187–89 (U.S. Patent No. 5,957,949, issued in 1999, disclosing "a percutaneously placed artificial valve," for "all valvular needs" made with "flexible and expandable . . . fabric" that can "conform[] to the surface of the living tissue"). Indeed, Elliot itself suggests that its fabric skirt seal has broader applicability, finding use in "implantable prosthes[es]" with "radially-expandable tubular bod[ies]" generally. J.A. 1702. Where "a technique has been used to improve one device, and a [PHOSITA] would recognize that it would improve similar devices in the same way, using the technique is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Accordingly, substantial evidence supports the conclusion that a PHOSITA would have been motivated to combine Spenser's THV with Elliot's fabric seal with flaps to better address paravalvular leakage in THVs, resulting in the claimed invention.

Further, substantial evidence supports the PTAB's finding that a PHOSITA would have a reasonable expectation of success in combining Spenser and Elliot. Specifically, prior to the 2004 priority date of the '608 patent, stent grafts using fabric skirt seals were commercially available and "successfully implanted in patients with a low rate of reported endoleaks." J.A. 1755 (Edwards' Expert Declaration); *see* J.A. 2155 (medical study, published in 2002, discussing the effectiveness of a stent graft with a fabric skirt seal, reporting a 4 percent endoleak rate); J.A. 2168 (commercial instructions for use of the same stent graft with fabric skirt seal, explaining that its "[e]ffectiveness was based on," inter alia, the "absence of an endoleak"). From this, a PHOSITA would have reasonably expected similar effectiveness and success using fabric skirt seals to prevent paravalvular leaks in THVs. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014) ("Conclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success."). Accordingly, substantial evidence supports the PTAB's finding that a PHOSITA would have had a reasonable expectation of success in combining Spenser and Elliot to achieve the claimed invention.

Boston Scientific's counterarguments are unpersuasive. First, Boston Scientific argues that the PTAB "erred by shifting the burden of proof" to Boston Scientific "to show a lack of motivation to combine." Appellant's Br. 54 (capitalization normalized and emphasis omitted). This argument is misplaced. The PTAB first found that Edwards had persuasively met its burden of proof, showing that a PHOSITA would have been motivated to combine Spenser and Elliot with a reasonable expectation of success. *See Edwards Lifesciences*, 2018 WL 1508704, at *28–29. The PTAB then considered Boston Scientific's "numerous arguments in opposition" and found them "insufficient . . . to rebut the strong rationale articulated by [Edwards]." *Id.* at *29; *see id.* at *29–32. The PTAB did not shift the burden

of proof to Boston Scientific by considering Boston Scientific's counterarguments. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013) (explaining that while "the burden of persuasion remains with the challenger," this does not "relieve the patentee of any responsibility to set forth evidence in opposition to a challenger's prima facie case which, if left unrebutted, would be sufficient to establish obviousness").

Second, Boston Scientific lists "several pieces of evidence," Appellant's Br. 57; *see id.* at 57–62, that, according to Boston Scientific, the PTAB variously "ignored," *see id.* at 58, 61–62, or misevaluated in its motivation to combine analysis, *id.* at 57, 58–60. This argument ignores our standard of review. Substantial evidence does not inquire whether Boston Scientific's "preferred [evidence] could support a conclusion." *In re Inland Steel Co.*, 265 F.3d 1354, 1366 (Fed. Cir. 2001). Rather, substantial evidence asks whether the there is "such relevant evidence as a reasonable mind might accept as adequate to support [the PTAB's] conclusion." *Consol. Edison Co. of New York v. NLRB*, 305 U.S. 197, 229 (1938). As discussed above, the record here does. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1197 (Fed. Cir. 2014) (providing that "motivation to combine" may be found expressly in "the prior art" or implicitly, as "supported by testimony of an expert witness regarding [the] knowledge of a [PHOSITA] at the time of invention" (citation omitted)).

Third, Boston Scientific argues that the PTAB "fail[ed] to address" evidence that a PHOSITA would not have a reasonable expectation of success in combining Spenser and Elliot. Appellant's Br. 53–54; *see id.* at 51–54. Specifically, Boston Scientific argues the PTAB's expectation of success analysis was flawed because it "ignored . . . undisputed" evidence that, while THVs are implanted in "the irregular, calcified environment of a diseased heart valve," stent grafts are implanted in "healthy" or at least "different[ly]" irregular or calcified tissue. *Id.* at 52. This argument is

without merit. It is unrelated to "the objective reach of the [Challenged] [C]laim[s]." *KSR*, 550 U.S. at 419; *see* '608 patent col. 22 ll. 29–31; J.A. 3259–60 (Boston Scientific's Expert Deposition) (agreeing that claim 1 of the '608 patent "could cover a device for treatment of pure aortic regurgitation"). Further, it demands "absolute certainty" where only "a reasonable expectation of success" is required. *PAR Pharm.*, 773 F.3d at 1198 (providing that "[t]he reasonable expectation of success requirement for obviousness does not necessitate an absolute certainty for success" (citation omitted)). The PTAB's finding that a PHOSITA would have been motivated to combine Spenser and Elliot with a reasonable expectation of success is, therefore, supported by substantial evidence and otherwise in accordance with law.

B. Substantial Evidence Supports the PTAB's Finding that Boston Scientific Failed to Offer Meaningful Evidence of Non-Obviousness

The PTAB determined that, for its objective evidence on non-obviousness, Boston Scientific "ha[d] not shown the requisite nexus" between its proffered evidence and the claimed invention, and "even if nexus had been shown, the objective evidence [Boston Scientific] identifie[d] . . . provide[d] only either very little or limited support for the non[-]obviousness of the [C]hallenged [C]laims." *Edwards Lifesciences*, 2018 WL 1508704, at *32. Boston Scientific argues that it "established a nexus between [its] objective indicia of non-obviousness and the [claimed] invention" because it offered objective evidence tied to Edwards' THV ("the Sapien 3") and established "how each element of the [C]hallenged [C]laims was practiced by [the] S[apien] 3." Appellant's Br. 66. Boston Scientific further argues that the PTAB "improperly analyzed [its] evidence of" objective indicia of non-obviousness—specifically its "evidence of the failure of others and the long-felt need to solve [paravalvular leakage]," *id.* at 64 (capitalization normalized and emphasis omitted), and its "evidence of copying, industry

praise, and commercial success," *id.* at 66. We disagree with Boston Scientific.

Substantial evidence supports the PTAB's determination that Boston Scientific failed to establish a presumption of nexus. Independent claim 1 of the '608 patent recites a THV with, inter alia, "a replacement valve commissure support element attached to an expandable anchor." '608 patent col. 22 ll. 26–27. To establish that the Sapien 3 embodies this limitation, Boston Scientific provided a picture of the Sapien 3 with three portions circled in red, labeled "'a replacement valve commissure support element attached to the expandable anchor' and 'a commissure portion of a replacement valve leaflet attached to the commissure support element.'" J.A. 526–27 (Boston Scientific's Response). In support, Boston Scientific cited expert testimony that provided a similar picture, but no explanation. J.A. 527; *see* J.A. 6908–10 (Boston Scientific's Expert Declaration) (citing J.A. 6712, a Sapien 3 presentation with an image of a Sapien 3 labeled "Commissure attachments"). Boston Scientific did not identify which aspect of the Sapien 3 meets the claim element "commissure support element" or which aspect of the Sapien 3 meets the claim element "the expandable anchor[.]" J.A. 526–27. Boston Scientific, therefore, failed to establish that the Sapien 3 embodies "the invention disclosed and claimed in the patent," *WBIP,* 829 F.3d at 1329 (internal quotation marks and citations omitted), and, as such, that its objective evidence of non-obviousness has "a legally and factually sufficient connection" to the patented invention, *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). Accordingly, substantial evidence supports the PTAB's determination that Boston Scientific failed to establish a presumption of nexus for its objective evidence of non-obviousness.

Further, substantial evidence supports the PTAB's determination that Boston Scientific's proffered objective evidence lends minimal support to a conclusion of non-

obviousness. Boston Scientific offered evidence that "others, including [Edwards], tried and failed to solve the problem of [paravalvular leakage]" and that "there was a long-felt need for a solution to the problem of paravalvular leakage" from 2004 until the release of the Sapien 3 in 2014. J.A. 533, 538 (Boston Scientific's Response) (capitalization normalized and emphasis omitted). However, as Boston Scientific acknowledged, there were other "strategies" used "to reduce [paravalvular leakage]" during that same time period. J.A. 535–36; *see Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH,* 139 F.3d 877, 884 (Fed. Cir. 1998) ("The relevant secondary consideration is 'long-felt but unsolved need,' not long-felt need in isolation." (emphasis omitted)).

Next, Boston Scientific offered evidence that "[Edwards] copied the [claimed] invention" to design the Sapien 3. J.A. 539 (capitalization normalized and emphasis omitted). However, Boston Scientific failed to establish that Edwards had access to an embodiment of the claimed invention prior to any alleged copying. J.A. 539–40 (arguing that Edwards had access to and copied Boston Scientific's THV, but only providing attorney argument to support the conclusion that this THV was "an embodiment of the claimed invention"); *see Institut Pasteur & Université Pierre et Marie Curie v. Focarino*, 738 F.3d 1337, 1347–48 (Fed. Cir. 2013) ("Copying requires duplication of features of the patentee's work based on access to that work, lest all infringement be mistakenly treated as copying.").

Last, Boston Scientific offered evidence that "the industry has praised" the Sapien 3, J.A. 541 (capitalization normalized and emphasis omitted), and that the Sapien 3 "has enjoyed commercial success," J.A. 545 (capitalization normalized and emphasis omitted). However, Boston Scientific's evidence of industry praise was undermined by evidence that this praise was linked to design features other than its fabric seal and resulted, in part, from Edwards' existing market share. J.A. 3414 (Edwards' Expert

Testimony) (explaining that the Sapien 3 and prior Sapien models have "received significant praise"), 3416 (discussing the "many other differences" between the Sapien 3 and prior models, in addition to the fabric seal); *see S. Ala. Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015) (providing that industry praise linked to "element[s] already known in the prior art" or "[un]connect[ed] . . . to the novel elements of the claims" carries little weight in an obviousness analysis). Further, Boston Scientific did not overcome evidence that Sapien 3's commercial success was a result of Edwards' pre-existing, dominant market share. J.A. 545 (Boston Scientific's Response) (conceding that the Sapien 3 "supplanted sales of the previously market-leading S[apien] XT"); *see Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010) (providing that evidence of commercial success "carries little weight" where it may be ascribed to "pre-existing market share"). Accordingly, substantial evidence supports the PTAB's determination that Boston Scientific's proffered objective evidence lends minimal support to a conclusion of non-obviousness.

Boston Scientific's counterarguments are unavailing. First, Boston Scientific argues that the PTAB failed to find a presumption of nexus because it misconstrued the claim term "attached" to incorrectly "require[] the 'commissure support element' and the 'expandable anchor' to be two separate elements." Appellant's Br. 68. Boston Scientific did not raise this claim construction argument in its briefing before the PTAB—rather, it only raised it during oral argument before the PTAB. *Compare* J.A. 965–66 (Transcript of Oral Argument) (arguing for the "broadest reasonable interpretation" of "the word 'attached'"), *with* J.A. 495 (Boston Scientific's Response) (proposing claim construction for only "'flaps' and 'pockets'"). It is, accordingly, waived. *See Redline Detection*, 811 F.3d at 450

(providing that arguments made only as "unsupported oral argument" before the PTAB are waived on appeal).[3]

Second, Boston Scientific argues that the PTAB erred when it found "no nexus to any of the objective indicia because" whether the "S[apien] 3 . . . practice[s] the '608 patent . . . is irrelevant to failure of others and long-felt need." Appellant's Br. 65 (emphasis omitted). However, Boston Scientific did not make this argument before the PTAB—rather, it argued the contrary. J.A. 538–39 (Boston Scientific's Response) (arguing that there was long-felt but unmet need to solve the problem of paravalvular leakage "until 2014, when [Edwards] launched S[apien] 3 with a fabric seal" and that "the failure of [Edwards] and others to solve the problem of [paravalular leakage] until [then] proves that the [Challenged Claims of the] '608 patent w[ere] not obvious"). This argument is also, therefore, waived. *See In re Watts*, 354 F.3d 1362, 1368 (Fed. Cir. 2004) (explaining that arguments "not raised before the [PTAB]" are waived on appeal); *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1363 (Fed. Cir. 1999) ("A party's argument should not be a moving target."). The PTAB's finding that Boston Scientific's objective evidence lends minimal support to a conclusion of non-obviousness is, therefore, supported by substantial evidence and otherwise in accordance with law.

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[3] Boston Scientific asserts that "there was no opportunity for [it] to [raise this argument] in writing, as [Edwards] made its claim construction arguments for the first time in its Reply." Appellant's Br. 69 (citing J.A. 742–43 (Edwards' Reply)). This is inadequate. Boston Scientific could have requested leave to submit a surreply—it did not. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1081 (Fed. Cir. 2015) (explaining that it is within the PTABs discretion to allow surreplies during IPRs).

CONCLUSION

We have considered Boston Scientific's remaining arguments and find them unpersuasive.[4] Accordingly, the Final Written Decision of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board is

AFFIRMED

[4] Because we affirm the PTAB's conclusion that the Challenged Claims are obvious over a combination of Spenser and Elliot, we do not reach the unpatentability determinations based on other prior art combinations. *See Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1332 n.1 (Fed. Cir. 2020) (declining to reach alternate unpatentability grounds upon affirmance of PTAB's obviousness findings).