

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

ARTHREX, INC.,
Appellant

v.

SMITH & NEPHEW, INC., ARTHROCARE CORP.,
Appellees

UNITED STATES,
Intervenor

2018-1584

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-00918.

Decided: August 21, 2019

ANTHONY P. CHO, Carlson, Gaskey & Olds, PC, Birmingham, MI, argued for appellant. Also represented by DAVID J. GASKEY, JESSICA E. ZILBERBERG.

NATHAN R. SPEED, Wolf, Greenfield & Sacks, PC, Boston, MA, argued for appellees. Also represented by RICHARD GIUNTA; MICHAEL N. RADER, New York, NY.

DENNIS FAN, Appellate Staff, Civil Division, United

States Department of Justice, Washington, DC, argued for intervenor. Also represented by SCOTT R. MCINTOSH, JOSEPH H. HUNT, KATHERINE TWOMEY ALLEN; THOMAS W. KRAUSE, JOSEPH MATAL, FARHEENA YASMEEN RASHEED, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

Before DYK, CHEN, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

In an inter partes review, the Patent Trial and Appeal Board ruled claims 10 and 11 of Arthrex, Inc.’s U.S. Patent No. 8,821,541 invalid. In doing so, the Board employed different language than Smith & Nephew, Inc.’s petition to explain why a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art. Arthrex asserts that this warrants reversal, but the Board’s minor variation in wording does not violate the safeguards of the Administrative Procedure Act (APA) and did not deprive Arthrex of an opportunity to be heard. Accordingly, we hold that the Board did not violate Arthrex’s procedural rights. And because the Board’s findings have substantial evidence support, its claim constructions are correct, and Arthrex has not articulated a cognizable constitutional challenge to IPR for its patent, we affirm the Board.

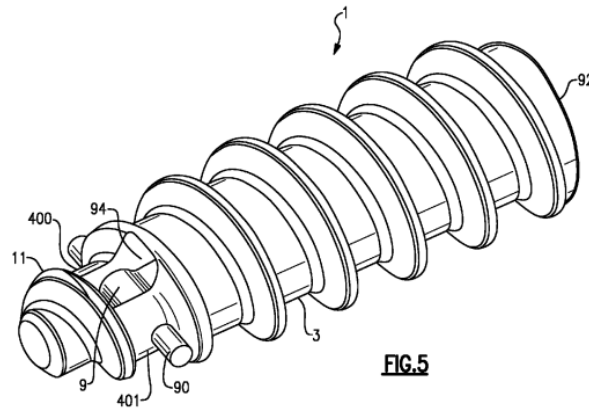
BACKGROUND

I

The ’541 patent describes a surgical suture anchor used to reattach soft tissue to bone. ’541 patent col. 1 ll. 25–35. The disclosed “fully threaded suture anchor” includes “an eyelet shield that is molded into the distal part of the biodegradable suture anchor.” *Id.* at col. 2 ll. 31–35. The eyelet shield acts as a rigid support for the sutures needed to hold the soft tissue, “provid[ing] the strength necessary to

secure the sutures.” *Id.* at col. 5 ll. 41–42, 51–57. The patent explains that because the support is molded into the anchor structure (as opposed to being a separate component), it “provides greater security to prevent pull-out of the suture.” *Id.* at col. 5 ll. 52–56.

Figure 5 of the ’541 patent illustrates the helical threading on body 3 and the integral rigid support (eyelet shield 9) of the suture anchor 1:



Independent claims 10 and 11 are at issue here. They recite:

10. A suture anchor assembly comprising:

an anchor body including a longitudinal axis, a proximal end, a distal end, and a central passage extending along the longitudinal axis from an opening at the proximal end of the anchor body through a portion of a length of the anchor body, wherein the opening is a first suture opening, the anchor body including a second suture opening disposed distal of the first suture opening, and a third suture opening disposed distal of the second suture opening, wherein a *helical thread* defines a perimeter at least around the proximal end of the anchor body;

a rigid support extending across the central passage, the rigid support having a first portion and a second portion spaced from the first portion, the first portion branching from a first wall portion of the anchor body and the second portion branching from a second wall portion of the anchor body, wherein the third suture opening is disposed distal of the rigid support;

at least one suture strand having a suture length threaded into the central passage, supported by the rigid support, and threaded past the proximal end of the anchor body, wherein at least a portion of the at least one suture strand is disposed in the central passage between the rigid support and the opening at the proximal end, and the at least one suture strand is disposed in the first suture opening, the second suture opening, and the third suture opening; and

a driver including a shaft having a shaft length, wherein the shaft engages the anchor body, and the suture length of the at least one suture strand is greater than the shaft length of the shaft.

11. A suture anchor assembly comprising:

an anchor body including a distal end, a proximal end having an opening, a central longitudinal axis, a first wall portion, a second wall portion spaced opposite to the first wall portion, and a suture passage beginning at the proximal end of the anchor body, wherein the suture passage extends about the central longitudinal axis, and the suture passage extends from the opening located at the proximal end of the anchor body and at least partially along a length of the anchor body, wherein the opening is a first suture opening that is encircled by a perimeter of the anchor body, a second suture opening extends through a portion of the anchor

body, and a third suture opening extends through the anchor body, wherein the third suture opening is disposed distal of the second suture opening;

a rigid support integral with the anchor body to define a single-piece component, wherein the rigid support extends across the suture passage and has a first portion and a second portion spaced from the first portion, the first portion branching from the first wall portion of the anchor body and the second portion branching from the second wall portion of the anchor body, and the rigid support is spaced axially away from the opening at the proximal end along the central longitudinal axis; and

at least one suture strand threaded into the suture passage, supported by the rigid support, and having ends that extend past the proximal end of the anchor body, and the at least one suture strand is disposed in the first suture opening, the second suture opening, and the third suture opening.

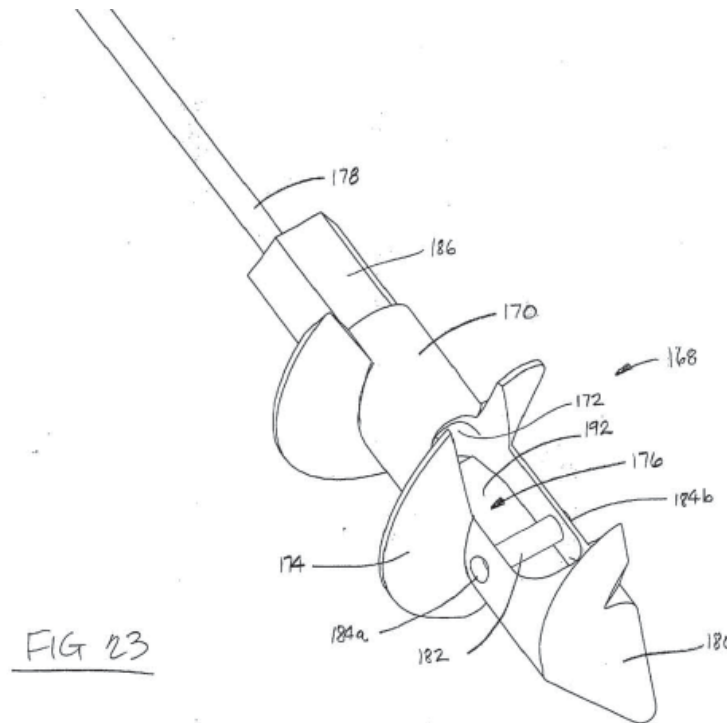
Id. at col. 7 l. 58–col. 8 l. 59 (as amended by Certificate of Correction) (emphases added to disputed claim terms).

II

Smith & Nephew sought IPR of claims 10 and 11 of the '541 patent. It challenged both claims as obvious over U.S. Pub. No. 2006/0271060 (“Gordon”) and U.S. Patent No. 7,322,978 (“West”).

Gordon discloses a bone anchor in which a suture loops about a pulley 182 positioned within the anchor body.

J.A. 1758, ¶¶ [0084]–[0086]. Figure 23 illustrates the pulley 182 held in place in holes 184a, b.



J.A. 1747. Smith & Nephew asserted that Gordon disclosed nearly all of the claimed features, including the rigid support, which Smith & Nephew identified as pulley 182. As relevant here, however, Smith & Nephew acknowledged that Gordon did not expressly disclose that the pulley was “integral with the anchor body to define a single-piece component,” as required by claim 11. J.A. 228. For that feature, Smith & Nephew relied on West.

West also describes a bone anchor 10, as shown in Figure 1, reproduced below.

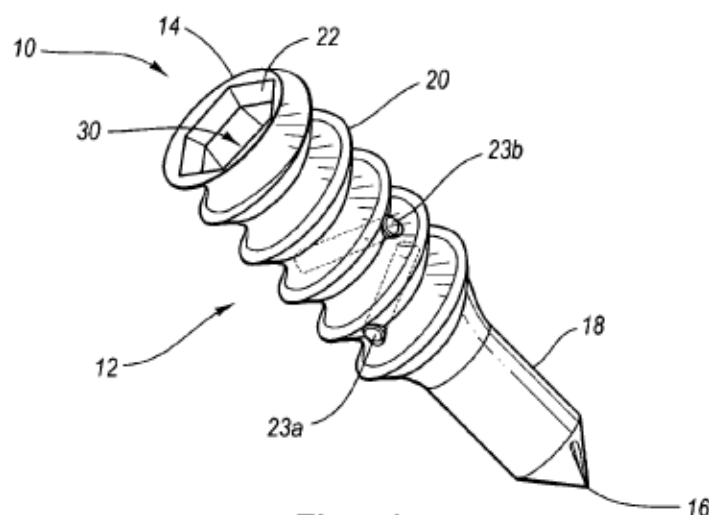


Fig. 1

J.A. 1762. In West's anchor, "[o]ne or more pins [23a and 23b] are fixed within the bore of the anchor body [12]. One or more sutures can be looped on the pins [23a and 23b]." J.A. 1760, Abstract. West explains that to manufacture the bone anchor, "anchor body 12 and posts 23 can be cast and formed in a die. Alternatively anchor body 12 can be cast or formed and posts 23a and 23b inserted later." J.A. 1768 at col. 7 ll. 41-44; *see also* J.A. 1767 at col. 5 ll. 58-60. Smith & Nephew argued that this disclosure would have motivated one of ordinary skill to manufacture the Gordon anchor using a casting process, creating a "rigid support integral with the anchor body to define a single-piece component," as recited in claim 11. J.A. 217-19. Relying on its expert's testimony, Smith & Nephew asserted that using the West casting process would minimize the materials used in the anchor, thus facilitating regulatory approval, and would reduce the likelihood of the pulley separating from the anchor body. J.A. 218-19. It also asserted that the casting process was "a well-known and accepted technique for creating medical implants" and "would have been a simple design choice." J.A. 218.

Smith & Nephew further argued that claim 11 was anticipated by U.S. Patent No. 5,464,427 (“Curtis”), which describes another bone anchor, and that claim 10 would have been obvious over a combination of Curtis and other references. Curtis discloses a threaded anchor that expands to lodge into the bone rather than being rotated into the bone. J.A. 1776–77 at col. 2 ll. 29–33, col. 3 ll. 12–16.

Among other things, Arthrex disputed whether a person of ordinary skill would have been motivated to modify Gordon in view of West to achieve the invention of claim 11, and it asserted that the Curtis ground did not include the “helical thread” of claim 10 under the correct construction of that term. In its final written decision, the Board disagreed and ruled that Smith & Nephew had shown both claims unpatentable on both the Gordon and West and the Curtis grounds. Arthrex appeals.

DISCUSSION

On review of the Board’s final written decisions, we evaluate whether the Board’s factual findings are supported by substantial evidence. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). We review the Board’s legal determinations de novo. *Id.* And we ensure the Board complies with statutory and constitutional requirements. *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1374 (Fed. Cir. 2018) (en banc) (“Enforcing statutory limits on an agency’s authority to act is precisely the type of issue that courts have historically reviewed.”); *Belden*, 805 F.3d at 1080 (reviewing alleged denial of procedural due process rights).

Arthrex challenges the Board’s determination that Smith & Nephew proved claims 11 and 10 unpatentable, and it attacks the constitutionality of IPRs as applied to its patent. We address each argument in turn.

I

We begin with claim 11. The Board determined that one of ordinary skill would have found the claimed invention obvious over Gordon and West, a conclusion Arthrex attacks both procedurally and substantively. Because the Board did not violate Arthrex's procedural rights, and because substantial evidence supports the Board's conclusion that a person of ordinary skill would have been motivated to combine the teachings of Gordon and West to achieve the claimed invention, we affirm. Because we affirm the Board's finding of unpatentability based on Gordon in view of West, we do not reach Arthrex's challenges to the Board's finding that claim 11 is anticipated by Curtis.

A

Arthrex first contends that the Board impermissibly relied on a new theory of motivation to combine in its final written decision. As we have often explained, IPR proceedings are formal administrative adjudications subject to the procedural requirements of the APA. *See, e.g., Dell Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1298 (Fed. Cir. 2016); *Belden*, 805 F.3d at 1080. One of these requirements is that “an agency may not change theories in mid-stream without giving respondents reasonable notice of the change’ and ‘the opportunity to present argument under the new theory.” *Belden*, 805 F.3d at 1080 (quoting *Rodale Press, Inc. v. FTC*, 407 F.2d 1252, 1256–57 (D.C. Cir. 1968)); *see also* 5 U.S.C. § 554(b)(3). Nor may the Board craft new grounds of unpatentability not advanced by the petitioner. *See In re NuVasive, Inc.*, 841 F.3d 966, 971–72 (Fed. Cir. 2016); *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016).

Arthrex argues that by describing West's casting method as “preferred,” a characterization not found in Smith & Nephew's petition, the Board crafted a new reason for combining Gordon and West and violated its procedural rights. We disagree. Though the Board used different

language than the petition in its discussion of whether one of ordinary skill would have been motivated to combine Gordon and West, it did not introduce new issues or theories into the proceeding. Rather, the Board properly resolved the parties' dispute about the scope and content of West's disclosure in order to evaluate the theory of obviousness raised in Smith & Nephew's petition.

West describes that an "anchor body 12 and posts 23 can be cast and formed in a die. *Alternatively* anchor body 12 can be cast or formed and posts 23a and 23b inserted later." J.A. 1768 at col. 7 ll. 41–47 (emphasis added). Pointing to this statement, the petition proposed that a person of ordinary skill would have had "several reasons" to combine West and Gordon, including that the casting process disclosed by West was a "well-known technique [whose use] would have been a simple design choice." J.A. 218. Smith & Nephew's expert relied on the same passage as support for his opinion that a person of ordinary skill would have found it obvious to implement Gordon's anchor using West's casting method. *See* J.A. 1648–50. Throughout the proceeding, the parties disputed how a person of ordinary skill would have understood that specific portion of West's disclosure and whether that disclosure would have motivated a person of ordinary skill to combine West and Gordon as Smith & Nephew proposed. Arthrex had—and took—the opportunity to argue these issues, asserting that West's casting method would be inherently problematic. J.A. 402–05, 421–30.

In the final written decision, the Board examined the parties' arguments and the portion of West's disclosure cited in the petition. In considering that disclosure, the Board noted that West's presentation of two manufacturing options suggests that the first option, casting, is "primary" and "preferred." *See Smith & Nephew, Inc. v. Arthrex, Inc.*, No. IPR2016-00918, 2017 WL 4677229, at *22, *27 (P.T.A.B. Oct. 16, 2017). It concluded that, as the petition had argued, one of ordinary skill, reviewing

West, would have applied West's casting method to Gordon because choosing the "preferred option" presented by West "would have been an obvious choice of the designer." *Id.* at *27.

Arthrex is correct that the Board's use of "preferred" differs from the petition's characterization of West's casting as "well-known," "accepted," and "simple." J.A. 218. But in finding motivation to combine, the Board relied on the same few lines of West as the petition. It considered the same proposed combination of West's casting technique and Gordon's anchor. And it ruled on the same theory of obviousness presented in the petition—that one of ordinary skill would have recognized that using West's casting with Gordon's anchor was a "simple design choice." *See id.*; *Smith & Nephew*, 2017 WL 4677229, at *27 (determining that use of casting "would have been an obvious choice of the designer").

In these circumstances, the mere fact that the Board did not use the exact language of the petition in the final written decision does not mean it changed theories in a manner inconsistent with the APA and our case law. In *Sirona Dental Systems GmbH v. Institut Straumann AG*, for example, we affirmed the Board even though it characterized a reference as providing "geometry data" rather than as providing 3-D plaster model data, as the petition had. 892 F.3d 1349, 1356 (Fed. Cir. 2018). We explained that, as in this case, the Board had cited the same disclosure as the petition and the parties had disputed the meaning of that disclosure throughout the trial. *Id.* As a result, the petition provided the patent owner with notice and an opportunity to address the portions of the reference relied on by the Board, and we found no APA violation. *Id.*; *see also Genzyme Therapeutic Prod. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016) (finding no violation where "[t]he Board's final written decisions were based on the same combinations of references that

were set forth in its institution decisions”). The same outcome follows here.

Though Arthrex argues otherwise, this case is unlike those in which we have found an APA issue. In *Magnum Oil Tools*, we found an APA violation where the Board mixed arguments raised in two different grounds of obviousness in the petition to craft its own new theory of unpatentability. 829 F.3d at 1372–73, 1377. Similarly, in *SAS Institute v. ComplementSoft, LLC*, we faulted the Board for announcing a claim construction that “varie[d] significantly” from the uncontested construction announced in the institution decision. 825 F.3d 1341, 1351 (Fed. Cir. 2016) (emphasis added), *rev’d and remanded on other grounds sub nom. SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018). And in *NuVasive*, we found error where the Board relied on portions of the prior art different than those presented in the petition as an “essential part of its obviousness findings.” 841 F.3d at 971. In all three cases, the Board departed markedly from the evidence and theories presented by the petition or institution decision, creating unfair surprise. Here, however, the Board properly relied on the same references, the same disclosures, and the same obviousness theories advanced by the petition and debated by the parties to conclude claim 11 would have been obvious.

Nor is this, as Arthrex elsewhere suggests, a case in which the Board’s decision is so divorced from the arguments presented by the petitioner as to impair appellate review. *See Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1029 (Fed. Cir. 2017) (vacating and remanding where the Board’s decision did not allow “determin[ation of] how the Board reached the conclusion that the challenged claims would have been obvious . . . [or] whether the Board’s actions complied with the APA’s procedural requirements”). Rather, the Board clearly identified the portion of West it relied on, explained the evidence and arguments, and agreed with Smith & Nephew that the

claims would have been obvious over Gordon in view of West. *See Outdry Techs. Corp. v. Geox S.p.A.*, 859 F.3d 1364, 1369–70 (Fed. Cir. 2017) (finding the Board’s decision sufficient where it “clearly articulated [party’s] arguments,” “engaged in reasoned decisionmaking,” and “sufficiently articulated its analysis in its opinion to permit our review”). We therefore reject Arthrex’s assertion that the Board violated its procedural rights.

B

Arthrex also contends that even if the Board’s decision was procedurally proper, the Board erred in finding Smith & Nephew had shown a motivation to combine Gordon and West by a preponderance of the evidence. We review this question of fact for substantial evidence. *In re Kahn*, 441 F.3d 977, 985 (Fed. Cir. 2006). When considering whether the teachings of multiple references render a claim obvious, courts “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The analysis is a flexible one, accounting for “the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.*

Substantial evidence supports the Board’s determination that a person of ordinary skill would have been motivated to apply West’s casting method to Gordon’s anchor. The Board correctly found that West expressly identifies two possible methods for making a rigid support. *See Smith & Nephew*, 2017 WL 4677229, at *26. West states that “anchor body 12 and posts 23 can be cast and formed in a die. *Alternatively* anchor body 12 can be cast or formed and posts 23a and 23b inserted later.” J.A. 1768 at col. 7 ll. 41–47 (emphasis added). As the Board found, this wording suggests that the default or preferred option disclosed by West is die casting. *See Smith & Nephew*, 2017 WL 4677229, at *27; *see also id.* at *22 (noting that West describes casting as the “primary” option). Given these two

options, the Board reasonably determined that forming the entire anchor integrally, as a single piece, “would have been an obvious choice of the designer.” *Id.* at *27.

Additional record evidence supports this result. Smith & Nephew’s expert, Mr. Mark Ritchart, offered detailed testimony explaining that using a casting process would result in a stronger anchor more likely to receive regulatory approval. J.A. 1649–50. Professor Alexander Slocum testified similarly, stating that the design would also “decrease . . . manufacturing costs,” “prevent the suture anchor from appearing in and obscuring the bone in x-rays,” and “reduce[] . . . stress concentrations” on the anchor. J.A. 2869–70.

Arthrex correctly notes that some evidence arguably cuts against the Board’s conclusion. Mr. Ritchart acknowledged potential complexities of casting, J.A. 3839, and Arthrex’s expert, Dr. Kenneth Gall, argued at length that a person of ordinary skill would not have applied West to Gordon as Smith & Nephew argued, *see, e.g.*, J.A. 3747–49. But the presence of evidence supporting the opposite outcome does not preclude substantial evidence from supporting the Board’s fact finding. *See, e.g., Falkner v. Inglis*, 448 F.3d 1357, 1364 (Fed. Cir. 2006) (“An agency decision can be supported by substantial evidence, even where the record will support several reasonable but contradictory conclusions.”). And our task on appeal is simply to evaluate whether substantial evidence supports the Board’s fact finding; “[w]e may not reweigh . . . evidence.” *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016). Because the Board’s finding of motivation to combine is supported by such evidence as “a reasonable mind might accept as adequate,” and, as noted above, the Board did not err procedurally, we affirm the Board’s conclusion that claim 11 would have been obvious over Gordon in view of West. *Kahn*, 441 F.3d at 985.

II

We next address claim 10. Arthrex challenges the Board’s construction of “helical thread,” asserting that this term should have been construed to require that the helical thread “facilitates rotary insertion of the anchor into bone.” Appellant’s Br. 55. Because the Board correctly construed the term and Arthrex does not otherwise challenge the Board’s finding that the Curtis ground renders claim 10 unpatentable, we affirm without considering whether claim 10 is also unpatentable based on Gordon and West.

We review the Board’s ultimate claim constructions de novo, *In re Man Mach. Interface Techs. LLC*, 822 F.3d 1282, 1285 (Fed. Cir. 2016), and we review any subsidiary factual findings involving extrinsic evidence for substantial evidence, *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The broadest reasonable interpretation standard applies to this IPR.¹ Thus, the Board’s construction must be reasonable in light of the record evidence and the understanding of one skilled in the art. *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc).

Here, the Board correctly construed “helical thread” as “a helical ridge or raised surface that serves to retain the anchor in bone” without limiting the term to threads used

¹ Per recent regulation, the Board applies the *Philips* claim construction standard to petitions filed on or after November 13, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). Because Smith & Nephew filed its petition before November 13, 2018, we apply the broadest reasonable interpretation standard.

to facilitate rotary insertion. *Smith & Nephew*, 2017 WL 4677229, at *19. Claim 10 recites “a helical thread defines a perimeter at least around the proximal end of the anchor body.” This plain claim language suggests that the “helical thread” is a structural feature that “defines a perimeter.” ’541 patent col. 8 ll. 7–8. Consistent with the Board’s construction, the claim does not include any functional limitations. A single sentence in the “detailed description of the preferred embodiments” in the specification describes rotating threaded anchors into bone using a driver. *Id.* at col. 6 ll. 4–8. But our case law counsels against incorporating a feature of a preferred embodiment into the claims, particularly where, as here, the feature at issue is mentioned only tangentially. *See, e.g., In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (“[L]imitations are not to be read into the claims from the specification.”). Nowhere does the specification mandate that threaded anchors must be rotated into bone. Rather, the specification acknowledges that only “[s]ome threaded suture anchors are designed to be inserted into a pre-drilled hole.” ’541 patent col. 1 ll. 36–39 (emphasis added).

The prosecution history further supports the Board’s decision not to limit the claimed “helical thread[s]” to those used for rotational insertion. As Arthrex concedes, Appellant’s Br. 60–61 & n.10, three references cited during prosecution describe threaded anchors that are not rotated into the bone. As we have explained, art “cited in the prosecution history of the patent constitutes intrinsic evidence.” *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (quoting *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364, 1368 (Fed. Cir. 2003)) (explaining that a claim term may be construed based on its “usage in the prior art that was cited in the patent”). These references confirm that the broadest reasonable construction of the term “helical thread” is not limited to threads used for rotatory insertion. Though Arthrex cites dictionaries that may support a narrower interpretation, *see* Appellant’s

Br. 57, that extrinsic evidence does not outweigh the intrinsic record. *See Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1328 (Fed. Cir. 2008) (“When construing claims, the claims and the rest of the patent, along with the patent’s prosecution history . . . are the primary resources; while helpful, extrinsic sources like dictionaries and expert testimony cannot overcome more persuasive intrinsic evidence.”). We thus affirm the Board’s construction.

III

Finally, we address Arthrex’s challenge to the constitutionality of certain IPRs. Arthrex notes that the Supreme Court has not addressed the constitutionality of IPR as applied to patents issued prior to the America Invents Act (AIA), which created IPRs. *See Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018) (“Oil States does not challenge the retroactive application of inter partes review, even though that procedure was not in place when its patent issued.”). It asks us to hold that IPR is unconstitutional when applied retroactively to pre-AIA patents.² *See* Appellant’s Br. 62.

We exercise our discretion and reach Arthrex’s argument rather than finding that Arthrex waived this issue by failing to present it to the Board. *See e.g., In re DBC*, 545 F.3d 1373, 1378–79 (Fed. Cir. 2008) (noting “discretion to reach issues raised for the first time on appeal” but holding party waived constitutional challenge based on Appointments Clause by failing to raise it before the Board); *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1251

² To the extent Arthrex intends to raise a general due process challenge unrelated to retroactivity, the single paragraph of conclusory assertions presented in its opening brief is “insufficient to preserve the issue for appeal.” *See Trading Techs. Int’l, Inc. v. IBG LLC*, 921 F.3d 1378, 1385 (Fed. Cir. 2019).

(Fed. Cir. 2005) (“An appellate court retains case-by-case discretion over whether to apply waiver.”). We need not reach the merits of the issue, however, because the ’541 patent issued on September 2, 2014, almost three years *after* passage of the AIA and almost two years after the first IPR proceedings began. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29, § 6(c)(2)(A), 125 Stat. 284, 304 (2011) (providing that IPR “shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act [Sept. 16, 2011]”). That Arthrex filed its patent applications prior to passage of the AIA is immaterial. As the Supreme Court has explained, “the legal regime governing a particular patent ‘depend[s] on the law as it stood at the emanation of the patent, together with such changes as have since been made.’” *Eldred v. Ashcroft*, 537 U.S. 186, 203 (2003) (quoting *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843)). Accordingly, application of IPR to Arthrex’s patent cannot be characterized as retroactive.

In any event, even if Arthrex’s patent had issued prior to the passage of the AIA, our court recently rejected arguments similar to Arthrex’s in *Celgene Corp. v. Peter*. No. 18-1167, 2019 WL 3418549, at *12–16 (Fed. Cir. July 30, 2019). As we explained, pre-AIA patents issued subject to both district court and Patent Office validity proceedings. Though IPR differs from these existing proceedings, we held that the differences between IPRs and the district court and Patent Office proceedings that existed prior to the AIA are not so significant as to “create a constitutional issue” when IPR is applied to pre-AIA patents. *Id.* at *15; *see also id.* at *12 & n.13 (affirming that our prior decisions ruling that retroactive application of reexamination does not violate the Fifth Amendment, the Seventh Amendment, or Article III “control the outcome” of similar challenges to IPR). When Arthrex’s patent issued, it is beyond dispute that patent owners expected that “the [Patent Office] could reconsider the validity of issued patents on particular grounds, applying a preponderance of

the evidence standard.” *Id.* at *16. Consequently, even if Arthrex’s patent pre-dated the AIA, application of IPR to the ’541 patent would not create a constitutional challenge.

CONCLUSION

We have reviewed the parties’ remaining arguments and find them unpersuasive. We therefore affirm the Board.

AFFIRMED