18-1584

United States Court of Appeals for the Federal Circuit

Arthrex, Inc.,

Patent Owner-Appellant

v.

Smith & Nephew, Inc and ArthroCare Corp.,

Petitioners-Appellees

United States,

Intervenor

Appeal from the U.S. Patent & Trademark Office, Patent Trial and Appeal Board, *Inter Partes* Review No. 2016-00918

APPELLANT ARTHREX, INC.'S COMBINED PETITION FOR REHEARING AND REHEARING EN BANC

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October 7, 2019

CERTIFICATE OF INTEREST

Counsel for Appellant certifies the following:

1. The full name of every party represented by me is:

Arthrex, Inc.

2. The names of the real party in interest represented by me is:

Arthrex, Inc.

3. There are no parent corporations and any publicly held companies that

own 10 percent of the stock of the parties represented by me.

4. The names of all law firms and the partners or associates that

appeared for the party or amicus now represented by me in the trial court or agency

or are expected to appear in this Court (and who have not or will not enter an

appearance in this case) are:

Anthony P. Cho, David Gaskey, John E. Carlson, Brian S. Tobin,

Quincy Harrison, and Jessica Zilberberg

Carlson, Gaskey & Olds, P.C.

5. The title and number of any case known to me to be pending in this or

any other court or agency that will directly affect or be directly affected by this

court's decision in the pending appeal:

None.

Dated: October 7, 2019 /s/ Anthony P. Cho

Anthony P. Cho

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe this appeal requires answers to

the following precedent-setting question of exceptional importance:

• Whether *inter partes* review, as retroactively applied to the '541 Patent,

is constitutional; and

• Whether inter partes review comports with the due process

requirements of the Constitution.

Based on my professional judgment, I believe the panel decision is contrary

to at least the following decisions of the Supreme Court of the United States and

precedents of this Court: Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988);

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002);

Commonwealth Edison Co. v. United States, 271 F.3d 1327 (Fed. Cir. 2001);

Matthews v. Eldridge, 424 U.S. 319 (1976); NEC Corp. v. United States, 151 F.3d

1361 (Fed. Cir. 1998); Belden Inc. v. Berk-Tek LLC, 805 F.3d 1064 (Fed. Cir. 2015);

Cutsforth, Inc. v. Motivepower, Inc., 636 Fed. Appx. 575 (Fed. Cir. 2016)

(unpublished)); *In re NuVasive*, 841 F.3d 996 (Fed. Cir. 2016).

Dated: October 7, 2019

/s/ Anthony P. Cho

Anthony P. Cho

Attorney of Record for Appellant Arthrex, Inc.

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POINTS OF LAW AND FACT OVERLOOKED OR MISAPPREHENDED BY THE PANEL BELOW

The following points of law and fact were overlooked or misapprehended by the panel below relative to Arthrex's constitutional arguments:

- 1. Neither *Eldred* nor *McClurg* determine at what point in time a patentee's expectations about its patent rights govern the analysis of whether those rights were disrupted by a change in law.
- 2. Retroactive application of the AIA to '541 Patent is contrary to *Commonwealth, Bowen*, and *Festo*.

The following points of law and fact were overlooked or misapprehended by the panel below relative to claim 11:

- 1. The PTAB's grounds for supporting its obviousness conclusion was not simply a difference in language between the PTAB and S&N's Petition, but instead a fundamentally different theory of obviousness.
- 2. Sirona Dental is dissimilar from this case, but NuVasive is instructive.

COMBINED PETITION FOR REHEARING AND REHEARING EN BANC I. INTRODUCTION AND STATEMENT OF THE CASE

There are two issues that require rehearing. The first issue relates to Arthrex's constitutionality challenge. There are two parts to this challenge: whether application of the America Invents Act ("AIA") to the '541 Patent is retroactive, and if so, whether the retroactivity violates Arthrex's due process rights. The panel below discharged the constitutional issues raised by Arthrex by citing to cases that do not directly answer the questions at hand. Instead, this is a question of first impression because this Court's precedent has never squarely decided whether the filing date or the issue date of a patent is the relevant date on which a party's settled expectations about is patent rights toll, where the patentee's existing patent rights may be extinguished by retroactively applied legislation. Furthermore, this Court's recent decision in *Celgene*, which the panel relied on (and which itself has not been heard en banc), does not address all of Arthrex's arguments. Accordingly, Arthrex respectfully requests rehearing or rehearing en banc.

Second, the panel affirmed the PTAB's decision that claim 11 of the '541 Patent was unpatentable over the combination of "Gordon" and "West" references. However, Arthrex explained that the PTAB supplied its own reasoning to support S&N's ground of unpatentability, contrary to this Court's prior case law requiring all of the grounds be set for in the petition. In finding that the PTAB simply used "different language" from S&N, the panel below essentially found the PTAB's

reasoning was "close enough" to S&N's Petition. However, the PTAB's actual reason to combine references was different from the grounds offered by S&N in its Petition. Arthrex's Opening Brief at 29-34. As set forth in S&N's Brief, the PTAB found reason to combine Gordon with West because West listed casting as an option first, a reason to combine not offered by S&N in its Petition. S&N's Brief at 42. Thus the PTAB found the reason for the combination laid in West alone whereas S&N never relied on the fact that casting was listed first as the reason for the combination. Accordingly, Arthrex never had the opportunity to explain or argue why listing casting first could not support obviousness before the PTAB. The panel overlooked this fact and instead shoehorned the PTAB's reasoning into one of the three grounds set forth in S&N's Petition. The PTAB's decision as to claim 11 and the Gordon/West ground should be reversed on rehearing or rehearing *en banc*.

II. ARGUMENT

A. The Panel Majority's Decision Dismissed Arthrex's Constitutionality Arguments Based on Cases that do not Squarely Answer the Issues Raised

Arthrex filed the application that became the '541 Patent, and that application became public, well before the AIA was enacted. Arthrex's Opening Brief ("Brief") at 63-64. But the AIA did not exist until years later—and only then did Arthrex learn that its patent rights would now be contingent on *inter partes* review ("IPR"). As Arthrex explained in its briefing before the panel below, retroactive application of

the AIA to Arthrex's '541 Patent contravenes "elementary considerations of fairness" because when Arthrex completed its end of the patent bargain by filing the application that became the '541 Patent, Arthrex had settled expectations that did not include the '541 Patent being subject to IPR. Brief at 62-65; *see also* Arthrex's Reply at 22-29 (citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994)). The panel below disposed of Arthrex's arguments by relying on case law that does not squarely address the specific issues raised. In so doing, the panel misapprehended and overlooked issues of law as to both parts of the constitutional issue. Additionally and/or alternatively, the constitutional issues raised in this appeal include questions of exceptional importance that warrant rehearing *en banc*.

1. The AIA is Retroactively Applied to the '541 Patent

The threshold question is whether the AIA was retroactively applied to the '541 Patent by subjecting the '541 Patent to IPR. The panel found that the relevant date for assessing a patentee's expectations is the issue date of the patent, noting "that Arthrex filed its patent applications prior to the passage of the AIA is immaterial." Opinion at 18. In so finding, the panel relied on *Eldred v. Ashcroft*, 537 U.S. 186, 203 (2003), which held that the legal regime governing a patent depends on the law at the time of issuance of the patent (citing *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843)). *Eldred* and *McClurg*, however, are fundamentally different from the present case. In both cases, the Supreme Court was considering an

expansion of intellectual property rights, not a termination of such rights, as in this case. In *Eldred*, the question was whether Congress had the authority to extend copyright terms. *Id.* at 199; see also Arthrex's Reply at 29, n.9. The *Eldred* court looked to its previous decision in *McClurg*, which similarly found "no constitutional barrier to the legislative expansion of existing patents." *Eldred*, 537 U.S. 186 at 202-03 (citing *McClurg*, 42 U.S. at 206)(emphasis added). For this reason, neither *Eldred* nor *McClurg* determine at what point in time a patentee's expectations about its patent rights govern the analysis of whether those rights were disrupted by a change in law. Indeed, this is a question of first impression for this Court.

Arthrex submits that the relevant point in time is the time at which the patentee made its side of the patent bargain, i.e., on the filing date of the patent. Brief at 63-64; Arthrex's Reply at 24. Arthrex had well-settled expectations about its patent rights based on pre-AIA law at the time that it filed a patent application, and in so doing gave the Patent Office the right to publish its invention. *Id.* Namely, Arthrex expected that the '541 Patent could be subject to a reexamination, which, true to its name, was simply a second look at the Patent Office's examination procedure in the first instance. But Arthrex did not expect that the '541 Patent would be subject to what amounts to a trial in the Patent Office in an IPR. *See In re Cuozzo Speed Techs., LLC*, 793 F.3d 1297, 1301 (Fed. Cir. 2015) (dissent) (IPRs are fundamentally different from reexaminations, as they do not bear "examinational hallmarks" and

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instead have "similarities to district court litigation"); *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) ("The new inter partes review regime looks a good deal more like civil litigation" than reexaminations). Not to mention, IPRs have a patent cancellation rate over twice that of pre-AIA reexaminations—something that Arthrex could not have anticipated when it filed the application that became the '541 Patent. Arthrex's Reply at 24-25. If Arthrex had known about IPR, Arthrex may have chosen to keep its invention secret. But as of filing the '541 Patent, Arthrex did not have the opportunity to make that choice, and is now trapped in the AIA regime. Because the AIA came years after Arthrex filed the patent application that became the '541 Patent, application of the AIA to the '541 Patent is retroactive.

For these reasons, rehearing or rehearing *en banc* is requested.

2. Retroactive Application of the AIA to the '541 Patent is Unconstitutional

The next question is whether retroactive application of the AIA to the '541 Patent is constitutional. Retroactive changes to a patentee's expectations "are not favored by the law" and statutes and administrative rules are not given "retroactive effect unless their language requires this result." Brief at 63-64; Arthrex's Reply at 24 (citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002)). The panel found that application of the AIA to the '541 Patent is constitutional, relying on *Celgene Corp. v. Peter*, No. 18-1167, 2019 WL 3418549 (Fed. Cir. July 30, 2019).

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Opinion at 18. At the outset, Arthrex notes that *Celgene* has not been heard *en banc*¹ and submits that this constitutionality question is precisely the type of precedent-setting question of exceptional importance that requires *en banc* review. As this Court is well-aware, the Supreme Court left open the question of whether retroactive application of the AIA is constitutional. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018).

In any case, *Celgene* does not address the issues raised by Arthrex. In particular, *Celgene* does not analyze application of the AIA under the standard set forth in *Commonwealth Edison Co. v. United States*, 271 F.3d 1327, 1346 (Fed. Cir. 2001) for severely retroactive statues. Arthrex's Reply at 23-27. *Commonwealth* sets forth a test for determining whether a severely retroactive statute is rational and satisfies due process. *Id.* at 23. The test has two parts: (1) determination of whether "the imposition of retroactive liability would not be contrary to that party's reasonable expectations," and (2) determination of whether "Congress reasonably concluded that the party subjected to retroactive obligations benefited from activity that contributed to a societal problem, and liability is not disproportionately imposed on that party." Arthrex's Reply at 23-24 (citing *Commonwealth*, 271 F.3d at 1346). To the extent that *Celgene* touches on the first part of the test, *Celgene* is silent as to

¹ Appellant Celgene Corp. submitted a Petition for Rehearing *En Banc* on September 27, 2019.

the second part. For at least these reasons, the panel below misapprehended or overlooked the law of retroactivity. Moreover, even if *Celgene* did apply here, the holding of *Celgene* has not been reviewed *en banc*, though it presents a question of exceptional important. Therefore, rehearing or rehearing *en banc* is warranted here.

3. This Court Should Decide Whether Inter Partes Review Comports with Due Process

The Supreme Court in *Oil States* also explicitly left open the question of whether IPR comports with due process generally. *Oil States*, 138 S. Ct. at 1379. The panel below did not consider this issue. Opinion at 17, n.2. Arthrex submits that the due process question is one of precedent-setting exceptional importance, and requires *en banc* review. Arthrex explained in its brief that the *inter partes* review procedures violate due process for a number of reasons under *Mathews v. Eldridge*, 424 U.S. 319 (1976). Brief at 64-65. The Government explained its position, and Arthrex replied to the Government's points. Government's Brief at 37-42; Arthrex's Reply at 23-29. However, there are a few important due process concerns raised by Arthrex that the Government had no answer for.

One concern is that *inter partes* review can lead to conflicting findings about the validity of a patent between an Article III court and an administrative body (the PTAB), as happened here. Brief at 64; Arthrex's Reply at 28, n.7. Moreover, in this case, the PTAB overrode the findings of an Article III Court—finding the '541 Patent unpatentable after a district court found it to be valid. *Id*.

Another concern is the fact that the same panel of PTAB judges can institute an IPR and then defend that same institution decision in a Final Written Decision. Brief at 64-65; Arthrex's Reply at 28, n.7 (citing *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1035-40 (Fed. Cir. 2016), (Newman, J., dissenting)). As Judge Newman has pointed out, this procedure violates due process and ignores this Court's precedent in *NEC Corp. v. United States*, 151 F.3d 1361 (Fed. Cir. 1998), requiring an impartial decisionmaker, and the AIA's language requiring bifurcation between the two decisions. *Id*.

A third concern is the propensity for bias amongst PTAB panels, because the PTAB has admittedly engaged in panel stacking whereby the Director chooses a panel to achieve a particular result in a given case. Brief at 64-63 (citing *Yassum Research Dev. Co.*, Nos. 2015-1342, 2015-1342, Oral Arg. at 43:17-42, 48:00-06). After the briefing in the instant appeal was closed, the Government has doubled down on this position in other appeals. For instance, in *Arthrex, Inc. v. Smith & Nephew, Inc.*, Case No. 2018-2140, the Government argued that the Director exercises control over PTAB's activities by selecting the judges that sit on each PTAB panel. *See Arthrex, Inc. v. Smith & Nephew, Inc.*, Case No. 2018-2140, Dkt. 37 at 32-33.

These due process issues are of exceptional importance and require this Court's attention. Accordingly, rehearing *en banc* is requested.

B. The Panel Misapprehended or Overlooked Points of Law and Fact in Finding that the PTAB Merely Used "Different Language" from S&N in Finding Claim 11 Unpatentable

As a brief introduction, claim 11 is directed to a suture anchor, which is used in surgery to repair tissue that has detached from bone. Brief at 6-11. Claim 11 recites "a rigid support integral with the anchor body to define a single-piece component." *Id.* at 11. This rigid support attaches the suture to the anchor. *Id.* at 9-10.

1. S&N's Ground of Unpatentability

S&N's proposed ground of unpatentability for claim 11 rested on the combination of two prior art references—"Gordon" [Appx1723-1759] and "West" [Appx1760-1771]. Gordon does not teach a rigid support integral with an anchor body, but S&N proposed changing Gordon's design to be integrally cast based on the teachings of West and its expert's testimony. [Appx218-219]. S&N provided three rationales for making this combination: (1) to minimize the materials used in the anchor, which eases the FDA approval process, (2) because casting was a "well-known and accepted technique for creating medical implants," and using casting would thus have been a "simple design choice," and (3) because the rigid support (which in Gordon, is a pulley), would be more securely attached in the anchor. [Id.].

2. The PTAB's Decision

The PTAB found in favor of S&N but arrived at S&N's conclusion by a different route. As Arthrex explained, rather than adopting any of the three rationales

that S&N proposed, the PTAB found that West discloses casting is a "preferred option," and thus would have been "an obvious choice of the designer." Brief at 29 (citing Appx62). As argued by S&N, the PTAB inferred from West that casting was the "primary" option because it was the first technique listed in a list of two options. S&N's Brief at 42. This was inference was never suggested by S&N. Again, S&N's Petition only relied on disclosure in West for what is says on its face—that West's anchor "can be" cast. [Appx218]. S&N never argued that West supplied the reason for the combination—instead, S&N's Petition points to expert testimony for this point. [*Id.*]. The problem is, the PTAB's theory was raised for the first time in the Final Written Decision, and only backed by S&N at the appeal stage. Hence, Arthrex never had an opportunity to respond or argue its position.

3. The Panel's Opinion Misapprehended or Overlooked Issues of Fact and Law in Finding There was Sufficient Reasoning to Combine Gordon and West

The panel below acknowledges that the PTAB cannot "change theories in midstream" or "craft new grounds of unpatentability not advanced by the petitioner." Opinion at 9. Instead, it is of "utmost importance" that a Petition for IPR include identification of the evidence that support the proffered grounds of unpatentability. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed Cir. 2016). Furthermore, this Court's case law requires that respondents in an agency action have reasonable notice of a change in the agency's position and opportunity

to present argument under the new position. Opinion at 9 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015); 5 U.S.C. § 554(b)(3)); *see also* Opinion at 11. The panel also recognized that the PTAB's characterization of casting as "preferred" differed from S&N's characterization of casting in its Petition. *Id.* However, the panel concluded that the PTAB ruled on the same theory of obviousness presented in the Petition, "design choice," but used different language. *Id.* at 9-11. In so doing, the panel misapprehended or overlooked both issues of fact and law.

First, the panel's finding that both S&N and the PTAB relied on a "design choice" theory of unpatentability misapprehends the law of "design choice." As Arthrex explained, merely stating that a combination is a design choice does not support a conclusion of obviousness. Brief at 33-34 (citing *Cutsforth, Inc. v. Motivepower, Inc.*, 636 Fed. Appx. 575 (Fed. Cir. 2016) (unpublished)). There must still be a founded reason for the combination. *Id.* Accordingly, a "design choice theory" is meaningless in and of itself. Here, S&N relied on West's teaching of casting as an option but not a reason for its combination with Gordon. [Appx218]. S&N relied only on expert testimony to support this reason for the combination. [*Id.*]. In contrast, the PTAB relied on West to supply the reason itself, i.e. because casting was listed first in a list of manufacturing options. This is not simply a divergence in the language chosen by S&N as compared to that of the PTAB

(Opinion at 11)—this is a fundamental difference in the theory of obviousness at issue. Thus, the panel's conclusion that the PTAB ruled on the same theory of obviousness (Opinion at 11) is incorrect.

To this end, the panel misapprehended or overlooked the facts when it found "the Board relied on the same few lines of West as the petition" in finding motivation to combine. Opinion at 11. Again, S&N never relied on West to supply the reason for the combination like the PTAB did.

The rest of the panel's analysis on claim 11 is based on the incorrect conclusions discussed above. First, the panel's reliance on *Sirona Dental* is misplaced. As the panel noted, in *Sirona Dental*, "the Board had cited the same disclosure as the petition and the parties had disputed the meaning of that disclosure throughout the trial." Opinion at 11 (citing *Sirona Dental Systems GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed Cir. 2018)). In this case, neither party argued below that disclosure in West provided a reason for the proposed combination—only the PTAB supplied this rationale. On the other hand, *NuVasive* is instructive here. There, as the panel noted, this Court "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." Opinion at 12 (citing *In re NuVasive*, 841 F.3d 996, 971 (Fed. Cir. 2016). A similar situation is present here—the PTAB

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relied on West for motivation to combine Gordon and West, while S&N's Petition relied on its expert to supply the motivation.

For these reasons, the panel below misapprehended or overlooked issues of fact and law with respect to its finding that claim 11 is obvious over Gordon and West. Under the correct facts and interpretation of the law, the relevant case law dictates that the PTAB improperly supplied its own theory of unpatentability for claim 11.² For this reason, rehearing or rehearing *en banc* is respectfully requested.

III. CONCLUSION

For all the reasons presented above, Arthrex respectfully requests rehearing or rehearing *en banc*.

CARLSON, GASKEY & OLDS, P.C.

Dated: October 7, 2019 /s/ Anthony P. Cho

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² The panel did not reach a second theory of unpatentability that was set forth for claim 11, anticipation by the "Curtis" reference. Opinion at 9. Should rehearing change the outcome of the Court's findings with respect to the Gordon/West combination, Arthrex requests that this case be remanded for the panel to consider

the Curtis ground on the merits.

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

I, Anthony P. Cho, counsel for Appellant, certify that the foregoing Brief

complies with the type-volume limitation set forth in Fed. R. App. P. 35(b)(2).

Specifically, this Brief contains 3,581 words (excluding the parts of the brief

exempted by Fed. Cir. R. 35(c)(2)) as determined by the word count feature of the

word processing program used to create this brief.

I further certify that the foregoing brief complies with the typeface

requirements set forth in Fed. R. App. P. 32(a)(5) and the type style requirements of

Fed. R. App. P. 32(a)(6). Specifically, this brief has been prepared using a

proportionally spaced typeface using Microsoft Word 2016, in 14-point Times New

Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2019, I electronically filed the foregoing document using the Court's CM/ECF system, which sent notification of such filing to all counsel of record as follows:

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Dated: October 7, 2019 /s/ Jessica Zilberberg

ADDENDUM

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.

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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.

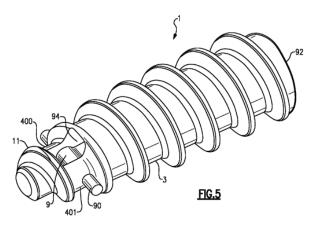
BACKGROUND

Ι

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

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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.

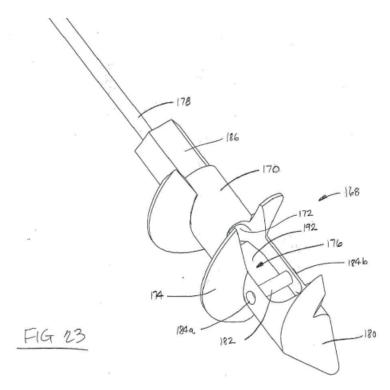
Id. at col. 7 l. 58–col. 8 l. 59 (as amended by Certificate of Correction) (emphases added to disputed claim terms).

H

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").

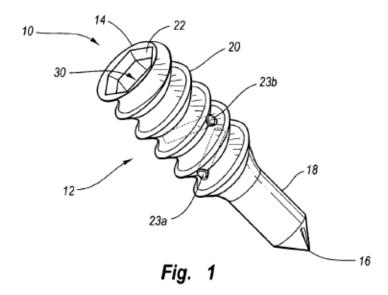
Gordon discloses a bone anchor in which a suture loops about a pulley 182 positioned within the anchor body.

J.A. 1758, \P [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.



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 singlepiece 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.

Ι

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. Acceleron, 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 midstream 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

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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.

В

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.

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II

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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. 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 *Phillips* 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. 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 "solome 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

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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.

TIT

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 Case: 18-1584 Document: 68 Page: 49 Filed: 08/07/2019

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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.

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CONCLUSION

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

AFFIRMED

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.

JUDGMENT

THIS CAUSE having been considered, it is

ORDERED AND ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

Casse: 1198-11558844 | Doccurreentt: 7639 | Pragge: 424 | FFileed: 0180/2017/2200199

August 21, 2019

/s/ Peter R. Marksteiner Peter R. Marksteiner Clerk of Court