No.

IN THE
Supreme Court of the United States

ARTHREX, INC.,
Petitioner,
v.
SMITH & NEPHEW, INC.; ARTHROCARE CORP.;
AND UNITED STATES OF AMERICA,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In 2011, Congress enacted a potent new mechanism for challenging patents through adversarial proceedings at the Patent Office known as inter partes review. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(a), 125 Stat. 284, 299 (2011). Congress made that new mechanism applicable even to patents that were applied for and issued before the statute's enactment. The Patent Office relied on that new procedure to revoke Arthrex's patent claims, even though Arthrex applied for its patent and disclosed its invention to the public in reliance on the prior regime.

While Arthrex's case was pending on appeal, the Federal Circuit decided in another case between the same parties that the administrative patent judges who conduct inter partes reviews hold office in violation of the Appointments Clause. See *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). The Federal Circuit has repeatedly refused to apply that ruling to cases like this one where the appellant did not challenge the appointments in its opening brief on appeal.

The questions presented are:

1. Whether the retroactive application of inter partes review to patents that were applied for before the America Invents Act violates the Fifth Amendment.

2. Whether a court of appeals can invoke forfeiture principles to refuse to address a constitutional claim in a pending appeal despite an intervening change in law.

PARTIES TO THE PROCEEDINGS BELOW

Petitioner Arthrex, Inc., was the patent owner in proceedings before the Patent Trial and Appeal Board and the appellant in the court of appeals.

Respondents Smith & Nephew, Inc., and ArthroCare Corp. were petitioners in proceedings before the Patent Trial and Appeal Board and appellees in the court of appeals.

Respondent United States of America was an intervenor in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioner Arthrex, Inc., states that it has no parent corporation and that no publicly held company owns 10% or more of its stock.

RELATED PROCEEDINGS

The following proceedings are directly related to this case within the meaning of Rule 14.1(b)(iii):

- *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, No. 2018-1584 (Fed. Cir.), judgment entered on August 21, 2019; and
- *Smith & Nephew, Inc.* v. *Arthrex, Inc.*, Case IPR2016-00918 (P.T.A.B.), final written decision entered on October 16, 2017.

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PETITION FOR A WRIT OF CERTIORARI

Arthrex, Inc., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion (App., *infra*, 1a-20a) is reported at 935 F.3d 1319. The Patent Trial and Appeal Board's final written decision (App., *infra*, 21a-100a) is unreported.

STATEMENT OF JURISDICTION

The court of appeals entered its decision on August 21, 2019. App., *infra*, 1a. The court denied rehearing and rehearing en banc on November 8, 2019. *Id.* at 101a. On January 24, 2020, the Chief Justice extended the time

to file a petition for a writ of certiorari to April 6, 2020. No. 19A817. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant provisions of the U.S. Constitution; Title 35 and Title 5 of the U.S. Code; Pub. L. No. 96-517, 94 Stat. 3015 (1980); the Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, §§4601 *et seq.*, 113 Stat. 1501A-567; and the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); are set forth in the appendix. App., *infra*, 103a-141a.

PRELIMINARY STATEMENT

The Patent Act strikes a "carefully crafted bargain" to encourage the development and disclosure of new technologies. *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989). The Act offers inventors "the exclusive right to practice the invention for a period of years." *Id.* at 151. In return, the inventor must "disclos[e]" how to make and use his invention, so others are "enabled without restriction to practice it and profit by its use" once that period expires. *Ibid.*

In 2006, Arthrex fulfilled its side of that bargain when it sought a patent for a new suture anchor that allows surgeons to reattach soft tissue to bones more securely. Arthrex's application described how to make and use its new suture anchor in detail. By disclosing its invention to the public, Arthrex surrendered its right to keep the invention secret in exchange for the protections the Patent Act promised at the time.

Years later, in 2011, Congress altered the terms of that bargain in the Leahy-Smith America Invents Act ("AIA"). That statute created a new mechanism for more

easily invalidating patents known as "inter partes review." Congress authorized the use of that mechanism even where the inventor applied for the patent and disclosed the invention years earlier, before the statute was enacted. The Patent Office invoked that procedure to revoke Arthrex's patent claims, even though a jury had already found them valid in litigation.

This petition challenges the constitutionality of applying inter partes review retroactively to earlier patents—an issue this Court left open in *Oil States Energy Services, LLC* v. *Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018). This Court is already considering a petition raising a similar challenge in *Celgene Corp.* v. *Peter*, No. 19-1074 (filed Feb. 26, 2020). In *Celgene*, however, the petitioner both applied for and received the patent before the AIA's enactment. *Celgene* thus does not present the important category of cases like this one where the applicant disclosed its invention in reliance on the pre-AIA regime but received the patent afterward. The Court should grant review in both *Celgene* and this case, and hear the two together, so it can resolve the question in both contexts.

This petition also presents a constitutional challenge to the appointment of the administrative patent judges ("APJs") who adjudicate inter partes reviews. In another case between the same parties, the Federal Circuit held that APJs are improperly appointed. See *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), reh'g denied (Mar. 23, 2020). But the court declined to apply that ruling in this case, where Arthrex had not raised the issue in its opening brief. Whether a court may refuse to address constitutional claims on forfeiture grounds despite an intervening change in law is another important and recurring issue. The Court should grant

review of that question as well—or at least hold the petition for others presenting the same issue.

STATEMENT

I. STATUTORY BACKGROUND

A. The Patent Act

Under the Patent Act, the inventor of a "new and useful process, machine, manufacture, or composition of matter" is entitled to obtain an exclusive right to practice the invention for a limited time. 35 U.S.C. §§101, 154(a)(2). To obtain that right, the inventor must disclose his invention to the public by submitting a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." *Id.* §112; see *id.* §122(b). That disclosure is the "*quid pro quo* of the right to exclude." *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001). The statute reflects "a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989).

A patent confers a property right on the owner. 35 U.S.C. §261. Anyone who "makes, uses, offers to sell, or sells any patented invention" without permission is an infringer liable for damages. *Id.* §271(a). An accused infringer may defend itself by challenging the patent's validity in court, but it must prove invalidity by clear and convincing evidence. See *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011).

B. Ex Parte Reexamination

For most of this Nation's history, the government had no power to revoke a patent without the owner's consent—only a court could eliminate that property right. In 1980, however, Congress provided for ex parte reexamination of previously issued patents. See Pub. L. No. 96-517, 94 Stat. 3015, 3015 (1980) (codified as amended at 35 U.S.C. §§301 *et seq.*). That procedure permits the Director of the Patent Office to reconsider a previously issued patent, on his own initiative or at the request of a third party, based on prior art that raises a "substantial new question of patentability." 35 U.S.C. §§303(a), 304.

Once instituted, ex parte reexaminations follow inquisitorial procedures similar to those for initial examination of patent applications. 35 U.S.C. §305. A patent examiner reviews the patent without further input from third parties. See 37 C.F.R. §§1.510(a), 1.550(g). The patent holder has a statutory right "to propose any amendment" to the challenged claims, so long as it does not enlarge their scope. 35 U.S.C. §305. Patentability determinations are made under a preponderance-of-the-evidence standard. *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008). The statute applied to patents then in force or issued thereafter. Pub. L. No. 96-517, §8(b), 94 Stat. at 3027.

C. Inter Partes Reexamination

In 1999, Congress supplemented that regime with inter partes reexamination. See Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, §§4601 *et seq.*, 113 Stat. 1501A-567 (formerly codified at 35 U.S.C. §§311 *et seq.*). Inter partes reexamination was another inquisitorial process with "slightly more" third-party participation. *SAS Inst., Inc.* v. *Iancu*, 138 S. Ct. 1348, 1353 (2018).

As with ex parte reexaminations, the Director could institute an inter partes reexamination based on prior art raising a "substantial new question of patentability." 35 U.S.C. §312(a) (2006). Once again, the reexamination generally followed the "procedures established for initial examination." *Id.* §314(a). Patent examiners determined whether claims were patentable under a preponderance-of-the-evidence standard. See *Swanson*, 540 F.3d at 1377. Patent owners could still "propose any amendment" that did not expand the scope of the claims. 35 U.S.C. §314(a) (2006). The third party could "participate in a limited manner" by filing responses and appealing an examiner's decision. *Oil States Energy Servs., LLC* v. *Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1371 (2018); see 35 U.S.C. §§314(b), 315(b) (2006).

Congress expressly declined to apply inter partes reexamination retroactively. The statute applies only to "patent[s] that issue[] from an original application filed in the United States on or after th[e] date" of enactment. Pub. L. No. 106-113, §4608(a), 113 Stat. at 1501A-572.

The Patent Office has reconsidered a number of patents under the two reexamination regimes, but invalidated only a small fraction. In 88% of ex parte reexaminations, patents survived with at least some claims. See U.S. Patent & Trademark Office, *Ex Parte Reexamination Filing Data* (Sept. 30, 2018), https://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_roll_up.pdf. In inter partes reexaminations, the survival rate was 66%. See U.S. Patent & Trademark Office, *Inter Partes Reexamination Filing Data* (Sept. 30, 2017), https://www.uspto.gov/sites/default/files/documents/inter_parte_historical_stats_roll_up.pdf. Most patents required only amendments. See Gregory Dolin & Irina Manta, *Taking Patents*, 73 Wash. & Lee L. Rev. 719, 758-759 (2016).

D. Inter Partes Review

In 2011, Congress dramatically altered that landscape by enacting the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011). Congress felt that patents were "too difficult to challenge." H.R. Rep. No. 112-98, pt. 1, at 39 (2011). It therefore replaced inter partes reexamination with new procedures, including "inter partes review." 35 U.S.C. §§311 *et seq.*

Any third party may seek inter partes review by filing a petition with the Patent Office. 35 U.S.C. §311. The Director determines whether there is a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged." *Id.* §314(a). Consequently, unlike in reexaminations, the Director need not find a "new" question of patentability. *Id.* §325(d). The statute permits inter partes review even where the petitioner is a defendant in ongoing infringement litigation, so long as it files the petition within the first year of litigation. *Id.* §315(b).

Once instituted, inter partes review follows a procedure markedly different from reexamination. The statute provides for discovery, adversarial briefing, and contested hearings, with the challenger participating at every stage. 35 U.S.C. §316(a). Cases proceed, not before patent examiners, but before a specialized adjudicative body: a Patent Trial and Appeal Board composed largely of administrative patent judges appointed by the Secretary of Commerce. *Id.* §316(c); *id.* §6(a), (b)(4). Inter partes review is thus a "party-directed, adversarial" process that "mimics civil litigation," rather than the "agency-led, inquisitorial" process for reexaminations. *SAS Inst.*, 138 S. Ct. at 1352, 1355. Even so, a petitioner need only establish unpatentability by a "preponderance of the evidence." 35 U.S.C. §316(e).

While patent owners had broad rights to amend their claims in reexamination, inter partes review sharply curtails those rights. Patent owners must request permission to amend. 35 U.S.C. §316(d)(1). They normally may do so only once, *id.*, and only early in the proceedings, 37 C.F.R. §42.121(a). The Patent Office has almost always denied leave to amend—nearly 90% of the time. U.S. Patent & Trademark Office, *Motion To Amend Study* 7 (Mar. 2019), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/motions-amend-study.

At the end of an inter partes review, the Board issues a final written decision. 35 U.S.C. §318(a). The parties can appeal directly to the Federal Circuit. *Id.* §319. No statute permits the Director to review Board decisions. And according to the statute, Board members may be removed "only for such cause as will promote the efficiency of the service." 5 U.S.C. §7513(a); see 35 U.S.C. §3(c).

While Congress declined to apply inter partes reexamination retroactively, it took the opposite approach for inter partes review. The new procedure applies "to any patent issued before, on, or after th[e] effective date" of the AIA. Pub. L. No. 112-29, §6(c)(2)(A), 125 Stat. at 304.

That new regime has had a major impact. As of February 2020, more than 10,400 petitions for inter partes review had been filed—more than 1,300 per year on average since inter partes reviews began in September 2012. See U.S. Patent & Trademark Office, *Trial Statistics: IPR, PGR, CMB* 3 (Feb. 2020), https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2020_02_29.pdf. Those petitions have resulted in invalidation of all challenged claims in 62% of final written decisions, and invalidation of at least some claims in 80% of final written decisions. *Id.* at 10.

II. PROCEEDINGS BELOW

A. Arthrex's Patent Application

Arthrex is a pioneer in the field of arthroscopy and a leading developer of medical devices and procedures for orthopedic surgery. More than 14 years ago, it developed a new suture anchor that surgeons can use to reattach torn soft tissue to bone. C.A. App. 802. The new design overcame problems of detachment and abrasion of sutures with existing anchors. *Ibid.* Arthrex filed several patent applications relating to different features of its invention. See *ibid.*

In September 2006, Arthrex applied for what later became U.S. Patent No. 8,821,541 (the "'541 patent"). C.A. App. 790. The application contained the required specification describing Arthrex's invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." 35 U.S.C. § 112. It explained how to make a suture anchor with a rigid support that was "molded into" the anchor structure—a feature designed to prevent suture failure. U.S. Patent Pub. No. 2007/0073299, ¶0014 (published Mar. 29, 2007). It included detailed illustrations:

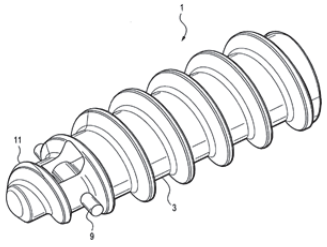

FIG. 5

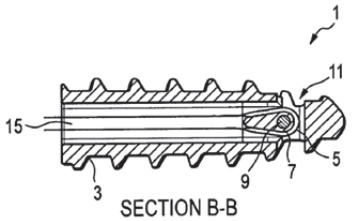

FIG. 7

Id. figs. 5 & 7. The Patent Office made Arthrex's application public in March 2007. C.A. App. 790.

Arthrex's application remained pending for years. Eventually, in September 2014, the Patent Office issued the '541 patent. C.A. App. 790. Claims 10 and 11 cover two versions of the suture anchor that Arthrex had disclosed in its application—one with a helical thread, one without. *Id.* at 805; App., *infra*, 3a-5a.

B. The Infringement Litigation

In June 2015, Arthrex sued Smith & Nephew, Inc., and subsidiary ArthroCare Corp., in the U.S. District Court for the Eastern District of Texas for infringing claims 10 and 11 of the '541 patent, among others. See *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, No. 15-cv-1047 (E.D. Tex. filed June 17, 2015); C.A. App. 4587. The case proceeded to trial.

The jury found that Smith & Nephew and ArthroCare willfully infringed, rejecting their defense that the claims were invalid as anticipated or obvious. C.A. App. 4520-4521. The jury awarded over $12 million in damages. *Id.* at 4521. Shortly thereafter, the case settled. *Id.* at 4524.

C. The Inter Partes Review

While the district court action was pending, Smith & Nephew and ArthroCare sought inter partes review of claims 10 and 11 of the '541 patent. App., *infra*, 22a. They argued, just as they had before the jury, that the claims were anticipated or obvious. *Ibid.* Several of the prior art references they invoked were the same ones the jury had rejected. Compare *ibid.* with E.D. Tex. Dkt. 339, at 1599.

In November 2017, after the district court litigation concluded, the Patent Trial and Appeal Board issued a final written decision finding the challenged claims unpatentable. App., *infra*, 21a, 23a. Both claims, the

Board held, were anticipated or obvious in light of prior art. See *id.* at 88a, 94a, 98a.

D. The Federal Circuit's Decision

The court of appeals affirmed.

1. The court first rejected Arthrex's challenges to the Board's finding of unpatentability. App., *infra*, 9a-18a. It held that the Board had not committed procedural error, even though the Board relied on a rationale that Smith & Nephew had not advanced to find that skilled artisans would have been motivated to combine prior art references. *Id.* at 9a-13a. The court also held that substantial evidence supported the Board's decision, while acknowledging that "some evidence arguably cuts against the Board's conclusion." *Id.* at 14a-15a.

2. The court also rejected Arthrex's constitutional challenge. App., *infra*, 18a-20a. It acknowledged that "the Supreme Court has not addressed the constitutionality of IPR as applied to patents issued prior to the America Invents Act." *Id.* at 18a (citing *Oil States*). But the court saw no constitutional problem here 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." *Id.* at 18a-19a.

In the court's view, the fact that "Arthrex filed its *patent applications* prior to passage of the AIA is immaterial." App., *infra*, 19a (emphasis added). "[T]he legal regime governing a particular patent," it asserted, "'depend[s] on the law as it stood at the emanation of the patent, together with such changes as have since been made.'" *Ibid.* (quoting *Eldred* v. *Ashcroft*, 537 U.S. 186, 203 (2003)). The court therefore held that "application of IPR to Arthrex's patent cannot be characterized as retroactive." *Ibid.*

Apart from that timing issue, the court observed that it had "recently rejected arguments similar to Arthrex's" in *Celgene Corp.* v. *Peter*, 931 F.3d 1342 (Fed. Cir. 2019), pet. for cert. filed, No. 19-1074 (Feb. 26, 2020). App., *infra*, 19a. *Celgene* held that Congress could apply inter partes review even to patents *issued* before the AIA because, even under the pre-AIA regime, patents were "subject to both district court and Patent Office validity proceedings." *Ibid.* Although those prior proceedings "differ[ed]" from inter partes review, *Celgene* ruled 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.'" *Ibid.* (quoting *Celgene*, 931 F.3d at 1362). Accordingly, "even if Arthrex's patent pre-dated the AIA, application of IPR to the '541 patent would not create a constitutional challenge." *Id.* at 20a.

3. Arthrex sought rehearing and rehearing en banc. C.A. Dkt. 70. While its petition was pending, the Federal Circuit held—in another case between the same parties—that the administrative patent judges ("APJs") who oversee inter partes reviews hold office in violation of the Appointments Clause. *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 941 F.3d 1320, 1335 (Fed. Cir. 2019) ("*Arthrex '907*") (citing U.S. Const. art. II, §2), reh'g denied (Mar. 23, 2020). APJs are appointed by the Secretary of Commerce, an arrangement appropriate only for inferior officers. *Id.* at 1327. The court held that APJs are principal rather than inferior officers due to "[t]he lack of any presidentially-appointed officer who can review, vacate, or correct [their] decisions" and the Secretary's "limited removal power." *Id.* at 1335. As a remedy, the court severed the removal restrictions and remanded the case

for a new hearing before a different panel of APJs. *Id.* at 1335-1340 (citing *Lucia* v. *SEC*, 138 S. Ct. 2044 (2018)).

Arthrex promptly filed a supplemental authority letter in this case urging that *Arthrex '907* required a new hearing here too. C.A. Dkt. 72. A week later, the court denied rehearing. App., *infra*, 101a.

REASONS FOR GRANTING THE PETITION

This petition presents an important constitutional question this Court expressly left open in *Oil States Energy Services, LLC* v. *Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018): whether Congress can apply inter partes review retroactively to patents that predate the statute's enactment.

Hundreds of inter partes reviews are filed each year, and more than 60% challenge patents issued before the America Invents Act. Around 15% more challenge patents like Arthrex's for which the application was filed before the statute's enactment but granted afterward. Innovators like Arthrex disclosed their inventions to the public in reliance on the patent regime that prevailed at the time. Revoking patents through a new and far more lethal mechanism is a classic bait and switch that violates basic Fifth Amendment norms against retroactivity.

This Court already has before it another petition raising similar issues in *Celgene Corp.* v. *Peter*, No. 19-1074 (filed Feb. 26, 2020). But *Celgene* presents only a partial picture. The inventor in *Celgene* both applied for and received the patent before the AIA's enactment. A decision in *Celgene* therefore would not necessarily resolve the retroactivity question for the significant category of cases such as Arthrex's, in which the inventor applied for a patent and disclosed his invention in reliance on the pre-AIA regime, but received the patent only afterward.

This Court should grant review in both *Celgene* and this case, and consolidate the two for argument, so it can definitively resolve both factual permutations.

This petition also presents important questions about the constitutionality of APJ appointments—and whether a court can ignore such claims on forfeiture grounds despite an intervening change of law. The Court should grant review to address those questions, or at least hold the case pending other related petitions.

I. The Court Should Grant Review To Resolve Whether Retroactive Application Of Inter Partes Review Violates The Fifth Amendment

In *Oil States*, this Court held that inter partes review does not violate Article III or the Seventh Amendment. 138 S. Ct. at 1379. But the Court "emphasize[d] the narrowness of [its] holding." *Ibid.* The petitioner in that case did not argue that the AIA's new inter partes review scheme could not constitutionally be applied to patents applied for or granted before the statute was enacted. The Court thus "address[ed] only the precise constitutional challenges that [the petitioner] raised," which did not include a "challenge [to] the retroactive application of inter partes review." *Ibid.* This case now presents that important and unresolved question.

A. The Issue Is Important

Because the Federal Circuit generally has exclusive jurisdiction over patent appeals, circuit conflicts almost never arise, and this Court evaluates petitions "largely on the importance of the questions presented." Stephen Shapiro, *et al.*, *Supreme Court Practice* §4.21, at 289 (10th ed. 2013). The issue here is more than important enough to warrant this Court's review.

1. Whether Congress may apply inter partes review retroactively is an important and recurring issue. As the Federal Circuit recently observed, there is "a growing number of retroactivity challenges following * * * *Oil States*." *Celgene*, 931 F.3d at 1356. This case is one of several in recent months alone. See *Genentech, Inc.* v. *Hospira, Inc.*, 946 F.3d 1333, 1343 (Fed. Cir. 2020); *OSI Pharm., LLC* v. *Apotex Inc.*, 939 F.3d 1375, 1386 (Fed. Cir. 2019); *Enzo Life Scis., Inc.* v. *Becton, Dickinson & Co.*, 780 F. App'x 903, 911 (Fed. Cir. 2019), pet. for cert. filed, No. 19-1097 (Mar. 3, 2020); *Collabo Innovations, Inc.* v. *Sony Corp.*, 778 F. App'x 954, 960-961 (Fed. Cir. 2019), pet. for cert. filed, No. 19-601 (Nov. 4, 2019); *Celgene*, 931 F.3d at 1355-1363.

The retroactivity issue will affect thousands of cases for years to come. More than 10,400 petitions for inter partes review have been filed since the proceedings began in September 2012. See *Trial Statistics*, *supra*, at 3. Nearly 550 were filed in the last fiscal year alone. *Id.* at 5. Even as late as 2018, more than 60% of those petitions challenged patents issued *before* the AIA's effective date. See Saurabh Vishnubhakat, *The Mixed Case for a PTAB Off-Ramp*, 18 Chi.-Kent J. Intell. Prop. 514, 520, 534 fig. 2 (2019). Ten percent involved "patents so old that they would not have been eligible even for *inter partes* reexamination." *Id.* at 520.

Those statistics are no surprise. Patents have a term of at least 20 years from the date of application. 35 U.S.C. § 154(a)(2). As a result, although inter partes review has been available for nearly eight years, a large portion of the challenged patents predate the statute. That will not change any time soon.

Cases like Arthrex's—where an inventor applied for a patent before the AIA but received it after—are also

very common. When Congress enacted the AIA, the average application was pending for more than 32 months. See U.S. Patent & Trademark Office, *Performance and Accountability Report: Fiscal Year 2012*, at 14, https://www.uspto.gov/sites/default/files/about/stratplan/ar/USPTOFY2012PAR.pdf. Many were pending much longer. It took *eight years* for the Patent Office to grant Arthrex's application. See pp. 9-10, *supra*. Although the Patent Office does not publish statistics on the number of inter partes reviews where the patent was applied for before, but granted after, the statute's enactment, a rough estimate indicates that nearly *one in seven cases* falls into that category.[1]

Congress recognizes the important policy implications of the often lengthy periods between the filing of an application and the patent's issuance. In 1994, Congress provided for patent term extensions of up to five years based on such delays. See Uruguay Round Agreements Act, Pub. L. No. 103-465, §532, 108 Stat. 4809, 4984 (1994) (codified as amended at 35 U.S.C. §154(b)). In 1999, it eliminated the five-year cap on extensions. See Patent Term Guarantee Act of 1999, Pub. L. No. 106-113, §4402, 113 Stat. 1501A-557. Even a longer ten-year cap, Congress explained, would be "too short in some cases." H.R. Conf. Rep. No. 106-464, at 125 (1999). Congress understands that issuance delays are often lengthy and deems them important enough to drive federal policy.

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[1] If patent application dates were distributed evenly over the twenty years before an inter partes review and all applications were pending for the average time, the portion with application and issuance dates straddling the AIA's enactment would be a 32-month subset of the total. Thirty-two months divided by twenty years is 13.3%.

Those same delays underscore the importance of the issue here. Whether inter partes review can constitutionally be applied to patents like Arthrex's that were applied for before, but granted after, the statute's enactment is an important issue with ramifications for many patents. That broad impact highlights the need for this Court's review.

2. Applying inter partes review retroactively has an enormous impact on prior patent rights. That impact was not part of the bargain when innovators like Arthrex applied for their patents.

Before the AIA, third parties had only limited means to challenge a patent at the Patent Office. Ex parte reexaminations gave third parties almost no role at all, and even inter partes reexaminations permitted only "slightly more" third-party involvement. *SAS Inst., Inc.* v. *Iancu*, 138 S. Ct. 1348, 1353 (2018); see *Oil States*, 138 S. Ct. at 1371 (third parties could "participate in a limited manner"). Reexamination was an "agency-led, inquisitorial" process modeled on initial examination. *SAS Inst.*, 138 S. Ct. at 1355; see 35 U.S.C. §305; 35 U.S.C. §314(a) (2006).

Inter partes review is "fundamentally different." *Return Mail, Inc.* v. *Postal Serv.*, 139 S. Ct. 1853, 1865-1866 (2019). It is a "party-directed, adversarial" process that "mimics civil litigation." *SAS Inst.*, 138 S. Ct. at 1352, 1355. It provides a new forum for an infringer to wage contentious and expensive litigation challenging a patent's validity.

Inter partes review is far more potent than its predecessors. In reexamination, the petitioner had to show a "substantial *new* question of patentability." 35 U.S.C. §303(a) (emphasis added); 35 U.S.C. §312(a) (2006); see *In re Recreative Techs. Corp.*, 83 F.3d 1394, 1396 (Fed.

Cir. 1996). In inter partes review, the Director can institute proceedings on grounds already rejected during the initial application. 35 U.S.C. §§314(a), 325(d). Reexaminations were conducted by examiners who specialized in the patent's subject matter, see Manual of Patent Examining Procedure §2636(I); inter partes reviews are heard by panels of administrative judges who may be assigned at the Director's discretion, 35 U.S.C. §6(c). In reexamination, the patent owner could appeal within the Patent Office, 35 U.S.C. §306; 35 U.S.C. §315(a) (2006); in inter partes review, the patent owner can appeal only to a court that applies a deferential standard of review, 35 U.S.C. §319; *Belden Inc.* v. *Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015).

In reexamination, moreover, patent owners could amend their claims to remedy any defects, even after an adverse ruling. 35 U.S.C. §305; 35 U.S.C. §314(a) (2006); 37 C.F.R. §1.550(b); 37 C.F.R. §1.937(b) (incorporating 37 C.F.R. §1.116). Patent owners routinely exercised that right, amending claims to avoid invalidation in 67% of ex parte reexaminations and 60% of inter partes reexaminations. See *Ex Parte Reexamination Filing Data*, *supra*; *Inter Partes Reexamination Filing Data*, *supra*. Inter partes review sharply curtails that right, 35 U.S.C. §316(d); 37 C.F.R. §42.121(a), and the Patent Office has denied the vast majority of motions to amend to date, *Motion To Amend Study*, *supra*, at 7.

The results speak for themselves. Patents survived 88% of ex parte reexaminations and 66% of inter partes reexaminations. See *Ex Parte Reexamination Filing Data*, *supra*; *Inter Partes Reexamination Filing Data*, *supra*. In inter partes review, that rate dropped to 38%. *Trial Statistics*, *supra*, at 10. Inter partes review is thus roughly twice as lethal as the old regime. Applying that

new regime retroactively to a large category of patents dramatically increases the risk of invalidation and thus substantially reduces the value of the patents.

3. The question presented also has broader implications. Inventors who make new discoveries face a choice: They can "keep [the] invention secret and reap its fruits indefinitely." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). Or they can disclose it to the public in a patent application, enabling others to "practice [the invention] and profit by its use" once the patent expires. *Ibid.* Inventors inevitably consider how much security a patent provides in making that choice—they "rely on the promise of the law" in deciding whether "to bring the[ir] invention[s] forth." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). A legal system where Congress can change the rules after an inventor has already made that choice casts a pall over others facing the same decision.

Companies invest hundreds of billions of dollars each year creating new technologies. See Congressional Research Service, *U.S. Research and Development Funding and Performance: Fact Sheet* 3 (Jan. 24, 2020), https://fas.org/sgp/crs/misc/R44307.pdf. Innovation is particularly costly in medical fields: Device makers like Arthrex typically spend $31 to $94 million to bring a single product to market. See Josh Makower, *et al.*, *FDA Impact on U.S. Medical Technology Innovation* 7 (2010), https://www.advamed.org/sites/default/files/resource/30_10_11_10_2010_Study_CAgenda_makowerreportfinal.pdf.

By one estimate, the mere existence of inter partes review has erased two-thirds of the value of pre-AIA patents. See Dolin & Manta, *supra*, at 791-792. Congress's retroactive application of that new regime dra-

matically undermines inventors' incentives to innovate and disclose new inventions to the public.

B. The Court of Appeals' Decision Is Wrong

Retroactive application of inter partes review violates longstanding constitutional principles.

1. "[T]he presumption against retroactive legislation is deeply rooted in our jurisprudence, and embodies a legal doctrine centuries older than our Republic." *Landgraf* v. *USI Film Prods.*, 511 U.S. 244, 265 (1994). "Elementary considerations of fairness" dictate that "settled expectations should not be lightly disrupted." *Ibid.* Those principles "find[ ] expression in several provisions of our Constitution"—the Fifth Amendment in particular "protects the interests in fair notice and repose that may be compromised by retroactive legislation." *Id.* at 266.

Retroactive legislation raises special concerns for "contractual or property rights, matters in which predictability and stability are of prime importance." *Landgraf*, 511 U.S. at 271. "[T]he Constitution places limits on the sovereign's ability to use its lawmaking power to modify bargains it has made with its subjects." *Lynce* v. *Mathis*, 519 U.S. 433, 440 (1997); see also *Cherokee Nation* v. *Leavitt*, 543 U.S. 631, 646 (2005) ("A statute that retroactively repudiates the Government's contractual obligation may violate the Constitution."); *Perry* v. *United States*, 294 U.S. 330, 353-354 (1935) (bond obligations); *Lynch* v. *United States*, 292 U.S. 571, 579 (1934) (contracts).

Patents raise precisely those concerns. Patents "have long been considered a species of property." *Fla. Prepaid Postsecondary Educ. Expense Bd.* v. *Coll. Sav. Bank*, 527 U.S. 627, 642 (1999); *e.g.*, *Ex parte Wood*, 22 U.S. (9 Wheat.) 603, 608 (1824) (Story, J.). The Patent Act expressly provides that patents are "personal prop-

erty." 35 U.S.C. §261. This Court's cases thus sharply limit Congress's authority to diminish patent rights retroactively. See, *e.g.*, *McClurg* v. *Kingsland*, 42 U.S. (1 How.) 202, 206 (1843) (statute may "not take away the rights of property in existing patents" and "can have no effect to impair the right of property then existing in a patentee"); *Richmond Screw Anchor Co.* v. *United States*, 275 U.S. 331, 345 (1928) (retroactive application of statute restricting patent assignments "would seem to raise a serious question as to the constitutionality of [the statute] under the Fifth Amendment").

Even before a patent issues, the promises the Government makes to induce an inventor to disclose his invention raise similarly compelling concerns. Patents are a "carefully crafted bargain" in which the inventor irrevocably discloses his invention to the public in exchange for the promise of certain protections. *Bonito Boats*, 489 U.S. at 150-151. Disclosure is the "*quid pro quo* of the right to exclude." *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001). Altering that bargain after the fact implicates property rights, just like diminishing rights in an already issued patent. See, *e.g.*, *Regents of Univ. of N.M.* v. *Knight*, 321 F.3d 1111, 1121 (Fed. Cir. 2003) (recognizing "legal ownership rights in patent applications"); 35 U.S.C. §183 (requiring "just compensation" for patents withheld from applicants due to secrecy orders).

2. The AIA purports to do exactly that. Inter partes review dramatically expands the opportunities for attacking a patent and thus diminishes the value of the rights conferred. Sharply reducing the value of a patent after an applicant has already made the irrevocable decision to disclose the invention is exactly the sort of bait and switch this Court's precedents forbid.

Previously, an accused infringer seeking to challenge a patent through adversarial proceedings had to litigate in court and prove invalidity by clear and convincing evidence. See *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). Now, the infringer can contest the patent in an adversarial proceeding at the Patent Office instead, and show invalidity by a mere preponderance of the evidence. 35 U.S.C. §316(e). The infringer can resort to that friendlier forum even if the patent owner has already sued it for infringement in court. *Id.* §315(b).

An infringer can pursue inter partes review even if it *loses* in court on the same grounds. Because of the different standards of proof, a jury verdict upholding a patent has no preclusive effects in inter partes review. See *Novartis AG* v. *Noven Pharm. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017). As a result, patent owners now routinely face *two* rounds of contentious and expensive litigation in different forums, brought by the same challenger asserting the same claims. The challenger may win the second round even if it lost the first—exactly what happened here. See pp. 10-11, *supra*.

To be sure, an infringer could request *reexamination* before the AIA. But reexamination was "fundamentally different." *Return Mail*, 139 S. Ct. at 1865-1866. A patent owner in inter partes review faces a fully adversarial, litigation-like proceeding in which its opponent vigorously advocates for the patent's demise at every turn. 35 U.S.C. §316(a). The standards and procedures differ in many ways that make it far easier to challenge the patent. See pp. 17-19, *supra*.

Those changes have had a profound effect. Inter partes review has essentially doubled the fatality rate for patents, from a regime where two-thirds survive to one where two-thirds fail (not even counting partial invalida-

tions). See *Ex Parte Reexamination Filing Data*, *supra*; *Inter Partes Reexamination Filing Data*, *supra*; *Trial Statistics*, *supra*, at 10. Patents are now less secure and therefore less valuable: By one estimate, inter partes review has obliterated *two-thirds* of the value of pre-AIA patents. See Dolin & Manta, *supra*, at 791-792.

The Fifth Amendment would obviously prohibit Congress from retroactively reducing patent terms from 20 years to 10. Reducing patent values by allowing competitors to challenge patents through a new and far more potent process violates retroactivity principles for the same reasons. That is not what inventors signed up for when they agreed to disclose their inventions to the public.

3. The court of appeals opined that "application of IPR to Arthrex's patent cannot be characterized as retroactive" because the Patent Office *issued* the patent after the statute was enacted. App., *infra*, 19a. But whether a statute is retroactive turns on "whether it would impair rights a party possessed *when he acted*." *Landgraf*, 511 U.S. at 280 (emphasis added); see also *Martin* v. *Hadix*, 527 U.S. 343, 358 (1999) (statute had "retroactive effect" where party "performed a specific task * * * in reasonable reliance" on prior law). Arthrex relied on prior law when it chose to apply for a patent and disclose how to make and use its invention in return for the protections Congress promised at the time. That the Patent Office took eight years to grant the application does not change the bait-and-switch nature of what happened.

The court of appeals cited *Eldred* v. *Ashcroft*, 537 U.S. 186, 203 (2003), for the proposition that "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.'" App., *infra*, 19a. But *Eldred* was addressing a law that "*expanded* patent

protection to an existing patent"—not one that *diminished* patent rights. 537 U.S. at 202-203 & n.9 (emphasis added) (discussing *McClurg*, 42 U.S. (1 How.) at 206). Moreover, *Eldred* distinguished patents from copyrights on the ground that "immediate disclosure is not the objective of, but is *exacted from*, the patentee," and "is the price paid for the exclusivity secured." *Id.* at 216. That bargain is precisely why the application date matters.

Congress recognized the application date's central role throughout the Patent Act. A patent term runs from the "date on which the application for the patent was filed." 35 U.S.C. §154(a)(2). Patent owners can recover damages for certain infringements after the "date of publication of the application." *Id.* §154(d)(1). And the application date determines which prior art affects the patent's validity. *Id.* §102(a). Congress repeatedly invoked the application date because that is the one that matters to the basic bargain on which patent protection stands.

When Congress made inter partes reexamination prospective only, it limited the statute to "patent[s] that issue[ ] from an *original application* filed * * * on or after th[e] date" of enactment. Pub. L. No. 106-113, §4608(a), 113 Stat. at 1501A-572 (emphasis added). Even within the AIA, Congress made other provisions applicable only where the *application* was filed on or after the statute's effective date. See Pub. L. No. 112-29, §3(n)(1), 125 Stat. 284, 293 (2011) (first-to-file regime); *id.* §6(f)(2)(A), 125 Stat. at 311 (post-grant review). Congress clearly appreciated that it was legislating retroactively when it made inter partes review applicable to prior patents, whether *issued* or merely *applied for* before the statute.

The court of appeals finally reasoned that, even if Arthrex *had* obtained its patent before the AIA, "the differences between IPRs and the * * * proceedings that

existed prior to the AIA are not so significant as to 'create a constitutional issue.'" App., *infra*, 19a (quoting *Celgene*, 931 F.3d at 1362). In fact, the differences are vast, as shown above. If the differences were "not so significant," they would not have caused survival rates to plummet from 66% to 38% and reduced the value of patents by two-thirds.

Congress retroactively impaired the value of Arthrex's patent by giving competitors greatly enhanced tools to attack it. The Fifth Amendment does not permit Congress to renege on its bargain in that manner.

C. The Court Should Grant Review in This Case and in *Celgene* and Consolidate the Two Cases

Even on its own, this case would be a good vehicle for deciding whether Congress can apply inter partes review retroactively. But this Court already has the same question before it in *Celgene*, the case on which the court relied below. See *Celgene Corp.* v. *Peter*, No. 19-1074 (filed Feb. 26, 2020). The same question is also presented in two other post-*Celgene* cases, *Collabo Innovations, Inc.* v. *Sony Corp.*, No. 19-601 (filed Nov. 4, 2019); and *Enzo Life Sciences, Inc.* v. *Becton, Dickinson & Co.*, No. 19-1097 (filed Mar. 3, 2020).[2]

Those cases, however, present the issue in a different posture. In those cases, the inventor both applied for and received the patent before the AIA. See *Celgene* Pet. 14-15; *Collabo* Pet. 4-5; *Enzo* Pet. 13. Arthrex, by contrast, applied for its patent and disclosed its invention to the

[2] *Collabo* was initially scheduled for the March 20, 2020, conference, but the Court rescheduled the case, presumably to consider it together with *Celgene*.

public before the statute, but the Patent Office issued the patent only afterward. See pp. 9-10, *supra*.

Given those circumstances, the Court should grant review in both this case and *Celgene* and consolidate the two for argument. The two postures raise arguably different issues: The court below rejected Arthrex's retroactivity challenge in part for reasons unrelated to *Celgene*. App., *infra*, 19a. A ruling from this Court in Celgene's favor would not necessarily resolve the issue for cases like Arthrex's where the inventor applied for the patent before the statute but received it afterward.

Those cases are numerous. Many of the hundreds of inter partes reviews each year—nearly one in seven—involve application and issuance dates that straddle the AIA's enactment. See p. 16 & n.1, *supra*. Those patents, moreover, are more recent than ones like Celgene's. As a result, they will continue to be a substantial category even as the share of patents like Celgene's recedes. It does not make sense to decide the retroactivity issue for cases like *Celgene* but leave this important category unresolved.

This Court often grants multiple cases to address different permutations of an issue. In *United States* v. *Stitt*, No. 17-765, the Government sought review of a federal sentence enhancement statute for prior state offenses, and suggested granting certiorari in two cases so the Court could "review the issue in the context of multiple state statutes." Pet. in No. 17-765 at 21-22. The Court agreed, granting two cases and consolidating them for argument, and then reversing in one while vacating and remanding in the other. See *United States* v. *Stitt*, 139 S. Ct. 399, 407-408 (2018).

In *Abbott* v. *United States*, No. 09-479, the petitioner sought review of a firearm conviction. He noted that the same issue arose in a related "predicate offense" context, and "[b]ecause predicate offense and firearm cases present different factual contexts and slightly different statutory contexts, the Court might wish to consolidate a firearm and a predicate offense case." Pet. in No. 09-479, at 27. The Court granted and consolidated two cases. See *Abbott* v. *United States*, 562 U.S. 8, 15, 28 (2010).

The Court should follow the same approach here. Granting review solely in *Celgene* would leave a large and important category of cases unresolved, even though patent owners like Arthrex relied on prior law when applying for and disclosing their inventions. The Court should grant review in both this case and *Celgene* and consolidate the two cases for argument.

II. The Court Should Address Whether *Arthrex '907*'s Appointments Clause Holding Applies To All Cases Pending On Appeal

While Arthrex's petition for rehearing was pending, the Federal Circuit decided, in another case between the same parties, that the statutory method for appointing administrative patent judges violates the Appointments Clause. See *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019) ("*Arthrex '907*"), reh'g denied (Mar. 23, 2020). That decision's reasoning applies equally here, and Arthrex promptly brought the decision to the Federal Circuit's attention. C.A. Dkt. 72. The court, however, refused to apply *Arthrex '907* to this case, evidently because Arthrex had not argued the issue in its opening brief. App., *infra*, 101a. That ruling, too, raises important issues that warrant review.

A. Administrative Patent Judges Are Appointed in Violation of the Appointments Clause

Under the Appointments Clause, principal officers must be nominated by the President and confirmed by the Senate, while inferior officers may be appointed by a department head. U.S. Const. art. II, § 2. The Secretary of Commerce appoints APJs—an approach permissible only if they are inferior officers. 35 U.S.C. § 6(a).

Arthrex '907 correctly held that they are not. "'[I]nferior officers' are officers whose work is directed and supervised at some level" by a principal officer. *Edmond* v. *United States*, 520 U.S. 651, 662-663 (1997). No principal officer reviews APJ decisions—they are appealable only to Article III courts. *Arthrex '907*, 941 F.3d at 1329-1331. And no principal officer can remove APJs from federal service at will—they are removable only under the same strict civil-service standard that governs federal employees. *Id.* at 1332-1334 (citing 5 U.S.C. § 7513(a)).

Arthrex '907 purported to remedy the defect by severing APJs' tenure protections. 941 F.3d at 1335-1340. All parties sought rehearing en banc. Smith & Nephew and the Government denied any constitutional violation. No. 18-2140, Dkt. Nos. 77, 79 (Fed. Cir. filed Dec. 16, 2019). Arthrex urged that severance was not an appropriate remedy because Congress intended APJs to be impartial and independent—and that severance was insufficient to cure the violation in any event. No. 18-2140, Dkt. No. 78 (Fed. Cir. filed Dec. 16, 2019).

The court of appeals denied all three petitions on March 23, 2020, with four judges dissenting. *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, No. 18-2140, 2020 WL 1328925 (Fed. Cir. Mar. 23, 2020). The dissents agreed with Arthrex that severing the removal restrictions was not an appropriate remedy. See *id.* at *7-10 (Dyk., J.,

dissenting); *id.* at *22 (Hughes, J., dissenting). Arthrex plans to seek this Court's review, and the Government and Smith & Nephew may do so as well.

B. *Arthrex '907*'s Applicability to Pending Cases Is an Important and Recurring Issue

The proceedings in this case suffered from the same defect as in *Arthrex '907*—the APJs who presided held office in violation of the Constitution. App., *infra*, 21a. The Federal Circuit, however, refused to grant Arthrex any relief. App., *infra*, 101a. That court has repeatedly refused to apply *Arthrex '907* to cases like this where the appellant did not raise the Appointments Clause issue in its opening brief. Whether a court may refuse to consider a constitutional claim on forfeiture grounds despite an intervening change of law is another recurring issue that warrants this Court's review.

One day after *Arthrex '907*, a different Federal Circuit panel refused to apply the decision where the appellant had not preserved the argument in its opening brief, denying a motion to vacate and remand. See *Customedia Techs., LLC* v. *Dish Network Corp.*, 941 F.3d 1173, 1174 (Fed. Cir. 2019). The court opined that it was "well established that arguments not raised in the opening brief are waived." *Ibid.* The court denied reconsideration en banc over Judge Newman's dissent on December 23, 2019, No. 19-1001, Dkt. 63, and denied rehearing en banc of the decision on the merits on March 5, 2020, *id.* Dkt. 73.

Meanwhile, another Federal Circuit panel confronted the same issue in *Sanofi-Aventis Deutschland GmbH* v. *Mylan Pharmaceuticals Inc.*, 791 F. App'x 916 (Fed. Cir. 2019). The majority refused to consider the constitutional claim, citing *Customedia*. *Id.* at 928 n.4. Judge Newman dissented, reasoning that, "at the time these appeals were filed, there was no holding of illegality of appoint-

ments of the PTAB's Administrative Patent Judges," and "[i]t is well established that when the law changes while a case is on appeal, the changed law applies." *Id.* at 932 (Newman, J., dissenting) (citing *Thorpe* v. *Hous. Auth. of Durham*, 393 U.S. 268, 282 (1969)). The court denied rehearing en banc on January 28, 2020. No. 19-1368, Dkt. 69. Sanofi sought a stay from this Court, which the Chief Justice initially granted but which the Court later denied after the respondent argued, among other things, that there was no threat of irreparable harm. No. 19A886.

Many other appellants are in the same situation. The Federal Circuit has continued to reject their challenges, sometimes in divided decisions. See *Bos. Sci. Neuromodulation Corp.* v. *Nevro Corp.*, No. 19-1582, Dkt. 56 (Fed. Cir. Nov. 22, 2019) (denying leave to file supplemental brief); *id.* Dkt. 73 (Fed. Cir. Jan. 23, 2020) (denying reconsideration en banc over Judge Newman's dissent); cf. *Ciena Corp.* v. *Oyster Optics, LLC*, No. 19-2117, Dkt. 31 (Fed. Cir. Jan. 28, 2020) (finding forfeiture where party claiming violation instituted inter partes review). The recurring nature of the question is no surprise: The Appointments Clause flaw affects every appeal from an inter partes review that was still pending when the court decided *Arthrex '907*. Although a few appellants were prescient enough to predict the decision, see, *e.g.*, *Polaris Innovations Ltd.* v. *Kingston Tech. Co.*, No. 18-1768, Dkt. 90 (Fed. Cir. Nov. 8, 2019), most were not. Whether forfeiture applies in such cases is thus a widely recurring and important issue.

C. The Federal Circuit's Approach Is Wrong

The Federal Circuit's approach defies this Court's precedents. While ordinary forfeiture principles may require a party to raise all arguments in its opening brief,

that rule does not apply where there is an intervening change of law while the appeal is pending.

This Court has repeatedly refused to find forfeiture where there was an intervening change of law. "[T]he mere failure to interpose [a constitutional] defense prior to the announcement of a decision which might support it cannot prevent a litigant from later invoking such a ground." *Curtis Publ'g Co.* v. *Butts*, 388 U.S. 130, 143 (1967); see also *Hormel* v. *Helvering*, 312 U.S. 552, 558-559 (1941) (no forfeiture where "there have been judicial interpretations * * * pending appeal * * * which if applied might have materially altered the result"). In such cases, the "failure to raise the claim in an opening brief reflects not a lack of diligence, but merely a want of clairvoyance." *Joseph* v. *United States*, 135 S. Ct. 705, 706 (2014) (Kagan, J., dissenting from denial of certiorari).

This case involves precisely the sort of intervening change of law to which that rule applies. *Arthrex '907* dramatically changed the law. Before that decision, the Federal Circuit had indicated that the current appointment scheme is constitutional. See *In re DBC*, 545 F.3d 1373, 1380 (Fed. Cir. 2008) (holding that Congress's 2008 vesting of appointment authority in the Secretary of Commerce "eliminat[ed] the issue of unconstitutional appointments going forward"), cert. denied, 558 U.S. 816 (2009). The Federal Circuit had rejected a challenge like Arthrex's in a non-precedential decision. See *Trading Techs. Int'l, Inc.* v. *IBG LLC*, No. 18-1489, 771 F. App'x 493 (Fed. Cir. 2019). This Court had similarly denied review of the issue. See *Smartflash LLC* v. *Samsung Elecs. Am., Inc.*, No. 18-189 (cert. denied Oct. 1, 2018). *Arthrex '907* completely upended that legal landscape.

This Court has reviewed structural constitutional challenges to an adjudicator's authority despite a failure to

preserve the argument, even absent a change in the law. See, *e.g.*, *Nguyen* v. *United States*, 539 U.S. 69, 73, 80-81 (2003) (addressing challenge to territorial judge's participation on appellate panel raised for the first time in petition for certiorari); *Freytag* v. *Comm'r*, 501 U.S. 868, 879 (1991) (reviewing Appointments Clause challenge despite waiver due to "the strong interest of the federal judiciary in maintaining the constitutional plan of separation of powers"); *Glidden Co.* v. *Zdanok*, 370 U.S. 530, 536 (1962) (plurality) (addressing challenge despite forfeiture and noting that Court had previously entertained a claim not raised "until the filing of a supplemental brief upon a second request for review"). Those principles apply *a fortiori* where the only reason for the alleged forfeiture was that the law changed while the appeal was pending.

D. The Court Should Either Grant the Petition or Hold the Case Pending *Sanofi*, *Customedia*, and *Arthrex '907*

The Court should grant review in this case to decide whether the intervening change of law in *Arthrex '907* applies to all cases pending on appeal. At a minimum, the Court should hold this case for the forthcoming petitions in *Sanofi* and *Customedia* raising the same issue.

Alternatively, the Court should hold this case pending the forthcoming petitions in *Arthrex '907*. Because the Federal Circuit held a provision of federal law unconstitutional, there is a substantial possibility the Court will grant review. See *Maricopa County* v. *Lopez-Valenzuela*, 135 S. Ct. 428, 428 (2014) (Thomas, J., respecting denial of stay) (noting the "strong presumption" of review for decisions holding a federal statute unconstitutional). This Court's decision in *Arthrex '907* could have significant implications for the Federal Circuit's decision here. For example, if this Court agrees with Arthrex's position

on the appropriate remedy and declares the entire statute unconstitutional while deferring to Congress to address the problem, that new legal ruling may well cause the court of appeals to exercise its discretion differently in considering an allegedly forfeited challenge. The Court should therefore hold the petition not only for *Sanofi* and *Customedia*, but for *Arthrex '907* as well.

CONCLUSION

With respect to the first question presented, the Court should grant the petitions in this case and in *Celgene Corp.* v. *Peter*, No. 19-1074, and consolidate the two for argument. With respect to the second question presented, the Court should grant the petition, or in the alternative, hold this case for the petitions in *Sanofi-Aventis Deutschland GmbH* v. *Mylan Pharmaceuticals Inc.*, 791 F. App'x 916 (Fed. Cir. 2019); *Customedia Technologies, LLC* v. *Dish Network Corp.*, 941 F.3d 1173 (Fed. Cir. 2019); and *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019); and then dispose of the petition in light of the Court's decisions in those cases.

Respectfully submitted.

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APRIL 2020

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 2018-1584

ARTHREX, INC.,

Appellant,

v.

SMITH & NEPHEW, INC., ARTHROCARE CORP.,

Appellees,

UNITED STATES,

Intervenor.

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

OPINION

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:

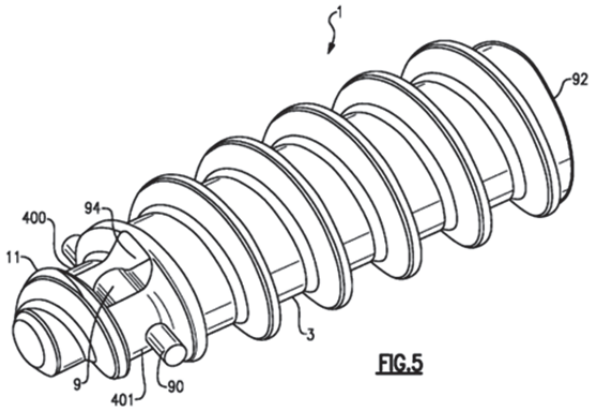


FIG.5

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.

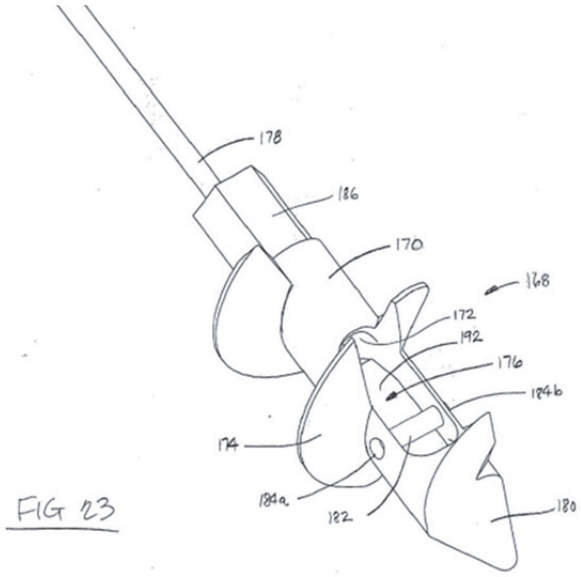
Id. at col. 7 l. 58-col. 8 l. 59 (as amended by Certificate of Correction) (emphases added to disputed claim terms).

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.

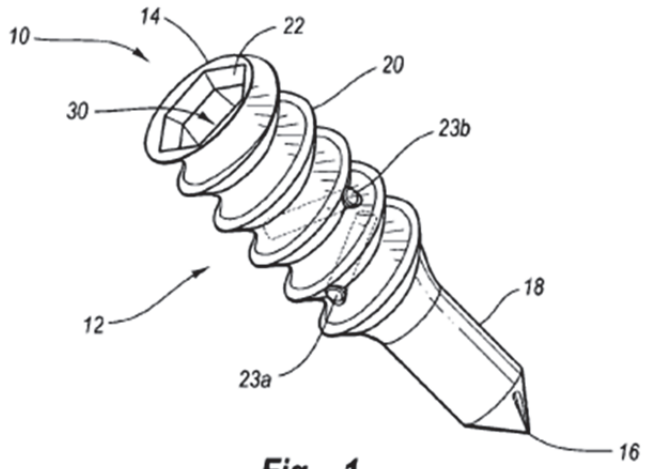


Fig. 1

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. *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 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 . . . [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 consid-

ering 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 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 "de-

[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.

tailed 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 (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

[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).

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

APPENDIX B

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. AND ARTHROCARE CORP.,

Petitioner,

v.

ARTHREX, INC.,

Patent Owner.

Case IPR2016-00918
Patent 8,821,541 B2

FINAL WRITTEN DECISION
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

Incorporating Decision on
PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

Paper 42

Entered: October 16, 2017

Before WILLIAM V. SAINDON, BARRY L. GROSSMAN, and TIMOTHY J. GOODSON, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge.*

I. INTRODUCTION

Petitioner requested an *inter partes* review of claims 10 and 11 of U.S. Patent No. 8,821,541 B2 (Ex. 1101, "the '541 patent"). Paper 2 ("Petition" or "Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp."). Claims 10 and/or 11 were challenged under four separate and distinct grounds. Pet. 8-9. We instituted review on three of the four grounds. Paper 9, 14 ("Dec. Inst."). We instituted a trial on the following grounds:

1. Whether claims 10 and 11 would have been obvious under 35 U.S.C. §103(a)[1] in view of Gordon[2] and West[3];

2. Whether claim 11 is anticipated under 35 U.S.C. §102(b) by Curtis[4]; and

3. Whether claim 10 would have been obvious under 35 U.S.C. §103(a) in view of Curtis, Overaker[5], and DiPoto[6].

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 296-07 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre-AIA versions of the statute.

[2] U.S. Pub. No. 2006/0271060 A1, published Nov. 30, 2006, filed May 26, 2006 (Ex. 1105).

[3] U.S. Patent No. 7,322,978 B2, issued Jan. 29, 2008, filed June 22, 2004 (Ex. 1106).

[4] U.S. Patent No. 5,464,427, issued Nov. 7, 1995 (Ex. 1107).

[5] U.S. Pub. No. 2003/0187444 A1, pub. Oct. 2, 2003, filed Mar. 29, 2002 (Ex. 1124).

[6] U.S. Patent No. 5,690,676, issued Nov. 25, 1997 (Ex. 1125).

Patent Owner filed a Response to the Petition (Paper 15, "PO Resp."), and Petitioner filed a Reply (Paper 19, "Pet. Reply").

Petitioner submitted 77 exhibits, including demonstratives used at the hearing (Exs. 1101-1170, 1172-1178). Paper 36. Patent Owner submitted 52 exhibits, including demonstratives used at the hearing (Exs. 2001-2043, 2045-2053). Paper 31.

Patent Owner filed a Motion to Exclude Certain Evidence. Paper 32. Petitioner filed an Opposition to the Motion to Exclude. Paper 35. Patent Owner Filed a Reply. Paper 35.

A hearing was held July 19, 2017. Paper 38 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. We enter this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioner has the burden of proving unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e). Based on the findings and conclusions below, we determine that Petitioner has met its burden to establish that claims 10 and 11 are unpatentable.

We deny Patent Owner's Motion to Exclude as moot.

A. Related Matters

As required by 37 C.F.R. § 42.8, the parties informed us that the '541 patent has been asserted in the U.S. District Court for the Eastern District of Texas, *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, Civil Action No. 2:2015-cv-01047 (E.D. Tex. Filed June 17, 2015) Pet. 7; Paper 5, 2. In its Response, Patent Owner informed us of a change in the status of this litigation. Patent Owner stated that:

> Since the institution of this *Inter Partes* Review, the District Court for the Eastern District of Texas en-

> tered judgment (Ex. 2030) holding challenged claims 10 and 11 of U.S. Patent 8,821,541 ("the '541 Patent") willfully infringed by Petitioners and valid over the *Gordon*, *West* and *Curtis* prior art asserted against the '541 Patent here.

PO Resp. 6. Patent Owner's Response was filed January 13, 2017. Exhibit 2030, cited by Patent Owner, is a one-page Judgment from the District Court, entered December 12, 2016, stating, in part, that "[c]laims 10 and 11 of the '541 Patent . . . are found not invalid." Ex. 2030. The Judgment was entered following a jury verdict. Ex. 3001. Patent Owner, however, has not directed us to any evidence in this *inter partes* review proceeding supporting its assertion that the evidence and arguments before the District Court were the same evidence and arguments asserted by Petitioner in this *inter partes* review proceeding.

Following the jury verdict, all claims and counterclaims asserted between Plaintiff Arthrex, Inc. (Patent Owner in this *inter partes* review) and Defendants Smith & Nephew, Inc. and ArthroCare Corp. (Petitioners in this *inter partes* review) were dismissed with prejudice. Ex. 3002 ("Dismissal"). The Dismissal was based on a Joint Stipulated Motion for Dismissal with Prejudice filed by the parties on February 13, 2017. Ex. 3003. The Joint Stipulated Motion was filed while post-trial motions were pending. See *e.g.*, Ex. 3004, 10 (Sealed Motion—Defendants' Renewed Motion for Judgment as a Matter of Law, or in the Alternative, for a New Trial, as to Patent Invalidity by ArthroCare, Corp., Smith & Nephew, Inc., District Court docket entry No. 328, entered January 9, 2017). Thus, the Judgment from the District Court entered December 12, 2016 (Exhibit 2030) effectively

was replaced by the Dismissal entered February 13, 2017 (Ex. 3002).

At the July 19, 2017 hearing, approximately five months after the February 13, 2017 settlement and dismissal in the District Court, Counsel for Patent Owner referred to the District Court Judgment but failed to inform us that the Judgment entered December 12, 2016 (Exhibit 2030) effectively was replaced by the Dismissal entered February 13, 2017 (Ex. 3002). See Tr. 53:10-12 ("I will say that we do have a judgment from the court in Texas . . .").

There are several related petitions for *inter partes* review: IPR2016-00505 (involving U.S. Patent No. 8,343,186, the parent of the '541 patent), IPR2016-00506 (involving U.S. Patent No. 8,623,052, a child of the '186 patent), and IPR2016-00507 and 508 (involving U.S. Patent No. 8,801,755, a child of the '052 patent). Pet. 7; Paper 5, 1. All four of these related proceedings were terminated as a result of a settlement. See, *e.g.*, *Smith & Nephew, Inc. et al* v. *Arthrex, Inc.*, IPR201 6-00505, Order Granting Joint Motion to Terminate (PTAB Oct. 19, 2016) (Paper 18).

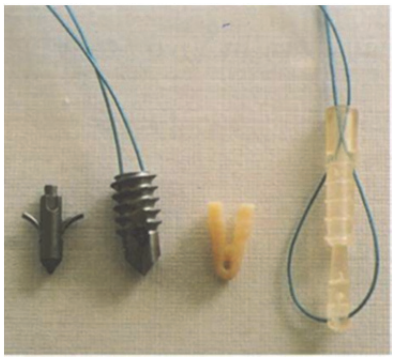
There are also a number of related patents and patent applications not presently at issue. Pet. 7; Paper 5, 2.

B. The '541 Patent

The '541 patent discloses and claims a suture anchor. A suture anchor is a medical-grade device that mechanically reattaches soft tissue, such as tendons and ligaments, to its supporting bone. Ex. 1101, 1:32-33; Ex. 2010 ¶47. Suture anchors are a sophisticated, nuanced, and highly developed medical technology. *Id.* at 1:40-57; see also *id.* at 2-4 (listing under "References Cited" 3

pages, with 2 columns per page, of U.S. and foreign patent documents and other publications).

In general use, all suture anchors perform a similar function: one end of the anchor is screwed into or otherwise connected to the supporting bone; suture material is threaded through or otherwise attached to the anchor; and the suture material is connected to the soft tissue. Ex. 1103 ¶33, 44. In general, all suture anchors also have a similar structure: a mechanism for holding the suture anchor in the bone, such as threads or barbs; and a mechanism for attaching the suture material to the anchor, such as suture passages, connecting posts, or frictional locks. See *id.* at ¶¶39-43 (illustrating and discussing numerous prior suture anchor designs). Four such exemplary prior art suture anchors are shown below.



Excerpt from Ex. 1103 ¶39 showing four prior art suture anchors.

The following illustration shows a commercially available implanted suture anchor using sutures to connect soft tissue to bone. See Ex. 1158, 2.[7]

[7] Ex. 1158 is a brochure illustrating a Smith & Nephew SpeedScrew suture anchor. It is cited to illustrate a suture anchor in use. It is not cited to illustrate features of the claimed invention. We have not

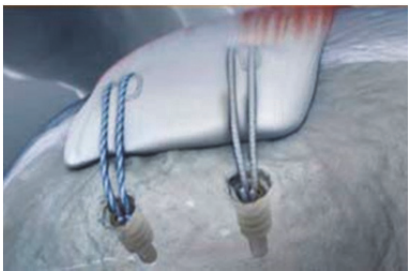
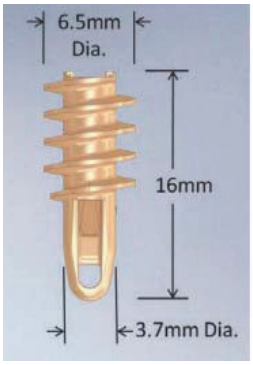
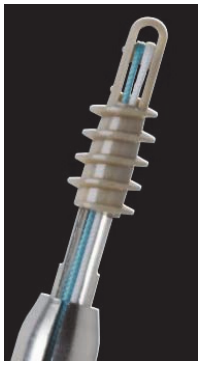


Illustration from Ex. 1158, 2 showing an implanted suture anchor connecting soft tissue to bone.

The suture anchor used in the illustration above is shown in the two illustrations below.



Commercial suture anchor. Ex. 1158, 3.[8]



Commercial suture anchor threaded with suture mounted on implantation device. Ex. 1158, 1.

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been directed to any evidence in the record before us of any similar illustration for a commercial product sold by Patent Owner that illustrates the claimed invention in use.

[8] See also Ex. 2010 ¶ 86 (showing images of two products commercialized by Patent Owner on top of a U.S. penny to show relative size of a suture anchor).

We now turn to the suture anchor disclosed in the '541 patent.

The '541 patent discloses three distinct embodiments. A first embodiment is illustrated in Figures 1-4 (*e.g.*, Ex. 1101, 2:53-67); a second embodiment is illustrated in Figures 5-8 (*e.g.*, *id.* at 2:1-10); and a third embodiment is illustrated in Figures 9-12 (*e.g.*, *id.* at 11-18).

Petitioner asserts, without dispute by Patent Owner, that the challenged claims are directed only to the second embodiment, disclosed in Figures 5-8 and the related text of the Specification. *E.g.*, Pet. 2 ("the challenged claims are directed to a second embodiment," citing "Figs. 5-8"); see also PO Resp. 9-10 (acknowledging that claims 10 and 11 do not read on the first embodiment).

Challenged claims 10 and 11 each recite first, second, and third suture openings. See Ex. 1101, 8:3-7; 8:38-44. As explained below, the second embodiment is the only embodiment with first, second, and third suture openings, as claimed.

The first embodiment is disclosed in Figures 1-4. *E.g.*, *id.* at 3:31-33 ("FIG. 1 illustrates a suture anchor according to a first preferred embodiment"). The first embodiment describes a suture anchor that includes central cylindrical bore 136 that mates with central "polygonally shaped bore 134" to form a single continuous bore. *E.g.*, *id.* at 3:55-4:10. Anchor pin 120 extends across the central bore and is supported within diametrically opposite bores 118 formed in anchor body 108. *E.g.*, *id.* at 4:14-17. One or more sutures are threaded into the central bore 134/136 and loop around anchor pin 120, as shown in Figure 4a. *Id.* at 4:21-23. The suture enters and exits anchor body 108 through proximal opening 112 (see Fig. 3), "polygonally shaped bore 134" (Ex. 1101, 3:55-60), and cylindrical bore 136 (*id.* at 4:5-10). See also *id.* at Figs. 4a

and 4c (showing the suture entering and exiting through the central bore). Opening 112 is the outer edge or lip of bore 134, and bore 134 mates with bore 136. Thus, there is only a single opening in anchor body 108, which is the central bore formed by opening 112 and bores 134, 136. This first embodiment does not have first, second, and third suture openings, as recited in challenged claims 10 and 11.

The third embodiment is a push-in suture anchor having suture molded directly into its body. Ex. 1101, 6:9-12. The anchor is solid and has no suture openings through which a suture is threaded. See *id.* at Fig. 10. Thus, this third embodiment does not have first, second, and third suture openings, as recited in challenged claims 10 and 11.

Figure 5, shown below, illustrates the second embodiment of a suture anchor according to the disclosed invention.

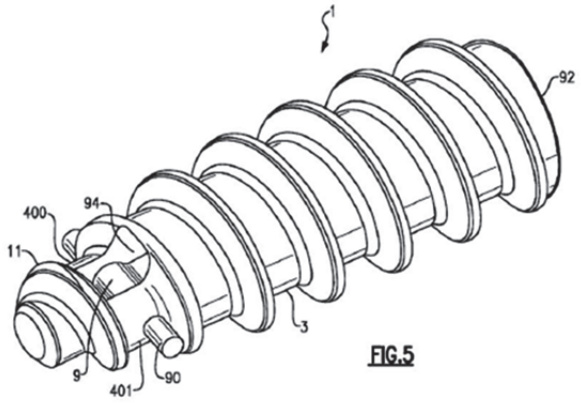


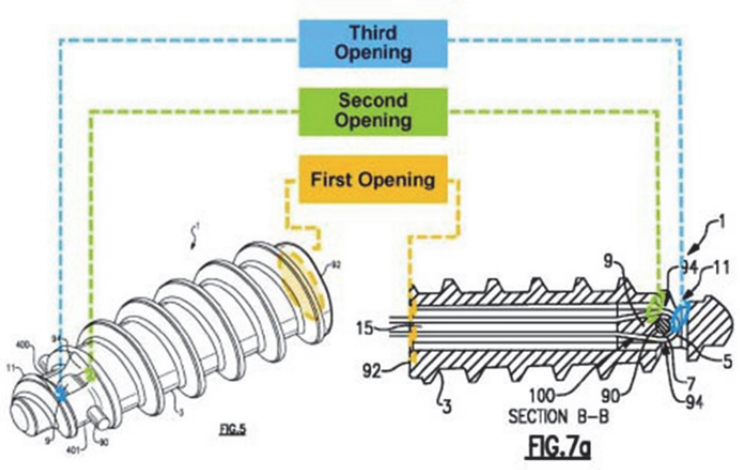
Fig. 5 of the '541 patent is a perspective view of a suture anchor.

As shown in Figure 5, suture anchor 1 includes threaded body 3. Rigid support or eyelet shield 9 is molded transversely into distal part 11 of threaded body

3. Eyelet shield 9 can include a length of suture 90 molded into threaded body 3. Ex. 1101, 5:18-31. As explained in the Specification, rather than having an anchor pin 120, as discussed in the first embodiment above, suture anchor 1 in the second embodiment has eyelet shield 9 molded transversely into distal part 11 of threaded body 3. *Id.* at 5:23-26. "Eyelet shield 9 is shown as a bar." *Id.* at 5:26-27.

In the disclosed second embodiment, two strands of sutures 5, 7 are threaded around eyelet shield 9 and threaded into suture passage 94. *Id.* at 5:37-39. Suture passage 94 may be on opposing sides of shield 9. *Id.* at 5:40-41, Figure 7a.

Petitioner provides the following annotated versions of Figures 5 and 7a of the '541 patent, illustrating the first second and third openings recited in the challenged claims:



Pet. 4. The annotations identify three openings through which suture passes. The first opening is bore 15 or opening 92. Ex. 1101, 5:42-48 ("The bore 15 extends from the proximal end 92 of the suture anchor 1 to a location

roughly halfway along the anchor body 1. . . . the bore 15 has an opening at the proximal end 92 of the suture anchor"). The second and third openings are suture passages 94 on opposing sides of shield 9.

Shield 9 provides a bearing surface around which sutures are threaded. *Id.* at 5:41-42. Sutures are threaded through central bore 15 (see Figs. 7a and 8) and disposed about shield 9, with suture ends 306 and 308 extending out of proximal end 92 of anchor 1. *Id.* at 5:42-45; see Fig. 7b. Bore 15 has an opening at proximal end 92, with the opening shaped to accommodate driver 300 for driving the suture anchor. *Id.* at 5:47-50.

C. Challenged Claims

Petitioner challenges independent claims 10 and 11. Claim 10 is reproduced below.

> 10. A structure 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.

Ex. 1101, 7:58-8:28.

Independent claim 11 is similar to claim 10. There are three substantive differences between claims 10 and 11:

(1) Claim 10 recites a "helical thread" around the proximal end of the anchor body (*id.* at 8:7-8); claim 11 does not recite a "helical thread;"

(2) Claim 11 recites that the "rigid support" is "integral with the anchor body" (*id.* at 8:45); claim 10 does not recite an "integral" relationship between the rigid support and anchor body;

(3) Claim 11 does not recite the "driver" recited in the last clause of claim 10.

II. ANALYSIS

A. Claim Construction

We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b); *Cuozzo*

Speed Techs., LLC v. *Lee*, 136 S. Ct. 2131, 2144-46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The correct inquiry in giving a claim term its broadest reasonable interpretation in light of the specification is "an interpretation that corresponds with what and how the inventor describes his invention in the specification, *i.e.*, an interpretation that is 'consistent with the specification.'" *In re Smith Int'l, Inc.*, No. 2016-2303, 2017 WL 4247407, at *5 (Fed. Cir. Sept. 26, 2017). The broadest *reasonable* interpretation differs from the "broadest *possible* interpretation." *Id.* Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We are careful, however, not to cross that "fine line" that exists between properly construing a claim in light of the specification and improperly importing into the claim a limitation from the specification. *Comark Commc'ns, Inc.* v. *Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998) ("We recognize that there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.").

Petitioner proposes constructions for the terms, "suture opening," "rigid support," "central passage," "suture passage," "branching from," and "a rigid support integral with the anchor body to define a single-piece component." Pet. 19-24. Patent Owner agrees that construing several of these terms "is necessary to resolve the controversy." PO Resp. 8; see also *id.* at 8-17 (proposing constructions

for the terms "rigid support," "branching from," and "rigid support integral" proposed by Petitioner, as well as the term "helical thread").

We did not specifically construe any claim terms in our Decision to Institute. Dec. Inst. 6.

Because claim construction is based on how a term would be understood by a person of ordinary skill in the art, we first determine the ordinary skill level.

1. *Level of Ordinary Skill*

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima* v. *Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology, and (6) educational level of workers active in the field. *Environmental Designs, Ltd.* v. *Union Oil Co.*, 713 F.2d 693, 696-697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co.* v. *All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381-82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc.* v. *Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). Additionally, the Supreme Court informs us that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l* v. *Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Neither party presents a detailed evidentiary showing of factors typically considered in determining the level of ordinary skill.

Petitioner asserts that a person of ordinary skill in the relevant technology would have had "(a) a master's degree in mechanical engineering or a bachelor's degree in mechanical engineering along with two or more years of experience designing suture anchors; or (b) a medical degree and several years of experience performing surgeries that involve suture anchors and/or advising engineers on suture anchor design." Pet. 18-19 (citing Ex. 1103 ¶¶24-26). Exhibit 1103 is a 152 page declaration from Mark A. Ritchart.[9] Mr. Ritchart's declaration testimony merely repeats the level of skill asserted by Petitioner without any analysis or discussion of the underlying facts or data on which his opinion is based. We give his testimony some, but little, evidentiary weight. 37 C.F.R. §42.65(a).

Patent Owner does not assert a level of ordinary skill to apply in this proceeding, nor does Patent Owner comment on Petitioner's proposed level of ordinary skill.

At the hearing, Counsel for Petitioner stated his understanding that "there is no dispute over the [ordinary level of skill] standard that, as we set forth in pages 18 and 19

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[9] Mr. Ritchart holds a degree in mechanical engineering. He has been involved in all aspects of designing and testing suture anchors since at least 1993. *Id.* ¶4. He also served as the President and Chief Technology Officer of Opus Medical, Inc., a medical device company that designed, manufactured and marketed soft-tissue-to-bone and tissue-to-tissue repair systems, including suture anchors. *Id.* ¶3. Mr. Ritchart is a named inventor on numerous patents related to medical devices, including suture anchors. *Id.* ¶4. We determine that Mr. Ritchart is qualified as an expert by his knowledge, skill, experience, training, and education to testify in the form of an opinion in this proceeding. Fed. R. Evid. 702.

of our petition, that is the standard." Tr. 28:19-22. Counsel for Patent Owner did not dispute at the hearing that the parties agree on Petitioner's proposed level of ordinary skill. See also Ex. 2010 ¶9 (testimony of Patent Owner's expert Dr. Ken Gall, Ph.D., testifying that "I qualify for the POSA standard set forth by Petitioners.").

In determining a level of ordinary skill, we may also look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Based on the record before us, we adopt Petitioner's proposed level of skill. A person of ordinary skill in the relevant technology would have had (a) a master's degree in mechanical engineering or a bachelor's degree in mechanical engineering along with two or more years of experience designing suture anchors; or (b) a medical degree and several years of experience performing surgeries that involve suture anchors and/or advising engineers on suture anchor design.

We now turn to construction of disputed claim terms.

2. *Suture Opening*

Petitioner asserts that the broadest reasonable interpretation of "suture opening" is "an open space serving as a passage or gap, or a breach or aperture, through which a suture passes." Pet. 19. Patent Owner does not propose a specific construction for this term, nor does Patent Owner comment on Petitioner's proposed construction.

a. *The Claims*

The claim construction inquiry "begins and ends in all cases with the actual words of the claim." *Renishaw PLC* v. *Marposs Società per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) (citations omitted). "[T]he resulting claim interpretation must, in the end, accord with the words

chosen by the patentee to stake out the boundary of the claimed property." *Id.* Thus, we begin with the words of the claims.

The term "suture opening" is used numerous times throughout both claims 10 and 11. For example, Claim 10 recites distinct "first," "second," and "third" suture openings:

> 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,

Ex. 1101, 7:58-8:7 (emphases added). Claim 11 recites these same three distinct "first," "second," and "third" suture openings. *Id.* at 8:38-44, 57-59. Although the first, second, and third suture openings are important elements in issued claims 10 and 11, they are not an emphasized element in the Specification. Other than in the claims, the term "suture opening" does not appear in the '541 Specification.

b. *The Specification*

Although the written description does not use the term "suture opening," it refers twice to "suture passages 94." *Id.* at 5:37-41 (". . . sutures 5, 7 are threaded around the eyelet shield 9 of the distal end 11 of the suture anchor 1 and threaded into a *suture passage* 94. In one example, there is a *suture passage* 94 on opposing sides of the shield 9." (emphases added)). The written descrip-

tion provides no structural or functional distinction between a "passage" and an "opening."

Petitioner equates "suture openings" with the disclosure of "suture passages." Pet. 19-20 ("The patent's description of suture passages 94 is consistent with that ordinary meaning, and the remainder of the patent contains no disclosure or description that would compel a narrower meaning of the term 'opening' as it is used in the claims." (citing Ex. 1103 ¶¶121-23)). Mr. Ritchart essentially repeats Petitioner's argument without any additional analysis.

In construing the claims, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw*, 158 F.3d at 1250. Thus, Petitioner's assertion that the claimed "openings" are disclosed by passages 94 has some evidentiary support.

Claim 11, however, uses both the term "suture openings" (*id.* at 8:38-44) and "suture passages" (*id.* at 8:38-44). This suggests that the term "suture opening" has a meaning separate and distinct from the term "suture passage." This is based on "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Andersen Corp.* v. *Fiber Composites, LLC*, 474 F.3d 1361, 1369 (Fed. Cir. 2007) (quoting *Karlin Tech. Inc.* v. *Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999)); see also *Merck & Co.* v. *Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." (citations omitted)). The preference for giving meaning to all terms, however, is not an inflexible rule that

supersedes all other principles of claim construction. *SimpleAir, Inc.* v. *Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 429 (Fed. Cir. 2016). The prosecution history, which we discuss below, sheds some light on this issue.

c. *Prosecution History*

The proceedings in the Patent and Trademark Office suggest that Applicants used the terms "suture opening" and "suture passage" interchangeably. During prosecution, Applicants identified suture passages 94 shown in Fig. 7a as "suture openings." Pet. 19 (citing Ex. 1102 at 630).

An Amendment submitted on May 21, 2014 (Ex. 1102, 617-633) laid the substantial foundation for the eventually issued claims. In this amendment, new application claims 55 and 59 were submitted, which eventually became patent claims 10 and 11, respectively. *Id.* at 627-628; see also *id.* at 727 (showing the concordance between the application ("Original") claims and the issued ("Final") claims). In the May 21 amendment, Applicants also amended application paragraph 46 to add two references to "*suture passage 94*." Ex. 1102, 620 (emphasis added). These are the same two references to "suture passages 94" that now appear in the issued patent. See Ex. 1101, 5:37-41. As filed, neither application paragraph 46, nor any other portion of the written description, referred to suture passages 94. See, *e.g.*, Ex. 1102, 9-10.

The May 21 amendment also amended Figures 5 and 7a "to show suture strands 5 and 7 threaded through a suture passage 94." *Id.* at 630. The drawings as filed did *not* include reference numeral 94. See *Id.* at 29-33, 36-43. In describing these drawing changes, Applicants stated "[r]egarding claims 43 to 44, two *suture openings 94* are

shown in Figure 7A. Figures 7a[10] and 7b show the path of claim 44." *Id.* at 630 (emphasis added).

Regarding a rejection under Section 112[11], Applicants also stated that "[r]egarding claim 43-44, Figure 7A shows two suture *openings*. The *suture openings 94* are disclosed in paragraph 46." *Id.* (emphasis added). Here, Applicants interchange the word "openings" for "passages" in describing element 94. Amended application claim 43 recited first, second, and third "suture openings." *Id.* at 626. Amended application claim 44 recited first and second "suture openings." Ex. 1102 at 630. It is these suture openings that Applicants asserted were illustrated by suture passages/openings 94.

"The very nature of words would make a clear and unambiguous claim a rare occurrence." *Autogiro Co. of Am.* v. *United States*, 384 F.2d 391, 396 (Ct. Cl. 1967). Using different words for the same element compounds the difficulties of claim interpretation.

d. *Construction of "Suture Opening"*

Based on our analysis above, including the claims, written description, and prosecution history, we conclude that the terms "suture opening" and "suture passage" represent a distinction without a substantive difference. We determine that the broadest reasonable interpreta-

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[10] The issued '541 patent, like these quoted sentences, refers to both "Figure 7a" (see Ex. 1101, drawing figures) and to "Figure 7A" (see *id.* at 3:4-5, 5:66).

[11] The Office Action mailed February 21, 2014, to which Applicants were responding, rejected claims 42-44 under 35 U.S.C. § 112, first paragraph, because "[c]laims 42-44 recite a second suture opening which is not found in the original disclosure therefore it is considered new matter." The Examiner did not repeat this rejection in subsequent Office Actions.

tion of both terms is a space through which a suture passes.

3. *Rigid Support*

Claims 10 and 11 each recite "a rigid support." Ex. 1101, 8:9, 8:45.

Petitioner asserts that the broadest reasonable interpretation of the term "rigid support" is "an inflexible part of the suture anchor that supports a tissue securing suture." Pet. 20 (citing Ex. 1103, the testimony of its expert Mr. Ritchart).

Patent Owner appears generally to agree with Petitioner's proffered construction. PO Resp. 9 ("Patent Owner's expert agrees with Petitioner's expert regarding the broadest reasonable construction for the term 'rigid support.'"). This apparent agreement, however, is based on Patent Owner's inaccurate summary of its expert's, Dr. Ken Gall's, testimony[12]. Patent Owner asserts "Dr. Gall explains that a 'rigid support' as that term is used in claims 10 and 11 requires an inflexible structure that withstands the loading on the sutures used to secure tissue after the anchor has been implanted in the patient." *Id.* (citing Ex. 2010 ¶¶103-106). In fact, Dr. Gall did not provide any such explanation or opinion concerning the construction of the term "rigid support" at the cited para-

[12] Dr. Gall is Chair of the Mechanical Engineering and Materials Science Department at Duke University and a Professor of Orthopedic Surgery in the School of Medicine. Ex. 2010 ¶3. He has a Ph.D. in mechanical engineering. *Id.* His publications include peer-reviewed journal articles on the mechanics of suture anchors. *Id.* at ¶4. Dr. Gall also has experience in the commercialization of orthopedic medical devices, including a suture anchor. *Id.* at ¶6. We determine that Dr. Gall is qualified as an expert by his knowledge, skill, experience, training, and education to testify in the form of an opinion in this proceeding. Fed. R. Evid. 702.

graphs of Exhibit 2010 on which Patent Owner relies to support its argument.

Paragraph 103 of Dr. Gall's testimony summarizes Petitioner's proposed construction of the term "rigid support." Ex. 2010 ¶103. Dr. Gall does not state in this paragraph any opinion as to whether he agrees or disagrees with Petitioner's proposed construction, whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support," nor does he provide his own opinion on the construction of the term "rigid support." *Id.*

Paragraph 104 of Dr. Gall's testimony summarizes excerpts from Mr. Ritchart's deposition testimony. *Id.* at ¶104. Dr. Gall does not state in this paragraph any opinion as to whether he agrees or disagrees with Mr. Ritchart's deposition testimony, whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support," nor does he provide his own opinion on the construction of the term "rigid support." *Id.*

Paragraph 105 of Dr. Gall's testimony summarizes his understanding of Petitioner's Exhibit 1136. *Id.* at ¶105. Exhibit 1136 is a five page article titled "Cyclic Loading of Anchor-Based Rotator Cuff Repairs: Confirmation of the Tension Overload Phenomenon and Comparison of Suture Anchor Fixation With Transosseous Fixation." Ex. 1136, 1. Dr. Gall does not state in Paragraph 105 of his testimony any opinion as to whether he agrees or disagrees with Petitioner's proposed construction of "rigid support," whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support," nor does he provide his own opinion on the construction of this term. Ex. 2010 ¶105.

Paragraph 106 of Dr. Gall's testimony summarizes trial testimony in a district court of "Petitioners' expert Dr. McAllister" regarding the "Curtis support." *Id.* at ¶106 (citing Ex. 2012, 1268:1-13). Dr. Gall does not state in Paragraph 106 of his testimony whether he agrees or disagrees with Petitioner's proposed construction of "rigid support" in this *inter partes* review, whether he agrees or disagrees with Mr. Ritchart's declaration testimony concerning the construction of "rigid support," nor does he provide his own opinion on the construction of this term. *Id.*

Whether the experts agree or not, Patent Owner asserts a slightly different construction of the term "rigid support" than asserted by Petitioner. According to Patent Owner, the broadest reasonable interpretation of the term "rigid support" is "an inflexible, or *stiff* part that *bears the loading* on the tissue securing suture." PO Resp. 9 (emphases added). The only evidence cited by Patent Owner to support its asserted construction is the testimony of Dr. Gall in paragraphs 103-106 of his Declaration (Ex. 2010), discussed above. *Id.* As discussed above, the cited testimony is not persuasive evidence supporting Patent Owner's asserted construction of the term "rigid support."

In its Reply, Petitioner asserts that "[t]he parties agree 'rigid support' is an 'inflexible part of the suture anchor' that supports the suture." Pet. Reply 5. It is Petitioner's position that the parties "disagree about whether it [the rigid support] *alone* must bear the *full load* on the suture *at all times* (Arthrex's [Patent Owner's] position), or simply bear some load on the suture at any time (S&N's [Petitioner's] position)." *Id.* (emphasis added). Petitioner, however, has not directed us to any persuasive evidence supporting Petitioner's characteri-

zation of Patent Owner's position. We have not been directed to any persuasive evidence that Patent Owner argues that the rigid support *alone* must bear the *full load* on the suture *at all times*. In this proceeding, Patent Owner has asserted that the meaning of the term the term "rigid support" is "an inflexible, or stiff part that bears the loading on the tissue securing suture." PO Resp. 9; see also Ex. 1165 ¶27 (testimony of Petitioner's expert Alexander H. Slocum, Ph.D.[13], testifying that in the Patent Owner Response, Patent Owner "argues that the BRI of 'rigid support' is 'an inflexible, or stiff part that bears the loading on the tissue securing tissue" (citing PO Resp. 9)).

At the hearing, Counsel for Patent Owner appeared to agree with Petitioner's construction of the term "rigid support." Tr. 55:13-17 ("When I looked at these claim constructions [on slide 10 of Patent Owner's demonstrative exhibits [Ex. 2053)]] and read them over and over again, I didn't discern much of a difference, if any."); see also *id.* at 56:13-59:12 (Patent Owner's discussion of claim construction concluding, for the term "rigid support,"

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[13] Dr. Slocum is a Professor of Mechanical Engineering at the Massachusetts Institute of Technology ("MIT"). Ex. 1165 ¶3. He received his Bachelor's, Master's, and Ph.D. degrees in Mechanical Engineering from MIT. *Id.* Dr. Slocum has approximately 30 years of experience in casting and molding. *Id.* at ¶6. He has published several articles and received many patents directed to designs and processes for casting and molding various components. *Id.* He also has designed molds for forming components through molding and casting, ranging in size from fractions of a millimeter (e.g., medical devices, razor blade edges) to meters in diameter. *Id.* We determine that Dr. Slocum is qualified as an expert by his knowledge, skill, experience, training, and education to testify in the form of an opinion in this proceeding. Fed. R. Evid. 702.

that "I don't know if there's much of a difference in terms of the construction").

We interpret the term "rigid support" in light of the Specification, which is a basic tool in reaching a proper claim construction. *In re Smith Int'l*, 2017 WL 4247407, at *5 ("The correct inquiry . . . is an interpretation that corresponds with what and how the inventor describes his invention *in the specification, i.e.*, an interpretation that is '*consistent with the specification*.'") (emphases added); *Retractable Techs., Inc.* v. *Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) ("In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than strictly limit the scope of claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention."). This focus on the Specification helps to avoid what has been called "the curse of . . . claims divorced from the written description." *Retractable Techs.*, 653 F.3d at 1311 (Plager, Circuit Judge, concurring). Before considering the Specification, however, we start with the actual words of the claim. *Renishaw*, 158 F.3d at 1248.

a. *The Claims*

Claim 10 recites the location and function of the rigid support as "a rigid support extending across the central passage . . . [with] at least one suture strand having a suture length threaded into the central passage, supported by the rigid support." Ex. 1101, 8:9, 8:16-17.

Claim 11 similarly recites "a rigid support integral with the anchor body to define a single-piece component, wherein the rigid support extends across the suture passage . . . [with] at least one suture strand threaded into the suture passage, supported by the rigid support." *Id.* at 8:45-47, 8:54-55.

Thus, the recited objective of the "rigid support" is to support a strand of suture.

b. *The Specification*

The term "rigid support" is used only in the claims. It is not used in the Specification.

In the first disclosed embodiment, the structure that supports the strands of suture is metal anchor pin 120. Ex. 1101, 4:21-23 ("One or more sutures 200 are *secured to the anchor* by looping the suture(s) around metal anchor pin 120 as shown in FIG. 4a"). Thus, the rigid support must support the sutures so that they are *secured* to the anchor.

In the third embodiment, the suture strands are molded into the body of the anchor, and thus do not have a separate support equivalent to anchor pin 120 or eyelet shield 9.

In the second disclosed embodiment, rather than having anchor pin 120 as a rigid support for supporting suture strands, as discussed above, suture anchor 1 has eyelet shield 9 molded transversely into a distal part 11 of the threaded body 3. Ex. 1101, 5:23-26. Shield 9 provides a bearing surface around which sutures 5, 7 are threaded and disposed. *Id.* at 5:41-42. As explained in the Specification:

> The eyelet shield 9 resists suture cut-[sic]. Further, the shield 9 *provides the strength necessary to secure the sutures* 5, 7. In addition, because the eyelet shield is molded transversely into the distal end of the suture anchor, this provides greater security *to prevent pull-out of the suture from within the suture anchor* or from an anchor pin, which could loosen. The eyelet shield also prevents the suture from fraying.

Id. at 5:51-57 (emphasis added). Thus, eyelet shield 9, the claimed rigid support, "provides the strength necessary to secure the sutures." *Id.* at 5:51-52.

Counsel for Patent Owner acknowledged that nothing in the Specification or claims establishes how rigid or flexible the rigid support may be. Tr. 63:19-64:1.

c. *Construction of "Rigid Support"*

We determine that the construction of the term "rigid support" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is the construction proposed by Petitioner—an inflexible part of the suture anchor that supports a tissue securing suture.

4. *Central Passage*

The term "central passage" is recited only in claim 10. Petitioner asserts that the broadest reasonable interpretation of this term is "a central path, channel, or duct of the anchor body." Pet. 20. For evidentiary support, Petitioner relies on the declaration testimony of Mr. Ritchart (Ex. 1103) and a dictionary definition (Ex. 1121). *Id.* at 20-21. Because the proposed interpretation uses the word "central" to define a "central passage," Petitioner essentially is asserting a construction of the word "passage." Patent Owner does not assert a construction for this term, nor does Patent Owner comment on the construction proposed by Petitioner.

a. *The Claims*

Claim 10 refers to a "central passage" four times. It recites:

(1) "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" (Ex. 1101, 7:59-8:3 (emphasis added));

(2) "a rigid support extending across the *central passage*" (*id.* at 8:9 (emphasis added));

(3) "at least one suture strand having a suture length threaded into the *central passage*" (*id.* at 8:16-17 (emphasis added)); and

(4) "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" (*id.* at 8:19-21 (emphasis added)).

b. *The Specification*

The term "central passage" does not appear in the Specification. The written description of the first embodiment refers to a "central opening" at the proximal end of the anchor. Ex. 1101, 3:62.

The word "passage" appears only twice in the Specification, referring to "passage 94" disclosed in the context of the second embodiment. *Id.* at 5:39-41. The Specification also states that sutures 5, 7 are threaded through bore 15, are disposed about shield 9, and have ends 306 and 308 that extend out of proximal end 92 of the anchor 1. *Id.* at 5:42-45; see Figures 7a and 7b. Bore 15 extends from proximal end 92 of suture anchor 1 to a location roughly halfway along anchor body 1. *Id.* at 5:45-47; see Figures 7a and 8.

c. *Construction of "Central Passage"*

We determine that the construction of the term "central passage" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is a pathway through the center of the

anchor body. The additional claim language in claim 10 locates the central passage along the longitudinal axis of the anchor body extending from a proximal end opening through a portion of the anchor body. See *id.* at 8:1-3.

5. *Suture Passage*

The term "suture passage" appears only in claim 11. *E.g.*, see Ex. 1101, 8:33-35. In our analysis of the term "suture opening" we determined that the terms "suture opening" and "suture passage" represent a distinction without a substantive difference. We determined that the broadest reasonable interpretation of both terms is a space through which a suture passes.

6. *Branching*

Claims 10 and 11 each recite first and second portions of the claimed rigid support "branching" from first and second wall portions of the anchor body, respectively. Petitioner asserts the broadest reasonable interpretation of this "branching" term is "extending." Pet. 21.

Patent Owner takes a contrary position. According to Patent Owner, the correct construction of the "branching" limitation is "continuous with the anchor body and the branching first and second portions of the rigid support spread out or diverge from the respective wall portions." PO Resp. 14. Patent Owner argues that Petitioner's proposed construction is wrong because claim 10 already recites "a rigid support *extending* across the central passage." PO Resp. 12. According to Patent Owner, if "branching" simply means "extending" across a gap then the "extending across a passage" clause in claim 10 becomes redundant, and thus superfluous. *Id.* Patent Owner asserts that a claim construction that makes a limitation superfluous or redundant is not proper. *Id.*

Petitioner argues that interpreting "branching to require the rigid support to be "continuous" is "inconsistent with the intrinsic evidence and Arthrex's prior positions." Pet. Reply 3. According to Petitioner, if the rigid support is "continuous" with the anchor body, as recited in both claims 10 and 11, the additional recitation in claim 11 that the rigid support also is "integral with the anchor body" (Ex. 1101, 8:45) becomes redundant and thus superfluous. Tr. 39, 14-16 ("in our opinion, their construction would render the integral limitation of Claim 11 entirely superfluous.").

Thus, the only agreement between the parties is that a claim construction that renders a claim term redundant and superfluous is neither correct nor reasonable.

We evaluate these issues and arguments by starting with the language of the claims.

a. *The Claims*

Claim 10 recites:

> 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.

Ex. 1101, 8:9-14 (emphasis added). Claim 11 is similar, but additionally recites that the rigid support is "integral with the anchor body to define a single-piece component." *Id.* at 8:45-46. Thus, claims 10 and 11 each require the rigid support to have first and second portions that "branch" from first and second wall portions of the anchor body, respectively. Claims 10 and 11 also each require the rigid support to extend across the central or suture passage. *Id.* at 8:9, 8:47.

Patent Owner misconstrues Petitioner's proposed construction. Petitioner's construction is more limited than argued by Patent Owner. Petitioner is asserting simply that the term "'branching' means 'extending.'" Pet. 21. Thus, under Petitioner's construction, the first and second portions of the rigid support branch or *extend from* first and second wall portions of the anchor body. Claim 10 and 11 also recites that the first and second portions of the rigid support *extend across* the central or suture passage. These two terms are neither redundant nor superfluous, as explained by counsel for Petitioner:

> JUDGE SAINDON: Counsel, let me ask you this.
>
> So if you have a hollow cylinder, *branching means* it's coming out from. Under your construction here, *extending across means* the two branches connect?
>
> MR. SPEED: Right.
>
> JUDGE SAINDON: And *integral means* formed all from the same material?
>
> MR. SPEED: Exactly.
>
> JUDGE SAINDON: Okay.
>
> MR. SPEED: So you could have a pin that branches from one wall to another and extends across the entire center of the hollow cylinder. You could conceivably have a pin that only extends partially across or something along those lines.
>
> JUDGE SAINDON: Okay. So that's what across adds[, it's] that they're connected as opposed to not?
>
> MR. SPEED: Right. Exactly.

Tr. 37, 5-20 (emphases added).

b. *The Specification*

The Specification does not use the term "branching from," "branching," "branch," or a similar word in describing the relationship of the rigid support to the walls of the anchor body. The written description also does not refer to first and second portions of the rigid support or first and second wall portions. Indeed, neither party directs us to any persuasive evidence in the written description supporting their position.

Regarding the first disclosed embodiment, the written description states "[t]wo longitudinal, diametrically opposite apertures 118 are formed in anchor body 108, the apertures 118 supporting a metal transverse anchor pin 120 which extends across cylindrical bore 136." Ex. 1101, 4:14-17. Anchor pin 120 is the claimed rigid support in this embodiment. The only disclosed relationship between anchor pin 120 and the walls of anchor body 108 is that anchor body 120 is supported by opposing apertures 118 in the anchor body walls.

Regarding the second disclosed embodiment, as discussed above, anchor pin 120 is replaced with eyelet shield 9 "molded transversely into" anchor body 3. *Id.* at 5:23-26. There is no disclosure of eyelet shield 9 having first and second portions. The only disclosed relationship between eyelet shield 9 and the walls of the anchor body is that shield 9 is "molded into" anchor body 3. *Id.* at 5:30.

Figures 1-8 illustrate the rigid support (120 or 9) that extends from opposing side walls of the anchor body, and also extends across the central passage or suture passage i.e., bore 134 or bore 15).

c. *Prosecution History*

The reference to "branching" and the claim language about first and second portions of the rigid support and

anchor body walls first appeared in claims in an amendment submitted on May 21, 2014, responding to an Office Action mailed February 21, 2014. Ex. 1102, 617-636. In this amendment, the Specification was supplemented extensively. *Id.* at 618-621. The pending claims also were amended extensively, some claims were cancelled, and new claims 50-67 were added. *Id.* at 622-629. Pending application claims 1 (*id.* at 622), 12 (*id.* at 623), and 39 (*id.* at 625) were amended to include the "branching" and first and second portion language.

In arguing that the amended claims were not anticipated by the Colleran reference (Ex. 1109), Applicants argued that "Colleran discloses a winding post 62 [a rigid support] that extends from a *single wall* 61." Ex. 1102, 632 (emphasis added). Colleran discloses winding post 62 that extends from wall 61. Ex. 1109, 5:8-9, see in Figs. 2A, 2D. As shown, post 62 is cantilevered from wall 61. See PO Resp. 11 ("That argument was based on the fact that Colleran's winding post 62 is cantilevered from a single wall 61."). Thus, the argued distinction is the difference between a rigid support that extends from *one* wall portion versus a claimed structure that extends from *two* wall portions. This asserted distinction does not require that the broadest reasonable interpretation of the disputed claim language is that the rigid support is "continuous" with the walls, as proposed by Patent Owner's construction.

In arguing that the claims were not anticipated by the Grafton reference (Ex. 1110), Applicants argued that a suture "molded inside the suture body" to form an eyelet, as disclosed in Grafton, was not a structure that included portions of a rigid body branching from wall portions, as recited in the claims. Ex. 1102, 632; see also Ex. 1110, ¶24 (disclosing that "a strand of suture 8 [is] molded into

the anchor body 4 during manufacture"). This asserted distinction also does not require that the broadest reasonable interpretation of the disputed claim language is that the rigid support is "continuous" with the walls, as proposed by Patent Owner's construction.

Applicants also argued the Dreyfuss reference[14] did not disclose a structure that included portions of a rigid body branching from wall portions, as recited in the claims. Ex. 1102, 632-633. Applicants simply stated this conclusion without further elaboration.

d. *Construction of "Branching"*

We determine that the construction of the term "branching" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is simply "extending."

7. *Integral to Define a Single-Piece Component*

We addressed the construction of the term "rigid support" above. Claim 11 recites that the claimed "rigid support" is "integral with the anchor body to define a single-piece component." Ex. 1101, 8:45-46. Claim 10 does not have a similar limitation. We now address the construction of an "integral . . . single-piece component."

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[14] For reasons not explained in the materials filed by Petitioner, the Dreyfuss reference submitted by Petitioner as an exhibit in this proceeding (Ex. 1111) is U.S. Patent App. Pub. No. 2003/0065361. See, *e.g.*, Paper 33, 2. The Dreyfuss reference applied by the Examiner, however, was U.S. Patent No. 6,652,563, the patent that issued from U.S. Patent App. Pub. No. 2003/0065361. Ex. 1102, 494 ("Claims 1, 12, 13, 22, 24, and 28-37 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over *Dreyfuss (6,652,563)* in view of Grafton et al. (5,964,783)." (emphasis added)). We have added the Dreyfuss patent to our record as Ex. 3005.

Petitioner asserts that the broadest reasonable interpretation of the phrase "a rigid support integral with the anchor body to define a single-piece component" is "a rigid support formed together with the anchor body as a unitary structure." Pet. 22. Petitioner relies on the prosecution history for evidentiary support, asserting that the Applicants argued that this phrase "cannot cover separately formed components that are somehow joined together, even by ultrasonic welding, and instead requires the stated elements to be formed as a unitary structure." *Id.* at 23-24 (citing Ex. 1103 ¶¶133-36). The cited testimony of Mr. Ritchart merely repeats Petitioner's argument.

Patent Owner agrees with Petitioner's proposed construction and prosecution history analysis (PO Resp. 16-17).

Accordingly, we adopt the agreed upon construction. The phrase "a rigid support integral with the anchor body to define a single-piece component" means a rigid support formed together with the anchor body as a unitary structure.

8. *Helical Thread*

Claim 10 recites that "a helical thread defines a perimeter at least around the proximal end of the anchor body." Ex. 1101, 8:7-8. Claim 11 does not include the "helical thread" term.

Mr. Ritchart testifies as to the basic types of insertion and fixation mechanisms used in suture anchors at the time of the claimed invention. Ex.1103 ¶¶46-58. These included screw-type anchors, which used helical threads, "much like the threads of a wood screw" (*id.* at ¶¶47-55); tap-in anchors, which are tapped into a predrilled hole in the bone with a hammer or by hand (*id.* at ¶¶56-57); and other anchors, which used a toggle-bolt design inserted

into a pre-drilled hole in the bone, and a portion of the anchor rotated to lock the suture anchor within the bone hole (*id.* at ¶58).

a. *Patent Owner's Proposal*

Patent Owner proposes that the term "helical thread" should be interpreted to require a helical ridge or raised surface that *facilitates rotary insertion of the anchor body into bone* and serves to retain the anchor in bone. PO Resp. 15 (citing Ex. 2010 ¶119 (emphasis added)). The cited testimony of Dr. Gall is that "'[t]hread' is understood by those skilled in the art as an inclined surface that facilitates advancing one object (e.g., a screw) into another (e.g., a hole) using a relative rotary motion to achieve longitudinal displacement." Ex. 2010 ¶119. Dr. Gall concludes that the term "helical thread" means "a helical ridge or raised surface that facilitates rotary insertion of the anchor body into bone and serves to retain the anchor in bone." *Id.* at ¶120.

Dr. Gall also testifies that he has reviewed the Oxford Dictionary (Ex. 2008) and the Machinery Handbook (Ex. 2009) definitions of "thread", which he found to be "consistent with my understanding of how a POSA interprets that term." Ex. 2010 ¶118.

Relevant to the claimed technology, the Oxford Dictionary defines thread as "*a spiral ridge* on the outside of a *screw or bolt* or on the inside of a hole to allow two parts to be *screwed* together." Ex. 2008 (emphases added).

The Machinery Handbook defines thread as "a portion of a *screw thread* encompassed by one pitch." Ex. 2009 (emphasis added).

b. *Petitioner's Proposal*

Petitioner agrees that "'helical thread' means a 'helical ridge or raised surface' that 'serves to retain the anchor

in bone,' but [Petitioner] disagrees with [Patent Owner's] assertion that it must 'facilitate rotary insertion.'" Pet. Reply 1. Petitioner also relies on dictionary definitions (*Id.* at 2 (citing Ex. 2009 and Exhibit 1155, 338)) and the declaration testimony of Dr. Slocum. *Id.* at 3 (citing Ex. 1165 ¶¶34-57).

The definition in Exhibit 2009, the Machinery Handbook, is stated above ("a portion of a screw thread encompassed by one pitch."). The cited page (338) of Exhibit 1155 is a dictionary definition of "screw thread." It defines "screw thread" as "[t]he ridge on the surface of a cylinder or cone produced by forming a *continuous helical or spiral groove* of uniform section and such that the distance between two corresponding points on its contour measured parallel to the axis is proportional to their relative angular displacement about the axis." Ex. 1155, 338 (emphasis added).

These various dictionary definitions suggest that, in the context of the relevant technology, the word "thread" is generally understood to suggest a spiral or helical thread of a screw. Although dictionaries may be helpful in claim interpretation in some cases, the use of a dictionary definition can conflict with a correct claim construction because "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all *possible* definitions for particular words. *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (emphasis added). The broadest *reasonable* interpretation differs from the "broadest *possible* interpretation." *In re Smith Int'l*, No. 2016-2303, slip op. at 13.

Dr. Slocum's testimony on behalf of Petitioner relies on the dictionaries cited above and other dictionaries. Ex. 1165 ¶¶54-57. He also relies on three prior art pat-

ents. *Id.* at 34-53. Dr. Slocum concludes that although "a helical thread may be used to facilitate rotary insertion of an anchor body into bone, the BRI of helical thread is not limited to that particular function." Ex. 1165 ¶36. Dr. Slocum states that it was "known in the art that *helical* threads were appropriate for use with suture anchors that were *not rotated* into bone." *Id.* (emphasis added).

(1) *Dr. Slocum's Review of Prior Patents*

Dr. Slocum testified about three prior art patents that he states support his opinion that it was "known in the art that helical threads were appropriate for use with suture anchors that were not rotated into bone." The three patents are Curtis (Ex. 1107), McDevitt (Ex. 1149), and Nicholson (Ex. 1161). We discuss Dr. Slocum's analysis of these three patents below.

Curtis (Ex. 1107) is asserted as a reference in this proceeding. Curtis is discussed in detail below in Section II.C.1. Curtis discloses a suture anchor that "presses" protrusions or barbs into bone to thereby fix the anchor in the bone. Ex. 1107, 2:34-38. Dr. Slocum (Petitioner's expert) testifies that he agrees with Dr. Gall (Patent Owner's expert) that Curtis discloses anchors that "are intended to be inserted, *not rotated*, into a bone hole." Ex. 1165 ¶40 (emphasis added). Dr. Slocum notes that although Curtis is *not* rotated, Curtis discloses the use of "protrusions" that may be "*threads* or barbs." *Id.* at ¶41 (citing Ex. 1107, claim 7 (emphasis added)).

Curtis discloses "protrusions 5, in the form of barbs distributed over the full length of the main body to facilitate retention of the suture anchor in cortical bone or cortical and cancellous bone." Ex. 1107, 2:20-23. The written description in Curtis does *not* disclose that the "protrusions" can take any form other than "barbs." The written description does not mention "threads." None-

theless, claim 7 in Curtis claims that the "protrusions" recited in claim 6 are "threads or barbs." *Id.* t 4:9-12. Neither the drawings nor the written description in Curtis show or describe protrusions, whether considered to be threads or barbs, that are "helical," as recited in challenged claim 10 of the '541 patent.

As described above, the cited dictionary definitions suggest that a person of ordinary skill would understand that the word "thread" in Curtis' claim 7 is a spiral or helical thread.

Thus, we find that Curtis supports Dr. Slocum's opinion that it was known in the art that *helical* threads were appropriate for use with suture anchors that were pressed, *not rotated*, into bone.

Dr. Slocum also testifies that the McDevitt patent (Ex. 1149), which is "a two part device with an interior stem (2) and an outer or expanding sleeve (4)" (Ex. 1165 ¶44), and uses "protrusions" in the form of "threads" (*id.* at ¶45) to secure the anchor in a "predrilled bone hole" (*id.* at ¶46). We note that McDevitt discloses that the anchoring element 4, which is the expanding sleeve, may have "protrusions 53 that may take the form of ribs, *threads*, a plurality of raised points or other shapes." Ex. 1149, 6:39-42 (emphasis added). According to Dr. Slocum, the McDevitt patent "is secured in the bone hole when the stem is pulled proximally drawing the larger diameter portion of the stem into the sleeve thereby forcing the sleeve to expand into contact with the surrounding bone." *Id.* at ¶44.

As discussed above, the cited dictionary definitions suggest that a person of ordinary skill would understand that the word "thread" in McDevitt is a spiral or helical thread.

Thus, we find that McDevitt also supports Dr. Slocum's opinion that it was known in the art that *helical* threads were appropriate for use with suture anchors that were not rotated into bone.

Dr. Slocum states that Nicholson (Ex. 1161) discloses an expandable suture anchor that uses screw threads to engage the bone. Ex. 1165 ¶51. As summarized by Dr. Slocum, Nicholson states that "*the threads are not used for turning the expandable member into the bore*." *Id.* (citing Ex. 1161, 18:39-40 (emphasis added)). Rather than turning the screw threads to facilitate engagement of bone, the screw threads "facilitate deformation of the outer portion of the member [only after] the member is expanded within the bone hole." *Id.* (citing Ex. 1161 at 18:39-46).

Thus, we find that Nicholson supports Dr. Slocum's opinion that it was known in the art that *helical* screw threads were appropriate for use with suture anchors that were not rotated into bone.

Based on this analysis, Dr. Slocum opines that a person of ordinary skill in the relevant technology would understand that the "*helical thread*" recited in claim 10 "need not facilitate rotational insertion of an anchor into bone." *Id.* at ¶53 (emphasis added). We agree with this analysis.

Neither Petitioner nor Dr. Slocum discuss the Specification of the '541 patent in their claim construction analysis of "helical thread."

We turn to the claim language and the Specification for guidance in completing our interpretation of the term "helical thread."

c. *The Claim*

Claim 10 does not refer to "rotary insertion." It does, however, refer to a structural feature that facilitates insertion. Specifically, claim 10 recites "a driver including a shaft having a shaft length" that engages the anchor body. Ex. 1101, 8:25-26. Claim 10 does not recite the purpose or function of the driver. To understand the purpose or function of the claimed driver, we turn to the written description in the Specification.

d. *The Specification*

The phrase "helical thread" or the word "helical" does not appear in the written description. Figures 1 and 5, however, shown below, clearly illustrate a thread that is helical.

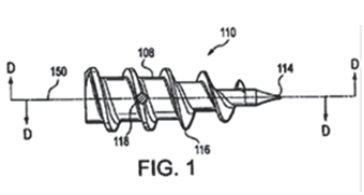


FIG. 1

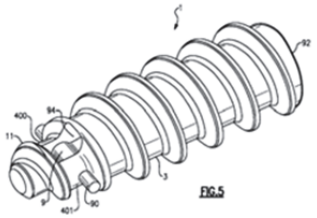


FIG.5

Figures 1 and 5 of the '541 patent illustrating a helical thread around the perimeter of a suture anchor body.

The helical thread shown in Figures 1 and 5 illustrate one form of retaining the anchor in bone. An alternative embodiment, shown in Figures 9-12, discloses "a push-in suture anchor 20" as an alternative to rotary insertion using helical threads. *Id.* at 6:9-10.

As explained in the written description, suture anchor 110, shown in Figure 1, is installed using driver 202 "to drive the anchor into bone." Ex. 1101, 4:11-13. The written description also states that "driver 202 is *rotated* to drive the anchor 110 into the bone until the proximal sur-

face of the anchor 110 is flush with the surface of the bone." *Id.* at 5:3-5 (emphasis added). As an alternative retaining structure, the suture anchor "need not be formed as a threaded device, but can also be formed as a tap-in type anchor." *Id.* at 4:35-37. Thus, the Specification, like Mr. Ritchart's testimony discussed above, draws a distinction between a screw-type anchor with helical threads, and a tap-in type anchor.

A similar description is provided for retaining suture anchor 1, shown in Figure 5. Suture anchor 1 is installed using driver 300. *Id.* at 5:64. The distal end of driver 300 is inserted into proximal end 92 of anchor 1, and driver 300 is *rotated* to drive anchor 1 into the bone until the proximal surface of anchor 1 is flush with the surface of the bone. *Id.* at 6:4-8. The same alternative retaining structure is disclosed for suture anchor 1 in Figure 5. *Id.* at 5:58-62 ("the suture anchor also need not be a threaded device, but can also be formed as a tap-in type anchor.").

In light of the alternative "tap-in" insertion disclosed in the Specification, and the substantial evidence discussed above from Dr. Slocum regarding threaded anchors that are *not* inserted by a rotary motion, we are not persuaded that the "rotational" driver disclosed in the Specification should be read into the claim term "helical thread" to require rotary insertion of the claimed anchor. Various drivers were known in the art. Curtis discloses the use of a "manipulation instrument" for installing the suture anchor, but does not provide details about its use or structure. Ex. 1107, 2:23-26. Non-rotary drivers were known in the art for inserting anchors. See DiPoto, Ex. 1125, 6:12-16 ("The anchor 16 is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet or the like. It is not necessary to rotate the assembly in order to install it in position.").

DiPoto (Ex. 1125) is discussed in detail in Section II.D.2 below.

In accord with settled practice, "we construe the claim as written, not as the patentees wish they had written it." *Chef America, Inc.* v. *Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004).

e. *Construction of "Helical Threads"*

We determine that the construction of the term "helical threads" that stays true to the claim language, most naturally aligns with the patent's written description of the invention, and is consistent with the other evidence discussed above is the construction proposed by Petitioner—a helical ridge or raised surface that serves to retain the anchor in bone.

9. *Summary of Claim Constructions*

The following is a summary of our claim constructions:

"suture opening" and "suture passage"—a space through which a suture passes;

"rigid support"—an inflexible part of the suture anchor that supports a tissue securing suture;

"central passage"—a pathway through the center of the anchor body;

"branching"—extending;

a rigid support "integral with the anchor body to define a single-piece component"—a rigid support formed together with the anchor body as a unitary structure; and

"helical threads"—a helical ridge or raised surface that serves to retain the anchor in bone.

We now address the grounds of unpatentability on which we instituted trial.

B. Obviousness in View of Gordon and West (Claims 10 and 11)

Petitioner asserts that the subject matter of claims 10 and 11 would have been obvious to a person of ordinary skill in the art in view of Gordon and West. Pet. 24-43.

Section 103(a) "forbids issuance" of a patent when "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 to which said subject matter pertains." *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others. *Graham* v. *John Deere Co.*, 383 U.S. 1, 17-18 (1966); see *KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."). The Court in *Graham* explained that these factual inquiries promote "uniformity and definiteness," for "[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context." *Id.* at 18.

The Supreme Court made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To

reach this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc.* v. *Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id.*

Moreover, in determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Litton Indus. Products, Inc.* v. *Solid State Systems Corp.*, 755 F.2d 158 (Fed. Cir. 1985) ("It is elementary that the claimed invention must be considered as a whole in deciding the question of obviousness."); see also *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 1537 (Fed. Cir. 1983) ("the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious. Consideration of differences, like each of the findings set forth in *Graham*, is but an aid in reaching the ultimate determination of whether the claimed invention as a whole would have been obvious.").

"A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect." *EWP Corp.* v. *Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

As a factfinder, we also must be aware "of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR*, 550

U.S. at 421. This does not deny us, however, "recourse to common sense" or to that which the prior art teaches. *Id.*

Against this general background, we consider the references, other evidence, and arguments on which the parties rely.

1. *Scope and Content of the Prior Art*

a. *Gordon (Ex. 1105)*

Gordon discloses devices and methods for securing sutures to a bone anchor without the requirement of knot tying. Ex. 1105 ¶24. The disclosed knotless anchor includes a bone engaging mechanism, a suture tensioning mechanism, and a suture locking mechanism. *Id.* at ¶26.

The bone engaging mechanism includes a helical threaded surface on its distal end that is rotatable to engage adjacent bone. *Id.* at ¶31. Figure 23 from Gordon is shown below.

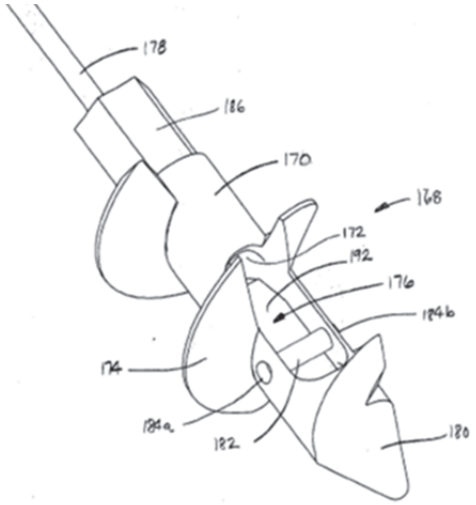


Figure 23 from Gordon is a perspective view of a suture anchor. As shown, the suture anchor includes anchor body 170 and a "lumen" or bore 172 formed through

anchor body 170. Ex. 1105 ¶84. Bore 172 is shown more clearly in Figure 25A, which is reproduced below.

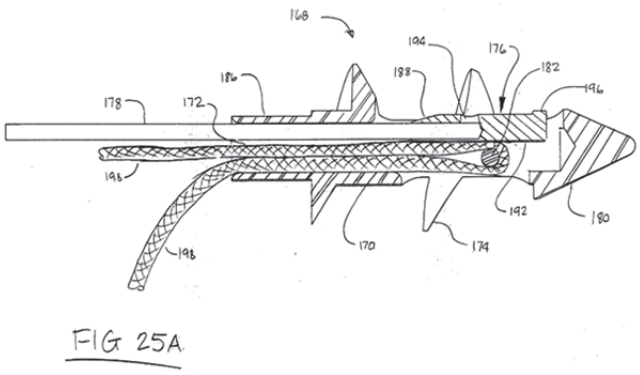


Figure 25A from Gordon is a cross-sectional view of the suture anchor shown in Figure 23.

As shown in the figures above, the Gordon suture anchor includes screw threads 174, "suture locking plug" 176, and "suture lock cable" 178. *Id.* Suture anchor body 170 also includes "pulley" 182. *Id.* Pulley 182 is disposed in holes 184a and 184b (see Fig. 23). Gordon does not elaborate further on the specific structure of pulley 182. Further elaboration of the pulley structure is provided, however, in then pending patent application No. 09/781,793, which Gordon incorporates by reference. *Id.* at ¶¶25, 83. This application was published as U.S. Pub. No. 2002/0111653 ("Foerster"), which is Exhibit 1108 in this proceeding.

Foerster, incorporated by reference into Gordon, discloses a suture pulley fixed with respect to the anchor body such that a length of suture may be introduced into the lumen from the proximal end, looped around pulley, and passed out of lumen through the proximal end. Ex. 1108 ¶22. The suture pulley may be "*formed in*" a sidewall of the lumen. *Id.* at ¶24 (emphasis added). Where

the anchor body is tubular, the suture pulley is desirably disposed at a distal end of the tubular body as a rod transverse to the lumen axis. *Id.* The rod may rotate with respect to the anchor body, or may be fixed. *Id.* Instead of a rod, the pulley may comprise a bridge formed between two spaced apertures at the distal end of the tubular body. *Id.*

Foerster, incorporated by reference into Gordon, discloses specifically that pulley 70 "comprises a pin oriented transversely to the axis of the suture anchor 46 and located along a sidewall thereof." Ex. 1108 ¶70. As shown in Figure 4A of Foerster, pin 70 may span axial slot 100 or lumen in a sidewall of anchor body 54. *Id.* Foerster also discloses that, alternatively, two axially spaced holes with chamfered or rounded edges may be formed in the sidewall of the anchor body 54 through which the free ends 34a, 34b can be threaded. *Id.* Foerster also discloses that pin-type pulley 70 can be formed separately from anchor body 54, and then be inserted within a pair of facing holes in the edges of the slot or lumen 100 so that pin-type pulley 70 rotates within the holes, thus reducing friction between the free ends 34a, 34b and the pulley. *Id.*

Returning to the Gordon reference, Gordon discloses that a driver, such as hex drive 186, is used to screw suture anchor 168 into bone for the purpose of creating a suture attachment point. Ex. 1105 ¶84. Screw threads 174 retain suture anchor 168 in the bone. *Id.*

The suture material, shown as suture strand 198, is threaded in lumen or bore 172 and around pulley 182. Ex. 1105 ¶86. As shown in Figure 25A, there is clearance between the walls of lumen 172 and suture strand 198 that allow suture strand 198 to move freely within lumen 172 and around the pulley 182. *Id.* at ¶87.

The next step in Gordon is to provide tension to the suture strand using the suture tensioning mechanism. In this step, the suture may be "tensioned" to approximate the soft tissues to be attached to the bone. *Id.* The tensioning step involves the surgeon tensioning the suture "in order to approximate the tendon 22 to the adjacent bone." *Id.* at ¶74; see also *id.* at ¶75 ("thus cinching the suture in order to tension it and therefore approximate the tendon 22 to the bone 26"). When the suture is cinched to a desired level, the "suture cinching mechanism" will "maintain the suture tension." *Id.* at ¶75. Thus, a tension load is applied and maintained on the pulley.

The next step is to lock the suture stands in place with the suture locking mechanism. Suture locking plug 176 includes tapered locking surface 192 (see Figs. 25A, B, C), weld hole 194, and travel stop 196. Ex. 1105 ¶85. Suture lock cable 178 is inserted into locking plug 176 so that the distal end of cable 178 is visible through weld hole 194. *Id.* Suture lock cable 178 and locking plug 176 may be joined together using a weld in weld hole 194 or by other suitable means. *Id.* As described below, however, the connection between lock cable 178 and locking plug 176 is breakable; the two parts separate on actuation of the suture locking mechanism.

The suture locking mechanism is actuated by pulling on suture lock cable 178. *Id.* The suture locking plug is movable within the lumen from a first position to a second position. The suture locking plug does *not* interfere with axial movement of the length of suture in the first position and does interfere with axial movement of the length of suture in the second position, by compressing the length of suture against the anchor body.

As shown in figure 25B, when actuated, locking plug 176 is forced into the lumen 172. At this point, tapered

locking surface 192 is in intimate contact with suture strand 198. *Id.* Locking plug 176 fills lumen 172 such that a frictional lock between lumen 172, plug 176, and suture 198 is created. *Id.*

As indicated in Figure 25C by the absence of suture lock cable 178, cable 178 includes a point of tensile weakness permitting it to be detached from the locking plug. Once actuated and pulled as described above, suture lock cable 178 is no longer attached to plug 176. Ex. 1105 ¶88. The frictional force between lumen 172, plug 176, and suture 198 overcomes the tensile strength of the weld or other attachment, described above, between lock cable 178 and plug 176. *Id.* This leaves knotless suture anchor 168 and suture 198 in place, securing the tissues. *Id.* Travel stop 196 is disposed on plug 176 to prevent it from being pulled completely through lumen 172. *Id.*

b. *West (Ex.1106)*

Figure 1 of West is shown below.

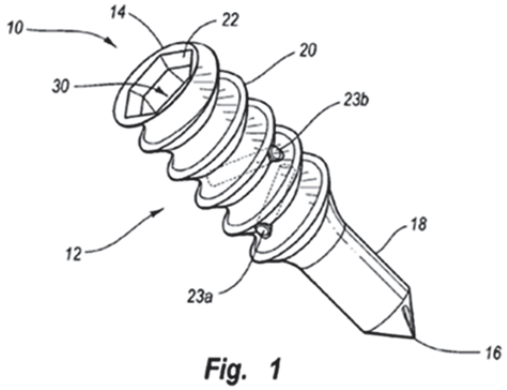


Fig. 1

Figure 1 from West is a perspective view of a suture anchor.

As shown in Figure 1, West discloses suture anchor 10 having hollow anchor body 12 that extends between proximal end 14 and a distal end 16. Ex. 1106, 4:39-41. Distal end 16 has a non-threaded portion that forms stabilizing extension 18 that prevents lateral movement of anchor body 12 within bone tissue. *Id.* at 4:41-44. Anchor body 12 also has a threaded portion, which includes threads 20 for engaging bone tissue. *Id.* at 4:44-46.

Proximal end 14 includes opening 30, which provides access to hollow interior bone 30 of anchor body 12. *Id.* at 4:4447-48. Hex socket 22 is formed in bore 30, which allows suture anchor 10 to be driven into a bone using a hex driver. *Id.* at 4:48-51.

Transverse pins 23a and 23b are disposed through anchor body 12 and provide attachment points for sutures. *Id.* at 4:53-55. Pins 23a and 23b are *formed or inserted in* anchor body 12 lying across bore 30. *Id.* at 5:58-60 (emphasis added). West discloses that in manufacturing bone anchor 10,

> 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*. For instance, anchor body 12 can be cast and formed from PLLA. Anchor body 12 can then be drilled to prepare holes for stainless steel pins 23a and 23b.

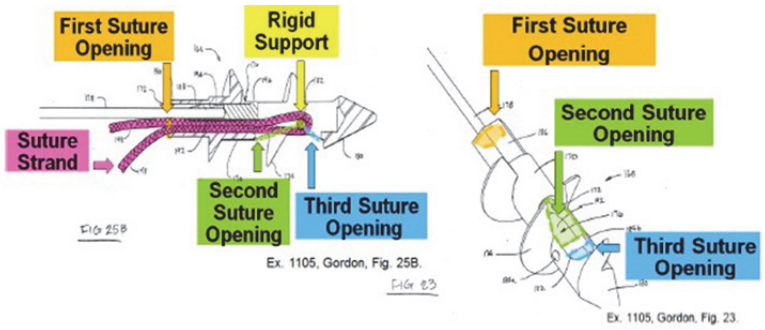
Id. at 7:41-47 (emphases added). The alternative option described in the second sentence, that the pins are "inserted later," suggests that the primary option, described in the first sentence, does *not* have the pins inserted later.

Pins 23a and 23b are placed below hex socket 22 so a hex driver can be inserted without hitting the pins. *Id.* at 6:20-22. An advantage of this position for the pins is that forces applied by sutures 36 are transferred to a more

central location within anchor body 12, and thus these forces are less likely to cause anchor 10 to become loosened or dislodged. *Id.* at 6:17-20. Although West discloses and illustrates the use of two pins, West also discloses more or fewer pins may be used depending on the required number of sutures and/or the space available within bore 30 for placing more sutures. *Id.* at 6:26-36.

2. *Differences Between the Claimed Subject Matter and the Prior Art*

Petitioner asserts that Gordon discloses a suture anchor having an anchor body with a central passage, a rigid support for the suture, a suture, and three openings, as depicted in Petitioner's annotated versions of Figures 25B and 23 of Gordon, reproduced below:



Pet. 33. Petitioner's annotated version of Figure 25B depicts a cross section of Gordon's anchor. Petitioner's annotated version of Figure 23 depicts a perspective view of Gordon's anchor.

According to Petitioner, two claim elements are missing from Gordon. The first missing element is helical threads defining a perimeter at least around the proximal end of the anchor body. Pet. 28. In Gordon, the proximal end of the anchor body is a male drive head, precluding the presence of threads at the proximal end. *Id.*; see, *e.g.*,

Ex. 1105, Fig. 23. Petitioner asserts that substituting an internal hex drive socket, as shown in West, would allow for the presence of threads on the proximal end, and would have been a known and predictable substitution. Pet. 28. Further, the socket in West "provides the bone anchor with the ability to better engage the cortical bone near the surface of the bone," due to the extra threads. Ex. 1106, 2:65-67; Ex. 1103 ¶¶162-166.

The second missing element, according to Petitioner, is to manufacture Gordon using a casting process, such as to make the rigid support (the pin around which the suture is threaded) an integral component of the anchor body. Pet. 28-30. This identified difference is relevant only to claim 11, which recites that the rigid support is "integral with the anchor body to define a single-piece component." Petitioner asserts it would have been obvious to manufacture Gordon's suture anchor by forming anchor body 170 and pulley 182 in Gordon (i.e., the asserted "rigid support") using a casting process. *Id.* at 28. According to Petitioner, the "casting process" would have resulted in pulley 182 being "integral" with anchor body 170 and a pulley integral with the anchor body as a "fixed structure." *Id.* at 29 (citing Ex. 1103 ¶167).

We note, however, that claim 11 does not recite or otherwise refer to a "casting process." It recites only "a rigid support integral with the anchor body to define a single-piece component." Ex. 1101, 8:45-46. The only reference to casting in the Specification is that "[i]n manufacturing the suture anchor 110 in accordance with the present invention, the anchor body 108 is cast in a die, with the bores, passageways and apertures described above either being formed during the casting process or formed afterwards." *Id.* 4:42-46.

According to Petitioner, West describes a similar anchor body having pins over which sutures are threaded, and that West describes making the anchor using a casting process. *Id.* at 28-29. Petitioner also asserts that this implementation is consistent with Gordon because Gordon incorporates Foerster, which describes how a pulley (like Gordon) may be a "fixed structure." *Id.*

Concerning a rationale for the proposed modifications, Petitioner asserts several other reasons to cast the structures, because it would minimize the materials used (allegedly useful in FDA approvals), because casting was well known, and because this would be more secure than an attached support. *Id.* at 29-30 (citing Ex. 1103 ¶¶169-171, 210).

Patent Owner takes a different view of the scope and content of the asserted references, the differences between the asserted references and the claimed invention, and the asserted reasons for combining the references, which we address in detail below.

3. *Discussion*

a. *Helical Threads Around the Proximal End (Claim 10)*

Claim 10 recites that "a helical thread defines a perimeter at least around the proximal end of the anchor body." According to Petitioner, "[t]he only feature [recited in claim 10] arguably not expressly disclosed in Gordon" is the "helical thread" limitation. Pet. 30.[15]

To provide screw threads at the proximal end requires an internal hex drive, as disclosed in West, rather than an external hex drive as disclosed in Gordon. See Ex. 2010

[15] Petitioner also asserts that "this limitation is arguably met by Gordon alone" (Pet. 30, fn3) but, nonetheless, challenges patentability of claim 10 in this ground only based on Gordon and West.

¶162 (Petitioners' proposed modification "seeks to replace the external hex drive 186 from Gordon with an internal hex socket 22 from West. Petitioners make this modification in order to incorporate the threads 20 from West at the proximal end of the anchor 168 in Gordon." (citations omitted)).

The benefits of having a proximal end socket are known. The background portion of West explains:

> Bone anchors can fail for various reasons. One reason is that existing bone anchors are not threaded to the proximal end of the anchor where the anchor meets the surface of the bone in the hard cortical bone region. In existing bone screws, the proximal end is not threaded because the driver tool used to insert the bone anchor fits over a hex shaped protrusion. The hex protrusion cannot extend above the bone surface so the screw is driven into the bone until the protrusion is below the surface. Since the protrusion has no threads, the bone anchor does not engage the bone near the surface, but only the soft cancellous bone beneath the cortical bone layer. This feature of existing bone anchors is very problematic because it prevents a practitioner from placing the threads of the bone anchor in the harder cortical bone, which is near the bone surface.

Ex. 1106, 1:50-64.

Patent Owner asserts Gordon is limited to inserting the suture anchor in "cancellous bone" completely below the "cortical bone" surface. PO Resp. 19. Cortical bone is the tough, dense outer layer of bone, whereas cancellous bone is the less dense, airy and somewhat vascular interior of the bone. Ex. 1105 ¶10. There is a clear demarcation between the cortical bone and cancellous bone; the cortical bone presents a hard shell over the less

dense cancellous bone. *Id.* Patent Owner's clear implication is that there is no reason for Gordon to have threads around the proximal end of the anchor body.

We note that the '541 patent does not mention the word "cortical" or "cancellous" in the Specification or claims. The '541 patent written description refers only to "bone." E.g., Ex. 1101, 1:25-26 ("The present invention relates to an apparatus for anchoring surgical suture to bone."). The '541 patent does not differentiate between cortical and cancellous bone. The word "bone" does not appear in either claim 10 or 11.

The patentability issue presented is not solely on what Gordon or West discloses or requires individually. The patentability issue is whether claim 10 would have been obvious based on the combined teachings of Gordon and West.

Gordon and West each disclose a "suture anchor" assembly, which is what is claimed. Gordon and West also each disclose the use of screw threads to retain the suture anchor in bone; they each disclose the use of a suture strand threaded through a central passage of the anchor body; they each disclose use of a driver for inserting the screw anchor; and they each disclose a structure for supporting the suture strand within the anchor body.

Patent Owner's criticism of the proposed combination fails to consider that the determination of whether a claimed invention would have been obvious is based on what the combined teachings of the references would have suggested to those of ordinary skill in the art. *MCM Portfolio LLC* v. *Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015) ("[W]e have consistently held, as the Board recognized, that '[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary

reference; *nor is it that the claimed invention must be expressly suggested in any one or all of the references*. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.'" (citations omitted; emphasis added)).

Moreover, *KSR* does not require that a combination only unite old elements without changing their respective functions. *KSR*, 550 U.S. at 416. Instead, *KSR* teaches that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421. And it explains that the ordinary artisan recognizes "that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420. The rationale of *KSR* does not support a theory that a person of ordinary skill can only perform combinations of a puzzle element A with a perfectly fitting puzzle element B. *ClassCo, Inc.* v. *Apple, Inc.*, 838 F.3d 1214, 1219 (Fed. Cir. 2016). To the contrary, *KSR* instructs that the obviousness inquiry requires a flexible approach. *KSR*, 550 U.S. at 415. When we apply this flexible approach to the evidence discussed above, we find that the combination of Gordon and West would have resulted in no more than a predictable result. *Id.* at 417 ("a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.").

Also, we consider the proposed combination from the viewpoint of a person of ordinary skill in the relevant technology. Here, that person is highly educated and skilled; an engineer or a medical doctor. The evidence does not support that such a highly skilled person would ignore a disclosure based on whether it was directed primarily to a suture anchor for cortical bone or a suture

anchor for cancellous bone. Both are suture anchors, as is the claimed invention. We are persuaded that a suture anchor designer of ordinary skill and creativity, facing the wide range of needs and design options known in this technological field, would have found it would have been obvious, based on the disclosure in West, to provide Gordon with helical threads that define a perimeter at least around the proximal end of the anchor body, as recited in claim 10.

b. *Rigid Support*

Patent Owner asserts that "the rigid support of claim 10 is missing from Petitioners' proposed combination because Gordon's pulley is not a rigid support as required by claim 10. Without that in the proposed combination, Claim 10 cannot be considered obvious." PO Resp. 21. Patent Owner asserts two reasons why the claimed rigid support is missing from Gordon.

First, Patent Owner asserts that Gordon's pulley 182 does not meet the "branching" requirement of claim 10. *Id.* We disagree.

Patent Owner acknowledges that Gordon's pulley 182 "extends across the central passage (lumen 172) and has a first portion (one end of pulley 182) and a second portion spaced from the first portion (the other end of pulley 182)." *Id.* Patent Owner asserts, however, that "[s]imply extending across a gap is not enough to satisfy the more specific claim language." *Id.* at 22 (citing Ex. 2010 ¶¶ 115-16). In our claim construction of the term "branching," we reached a contrary determination. We found that "branching" means "extending." Applying this construction to Patent Owner's recognition that Gordon's pulley 82 extends across the central passage defined by lumen 172 establishes that Gordon's pulley or rigid support

meets the requirements for the claimed "branching" of the rigid support from sidewalls of the anchor body.

Second, Patent Owner asserts that Gordon's pulley 182 does not, in fact, support any load placed on it by the suture. PO Resp. 24. According to Patent Owner, after Gordon's anchor is installed, locking plug 176 clamps and frictionally locks the suture strand in place. *Id.* Patent Owner asserts that this results in the portion of suture that is looped around pulley 182 being isolated from any load on the suture. *Id.* We disagree. Pulley 182 is *not* isolated from *any* load on the suture.

Based on the clear disclosure in Gordon, discussed above, the suture in Gordon is placed under tension in order to approximate the tension existing when a tendon is connected to the adjacent bone, and this tension is maintained on the pulley. Ex. 1105 ¶¶74-75; see also *id.* ¶87 (describing that in the configuration in which suture strand 198 has been positioned around pulley 182, "the suture may be tensioned as previously described to approximate the soft tissues to be repaired to the bone or other tissues."). Thus, the pulley clearly is able to support this load.

We defined "rigid support" to mean an inflexible part of the suture anchor that supports a tissue securing suture. We also explained that by including the phrase "tissue securing," the adopted construction recognizes the fundamental purpose of the disclosed and claimed invention is to mechanically reattach soft tissue to its supporting bone. Thus, the support provided to the suture is support sufficient for that suture to secure tissue to bone. This is the tension or load applied to pulley 182 in Gordon—a load that approximates the load sufficient to secure tissue to bone.

The experts disagree as to whether Gordon's pulley does, or does not, provide support sufficient for the suture to secure tissue to bone.

Petitioner's expert, Mr. Ritchart testified that Gordon's pulley "is inflexible *in order to keep a suture in a fixed position* and to withstand the *cyclical* loads placed upon the pulley after the anchor has been installed in a patient. He concluded that pulley 182 is thus a "'rigid support' under the BRI." Ex. 1103 ¶187 (emphasis added). We note that the claims do not recite any requirement that the rigid support is the structure that keeps a suture in a *fixed* position or that the rigid support withstand *cyclical* loads.

Patent Owner's expert, Dr. Gall, is of the opinion that "[t]he pulley 182 in Gordon is *not intended to bear any load* from the suture to secure the suture and soft tissue after the locking plug has been installed." Ex. 2010 ¶159 (emphasis added). Dr. Gall explains that "[t]his is the result of the locking plug 176 clamping and frictionally locking the suture against the inside of the anchor body in a position between the pulley and the tissue that is being secured by the suture." *Id.* (citing Ex. 1105, ¶87). Dr. Gall concludes that "pulley 182 is not a 'rigid support.'" *Id.*

As explained above, Gordon discloses that the suture looping around pulley 182 is placed and maintained in tension to approximate the load between the tissue and bone. Thus, it is not accurate to state that pulley 182 in Gordon does not bear any load.

Thus, we agree with Petitioner that Gordon discloses a rigid support as claimed.

c. *Integral (Claim 11)*

Claim 11 recites "a rigid support integral with the anchor body to define a single-piece component." We

construed this to mean a rigid support formed together with the anchor body as a unitary structure.

Patent Owner asserts that pulley 182 in Gordon is a separate piece attached to anchor body 170 and, therefore, is not integral with the anchor body to define a single-piece component. PO Resp. 36. Petitioner relies on West's disclosure that West's "anchor body 12 and posts 23 can be cast and formed in a die." Pet. 42-43 (citing Ex. 1106, 7:41-43; Ex. 1103, ¶¶205-10).

As stated above, West states clearly that "[i]n manufacturing bone anchor 10, in accordance with the present invention, 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." This presents two clear alternatives—form anchor body 12 and posts 23 together, *i.e.*, as an integral component, or, alternatively, create them as separate components and insert the posts after the body is formed. Forming them integrally is consistent with the disclosure in Foerster, incorporated into Gordon, that the suture pulley may be "*formed in*" a sidewall of the lumen. Ex. 1108 ¶24 (emphasis added).

Thus, we determine that West suggests that pulley 182 of Gordon can be formed integral with the suture anchor body, as recited in claim 11.

d. *Rationale*

Petitioner asserts that it would have been obvious to a person of ordinary skill to modify Gordon's suture anchor 168 to replace the external hex drive head 186 of Gordon with an internal hex drive socket, as taught by West. Pet. 28 (citing Ex. 1103 ¶¶162-71). The reason why this change would be made, according to Petitioner, is because it would allow Gordon's screw threads 174 to ex-

tend all the way to the proximal end of anchor body 170 and thus provide the bone anchor with the ability to better engage the cortical bone. *Id.* (citing Ex. 1106, 2:65-67). As we discussed above, West discloses the benefits of having a proximal end socket. See Ex. 1106, 1:50-64.

West also discloses the option of forming the rigid support, that is the pulley in Gordon or pins in West, integral with the body, or inserting the pins in the body after the body is formed. Choosing the preferred option would have been an obvious choice of the designer.

Patent Owner asserts that "the legally required rationale for the combination is missing." PO Resp. 21. According to Patent Owner, the proposed modification would interfere with Gordon's intended operation and result; there is no reasonable expectation of success; and there is no benefit to making the modification. *Id.* This assertion is based, in part, on Patent Owner's argument that Gordon is intended to be secured in the cancellous bone, not cortical bone. This argument is not persuasive for reasons we have addressed above.

Patent Owner also argues that Gordon could not function if modified as proposed. *Id.* at 26-34. As we stated above, whether a claimed invention would have been obvious is based on what the combined teachings of the references would have suggested to those of ordinary skill in the art. *MCM Portfolio*, 812 F.3d at 1294. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. *Id.* Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *Id.* Moreover, a person of ordinary skill and creativity would rec-

ognize that familiar items may have obvious uses beyond their primary purposes, *KSR*, 550 U.S. at 420.

We recognize that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. *Id.* at 418-419; see also *Metalcraft of Mayville, Inc.* v. *The Toro Company*, 848 F.3d 1358, 1367 (Fed. Cir. 2017) (holding it is not enough "to merely demonstrate that elements of the claimed invention were independently known in the prior art. Often, every element of a claimed invention can be found in the prior art."). For this reason, it is necessary to identify "why" a person of ordinary skill would have selectively gleaned some elements or structure from the references relied on to come up with the limitations in the challenged claims. *Metalcraft* v. *Toro*, at 1366 ("In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination.").

Here, as discussed above, West provides a persuasive rationale for "why" the proposed features would have been combined.

Before determining patentability under Section 103, we consider the objective evidence presented by Patent Owner.

e. *Objective Evidence*

Patent Owner asserts that "secondary considerations" establish that the claims 10 and 11 would not have been obvious. PO Resp. 65-69.

Objective indicia of non-obviousness play an important role as a guard against the statutorily proscribed hindsight reasoning in the obviousness analysis. *WBIP, LLC* v. *Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). "[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record." *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). "[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Id.* at 1538. "For objective evidence . . . to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (quoting *Wyers* v. *Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010)) (emphasis omitted) (internal quotation marks omitted).

Patent Owner offers evidence it asserts shows objective evidence of non-obviousness in the form of copying by competitors (PO Resp. 65-68), licensing (*id.* at 68-69), and commercial success (*id.* at 69).

(1) *Copying*

Patent Owner asserts seven competitors introduced suture anchors having the combination of features in the challenged claims after Patent Owner began selling its patented anchors: PO Resp. 65. To support its assertion, Patent Owner provides a chart comparing a figure from the '541 patent to pictures of alleged "copied designs." *Id.* at 66-67 (citing Ex. 2014). Exhibit 2014 is a claim chart comparing the alleged products that copied the '541

patented invention to claims 10 and 11. There is no identification of the source of this chart or the authenticity of the products identified on the chart.

Patent Owner states that each of the copied designs includes first, second, and third suture openings, threads to a proximal end, and a rigid support integral with the anchor body. *Id.* at 67 (citing "Gall ¶ __." [sic]). Patent Owner also states there is a nexus (*id.*) but provides no evidence to support this argument. *Garrido* v. *Holt*, 547 F. App'x 974, 979 n.3 (Fed. Cir. 2013) (citing *In re Schulze*, 346 F.2d 600, 602 (CCPA 1965) ("Argument in the brief does not take the place of evidence in the record.")).

Moreover, for copying to be effective in showing non-obviousness, there must be more than simply a competing version of the product. *Iron Grip Barbell Co.* v. *USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Not every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent."). Evidence of copying can be particularly persuasive when a competitor had tried and failed to introduce a competing product until the patented product became available. *Vandenberg* v. *Dairy Equipment Co., a Div. of DEC Int'l, Inc.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984). We have no such evidence in this case.

Merely offering competing products or alleging infringement are not signs of non-obviousness. *Wyers*, 616 F.3d at 1246. The secondary consideration of copying is very specific—"evidence of efforts to replicate a specific product." *Id.* This specifically is not evidence of efforts to provide a competing product or evidence of a product having the same features, or we would be reading out the crux of the basis for the court's reasoning in *Wyers*, that

"[n]ot every competing product that arguably falls within the scope of a patent is evidence of copying." *Id.* Patent Owner's timeline of when competing products were introduced (PO Resp. 68) is not persuasive evidence of copying because the timeline does not indicate that the later introduced competing products were intended to replicate the subject matter of the '541 patent. Indeed, the timeline could just as readily support the notion that the competing products were intended to replicate features from Gordon (see Ex. 1105, Fig. 23) or other suture anchors (see Ex. 1103 ¶¶39-43 (illustrating and discussing numerous prior suture anchor designs)).

Here, we have no evidence of a nexus or of efforts to replicate a specific product. Thus, the evidence on which Patent Owner relies has no probative weight of copying.

(2) *Licensing*

Patent Owner argues we should "infer" from the fact that one license to Parcus Medical has been granted under the '541 patent that the one license "was taken based on the merits of the claimed invention." PO Resp. 68. Again, Patent Owner provides no evidence to support this argued inference. Petitioner states Parcus's CEO testified that the license was executed to resolve litigation and "ninety-five percent" of the motivation was to avoid legal fees. Pet. Reply 31 (citing Ex. 1169).

Here, we have no evidence of a nexus of the one license to claims 10 and 11 of the '541 patent. Thus, the evidence on which Patent Owner relies has no probative weight of copying.

(3) *Commercial Success*

Patent Owner asserts the "'541 Anchors" were commercially successful. PO Resp. 69 (citing Ex. 2029 and "Ex. 2025, ¶#-#." [sic]). Exhibit 2029 is a Declaration of

Christopher Holter, Patent Owner's Senior Director of Commercial Finance that reports quarterly sales data for certain product codes. No market share information is included, and there is no illustration or description of the products. Exhibit 2025 is a Declaration of Christopher Vellturo, a consultant retained by Patent Owner to "provide summaries and charts of sales data (as provided to [him] by Arthrex) for Arthrex suture anchor products made under U.S. Patent No. 8,821,541 (Claims 10 and 11)." Ex. 2025 ¶2. The graph and chart in Mr. Vellturo's declaration list the products that he "understand[s] . . . practice the '541 patent," but there is no depiction or description of those products, nor is there any analysis or explanation of why those products embody claims 10 or 11 of the '541 patent. *Id.* at 17-18. The only "[s]ource" listed for Mr. Vellturo's chart and graph is "Holter Declaration, Exhibit 1." *Id.*

Patent Owner also asserts "a nexus should be presumed because each of the '541 Anchors at issue are coextensive with at least one of claims 10 and 11." PO Resp. 69. But Patent Owner does not point us to evidence or explanation supporting its contention that the anchors embody claim 10 or 11 of the '541 patent. We have not been directed to persuasive evidence of any nexus between the Patent Owner's sales and the patented invention. Accordingly, the evidence of commercial success has no probative weight.

4. *Conclusion Regarding Patentability of Claims 10 and 11 Based on Gordon and West*

Based on the evidence and analysis above, we determine that a preponderance of the evidence establishes that claims 10 and 11 would have been obvious based on Gordon and West.

C. Anticipation by Curtis (Claim 11)

Petitioner asserts that claim 11 is anticipated by Curtis. Pet. 43-52.

> [U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Net MoneyIN, Inc. v. *VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008); see also *Verdegaal Bros.* v. *Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson* v. *Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

1. *Curtis (Ex. 1107)*

Curtis is titled "Expanding Suture Anchor." Ex. 1107. Figures 2 and 3 (annotated) from Curtis are shown below.

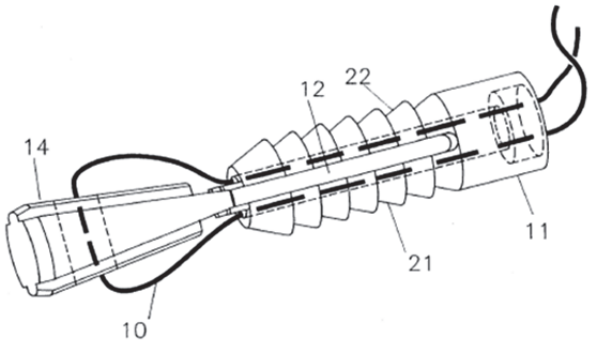


Figure 2 from Curtis is a perspective view of an expanding suture anchor after introduction of the suture.

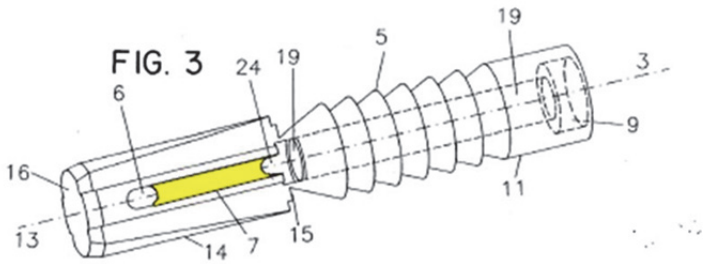


Figure 3 (annotated) from Curtis is a perspective view of the expanding suture anchor according to Figure 1 rotated by 90°.

The disclosed suture anchor has a main body (11) and a conical body (14). *Id.* at Abstract; 2:16-17. Main body 11 is provided with protrusions 5, in the form of barbs or threads, distributed over the full length of the main body to facilitate retention of the suture anchor in cortical bone or cortical and cancellous bone. *Id.* at 2:20-23; claim 7 (4:11-12).

Main body 11 and conical body 14 may be either two distinct parts or, as shown in Figures 1 to 4, *temporarily* connected coaxially by an intermediate portion 20. Ex. 1107, 2:66-3:1. If temporarily connected, the two body parts are separated when inserted into bone. In use, as shown in Figure 5, main body 11 separates from conical body 14 at intermediate portion 20 so that conical body 14 enters slot 12, expands legs 21, 22 of main body 11, and thereby presses the protrusions or barbs into bone to thereby fix the anchor in the bone. *Id.* at 2:34-38.

Petitioner's argument is based on the one-piece configuration of the suture anchor *prior* to fixation in the bone. Pet. 44.

As shown in Figure 3, "through-hole" 6 is transverse to longitudinal axis 13 of conical body 14. Ex. 1107 2:40-

42. Through-hole 6 is intended to receive a suture strand threaded through it. *Id.*

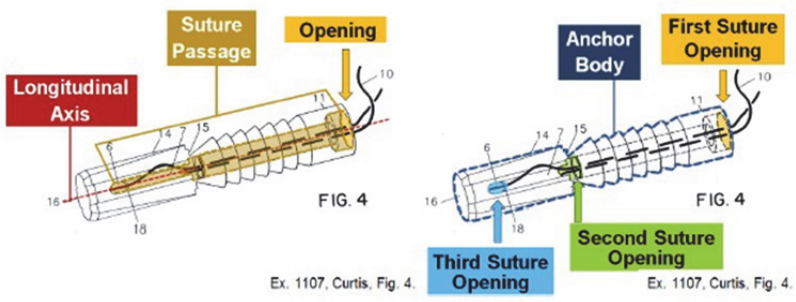
Two channels 7 are positioned on curved surface 17 of conical body 14. *Id.* at 2:47-48. Channels 7 extend from through-hole 6 to base 15. Channels 7 provide a recessed area to house suture 10 when the two bodies are assembled, as described above. Because there is a channel on opposing side of conical body 14, the inner surface of each channel defines a web or bridge, somewhat like an I-beam, between the two channels. This web or bridge is highlighted in the annotated Figure 3 above.

2. *Discussion*

Patent Owner asserts two reasons why claim 11 is not anticipated by Curtis: (1) Curtis does not have a "rigid support integral with the anchor body to define a single-piece component" as required by claim 11 (PO Resp. 45-51); and (2) Curtis discloses a "multiple piece anchor" (*id.* 51-57).

a. *Rigid Support*

Petitioner provides the following annotated versions of Figure 4 of Curtis to show most of the claimed features.



Pet. 46; see also Pet. 50-52 (providing a claim chart identifying each element in claim 11 and the corresponding structure in claim 11).

As shown by the dotted blue outline in the Figure above on the right, in its assembled state, Petitioner regards the anchor body as a single element. This single element has a first part 11 and a second part 14 that are connected temporarily, as described above.

The structure Petitioner identifies as the "rigid support" in claim 11 is the web or bridge discussed above and shown in the annotated Figure 3 above. Pet. 44 (suture "loop[s] around the member between channels 7"); *id.* at 48 ("Curtis discloses the rigid support (i.e., the member between channels 7)"). Petitioner also provides the following annotated Figure 4 from Curtis identifying the rigid support.

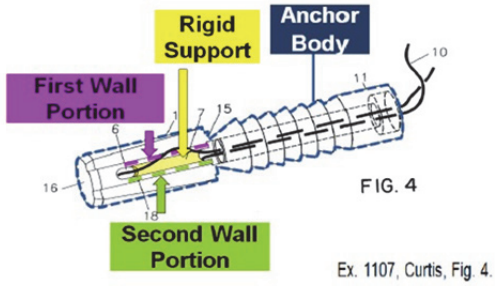


Figure 4 from Curtis annotated by Petitioner.

Id. at 48. As shown in annotated Figure 3 above and also in Petitioner's annotated Figure 4, the web or bridge also extends from the walls of conical body 14. Petitioner also relies on the testimony of Mr. Ritchart, which supports Petitioner's argument. *Id.* (citing Ex. 1103 ¶¶230-233).

At the hearing, Petitioner's Counsel stated: "If we take a look at Slide 10, the petition demonstrates this rigid support is met in Curtis by the portion of the conical body, 14, through which the suture is threaded and disposed. That's highlighted in yellow in the petition as

reproduced here on Slide 10." Tr. 5:19-23. Slide 10 contained a reproduction of page 48 of the Petition and the Figure reproduced above showing the rigid support highlighted in yellow. Ex. 1178, slide 10.

Patent Owner argues that Curtis does not have a rigid support integral with the anchor body to define a single-piece component. PO Resp. 47. According to Patent Owner, "Curtis' anchor is flexible in a way that leaves it unable to satisfy the rigid support claim language." *Id.* Patent Owner reaches this conclusion based on the assertion that "the Curtis anchor's intermediate portion 20 'breaks away' in response to a 'certain pulling force to the suture 10.'" *Id.* Patent Owner does not persuasively refute Petitioner's position, which is that the web or bridge material defined by channels 7 corresponds to the claimed "rigid support." Petitioner makes clear that intermediate portion 20 in Curtis is not part of the "rigid support" in Curtis. Pet. Reply 27 (citing Ex. 1165 ¶¶233-234).

We are persuaded by the evidence that the web or bridge material between the channels 7 is a rigid support integral with the conical body to define a single-piece component.

b. *Multiple Piece Anchor*

Patent Owner argues that Curtis is a multiple piece anchor, not a single piece anchor. PO Resp. 51. This argument is related to the requirement that the "rigid support" be integral with the side wall of the anchor body.

Patent Owner asserts, correctly, that the Curtis anchor is "assembled" into the two piece condition shown in Figure 5 when inserted into bone for supporting suture to hold tissue in a desired position." *Id.* at 47. Patent Owner's logic appears to be that if the anchor body is in two pieces, the rigid support in conical body 14 cannot be

integral with the entire body. Patent Owner relies on the testimony of Dr. Gall for support. PO Resp. 51 (citing Ex. 2010 ¶¶200-204. Dr. Gall's testimony is that because main body 11 and conical body 14 are only temporarily connected, that means that the web or bridge material defined by channels 7 cannot be a rigid support integral with the anchor body, as recited in claim 11. Ex. 2010 ¶201. His opinion is that "'[t]emporary connections' and 'breaking' do not dictate the two components are integrally formed." *Id.*

Petitioner's position, however, is that the structure that anticipates claim 11 is the one-piece suture anchor that exists prior to being inserted in the bone. Pet. 44. The web or bridge material in Curtis is always integral with conical body 14. When conical body 14 and main body 11 are connected, they form a single body unit. The web or bridge material is integral with this single body unit.

Patent Owner has not directed us to any persuasive argument or evidence that establishes that the broadest reasonable interpretation of claim 11 is limited to an installed suture anchor. We recognize that there are differences, when installed in a bone, between Curtis and the claimed invention. When manufactured, however, and prior to installation, the one-piece configuration shown in Figures 1-4 of Curtis is a "suture anchor assembly" that has a rigid support integral with the suture body, as recited in claim 11. There is no persuasive evidence that a temporary attachment of the two Curtis body parts precludes the rigid support from being "integral with the anchor body."

Thus, we conclude that a preponderance of the evidence establishes that Curtis anticipates claim 11.

D. Curtis, Overaker, and DiPoto (Claim 10)

Claim 10 recites both a "helical thread" and a "driver."

Petitioner asserts that claim 10 would have been obvious based on Curtis, Overaker, and DiPoto. Pet. 53-60.

First we consider the scope and content of the prior art. Curtis has been discussed above.

1. *Overaker (Ex. 1124)*

Overaker describes an expandable suture anchor similar to that of Curtis. Pet. 53-54 (citing Ex. 1103 ¶¶155-57). As shown in Figure 1, outer wall surface 32 of sheath 8 includes a plurality of engagement ribs 46. Ex. 1124 ¶20. Each rib 46 has an engagement edge 48 for engaging the bone tissue within a bone hole opening in which the bone anchoring device 10 is deployed, as shown in Figure 3. *Id.* As shown in Figure 1, ribs 46 are circumferentially aligned, as well as being transversely aligned relative to slot 44. *Id.* Alternatively, Overaker discloses that "*ribs 46 could have a helical configuration*." *Id.* (emphasis added).

2. *DiPoto (Ex. 1125)*

DiPoto discloses driver 80 used to position a suture anchor in place within a bone. Ex. 1125, 6:17-23; Fig. 9. Driver 80 engages the suture anchor and has a handle and shaft 84 that are cannulated to allow ends of suture 16 to pass through it and be held temporarily on fixation post 86. *Id.*

After the hole in the bone or tissue is formed by drilling, anchor 16 is "snapped" into position on the end of the shaft of the driver. *Id.* at 6:5-16. The anchor and driver assembly is moved into position by the surgeon. *Id.* The anchor is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet

or the like. *Id.* "It is not necessary to rotate the assembly in order to install it in position." *Id.* at 6:14-16.

3. *Differences Between the Claimed Subject Matter and the Prior Art*

Petitioner acknowledges that Curtis does not disclose helical threads, as recited in claim 10. Pet. 53 ("Curtis does not, however, identify what types of protrusions 5 can be employed over its full length."). Curtis also discloses the use of a "manipulation instrument" for installing the suture anchor, but does not provide details about its use or structure.

Overaker discloses that helical threads are an option for use on an expansion-type suture anchor.

DiPoto discloses a "manipulation instrument," a driver, for installing a suture anchor without rotary motion.

4. *Discussion*

Petitioner asserts that Curtis does not disclose the claimed helical threads of claim 10, but that Overaker does. Pet. 53-54. Petitioner asserts modifying Curtis's barbs to be helical as shown in Overaker would have been a known substitution and option available to a suture anchor designer, and that using this option provides the predictable result of retaining the anchor in bone. *Id.* at 54-55.

Petitioner also asserts that a person of ordinary skill would have been motivated to use the driver of DiPoto as the "manipulation instrument" disclosed in Curtis. This known option allows a surgeon to accurately place Curtis's suture anchor within a bone cavity. *Id.* DiPoto's driver is fully consistent with Curtis and Overaker because all three suture anchors are push-in type anchors; they are not rotated into engagement. DiPoto discloses specifically that it is *not* necessary to rotate the suture

anchor assembly using the DiPoto driver in order to install the suture anchor in position." Ex. 1125, 6:14-16.

Patent Owner argues that Petitioners' proposed combination of Curtis, Overaker, and DiPoto (1) does not have the required helical thread at the proximal end of the anchor body; (2) does not provide a workable result so it cannot be made, (3) does not yield a predictable result, and (4) there is no reason for the proposed combination. PO Resp. 57.

Regarding the helical thread at the proximal end limitation in claim 10, Petitioner asserts that Patent Owner ignores Curtis's explicit statements that protrusions 5 are "distributed over the full length of the main body" (Ex. 1107, 2:20-23) and retain the "anchor in cortical bone," (*id.*), both of which require protrusions at the proximal end. Pet. Reply 28 (citing Ex. 1165 ¶¶240-243), Ex. 1103 ¶¶256-257. Notwithstanding the illustrations in Curtis, the disclosure clearly suggests to a person of ordinary skill to use protrusions over the "full length" of the suture body.

It is also beyond reasonable dispute that Overaker discloses the use of helical threads to retain an expansion-type suture anchor. Ex. 1124 ¶20 ("Alternatively, the ribs 46 could have a helical configuration.").

Helical threads over the full length of the suture anchor body are a known design option. It would have been obvious to a person of ordinary skill and creativity to choose the preferred option for the task at hand. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. There is no persuasive evidence that the proposed changes in

Curtis exceed the skill level of our highly skilled person of ordinary skill.

Patent Owner speculates, without citation of evidence, that using a threaded engagement in Curtis "*could* interfere with the ability of the legs to splay, thereby interfering with the intended operation of the anchor." PO Resp. 61 (emphasis added). Patent Owner relies on the testimony of Dr. Gall. *Id.* at 61-62 (citing Ex. 2010 ¶¶220-221). Dr. Gall merely repeats Petitioner's argument without any additional facts or data on which the opinion is based. Thus, it is entitled to little if any probative weight. 37 C.F.R. 42.65(a). There is no persuasive evidence that the proposed helical thread would interfere with the ability of legs in Curtis to splay into engagement with adjacent bone any more so than the existing protrusions 5 disclosed in Curtis.

Patent Owner also argues that there is no reason for the proposed modifications. The references themselves suggest design options available to a person of ordinary skill. There is no persuasive evidence that use of known helical threads and drivers, as broadly recited in claim 10, is beyond the skill and creativity of a person with degrees in engineering or medicine, and also having experience designing suture anchors.

Patent Owner argues that there is no reason to use the driver from DiPoto with the anchor in Curtis because Curtis is a "push-in style anchor." PO Resp. 63. The driver in DiPoto is disclosed specifically for use with push-in style anchors. Ex. 1125 6:12-16 ("The anchor 16 is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet or the like. It is not necessary to rotate the assembly in order to install it in position.").

5. *Secondary Considerations*

Our analysis above in Section II.B.3.e. applies equally to this asserted ground of patentability.

6. *Conclusion Regarding Patentability of Claim 10 Based on Curtis, Overaker, and DiPoto*

Based on the evidence and analysis above, we determine that a preponderance of the evidence establishes that claim 10 would have been obvious based on Curtis, Overaker, and DiPoto.

III. PATENT OWNER'S MOTION TO EXCLUDE CERTAIN EVIDENCE

Patent Owner moves to exclude Paragraph 119 of Dr. Slocum's Declaration, Ex. 1165, because Dr. Slocum failed to produce test data inconsistent with his opinion. Mot. Excl. 1. Patent Owner also moves to exclude Exhibit 1170 and corresponding ¶100 of Dr. Slocum's declaration under FRE 401, 402 and 901. *Id.* at 3. Exhibit 1170 is a website relied on by Dr. Slocum.

We deny the Motion as moot. We have not relied on or cited the evidence Patent Owner seeks to exclude. Moreover, the Board acts as both the gatekeeper of evidence and as the weigher of evidence. Rather than excluding evidence that is allegedly confusing, misleading, and/or irrelevant, we will simply not rely on it or give it little weight, as appropriate, in our analysis. Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well positioned to determine and assign appropriate weight to evidence presented, including giving it no weight. See, *e.g.*, *Donnelly Garment Co.* v. *NLRB*, 123 F.2d 215, 224 (8th Cir. 1941) ("One who is capable of ruling accurately upon the admissibility of evidence is equally capable of sifting it accurately after it has been received . . . .").

Thus, in this *inter partes* review, the better course is to have a complete record of the evidence to facilitate public access as well as appellate review.

IV. ORDER

In view of the foregoing, it is hereby:

ORDERED that claims 10 and 11 of the '541 patent have been shown by a preponderance of the evidence to be unpatentable on the basis they would have been obvious under 35 U.S.C. § 103 in view of Gordon and West;

FURTHER ORDERED that claim 11 of the '541 patent has been shown by a preponderance of the evidence to be unpatentable on the basis that it is anticipated under 35 U.S.C. § 102 by Curtis;

FURTHER ORDERED that claim 10 of the '541 patent has been shown by a preponderance of the evidence to be unpatentable on the basis it would have been obvious under 35 U.S.C. § 103 in view of Curtis, Overaker, and DiPoto;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot; and

FURTHER ORDERED that this is a Final Written Decision under 35 U.S.C. § 318(a), and that parties to the proceeding seeking judicial review of the decision under 35 U.S.C. § 319 must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Richard F. Giunta
Michael N. Rader
Randy J. Pritzker
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APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NO. 2018-1584

ARTHREX, INC.,
Appellant,

v.

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

UNITED STATES,
Intervenor.

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

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

November 8, 2019

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM.

ORDER

Appellant Arthrex, Inc. filed a combined petition for panel rehearing and rehearing en banc. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on November 15, 2019.

FOR THE COURT

November 8, 2019	/s/ Peter R. Marksteiner
Date	Peter R. Marksteiner
	Clerk of Court

APPENDIX D

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

1. The United States Constitution provides in relevant part as follows:

Article II, § 2

* * * * *

[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

* * * * *

Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

2. Title 35 of the United States Code provides in relevant part as follows:

§ 3. Officers and employees

* * * * *

(c) CONTINUED APPLICABILITY OF TITLE 5.—Officers and employees of the Office shall be subject to the provisions of title 5, relating to Federal employees.

* * * * *

§ 6. Patent Trial and Appeal Board

(a) IN GENERAL.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

(b) DUTIES.—The Patent Trial and Appeal Board shall—

(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a);

(2) review appeals of reexaminations pursuant to section 134(b);

(3) conduct derivation proceedings pursuant to section 135; and

(4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.

(c) 3-MEMBER PANELS.—Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.

(d) TREATMENT OF PRIOR APPOINTMENTS.—The Secretary of Commerce may, in the Secretary's discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge. It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge's having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.

§ 101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

§ 102. Conditions for patentability; novelty

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

* * * * *

§ 111. Application

(a) IN GENERAL.—

(1) WRITTEN APPLICATION.—An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Director.

(2) CONTENTS.—Such application shall include—

(A) a specification as prescribed by section 112;

(B) a drawing as prescribed by section 113; and

(C) an oath or declaration as prescribed by section 115.

* * * * *

§ 112. Specification

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and dis-

tinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

(c) FORM.—A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

(e) REFERENCE IN MULTIPLE DEPENDENT FORM.—A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

§ 122. Confidential status of applications; publication of patent applications

(a) CONFIDENTIALITY.—Except as provided in subsection (b), applications for patents shall be kept in confidence by the Patent and Trademark Office and no infor-

mation concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of an Act of Congress or in such special circumstances as may be determined by the Director.

(b) PUBLICATION.—

(1) IN GENERAL.—(A) Subject to paragraph (2), each application for a patent shall be published, in accordance with procedures determined by the Director, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title. At the request of the applicant, an application may be published earlier than the end of such 18-month period.

(B) No information concerning published patent applications shall be made available to the public except as the Director determines.

(C) Notwithstanding any other provision of law, a determination by the Director to release or not to release information concerning a published patent application shall be final and nonreviewable.

(2) EXCEPTIONS.—(A) An application shall not be published if that application is—

(i) no longer pending;

(ii) subject to a secrecy order under section 181;

(iii) a provisional application filed under section 111(b); or

(iv) an application for a design patent filed under chapter 16.

(B)(i) If an applicant makes a request upon filing, certifying that the invention disclosed in the application has not and will not be the subject of an application filed in another country, or under

a multilateral international agreement, that requires publication of applications 18 months after filing, the application shall not be published as provided in paragraph (1).

(ii) An applicant may rescind a request made under clause (i) at any time.

(iii) An applicant who has made a request under clause (i) but who subsequently files, in a foreign country or under a multilateral international agreement specified in clause (i), an application directed to the invention disclosed in the application filed in the Patent and Trademark Office, shall notify the Director of such filing not later than 45 days after the date of the filing of such foreign or international application. A failure of the applicant to provide such notice within the prescribed period shall result in the application being regarded as abandoned.

(iv) If an applicant rescinds a request made under clause (i) or notifies the Director that an application was filed in a foreign country or under a multilateral international agreement specified in clause (i), the application shall be published in accordance with the provisions of paragraph (1) on or as soon as is practical after the date that is specified in clause (i).

(v) If an applicant has filed applications in one or more foreign countries, directly or through a multilateral international agreement, and such foreign filed applications corresponding to an application filed in the Patent and Trademark Office or the description of the invention in such foreign filed applications is less extensive than the application or description of the invention in

the application filed in the Patent and Trademark Office, the applicant may submit a redacted copy of the application filed in the Patent and Trademark Office eliminating any part or description of the invention in such application that is not also contained in any of the corresponding applications filed in a foreign country. The Director may only publish the redacted copy of the application unless the redacted copy of the application is not received within 16 months after the earliest effective filing date for which a benefit is sought under this title. The provisions of section 154(d) shall not apply to a claim if the description of the invention published in the redacted application filed under this clause with respect to the claim does not enable a person skilled in the art to make and use the subject matter of the claim.

* * * * *

§ 154. Contents and term of patent; provisional rights

(a) IN GENERAL.—

(1) CONTENTS.—Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) TERM.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, 365(c), or 386(c) from the date on which the earliest such application was filed.

* * * * *

(b) ADJUSTMENT OF PATENT TERM.—

(1) PATENT TERM GUARANTEES.—

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—

(I) the date on which an application was filed under section 111(a); or

(II) the date of commencement of the national stage under section 371 in an international application;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Patent Trial and Appeal Board under section 134 or 135 or a

decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied,

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark

Office requested by the applicant except as permitted by paragraph (3)(C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OF ADJUSTMENTS FOR DELAYS DUE TO DERIVATION PROCEEDINGS, SECRECY ORDERS, AND APPEALS.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135(a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Patent Trial and Appeal Board or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability,

the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

* * * * *

(d) PROVISIONAL RIGHTS—

(1) IN GENERAL.—In addition to other rights provided by this section, a patent shall include the right to obtain a reasonable royalty from any person who, during the period beginning on the date of publication of the application for such patent under section 122(b), or in the case of an international application filed under the treaty defined in section 351(a) designating the United States under Article 21(2)(a) of such treaty or an international design application filed under the

treaty defined in section 381(a)(1) designating the United States under Article 5 of such treaty, the date of publication of the application, and ending on the date the patent is issued—

(A)(i) makes, uses, offers for sale, or sells in the United States the invention as claimed in the published patent application or imports such an invention into the United States; or

(ii) if the invention as claimed in the published patent application is a process, uses, offers for sale, or sells in the United States or imports into the United States products made by that process as claimed in the published patent application; and

(B) had actual notice of the published patent application and, in a case in which the right arising under this paragraph is based upon an international application designating the United States that is published in a language other than English, had a translation of the international application into the English language.

* * * * *

§ 183. Right to compensation

An applicant, his successors, assigns, or legal representatives, whose patent is withheld as herein provided, shall have the right, beginning at the date the applicant is notified that, except for such order, his application is otherwise in condition for allowance, or February 1, 1952, whichever is later, and ending six years after a patent is issued thereon, to apply to the head of any department or agency who caused the order to be issued for compensation for the damage caused by the order of secrecy and/or for the use of the invention by the Government, resulting from his disclosure. The right to compensation for use

shall begin on the date of the first use of the invention by the Government. The head of the department or agency is authorized, upon the presentation of a claim, to enter into an agreement with the applicant, his successors, assigns, or legal representatives, in full settlement for the damage and/or use. This settlement agreement shall be conclusive for all purposes notwithstanding any other provision of law to the contrary. If full settlement of the claim cannot be effected, the head of the department or agency may award and pay to such applicant, his successors, assigns, or legal representatives, a sum not exceeding 75 per centum of the sum which the head of the department or agency considers just compensation for the damage and/or use. A claimant may bring suit against the United States in the United States Court of Federal Claims or in the District Court of the United States for the district in which such claimant is a resident for an amount which when added to the award shall constitute just compensation for the damage and/or use of the invention by the Government. The owner of any patent issued upon an application that was subject to a secrecy order issued pursuant to section 181, who did not apply for compensation as above provided, shall have the right, after the date of issuance of such patent, to bring suit in the United States Court of Federal Claims for just compensation for the damage caused by reason of the order of secrecy and/or use by the Government of the invention resulting from his disclosure. The right to compensation for use shall begin on the date of the first use of the invention by the Government. In a suit under the provisions of this section the United States may avail itself of all defenses it may plead in an action under section 1498 of title 28. This section shall not confer a right of action on anyone or his successors, assigns, or legal representatives who, while in the full-time employment or service of

the United States, discovered, invented, or developed the invention on which the claim is based.

§ 261. Ownership; assignment

Subject to the provisions of this title, patents shall have the attributes of personal property. The Patent and Trademark Office shall maintain a register of interests in patents and applications for patents and shall record any document related thereto upon request, and may require a fee therefor.

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

A certificate of acknowledgment under the hand and official seal of a person authorized to administer oaths within the United States, or, in a foreign country, of a diplomatic or consular officer of the United States or an officer authorized to administer oaths whose authority is proved by a certificate of a diplomatic or consular officer of the United States, or apostille of an official designated by a foreign country which, by treaty or convention, accords like effect to apostilles of designated officials in the United States, shall be prima facie evidence of the execution of an assignment, grant or conveyance of a patent or application for patent.

An interest that constitutes an assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage.

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * * * *

§ 301. Citation of prior art and written statements

(a) IN GENERAL.—Any person at any time may cite to the Office in writing—

(1) prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent; or

(2) statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.

(b) OFFICIAL FILE.—If the person citing prior art or written statements pursuant to subsection (a) explains in writing the pertinence and manner of applying the prior art or written statements to at least 1 claim of the patent, the citation of the prior art or written statements and the explanation thereof shall become a part of the official file of the patent.

(c) ADDITIONAL INFORMATION.—A party that submits a written statement pursuant to subsection (a)(2) shall include any other documents, pleadings, or evidence from the proceeding in which the statement was filed that addresses the written statement.

(d) LIMITATIONS.—A written statement submitted pursuant to subsection (a)(2), and additional information submitted pursuant to subsection (c), shall not be consid-

ered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section 304, 314, or 324. If any such written statement or additional information is subject to an applicable protective order, such statement or information shall be redacted to exclude information that is subject to that order.

(e) CONFIDENTIALITY.—Upon the written request of the person citing prior art or written statements pursuant to subsection (a), that person's identity shall be excluded from the patent file and kept confidential.

§ 302. Request for reexamination

Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301. The request must be in writing and must be accompanied by payment of a reexamination fee established by the Director pursuant to the provisions of section 41. The request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested. Unless the requesting person is the owner of the patent, the Director promptly will send a copy of the request to the owner of record of the patent.

§ 303. Determination of issue by Director

(a) Within three months following the filing of a request for reexamination under the provisions of section 302, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications dis-

covered by him or cited under the provisions of section 301 or 302. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) A record of the Director's determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent and to the person requesting reexamination, if any.

(c) A determination by the Director pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and non-appealable. Upon such a determination, the Director may refund a portion of the reexamination fee required under section 302.

§ 304. Reexamination order by Director

If, in a determination made under the provisions of subsection 303(a), the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question. The patent owner will be given a reasonable period, not less than two months from the date a copy of the determination is given or mailed to him, within which he may file a statement on such question, including any amendment to his patent and new claim or claims he may wish to propose, for consideration in the reexamination. If the patent owner files such a statement, he promptly will serve a copy of it on the person who has requested reexamination under the provisions of section 302. Within a period of two months from the date of service, that person may file and have considered in the reexamination a reply to any statement filed by the patent owner. That

person promptly will serve on the patent owner a copy of any reply filed.

§ 305. Conduct of reexamination proceedings

After the times for filing the statement and reply provided for by section 304 have expired, reexamination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133. In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter. All reexamination proceedings under this section, including any appeal to the Patent Trial and Appeal Board, will be conducted with special dispatch within the Office.

§ 306. Appeal

The patent owner involved in a reexamination proceeding under this chapter may appeal under the provisions of section 134, and may seek court review under the provisions of sections 141 to 144, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

§ 307. Certificate of patentability, unpatentability, and claim cancellation

(a) In a reexamination proceeding under this chapter, when the time for appeal has expired or any appeal proceeding has terminated, the Director will issue and publish a certificate canceling any claim of the patent finally

determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.

(b) Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.

§ 311. Inter partes review

(a) IN GENERAL.—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.

(b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

(c) FILING DEADLINE.—A petition for inter partes review shall be filed after the later of either—

(1) the date that is 9 months after the grant of a patent; or

(2) if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review.

§ 312. Petitions

(a) REQUIREMENTS OF PETITION.—A petition filed under section 311 may be considered only if—

(1) the petition is accompanied by payment of the fee established by the Director under section 311;

(2) the petition identifies all real parties in interest;

(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including—

(A) copies of patents and printed publications that the petitioner relies upon in support of the petition; and

(B) affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions;

(4) the petition provides such other information as the Director may require by regulation; and

(5) the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

(b) PUBLIC AVAILABILITY.—As soon as practicable after the receipt of a petition under section 311, the Director shall make the petition available to the public.

§ 313. Preliminary response to petition

If an inter partes review petition is filed under section 311, the patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter.

§ 314. Institution of inter partes review

(a) THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

(b) TIMING.—The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after—

(1) receiving a preliminary response to the petition under section 313; or

(2) if no such preliminary response is filed, the last date on which such response may be filed.

(c) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director's determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

(d) NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

§ 315. Relation to other proceedings or actions

(a) INFRINGER'S CIVIL ACTION.—

(1) INTER PARTES REVIEW BARRED BY CIVIL ACTION.—An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

(2) STAY OF CIVIL ACTION.—If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes review of the patent, that civil action shall be automatically stayed until either—

(A) the patent owner moves the court to lift the stay;

(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

(C) the petitioner or real party in interest moves the court to dismiss the civil action.

(3) TREATMENT OF COUNTERCLAIM.—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

(b) PATENT OWNER'S ACTION.—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the

preceding sentence shall not apply to a request for joinder under subsection (c).

(c) JOINDER.—If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

(e) ESTOPPEL.—

(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under

section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

§ 316. Conduct of inter partes review

(a) REGULATIONS.—The Director shall prescribe regulations—

(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

(3) establishing procedures for the submission of supplemental information after the petition is filed;

(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to—

(A) the deposition of witnesses submitting affidavits or declarations; and

(B) what is otherwise necessary in the interest of justice;

(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary

delay or an unnecessary increase in the cost of the proceeding;

(7) providing for protective orders governing the exchange and submission of confidential information;

(8) providing for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

(10) providing either party with the right to an oral hearing as part of the proceeding;

(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

(12) setting a time period for requesting joinder under section 315(c); and

(13) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

(b) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

(c) PATENT TRIAL AND APPEAL BOARD.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

(d) AMENDMENT OF THE PATENT.—

(1) IN GENERAL.—During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

(A) Cancel any challenged patent claim.

(B) For each challenged claim, propose a reasonable number of substitute claims.

(2) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.

(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

(e) EVIDENTIARY STANDARDS.—In an inter partes review instituted under this chapter, the petitioner shall

have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

§ 317. Settlement

(a) IN GENERAL.—An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the inter partes review is terminated with respect to a petitioner under this section, no estoppel under section 315(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner's institution of that inter partes review. If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).

(b) AGREEMENTS IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of an inter partes review under this section shall be in writing and a true copy of such agreement or understanding shall be filed in the Office before the termination of the inter partes review as between the parties. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.

§ 318. Decision of the Board

(a) FINAL WRITTEN DECISION.—If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

(b) CERTIFICATE.—If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

(c) INTERVENING RIGHTS.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

(d) DATA ON LENGTH OF REVIEW.—The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.

§ 319. Appeal

A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal.

§ 325. Relation to other proceedings or actions

* * * * *

(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

* * * * *

3. Former Title 35 of the United States Code, as in effect in 2006, provided in relevant part as follows:

§ 311. Request for inter partes reexamination

(a) IN GENERAL.—Any third-party requester at any time may file a request for inter partes reexamination by the Office of a patent on the basis of any prior art cited under the provisions of section 301.

(b) REQUIREMENTS.—The request shall—

(1) be in writing, include the identity of the real party in interest, and be accompanied by payment of an inter partes reexamination fee established by the Director under section 41; and

(2) set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested.

(c) COPY.—The Director promptly shall send a copy of the request to the owner of record of the patent.

§ 312. Determination of issue by Director

(a) REEXAMINATION.—Not later than 3 months after the filing of a request for inter partes reexamination under section 311, the Director shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) RECORD.—A record of the Director's determination under subsection (a) shall be placed in the official file of the patent, and a copy shall be promptly given or

mailed to the owner of record of the patent and to the third-party requester.

(c) FINAL DECISION.—A determination by the Director under subsection (a) shall be final and non-appealable. Upon a determination that no substantial new question of patentability has been raised, the Director may refund a portion of the inter partes reexamination fee required under section 311.

§ 313. Inter partes reexamination order by Director

If, in a determination made under section 312(a), the Director finds that a substantial new question of patentability affecting a claim of a patent is raised, the determination shall include an order for inter partes reexamination of the patent for resolution of the question. The order may be accompanied by the initial action of the Patent and Trademark Office on the merits of the inter partes reexamination conducted in accordance with section 314.

§ 314. Conduct of inter partes reexamination proceedings

(a) IN GENERAL.—Except as otherwise provided in this section, reexamination shall be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133. In any inter partes reexamination proceeding under this chapter, the patent owner shall be permitted to propose any amendment to the patent and a new claim or claims, except that no proposed amended or new claim enlarging the scope of the claims of the patent shall be permitted.

(b) RESPONSE.—(1) With the exception of the inter partes reexamination request, any document filed by either the patent owner or the third-party requester shall be served on the other party. In addition, the

Office shall send to the third-party requester a copy of any communication sent by the Office to the patent owner concerning the patent subject to the inter partes reexamination proceeding.

(2) Each time that the patent owner files a response to an action on the merits from the Patent and Trademark Office, the third-party requester shall have one opportunity to file written comments addressing issues raised by the action of the Office or the patent owner's response thereto, if those written comments are received by the Office within 30 days after the date of service of the patent owner's response.

(c) SPECIAL DISPATCH.—Unless otherwise provided by the Director for good cause, all inter partes reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, shall be conducted with special dispatch within the Office.

§ 315. Appeal

(a) PATENT OWNER.—The patent owner involved in an inter partes reexamination proceeding under this chapter—

(1) may appeal under the provisions of section 134 and may appeal under the provisions of sections 141 through 144, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent; and

(2) may be a party to any appeal taken by a third-party requester under subsection (b).

(b) THIRD-PARTY REQUESTER.—A third-party requester—

(1) may appeal under the provisions of section 134, and may appeal under the provisions of sections 141

through 144, with respect to any final decision favorable to the patentability of any original or proposed amended or new claim of the patent; and

(2) may, subject to subsection (c), be a party to any appeal taken by the patent owner under the provisions of section 134 or sections 141 through 144.

(c) CIVIL ACTION.—A third-party requester whose request for an inter partes reexamination results in an order under section 313 is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the inter partes reexamination proceedings. This subsection does not prevent the assertion of invalidity based on newly discovered prior art unavailable to the third-party requester and the Patent and Trademark Office at the time of the inter partes reexamination proceedings.

§ 316. Certificate of patentability, unpatentability, and claim cancellation

(a) IN GENERAL.—In an inter partes reexamination proceeding under this chapter, when the time for appeal has expired or any appeal proceeding has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.

(b) AMENDED OR NEW CLAIM.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes re-

examination proceeding shall have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, prior to issuance of a certificate under the provisions of subsection (a) of this section.

4. Title 5 of the United States Code provides in relevant part as follows:

§ 7513. Cause and procedure

(a) Under regulations prescribed by the Office of Personnel Management, an agency may take an action covered by this subchapter against an employee only for such cause as will promote the efficiency of the service.

* * * * *

5. Pub. L. No. 96-517, 94 Stat. 3015 (1980), provides in uncodified relevant part as follows:

SEC. 8.

* * * * *

(b) Section 1 of this Act will take effect on the first day of the seventh month beginning after its enactment and will apply to patents in force as of that date or issued thereafter.

* * * * *

6. The Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, §§ 4601 *et seq.*, 113 Stat. 1501A-567, provides in uncodified relevant part as follows:

SEC. 4608. Effective Date.

(a) IN GENERAL—Subject to subsection (b), this subtitle and the amendments made by this subtitle shall take effect on the date of the enactment of this Act and shall apply to any patent that issues from an original application filed in the United States on or after that date.

* * * * *

7. The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), provides in uncodified relevant part as follows:

SEC. 3. First Inventor To File.

* * * * *

(n) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

* * * * *

SEC. 6. Post-Grant Review Proceedings.

(a) INTER PARTES REVIEW.—Chapter 31 of title 35, United States Code, is amended to read as follows:

* * * * *

(c) REGULATIONS AND EFFECTIVE DATE.—

* * * * *

(2) APPLICABILITY.—

(A) IN GENERAL.—The amendments made by subsection (a) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

* * * * *

(d) POST-GRANT REVIEW.—Part III of title 35, United States Code, is amended by adding at the end the following:

* * * * *

(f) REGULATIONS AND EFFECTIVE DATE.—

* * * * *

(2) APPLICABILITY.—

(A) IN GENERAL.—The amendments made by subsection (d) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and, except as provided in section 18 and in paragraph (3), shall apply only to patents described in section 3(n)(1).

* * * * *