

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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STRYKER CORPORATION AND HOWMEDICA OSTEONICS CORP.,  
Petitioner,

v.

KFX MEDICAL, LLC,  
Patent Owner.

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Case IPR2019-00817  
Patent 7,585,311 B2

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Before JOSIAH C. COCKS, MICHAEL L. WOODS, and  
SEAN P. O'HANLON, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review  
*37 C.F.R. § 42.108*

## I. INTRODUCTION

Stryker Corporation and Howmedica Osteonics Corp., (collectively, “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–3, 5–12, 14, 15, 21–26, and 28–30 of U.S. Patent No. 7,585,311 B2 (“the ’311 patent”). Pet. 3. KFx Medical, LLC (“Patent Owner”), filed a Preliminary Response (Paper 8, “Prelim. Resp.”) to the Petition, contending that the Petition should be denied as to all challenged claims. Prelim. Resp. 1–3.

We have authority under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition “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.” Having considered the arguments and the evidence presented, for the reasons described below, we do not institute an *inter partes* review of any challenged claim.

### A. Related Proceedings

Petitioner represents that Patent Owner filed a lawsuit against Petitioner alleging infringement of the ’311 patent and of related U.S. Patent No. 8,951,287 (“the ’287 patent”). Pet. 1 (citing *KFx Med., LLC v. Stryker Corp.*, C.A. No. 18-1799 (S.D. Cal.)).

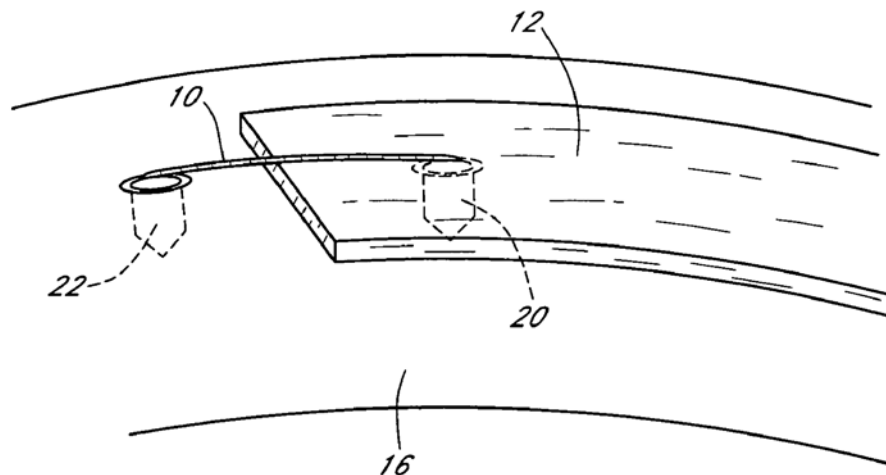
Petitioner also represents that it filed a petition for *inter partes* review of the ’287 patent (*id.*), which we identify as IPR2019-00818.

Patent Owner represents that the validity of the ’311 patent was challenged unsuccessfully in *KFx Medical Corp. v. Arthrex Inc.*, No. 11-cv-1698-DMS (BLM) (S.D. Cal.) (“Arthrex Litigation”). Prelim. Resp. 9, 11.

*B. The '311 Patent (Ex. 1001)*

The '311 patent, titled "System and Method for Attaching Soft Tissue to Bone," describes medical devices and surgical procedures for attaching soft tissue to bone. Ex. 1001, [54], 1:15–18. The '311 patent describes its invention as used in arthroscopic procedures, including rotator cuff surgeries. *Id.* at 1:50–52. The patent alleges a need for methods and devices that allow "easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying." *Id.* at 1:43–46.

In order to explain one of the surgical methods described in the '311 patent, we reproduce its Figure 2, below:



**FIG. 2**

According to the '311 patent, Figure 2 depicts one bone anchor 20 positioned underneath soft tissue 12 and another bone anchor 22 positioned lateral to soft tissue 12, with suture 10 attached to both anchors. *Id.* at 3:67–4:3. The '311 patent describes that in some of its embodiments, suture 10 can be attached without tying any knots. *Id.* at 4:20–22.

*C. Illustrative Claims*

Claim 1 is the sole independent claim. *Id.* at 14:31–16:36. We reproduce claim 1 below, with emphasis added to a particular limitation discussed in this decision.

1. A method of attaching soft tissue to bone, comprising:
  - inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue;
  - passing a first length of suture from said first anchor over the soft tissue;
  - inserting a second anchor into bone, wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue;*
  - after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and
  - fixedly securing the first length of suture to the second anchor without tying any knots.

*Id.* at 14:32–45 (emphasis added).

*D. References Relied Upon*

Petitioner’s challenges rely on the following references (Pet. 3):

Name	Reference	Ex. No.
Colleran	US Pub. No. 2003/0088250 A1, published May 8, 2003	Ex. 1015
Millett	Excerpts of presentation entitled “Mattress Double Anchor Arthroscopic Rotator Cuff Repair,” presented at a surgeon meeting in Naples, Florida, January 8–10, 2004.	Ex. 1016
Lubbers	WO 03/034895 A2, published May 1, 2003	Ex. 1017

*E. Alleged Grounds of Unpatentability*

Petitioner contends that claims 1–3, 5–12, 14, 15, 21–26, and 28–30 of the ’311 patent are unpatentable under the following grounds:

References	Basis	Claim(s)
Colleran and Millett	§ 103(a) <sup>1</sup>	1–3, 5–12, 14, 15, 21–25, and 28–30
Colleran and Lubbers	§ 103(a)	1–3, 5–12, 14, 15, 21–26, and 28–30

Pet. 3.

Petitioner also relies on the declaration testimony of Dr. Jonathan E. Greenleaf, M.D., (Ex. 1002) in support of its Petition. *See, e.g.*, Pet. 17.

II. ANALYSIS

*A. Claim Construction*

We determine that no claimed limitation requires express construction for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’”) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

*B. Original Examination of the ’311 Patent*

During the original examination of the ’311 patent, the examiner rejected claim 91—which ultimately issued as independent claim 1—in view of U.S. Patent Nos. 5,891,168 (“Thal”) and 5,634,926 (“Jobe”). Ex. 1007,

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<sup>1</sup> Because the challenged claims of the ’311 patent have an effective filing date before the effective date of the applicable AIA amendment, we refer to the pre-AIA version of 35 U.S.C. § 103.

66. The Examiner found that “Jobe discloses anchors being positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue.” *Id.*

In response to the rejection, the patent applicant amended claim 91 to recite that “no part of the [first] anchor extends beyond an edge of the soft tissue” and “tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor.” *Id.* at 52. Applicant argued that neither Thal nor Jobe teaches tensioning the suture after anchor insertion to compress an area of tissue to bone between the edge of the soft tissue and an anchor underneath the soft tissue. *Id.* at 57–58.

In its reasons for allowance, the examiner agreed with the patent applicant (*id.* at 32), and further explained that “[t]he prior art of record nor the prior art at large, alone or in combination, cannot remedy the deficiencies of the Thal and Jobe references and thus the claims are allowed” (*id.* at 32–33).

The ’311 patent issued on September 8, 2009, listing several prior art references, including the Millett procedure (*see* Ex. 1001, 3 (OTHER PUBLICATIONS)); *see also* Prelim. Resp. 17 (“The Millett procedure was also before the Examiner during prosecution” (citing Ex. 1001, 3)).

### *C. Reexamination of the ’311 Patent*

On January 11, 2011, an anonymous third party filed a request for reexamination of the ’311 patent. Ex. 1008, 88. The request asserted substantial new questions (SNQs) of patentability based on ten challenges.

*Id.* at 90–91. The challenges relied on several references, including U.S. Patent Pub. No. 2003/012309 to Colleran (“Colleran ’309”). *Id.* at 91.

Although the reexamination examiner granted the request as to grounds of unpatentability based on U.S. Pat. No. 6,585,730 (“Foerster”) (*see id.* at 60 (“[i]t is agreed that Foerster raises a SNQ with respect to claims 1–3, 5–25, and 28–30 in the ’311 patent”)), the examiner ultimately determined that “[t]he prior art of record fails to anticipate or render obvious a method of attaching soft tissue to bone comprising inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue and inserting a second anchor in combination with all the limitations of claim 1” (*id.* at 37).

A reexamination certificate issued on September 13, 2011, listing Colleran ’309 (Ex. 1001, 37) and confirming the patentability of the reexamined claims (*id.* at 38).

#### *D. Arthrex Litigation*

Patent Owner filed a patent infringement lawsuit against Arthrex, Inc., for infringement of the ’311 patent. Prelim. Resp. 9 (citing the Arthrex Litigation).

During the Arthrex Litigation, Arthrex challenged the validity of the ’311 patent based on Millett. *Id.* In the litigation, Arthrex relied on Dr. Greenleaf’s expert testimony in contending that it would have been obvious to include a knotless anchor (as disclosed in U.S. Patent No. 5,584,835 to Greenfield (“Greenfield”)) to Dr. Millett’s procedure. *Id.* at 10–11.

In response to the contention that the claims of the '311 patent were obvious, Patent Owner submitted secondary considerations evidence. *Id.* at 34.

The jury ultimately rejected Arthrex's theory of invalidity, finding that the '311 patent was not invalid for anticipation or obviousness. Ex. 2043, 3.

Notwithstanding the jury's verdict, Arthrex filed a motion for judgment as a matter of law on several issues, including the issue of obviousness. Ex. 2003, A2. In its motion, Arthrex argued, *inter alia*, that it was entitled to judgment as a matter of law that the '311 patent is invalid as obvious in view of Millett and Greenfield. *Id.*

The district court disagreed, finding that the jury's verdict was supported by substantial evidence. *Id.* at 3. The district court cited the testimony of Patent Owner's expert *and* the secondary considerations evidence of nonobviousness. *Id.* Most notably, the District Court determined that

KFx presented evidence that others, including Arthrex, tried and failed to arrive at the patented method. KFx also presented evidence that there was a long-felt need for the patented method, and that Arthrex enjoyed considerable commercial success after adopting the patented method. In view of all of the evidence, Arthrex is not entitled to judgment as a matter of law on the issue of obviousness.

*Id.* at 4.

Arthrex appealed to the Federal Circuit, but that court summarily affirmed the district court's decision without rendering an opinion. Ex. 2044.



*E. Principles of Law*

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art 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 skill in the art; and (4) *objective evidence of nonobviousness, i.e., secondary considerations*. See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (emphasis added).

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

*F. Level of Ordinary Skill in the Art*

Petitioner, citing Dr. Greenleaf’s testimony, asserts that a person of ordinary skill in the art at the time of the invention of the ’311 patent “would have been an orthopedic surgeon with several years of experience, or an engineer with several years of experience in developing and designing orthopedic surgical methods and instruments.” Pet. 16 (citing Ex. 1002 ¶ 16). Patent Owner does not dispute Petitioner’s assertion regarding the level of ordinary skill in the art. See generally Prelim. Resp.

For purposes of this decision, we adopt Petitioner’s proposed level of skill in the art and we consider Petitioner’s declarant, Dr. Greenleaf, qualified to opine from the perspective of an ordinary skilled artisan at the time of the invention of the ’311 patent. *See* Ex. 1002 ¶ 4 (“I have been a practicing orthopedic surgeon for more than 28 years.”).

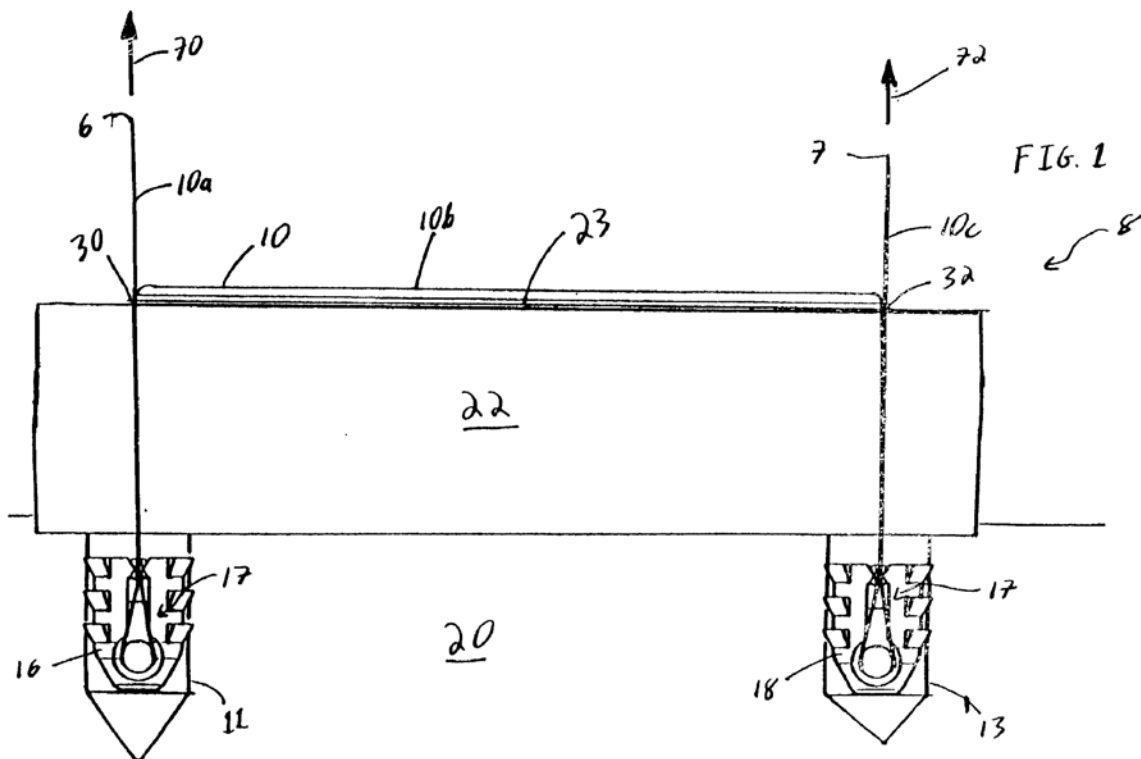
*G. References Asserted*

We summarize briefly the references relied on by Petitioner.

1. *Colleran (Ex. 1015)*

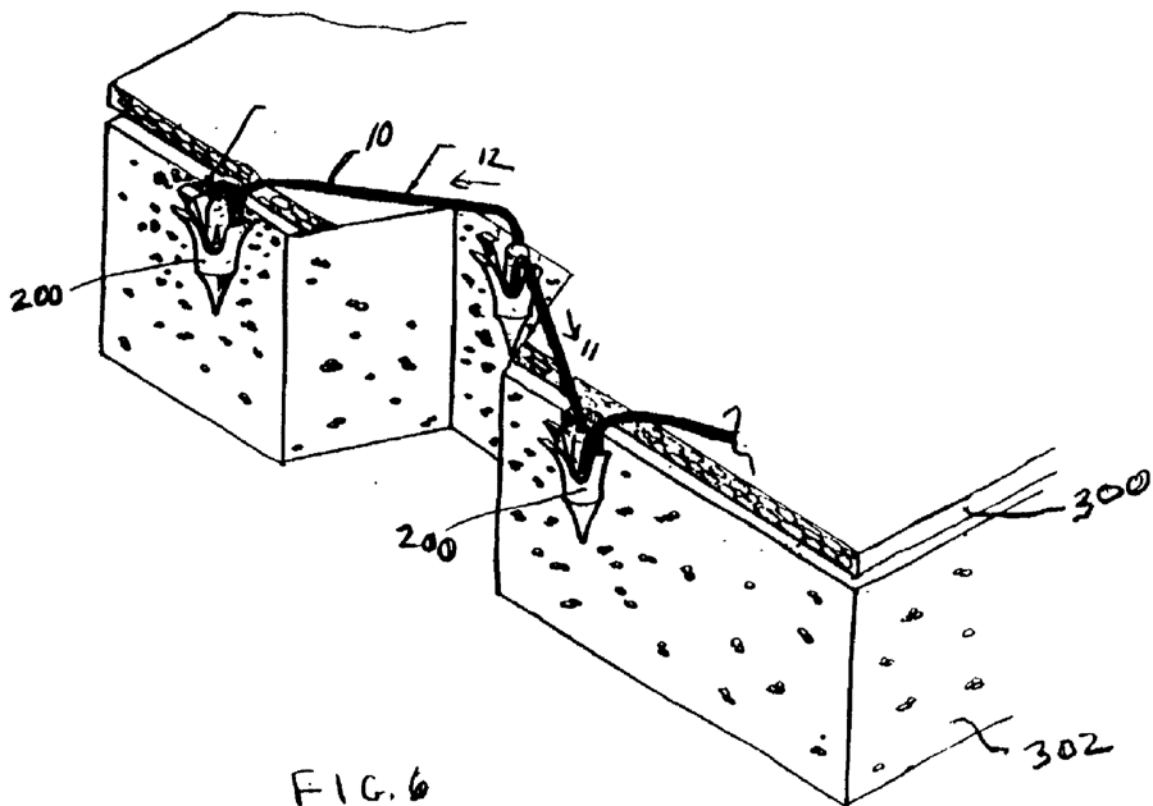
Colleran is a U.S. Patent Publication entitled “Tissue Repair System” and discloses “tissue fixation devices and methods for tissue repair.” Ex. 1015, [54], ¶ 1.

Figure 1 of Colleran is reproduced, below:



According to Colleran, Figure 1 is a “diagrammatic illustration of a system for reattaching fibrous tissue to bone.” *Id.* ¶ 28. Specifically, Figure 1 depicts tissue repair system 8 for attaching soft tissue 22 (e.g., tendon, ligament, cartilage) to bone 20 with suture 10 coupled to first and second bone anchors 16, 18. *Id.* ¶ 47.

To illustrate one of Colleran’s bone anchors and suture in use, we reproduce Figure 6, below:



According to Colleran, Figure 6 depicts anchors 200 with suture 10 deployed through tissue 300 and into bone 302. *Id.* ¶ 62. By moving suture 10 in the direction of arrow 11, the length of suture 10 between anchors 200 is shortened, pulling suture 10 taut. *Id.*

2. *Millett (Ex. 1016)*

Millett includes excerpts from a presentation given by Dr. Peter J. Millett to surgeons. *See Pet. v.*, 17.

Specifically, Millett is a collection of 9 slides (*see Ex. 1016*), which can best be summarized by reproducing those four slides primarily relied on by Petitioner. *See Pet. 20–21* (citing in relevant part *Ex. 1016, 4, 7, 8, 9*).

Slide 3 (page 4 of Exhibit 1016) is reproduced below:

The slide features a blue background with a red-bordered title box at the top containing the text "Mattress Double Anchor Repair" in yellow. Below the title, there are three bullet points in white text: "New - evolution", "Permits interlocking of one suture between two anchors", and "Footprint type of repair". To the left of the second and third bullet points is a small inset image showing a black suture with two green anchors. To the right of the bullet points is a larger anatomical diagram of a knee joint with two blue anchors and a blue suture. A copyright notice "© 2003" is visible at the bottom of the diagram. In the bottom right corner of the slide is the Harvard Medical School logo.

Ex. 1016, 4. Slide 3, titled Mattress Double Anchor Repair, states, “Permits interlocking of one suture between two anchors.” *Id.*

Slide 6 (page 7 of Ex. 1016) is reproduced below:

## Lateral Anchor

- 1 to 1.5 cm lateral to first anchor
- Insert so that loop runs from lateral to medial
- Restores footprint by pulling cuff laterally



*Id.* at 7. Slide 6, titled Lateral Anchor, states that the lateral anchor is 1 to 1.5cm lateral to the first anchor. *See id.*

Slide 7 (page 8 of Ex. 1016) is reproduced below:

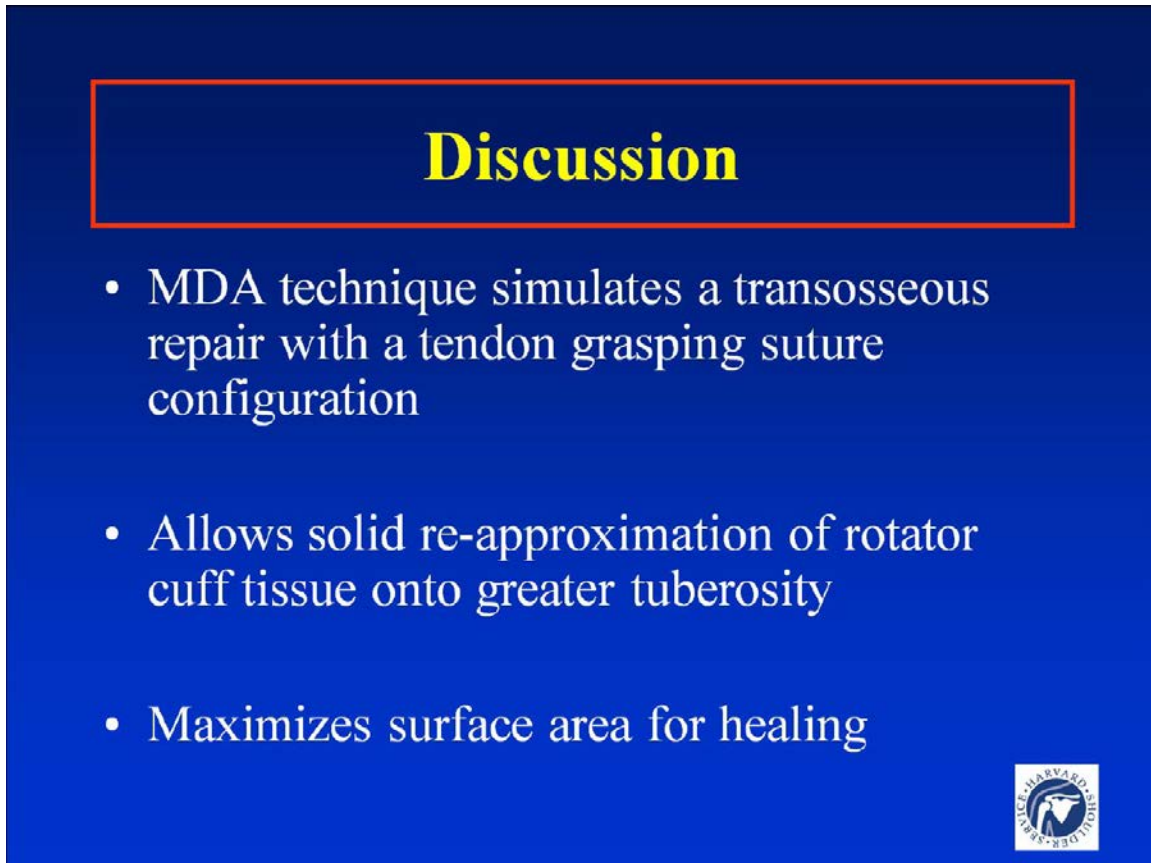
## Pass sutures between anchors

- Creates a double row of anchors with a single suture between the two anchors in a mattress configuration (MDA)
- Compresses tissue onto the footprint




*Id.* at 8. Slide 7 states the creation of a “double row of anchors with a single suture between the two anchors in a mattress configuration” that “[c]ompresses tissue onto the footprint.” *Id.*

Slide 8 (page 9 of Ex. 1016) is reproduced below:

A blue rectangular slide with a red border. The word "Discussion" is centered at the top in a bold, yellow, serif font. Below it, there are three bullet points in a white, serif font. In the bottom right corner, there is a small circular logo for Harvard Medical School.

**Discussion**

- MDA technique simulates a transosseous repair with a tendon grasping suture configuration
- Allows solid re-approximation of rotator cuff tissue onto greater tuberosity
- Maximizes surface area for healing

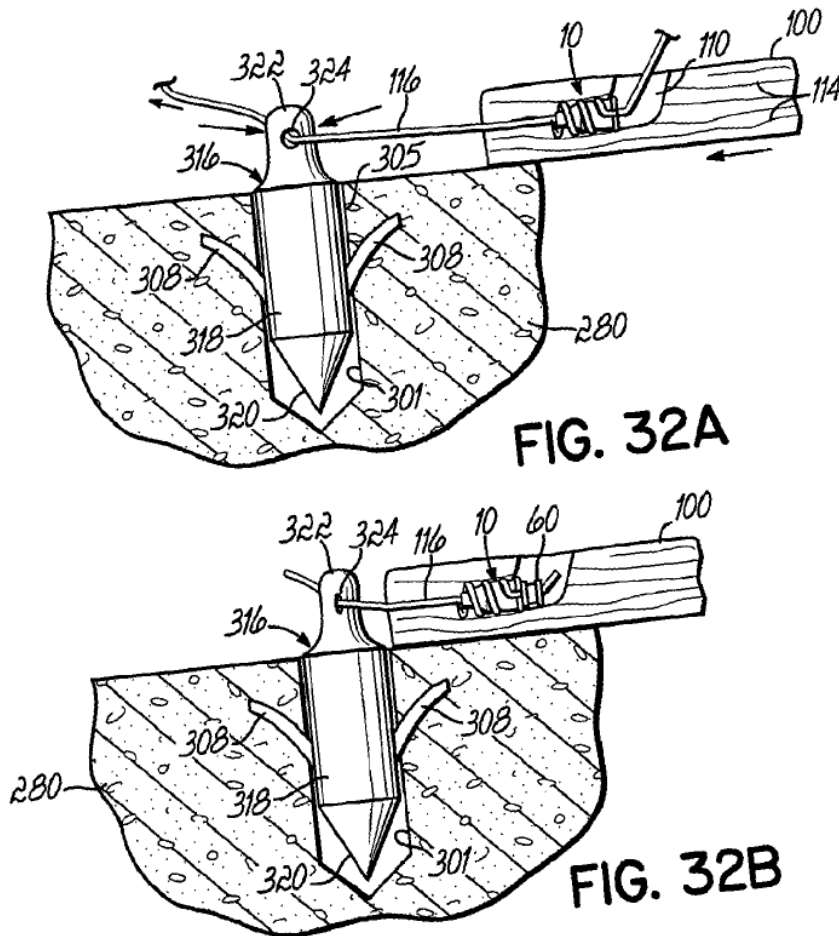


*Id.* at 9. Slide 8 states that the procedure “[a]llows solid re-approximation of rotator cuff tissue onto greater tuberosity” and “[m]aximizes [the] surface area for healing.” *Id.*

Although the Millett presentation itself was not considered by the examiner during prosecution or reexamination of the ’311 patent, a related article from Dr. Millett on similar subject matter was made of record during the original prosecution. *See* Prelim. Resp. 13; *see also* Ex. 1001, 3 (OTHER PUBLICATIONS) (“Millet et al., Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique, *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, 20(8):875–879 (2004)”).

3. *Lubbers (Ex. 1017)*

Lubbers is a PCT publication entitled “Apparatus and Methods for Tendon or Ligament Repair.” Ex. 1017, [54]. Lubbers discloses installing a soft tissue anchor within a tendon and using a suture to pull the anchor (and tendon) toward a bone anchor. *Id.* at 27:14–24 (referencing Figures 32A, 32B). We reproduce Lubbers’s Figures 32A and 32B, below:



According to Lubbers, Figures 32A and 32B depict soft tissue anchor, or anchor assembly 10, anchored in tendon 100. *See id.* at 26:5–7, 17–18 (discussing anchor assembly 10 and tendon 100 in Figures 29A and 29B). Elongate tensile member 116 is secured to anchor assembly 10 and tendon 100. *See id.* at 26:34–36. Tensile member 116 is also secured to bone



anchor 316. *See id.* at 27:21–24. As distinguished from Figure 32A, Figure 32B depicts tendon 100 positioned in its desired location *after* elongate tensile member 116 has been tensioned. *See id.* at 27:21–24

Lubbers was not considered by the examiner during the initial patent prosecution or during its reexamination. *See* Pet. 18 (confirming the same).

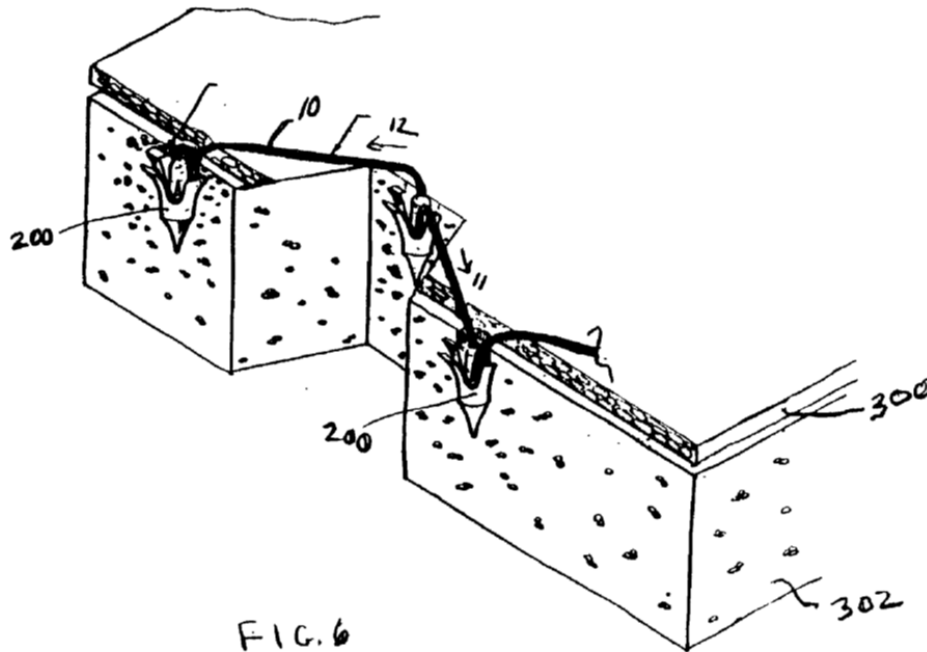
#### *H. Petitioner’s Challenges*

In its Petition, Petitioner presents two similar challenges based on the combined teaching of: (1) Colleran and Millett and (2) Lubbers and Millett. *See* Pet. 3. We summarize each challenge separately, below.

##### *1. Colleran and Millett*

Petitioner asserts that Colleran discloses all of the claimed limitations of claim 1, with the exception of the claimed “wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue.” *See id.* at 23, 24 (asserting that Colleran’s embodiments shown in Figures 1 and 6 each “expressly discloses every limitation of claim 1 with the exception of the specific ‘second anchor’ placement”).

We reproduce Colleran's Figure 6, below:

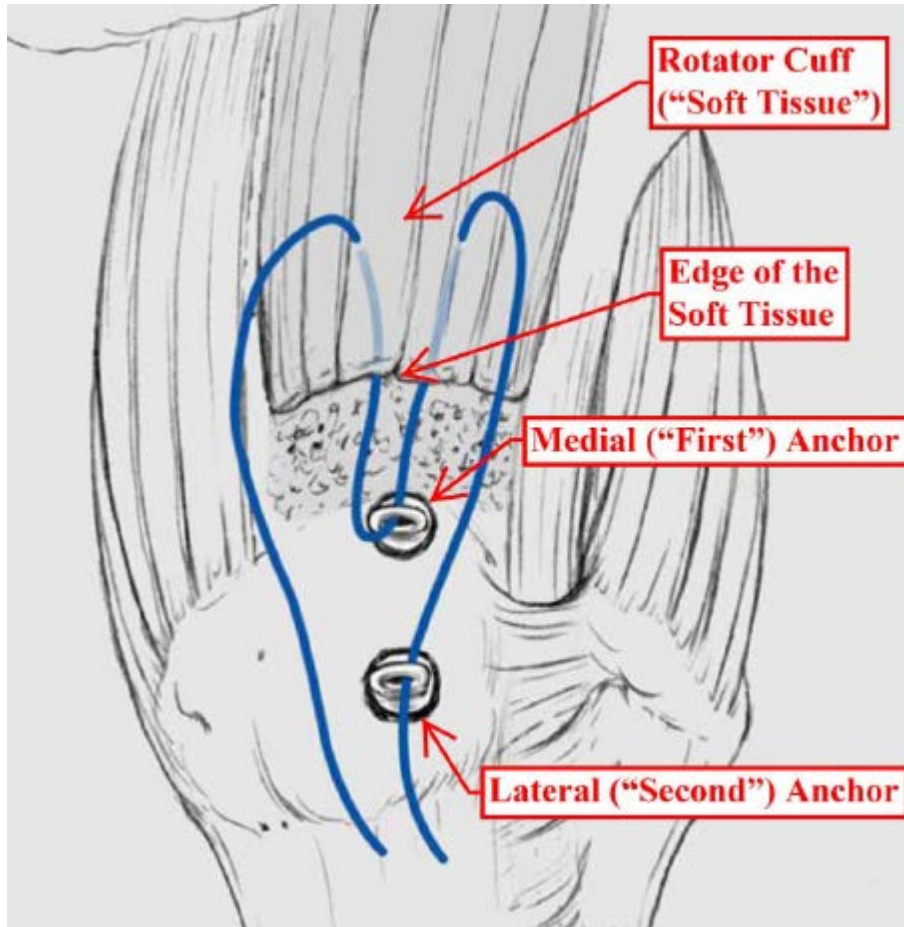


According to Colleran, Figure 6 depicts anchors 200 with suture 10 deployed through tissue 300 and into bone 302. Ex. 1015 ¶ 62.

According to Petitioner, Colleran discloses the claimed “first” and “second” anchors 200. Pet. 24. Petitioner acknowledges, however, that both of these anchors are deployed through tissue 300 and into bone 302, and the second anchor is *not positioned* beyond the edge of the soft tissue. *See id.* (citations omitted).

To address the missing limitation, Petitioner relies on Millett and asserts that Millett teaches the benefits of locating the second anchor beyond the edge of the soft tissue in rotator cuff surgeries. *See id.* at 20–21. Dr. Greenleaf testifies that “as the rotator cuff will retract medially once it detaches from the bone, inserting the lateral anchor beyond the edge of the soft tissue enables the surgeon to use tension on the suture to pull the torn tendon laterally toward the anchor and compress it back onto its original

anatomical footprint.” Ex. 1002 ¶ 76. Petitioner submits an annotated version of a portion of Millett’s slide 3, which we reproduce below:

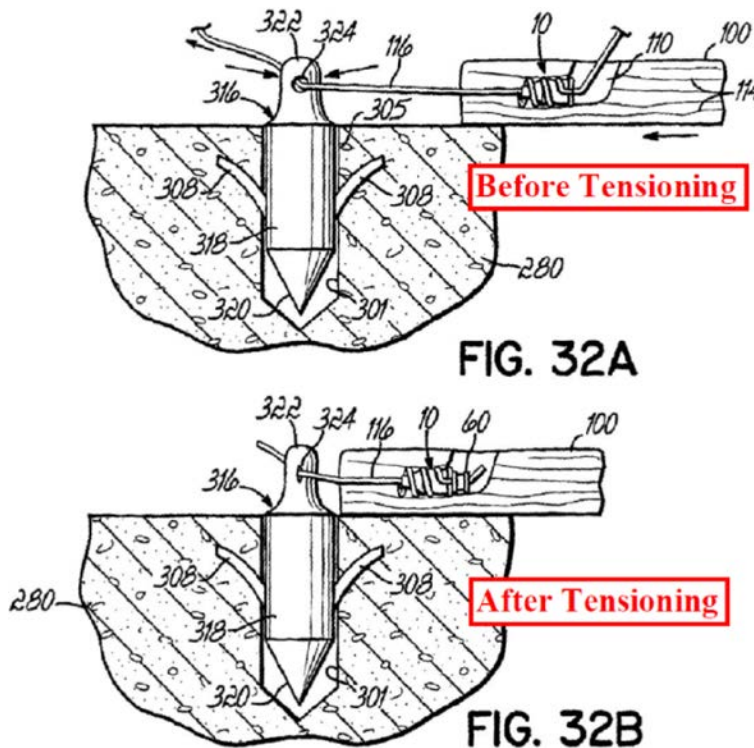


Pet. 25. The slide shows placement of anchors in a rotator cuff repair, and is annotated by Petitioner to identify the soft tissue and the medial and lateral anchors. *Id.* According to Petitioner, and as shown in the above-annotated figure, “Millett’s ‘second’ anchor is positioned ‘1 to 1.5 cm lateral to the first anchor,’ beyond the edge of the soft tissue.” *Id.* (citations omitted). Petitioner further asserts that “[a]s a result of this placement, tensioning the suture not only ‘compresses [the] tissue onto the footprint,’ but also pulls the tendon laterally toward the ‘second’ anchor so that it can be restored to its original position on the bone.” *Id.* at 25–26 (citations omitted).

In combining Colleran with Millett, Petitioner's expert reasons that a skilled artisan would have modified Colleran's procedure to place its "second" anchor during rotator cuff surgery, in light of Millet's teachings. *See* Ex. 1002 ¶ 83 ("it would have been obvious to a POSA to substitute the second anchor placement of Millett into Colleran's knotless 'double-row' procedure . . . [for] the rotator-cuff-specific reconstructive benefits taught in Millett.").

## 2. *Colleran and Lubbers*

In presenting this alternative challenge, Petitioner asserts that "[l]ike Millett, Lubbers also teaches locating the lateral ('second') anchor beyond the edge of the soft tissue in rotator cuff repairs," and contends, similarly, that "doing so allows the surgeon to pull the tendon laterally and thus approximate the rotator cuff to a desired location near the lateral anchor." Pet. 53 (citations omitted). In support of this argument, Petitioner submits an annotated version of Lubbers' Figures 32A and 32B, which we reproduce, below:



Pet. 55. According to Lubbers, Figures 32A and 32B depict soft tissue anchor, or anchor assembly 10, anchored in tendon 100. *See* Ex. 1017, 26:5–6 (referencing Figures 29A–29B). As shown by the annotations, Figure 32A depicts tendon 100 before tensioning, while Figure 32B depicts tendon 100 after tensioning.

According to Petitioner, and as shown in Lubbers’ annotated Figures 32A and 32B, “Lubbers also teaches that the lateral anchor is placed beyond the edge of the soft tissue . . . and that the surgeon can therefore use tension on the suture to pull the rotator cuff laterally and thus ‘approximate the tendon 402 to a desired location adjacent the bone anchor 408.’” Pet. 55 (citations omitted).

In combining Colleran with Lubbers, Petitioner’s expert reasons that a skilled artisan would have “substitute[d] the lateral-anchor positioning step of Lubbers . . . into Colleran’s . . . procedure . . . [for] the rotator-cuff-

specific reconstructive benefits and procedural advantages taught in Lubbers.” Ex. 1002 ¶ 84.

*I. Discretionary Denial Under 35 U.S.C. §§ 314(a) and 325(d)*

Institution of *inter partes* review is discretionary. See 35 U.S.C. § 314(a) (stating “[t]he Director may not authorize an *inter partes* review to be instituted unless the Director determines that the information presented in the petition . . . 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” (emphasis added)); see also *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“the PTO is permitted, but never compelled, to institute an IPR proceeding”).

The exercise of our discretion to institute an *inter partes* review is informed by 35 U.S.C. § 325(d), which requires us to “take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office.” In evaluating whether to exercise our discretion under § 325(d), we weigh the following non-exclusive factors:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

*Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, slip op. at 17–18 (Paper 8) (PTAB Dec. 15, 2017) (precedential-in-part, indentations added for clarity).

We also consider the status of related district court proceedings in exercising our discretion under 35 U.S.C. § 314(a). *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752, slip op. at 19–20 (Paper 8) (PTAB Sept. 12, 2018) (precedential); *see also id.* at 20 (“simply because we exercise our discretion to deny the Petition under § 325(d) does not mean that we cannot consider and weigh additional factors that favor denying institution under § 314(a) . . . [namely,] the advanced state of the district court proceeding”). In *NHK*, a panel of the Board exercised its discretion to deny a Petition under 35 U.S.C. § 325(d) based on the original examination of the challenged patent and considered a parallel district court action involving the same parties as an “additional factor” that supported denial under § 314(a). *Id.* at 11–20. *NHK* makes clear that we may consider the stage of a parallel district court litigation considering the same art, but that we should do so in the context of all the other factors, such as those outlined in *Becton, Dickinson*.

Upon reviewing the factors enumerated in *Becton, Dickinson* and *NHK Spring*, we find that, on balance, the factors weigh in favor of exercising our discretion to deny institution under 35 U.S.C. §§ 314(a) and 325(d).

1. *the similarities and material differences between the asserted art and the prior art involved during examination*

We find that the teachings of Lubbers and Millett—as relied on by Petitioner—are similar to the teachings of other references relied on by the examiner during the initial prosecution. In particular, during the original prosecution, the examiner relied on Jobe for disclosing a lateral anchor positioned beyond the edge of the soft tissue. Ex. 1007, 66; *see also supra* Part II.B. Indeed, we find that Jobe, Lubbers, and Millet each teach this feature. *Compare* Ex. 1017, Figs. 32A, 32B, *and* Ex. 1016, 4, *with* Ex. 2040, Fig. 9; *see also* Prelim. Resp. 19 (reproducing the same).

We also find that during the reexamination of the '311 patent, the examiner considered Foerster (*supra* Part II.C), and we find that Foerster also teaches “wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue.” *See, e.g.*, Ex. 2038, Fig. 14.

Thus, the art relied on here is similar to the art involved during examination, and this factor weighs in favor of denying institution.

2. *the cumulative nature of the asserted art and the prior art evaluated during examination*

As explained above (*supra* Part II.C), the reexamination examiner considered Colleran during the reexamination. *See* Ex. 1001, 37 (U.S. PATENT DOCUMENTS) (listing 2003/0120309 A1 to Colleran et. al. (“Colleran '309”)). We agree with Patent Owner that the Colleran '309 document contains the same disclosure as the Colleran reference relied upon by Petitioner. Prelim. Resp. 17.



As also explained above (*supra* Part II.B), the initial prosecution examiner considered the Millett procedure during the original examination. *See* Ex. 1001, 3 (OTHER PUBLICATIONS) (“Millet et al., Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique, *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, 20(8): 875–879 (2004)”); *see also* Prelim. Resp. 17 (“The Millett procedure was also before the Examiner during prosecution” (citing Ex. 1001, 3)).

Although the Examiner did not consider Lubbers during the original prosecution or reexamination, Petitioner relies on Lubbers for teaching that which is taught by Millett. *See* Pet. 53 (“Like Millett, Lubbers also teaches locating the lateral (‘second’) anchor beyond the edge of the soft tissue in rotator cuff repairs.”). Accordingly, Lubbers is cumulative to Millett in the evidentiary context.

We find the asserted art to be cumulative to the art evaluated during prosecution, and this factor weighs in favor of denying institution.

3. *the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection*

Although Colleran (*vis-à-vis* Colleran ’309) was presented in the request for reexamination (Ex. 1008, 91), the reexamination examiner ultimately did not address Colleran (*id.* at 39). During the reexamination, the examiner stated that Colleran “will not be specifically addressed because the request did not advance [that this reference raises] a substantial new question of patentability.” *Id.* at 39.

Although the Millett procedure was before the Office during the original examination (*see supra* Part II.B), neither the prosecution examiner

nor the reexamination examiner relied on this document in rejecting the claims during the original examination or reexamination, respectively.

As to Lubbers, Lubbers was not considered by either examiner during the initial prosecution or the reexamination.

We find that the asserted art was not a basis for rejection during prosecution or reexamination. This factor weighs against denying institution under § 325(d).

*4. the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art*

Petitioner relies on Colleran for disclosing all of the claimed limitations with the exception of the “second anchor . . . positioned beyond the edge of the soft tissue.” Pet. 20, 54. Petitioner relies on Millett and Lubbers, in the alternative, for each teaching positioning the second/lateral anchor beyond the edge of the soft tissue. *Id.* at 20–21, 53.

During the initial prosecution, the examiner rejected claim 91 (now issued claim 1) as unpatentable over Thal and Jobe. Ex. 1007, 66. The Examiner found that Thal disclosed each feature of the claim except “the anchors being positioned beyond an edge of the soft tissue.” *Id.* To address this limitation, the Examiner relied on Jobe for disclosing “anchors being positioned beyond an edge of the soft tissue.” *Id.*

We find that Petitioner’s challenges are similar to the rejections made by the examiner during the initial prosecution. This factor weighs in favor of denying institution.

5. *whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art*

Petitioner has not argued that either examiner erred during the initial examination or the reexamination. *See* Pet. 18–19 (STATEMENT CONCERNING 35 U.S.C. § 325(d)); *see also* Prelim. Resp. 21 (confirming the same).

This factor weighs in favor of denying institution.

6. *the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments*

Petitioner identifies no additional facts that warrant reconsideration of prior art or arguments. *See* Pet. 18–19 (STATEMENT CONCERNING 35 U.S.C. § 325(d)); *see also* Prelim. Resp. 22 (confirming the same).

This factor weighs in favor of denying institution.

7. *the status of any related district court proceeding*

As discussed above, the validity of the '311 patent was challenged during the Arthrex Litigation. *See supra* Part II.D. During the Arthrex Litigation, the jury considered evidence of secondary considerations and determined that the claims of the '311 patent are not obvious over Millett and Greenleaf. *Id.*; Ex. 2043.

Because the secondary considerations evidence was developed fully during the Arthrex Litigation, and the Federal Circuit affirmed the jury's verdict that the same claims (including independent claim 1) are not obvious based in-part on the evidence of secondary considerations, it is appropriate for us to consider this evidence in determining whether to exercise our

discretion to deny institution. *See* Ex. 1001, Claims (listing only one independent claim, claim 1).

Turning to the evidence itself, Patent Owner presents evidence of long-felt need, failure of others, and commercial success. Prelim. Resp. 37–49. The jury, district court, and Federal Circuit found this evidence persuasive. *Supra* Part II.D; Ex. 2003; Ex. 2044. Specifically, in denying Arthrex’s motion for judgment as a matter of law, the District Court explained that

Kfx presented evidence that others, including Arthrex, tried and failed to arrive at the patented method. Kfx also presented evidence that there was a long-felt need for the patented method, and that Arthrex enjoyed considerable commercial success after adopting the patented method. In view of all of the evidence, Arthrex is not entitled to judgment as a matter of law on the issue of obviousness.

Ex. 2003, 4. Thus, we find that the secondary considerations evidence presented during the Arthrex Litigation established that the claims of the ’311 patent may not have been obvious.

The Arthrex Litigation and, specifically, the evidence of secondary considerations developed therein, weighs in favor of denying institution.

We next point out that that Petitioner knew of the Arthrex Litigation. *See, e.g.*, Pet. v (referencing the Arthrex Litigation in Exhibits 1004, 1005, 1006, 1009, 1013, 1018). Despite knowing of the Arthrex litigation, Petitioner did not address the secondary considerations evidence in its Petition. *See generally* Pet.; *see also* Prelim. Resp. 36 (confirming the same).

We have cautioned petitioners in prior proceedings that petitions may be denied if they do not address known evidence of secondary

considerations. *See Robert Bosch Tool Corp. v. SD3 LLC*, IPR2016-01751 (PTAB Mar. 22, 2017) (Paper 15) (denying institution for failure to address objective indicia presented during an ITC proceeding); *see also Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc.*, IPR2015-01792 (PTAB Mar. 11, 2016) (Paper 14) (denying institution for failure to address objective indicia considered by Examiner during original prosecution); *see also Merial Ltd. v. Virbac*, IPR2014-01279 (PTAB Jan. 22, 2015) (Paper 13) (denying institution for failure to address objective indicia considered by Examiner during original prosecution and noting “Merial was aware of the unexpected results showing which the Examiner found persuasive . . . . Merial should have addressed unexpected results in the first instance.”); *see also Omron Oilfield & Marine Inc. v. MD/TOTCO*, IPR2013-00265 (PTAB Oct. 31, 2013) (Paper 11) (denying institution for failure to address objective indicia successfully argued in a reexamination).

Petitioner’s failure to address the known evidence of secondary considerations further weighs in favor of denying institution.

#### 8. *Conclusion*

After balancing the above factors, we exercise our discretion to deny institution under 35 U.S.C. §§ 314(a) and 325(d). In this instance, we deny institution considering the factors enumerated in *Becton, Dickinson* and in further view of the secondary considerations evidence developed and persuasively presented during the Arthrex Litigation.

III. ORDER

For the reasons given, it is:

ORDERED that no *inter partes* review is instituted.

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