

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CONMED CORPORATION AND LINVATEC CORPORATION
Petitioner

v.

BONUTTI SKELETAL INNOVATIONS LLC
Patent Owner

Case IPR2013-00628
Patent 5,527,343

Before MICHAEL R. ZECHER, BENJAMIN D. M. WOOD, and
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

ConMed Corporation and Linvatec Corporation (collectively “Petitioner”) filed a petition (Paper 1, “Pet.” or “Petition”) to institute an *inter partes* review of claims 1 and 4–7 (the “challenged claims”) of U.S. Patent No. 5,527,343 (Ex. 1001, the “343 patent”). 35 U.S.C. § 311. Bonutti Skeletal Innovations LLC (“Patent Owner”) did not file a Preliminary Response within the time period set by 37 C.F.R § 42.107(b). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

(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.

35 U.S.C. § 314(a).

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §§ 102 and/or 103 based on the following grounds (Pet. 19–42):

References	Basis	Claims challenged
U.S. Patent No. 5,203,787 (“Noblitt”) (Ex. 1002)	§ 102(a), (e)	1 and 4–7
U.S. Patent No. 4,946,468 (“Li”) (Ex. 1004)	§ 102(b)	1 and 4–7
Noblitt and U.S. Patent No. 5,123,914 (“Cope”) (Ex. 1003)	§ 103(a)	4
U.S. Patent No. 5,041,129 (“Hayhurst”) (Ex. 1005) and Noblitt	§ 103(a)	1 and 4–7

References	Basis	Claims challenged
Hayhurst, Noblitt, and Cope	§ 103(a)	4

For the reasons described below, we institute an *inter partes* review of claims 1 and 4–7 based on the obviousness grounds specified below.

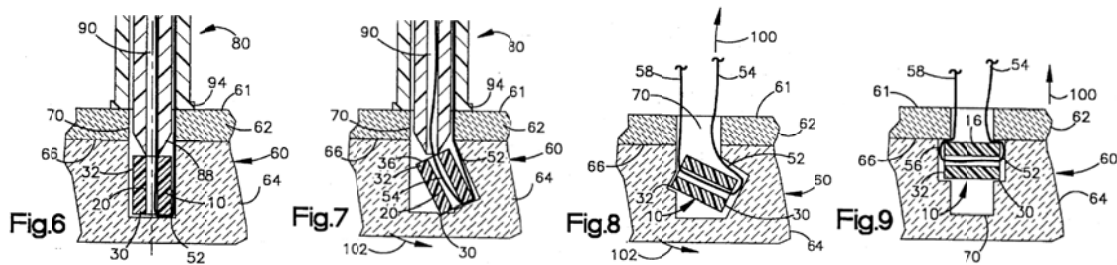
Additionally, we do not institute an *inter partes* review of claims 1 and 4–7 on the anticipation grounds.

B. Related Proceedings

Petitioner identified, as related proceedings, the co-pending litigation, *Bonutti Skeletal Innovations, LLC v. Linvatec Corporation*, Case Number 12-cv-01379 (M.D. Fla.) and *Bonutti Skeletal Innovations, LLC v. DePuy Mitek LLC*, Case No. 12-cv-11667 (D. Mass.). Pet. 4.

C. The '343 Patent

The '343 patent describes an anchor used to secure a suture in body tissue and methods for using the anchor. Ex. 1001, 2:60-63. Figures 6–9 illustrate selected steps of a method of using the anchor to secure a suture in bone and are reproduced in pertinent part below.



Figures 6–9 illustrate steps of inserting a generally tubular suture anchor through a hole in the hard outer layer of bone, implanting the anchor in the softer cancellous layer, and reorienting the anchor in a blocking orientation so that it cannot be pulled back through the hole and removed from the bone.

Ex. 1001, 5:12 – 6:5. The suture anchor is longer than it is wide and generally tubular with a hole extending along the longitudinal axis. *Id.* at 2:60 – 3:45. As shown in Figure 7, a suture is threaded through the hole in the anchor, and the anchor is oriented lengthwise in a tool so that a surgeon may insert it through a hole in the hard outer layer of bone. *Id.* at 5:12–31; *see id.* at Fig. 6. The surgeon advances the anchor through the hole in the bone and embeds it into the soft, cancellous layer of bone tissue. *Id.* Figures 7 and 8 illustrate how the surgeon pulls on one end of the suture in direction 100 to reorient the anchor by rotating it 90 degrees inside the cancellous layer. *Id.* at 5:32–49. Figure 9 illustrates how the reoriented anchor spans the hole in the hard bone layer so that it cannot be pulled back through the hole. *Id.* at 5:50–6:5. In this orientation, the anchor provides a firm base for the suture so that the free ends may secure another object (e.g., an implant, splint, or soft tissue) to the bone. *Id.* at 6:6–13.

Claim 1, which is the only independent claim among the challenged claims, is reproduced below:

1. A method of anchoring a suture to a bone having an outer layer of harder bone and an inner layer of softer bone, said method comprising the steps of:

providing an opening extending from a location outside of the bone through the outer layer of bone to the inner layer of bone;

connecting a suture with a suture anchor;

inserting the suture anchor with the suture connected thereto through the opening into the inner layer of bone; and

pulling on the suture to change the orientation of the anchor within the inner layer of bone to block movement of the anchor out of the opening in the outer layer of bone.

Id. at 9:2–15.

D. Claim Interpretation

The Board generally interprets claims of an unexpired patent using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b); *see* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). The ’343 patent expired June 18, 2013. For claims of an expired patent, however, our claim interpretation analysis is similar to that of a district court. *See In re Rambus Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012). Claim terms are given their ordinary and customary meaning as those terms would be understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). We apply this standard to the claims of the expired ’343 patent.

Petitioner proposes interpretations for “suture anchor” and “release orientation.” Pet. 12–19. We address both terms as set forth below.

1. Suture Anchor

Petitioner contends that we should interpret “suture anchor” to mean “a surgical appliance without sharp edges or pointed ends used to anchor a suture to bone.” Pet. 14. Petitioner argues that its proposed interpretation is warranted because the Specification repeatedly disavows coverage of suture anchors having sharp edges or pointed ends. *Id.* at 15. For example, the Specification states:

There are several features of the anchors *of the present invention* which contribute to their ease of use, especially in removal. They do not anchor themselves by digging into tissue as does a screw or an anchor with a pointed end. Instead, they rely on not being able to fit back through the hole they went in.

Ex. 1001, 6:56–59 (emphasis added). Petitioner also cites other passages of the Specification that disparage suture anchors with sharp edges. Pet. 15 (citing Ex. 1001, 7:23–24, 8:60–62, figs. 1–22, 26, and 27). Finally, Petitioner points out that all embodiments of the suture anchor described in the Specification lack sharp edges and pointed ends. *Id.* at 15–16. Our review of the Specification reveals that every embodiment of the suture anchor that is illustrated and described lacks sharp edges or pointed ends.

We agree with Petitioner’s proposed construction. As Petitioner shows, the Specification describes the anchors “of the present invention” as lacking pointed ends. Ex. 1001, 6:56–59. “When a patent . . . describes the features of the present invention as a whole, this description limits the scope of the invention.” *Verizon Svcs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) (internal citation omitted); *see SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (“[T]he characterization of the coaxial configuration as part of the present invention is strong evidence that the claims should not be read to encompass the opposite structure”). That all embodiments lack sharp edges and pointed ends, and the Specification’s disparagement of anchors with sharp edges, further support Petitioner’s interpretation. *See Saffran v. Johnson & Johnson*, 712 F.3d 549, 560 (Fed. Cir. 2013). Accordingly, we adopt Petitioner’s proposed interpretation of “suture anchor” as meaning “a surgical appliance without sharp edges or pointed ends used to anchor a suture to bone.”

2. Release Orientation

Petitioner contends that we should interpret “release orientation” as recited in claim 4 to mean “the orientation prior to the removal of the

anchor.” Pet. 17 (emphasis omitted) (citing Ex. 1011 ¶ 28). Claim 4 is reproduced below:

4. A method as set forth in claim 1 wherein said step of pulling on the suture to change the orientation of the anchor within the softer layer of bone to block movement of the anchor out of the opening includes the steps of causing the anchor to pivot within the bone to an anchoring orientation different from the insertion/release orientation by pulling at the location outside of the bone on the second end portion of the suture.

Ex. 1001, 9:39–46.

Focusing on “release orientation” carves from the limitation half of the descriptive adjective that modifies “orientation.” More specifically, claim 4 recites “insertion/release orientation” rather than “release orientation” alone. We, therefore, are not persuaded by Petitioner’s assertion that “release orientation” is a meaningful limitation that requires interpretation separate and apart from “insertion/release orientation.”

Even if “release orientation” were a meaningful, independent limitation, the proposed interpretation improperly introduces ambiguity in two ways. First, many orientations of the suture anchor may exist “prior to the removal of the anchor.” Second, the proposed interpretation refers to a “removal” step that is not recited in claim 4, which therefore may or may not ever occur. We conclude that the open-ended nature of the proposed interpretation introduces an unacceptable ambiguity into claim 4. We are, therefore, not persuaded by Petitioner’s argument in support of its proposed interpretation of “release orientation.”

On its face, “the insertion/release orientation” refers to the orientation of the anchor that permits insertion into and release from the bone tissue. The Specification supports this interpretation by stating that “[t]he anchor 10

rotates within the bone 60 until it is disposed transverse to the bone surface 61 and parallel to the opening 70, as illustrated in FIG. 14. The anchor 10 is then in a release condition which is effectively the same as its insertion condition (FIG. 6).” Ex. 1001, 6:46–51. Figures 6 and 14, which are reproduced in pertinent part below, illustrate the insertion and release conditions as being the same orientation.

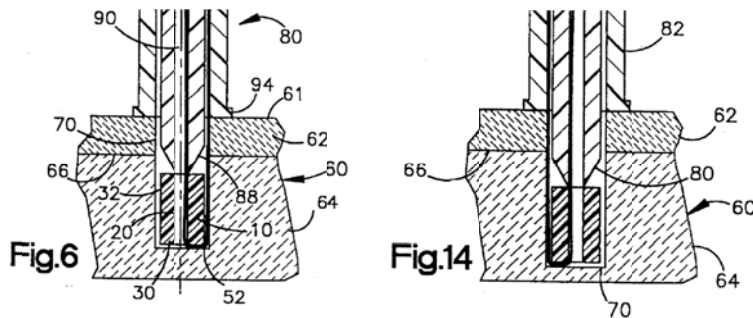


Figure 6 illustrates the suture anchor in an insertion condition, and Figure 14 illustrates the suture anchor in a release condition. The suture anchors in each Figure are in the same orientation relative to the bone.

Id. Accordingly, we interpret “insertion/release orientation” to refer to an orientation of the suture anchor that facilitates inserting or removing the suture anchor through a hole in the outer hard layer of bone. This construction is consistent with the ordinary and customary meaning of “insertion/release orientation” as would be understood by a person of ordinary skill in the art in the context of the ’343 patent. *Translogic*, 504 F.3d at 1257.

II. ANALYSIS

A. Anticipation

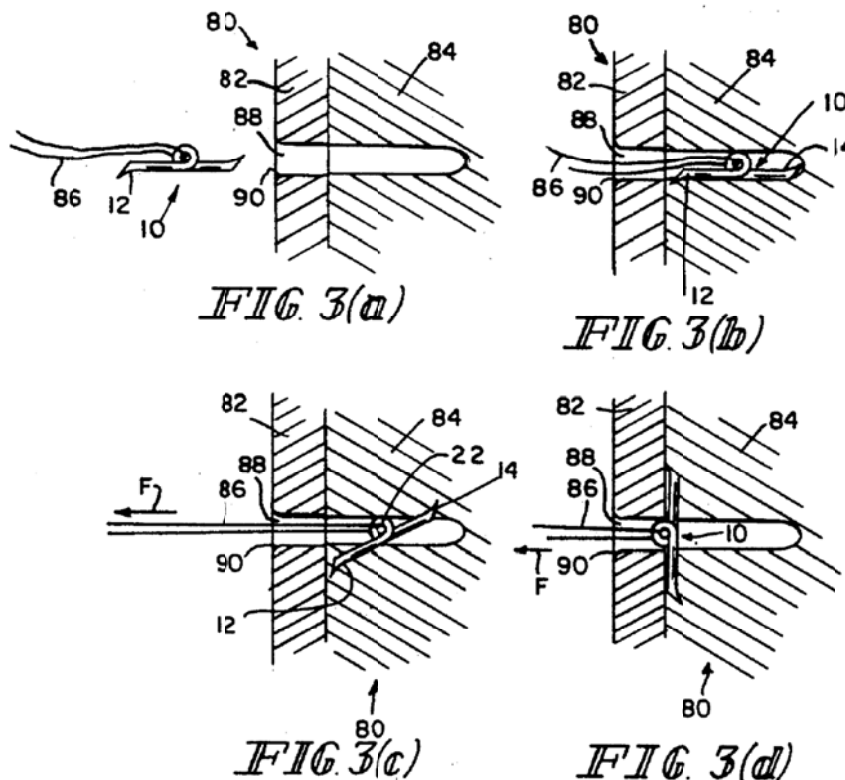
Petitioner contends that Noblitt and Li both anticipate claims 1 and 4–7. Pet. 19-25, 27-33. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in

a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). With this standard in mind, we address each alleged anticipation challenge below.

1. *Noblitt and claims 1 and 4–7*

Petitioner contends that Noblitt anticipates claims 1 and 4–7 under 35 U.S.C. § 102(a) and (e). Pet. 19–25. Petitioner provides detailed comparisons of Noblitt’s disclosed features to the limitations of claims 1 and 4–7 in claim charts. *Id.* at 22–25. Petitioner also proffers the testimony of Dr. Philip Hardy in support of its contentions. Ex. 1011 ¶¶ 42–83. For reasons explained below, we determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion that Noblitt anticipates claims 1 and 4–7.

Noblitt’s Figures 3(a)–3(d), which are reproduced below, illustrate a method of securing anchoring device 10 into the cancellous layer of bone.

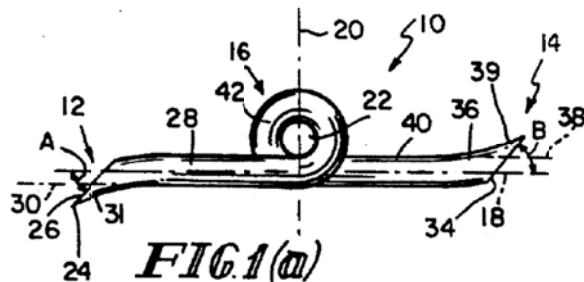


Noblitt's Figures 3(a)–3(d) illustrate inserting and securing a suture anchoring device in bone.

Ex. 1002, 4:57 – 5:22. As shown in the figures above, Noblitt's anchor is inserted through a hole in the hard outer layer of bone (Fig. 3(a)). The device is positioned in the underlying soft, cancellous layer (Fig. 3(b)) and then rotated into a locking orientation that prevents the anchor from passing back through the hole in the hard outer layer of bone (Figs. 3(c) and 3(d)).

Id.

Noblitt's anchoring device is illustrated in more detail in Noblitt's Figure 1(a), which is reproduced below.



Noblitt's Figure 1(a) illustrates an anchoring device with two pointed ends.

Id. at 3:50 – 4:15. Noblitt describes first end 12 of anchoring device 10 as having sharp point 24. *Id.* at 3:50. Nonetheless, Noblitt further describes first end 12 as being potentially blunt when the angle A formed by surface 26 and longitudinal axis 18 is 90 degrees. *Id.* at 3:56–61. Petitioner identifies blunted end 12 of Noblitt as describing the suture anchor recited in the claims that is “without sharp edges or pointed ends.” Pet. 21.

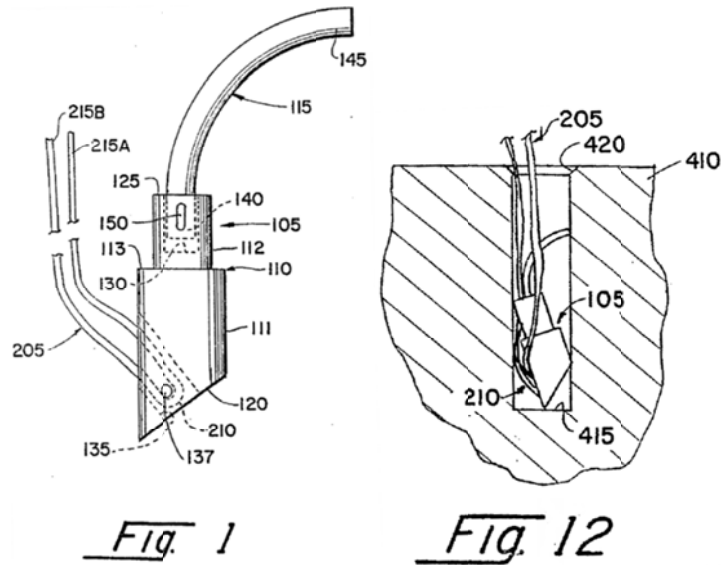
Petitioner fails, however, to establish that second end 14 of Noblitt's anchoring device 10 is “without sharp edges or pointed ends.” *See id.* (addressing only angle A at first end 12 has having values up to 90 degrees). Instead, we determine that Noblitt describes second end 14 as having point

32 including barb 39. Ex. 1002, 4:6–15. Noblitt describes angle B defined by the intersection of surfaces 34 and 36 as being “approximately 45°” without the range of variation described for angle A. Thus, we conclude that Noblitt does not describe second end 14 as being potentially blunt. We have determined that the suture anchor recited in claim 1 may not include sharp edges or pointed ends. *See* Part I.D.1 above. Accordingly, Petitioner has not provided sufficient evidence to establish a reasonable likelihood that it would prevail in its assertion that Noblitt anticipates independent claim 1 or its dependent claims 4–7.

2. *Li and claims 1 and 4–7*

Petitioner contends that Li anticipates claims 1 and 4–7 under 35 U.S.C. § 102(b). Pet. 27–33. Petitioner provides detailed comparisons of Li’s disclosed features to the limitations of claims 1 and 4–7 in claim charts. *Id.* at 31–33. Petitioner also proffers the testimony of Dr. Philip Hardy in support of its contentions. Ex. 1011 ¶¶ 91–132. For reasons explained below, we determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion that Li anticipates claims 1 and 4–7.

Li’s Figures 1 and 12, which are reproduced below, illustrate suture anchor 105 having barb 115. Figure 12 illustrates suture anchor 105 in its anchored condition within the soft, cancellous layer of bone.



Li's Figure 1 (above left) illustrates Li's suture anchor 105 with barb 115. Li's Figure 12 (above right) illustrates suture anchor 105 as it is anchored in the soft bone layer.

Ex. 1004, 7:46 – 8:16. As Li's barb 115 "passes by the hard cortical outer portion of the bone and enters the softer cancellous interior region of the bone, the barb's resilient nature will cause it to bend itself back into a curved length, with the barb acting as a resilient hook to engage adjacent bone matter." *Id.* at 7:62–67. Petitioner contends that pulling on Li's sutures 205 will result in the "barb digging into the soft cancellous bone 'as a resilient hook.'" Pet. 29 (citing Ex. 1011, ¶ 112). Petitioner also contends, without evidentiary support, that: "As shown in figure 1 . . . , the anchor lacks sharp edges or pointed ends. Instead, the barb (145) has a blunt face and the bottom of the surgical possesses a relatively large angle." Pet. 30.

We are not persuaded by Petitioner's unsupported argument because it is inconsistent with the evidence that Li's barb 115 digs into the soft, cancellous bone as a resilient hook. Accordingly, we determine that Li fails to describe a suture anchor "without sharp edges or pointed ends" as required by independent claim 1 and its dependent claims 4–7. For this

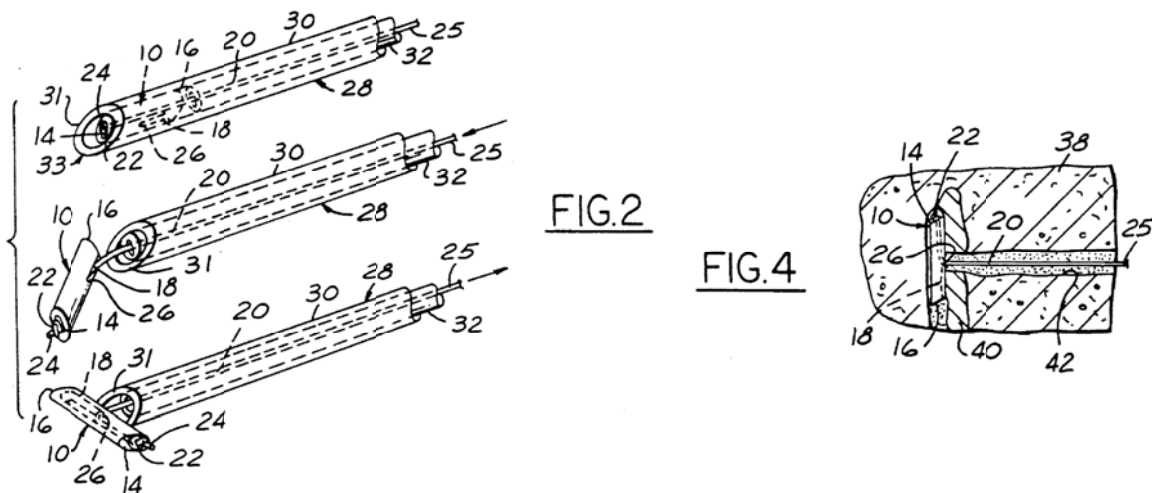
reason, we conclude that Petitioner has not provided sufficient evidence to establish a reasonable likelihood that it would prevail in proving that Li anticipates independent claim 1 or its dependent claims 4–7.

B. Obviousness

Petitioner contends that selections of all challenged claims are obvious in light of various combinations of Noblitt, Hayhurst, and Cope. We address each alleged obviousness challenge below.

1. Hayhurst in view of Noblitt relating to claims 1 and 4–7

Petitioner contends that claims 1 and 4–7 are unpatentable over the combination of Hayhurst and Noblitt. Pet. 33-40. Hayhurst describes “small elongated structures which are attached to a suture and which are inserted lengthwise through a hole in body tissue and deployed by rotating the structure generally transverse to the suture after insertion.” Ex. 1005, 1:7–11. Figures 2 and 4, reproduced below, illustrate Hayhurst’s apparatus:



Hayhurst’s Figures 2 and 4 illustrate the manner in which a surgeon uses an insertion tool to insert a suture anchor into soft tissue behind cartilage and rotate the anchor to a locking orientation.

Id. at 4:18 – 5:37.

Figure 2 of Hayhurst depicts suture anchor 10 formed as a hollow tube with angled ends and a slot extending half-way along its length. *Id.* at 3:37–43. Suture 20 extends through anchor 10 and is tied off at the leading end. *Id.* at 4:5–13. Prior to deployment, anchor 10 and suture 20 are confined within hollow outer needle 30 of cannulated insertion tool 28, with suture 20 parallel to and trailing behind anchor 10. *Id.* at 4:19–25. In a preferred use of Hayhurst’s apparatus, insertion tool 28 is inserted through holes formed in the body tissue segments being repaired. *Id.* at 5:12–17; Fig. 4. Anchor 10 is pushed out of tube 30 using hollow pusher tube 32 and rotated to a “toggle” position perpendicular to suture 20. *Id.* at 4:27–36. Although one embodiment of Hayhurst’s suture anchor 10 is described as having angular leading and trailing faces that define “sharp edges,” Hayhurst alternatively describes the anchor as having leading and trailing faces that are perpendicular to the axis of the tubular body of the anchor. *Id.* at 4:47–51.

Petitioner provides a detailed claim chart explaining how the combination of Hayhurst and Noblitt describes each limitation of claims 1 and 4–7. Pet. 37–40. Petitioner contends that Hayhurst discloses all limitations of the challenged claims, except that Hayhurst describes inserting the anchor through cartilage rather than bone, as required of claim 1. *Id.* at 35. Petitioner contends that Noblitt teaches this limitation. *Id.* at 35–36. Petitioner further contends that an ordinarily skilled artisan would have found it obvious that Hayhurst’s suture anchor could have been employed in bone, as disclosed in Noblitt. *Id.* at 36 (citing Ex. 1011, ¶¶ 134–39). Petitioner also argues that an ordinarily skilled artisan would have been motivated to adapt Hayhurst’s method based on Noblitt to permit Hayhurst’s anchor to be used “in a broader array of surgeries,” and that implanting

Hayhurst's anchor in bone "would increase the effective range of force that could be applied to the anchor without dislodging." Pet. 36 (citing Ex. 1011 ¶ 139). In view of Petitioner's analysis and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in establishing that the combination of Hayhurst and Noblitt renders claims 1 and 4–7 unpatentable under 35 U.S.C. § 103.

2. (a) *Noblitt and Cope* and (b) *Hayhurst, Noblitt, and Cope relating to claim 4*

Petitioner argues that claim 4 is obvious over two different combinations of references: (a) Noblitt and Cope (Pet. 25–27), and (b) Hayhurst, Noblitt, and Cope (*id.* at 40–42). Both arguments rely upon a presumption that we adopt the construction of "release orientation" that was allegedly proposed by Patent Owner in related litigation. *Id.* at 26 and 40–41. As explained in part 0 above, we have not adopted any such interpretation of "release orientation," or even agreed that "release orientation" is a term requiring interpretation separate from "insertion/release orientation."

Petitioner argues that "Cope discloses the . . . removal of a suture anchor." Pet. 26, 41. Because claim 4 does not recite a step of removing the suture anchor from the bone, we consider Cope's teaching of removing an anchor to be irrelevant to the analysis of claim 4. Petitioner also fails to point out how, if at all, its reliance on Cope cures Noblitt's failure to describe an anchor "without sharp edges or pointed ends." Therefore, we determine that Petitioner's use of Cope in the challenges adds nothing material to the obviousness challenge based on Noblitt and Hayhurst on which we institute *inter partes* review. Under these circumstances, we deny

the Petition as it relates to the challenges to the patentability of claim 4 that are based, in part, on Cope as redundant to the obviousness challenge based on Noblitt and Hayhurst. *See* 37 C.F.R. § 42.108(a).

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in proving the unpatentability of claims 1 and 4–7 of the '343 patent. At this stage of the proceeding, the Board has not finally determined the patentability of any challenged claim.

IV. ORDER

For the reasons given, it is:

ORDERED that the Petition is granted and an *inter partes* review is instituted for claims 1 and 4–7 of the '343 patent on the grounds that the claims are obvious over Hayhurst and Noblitt.

FURTHER ORDERED that no other grounds of unpatentability alleged in the Petition are authorized for this *inter partes* review.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '343 patent is instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial.

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2:00 PM Eastern Time on May 1, 2014. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765–66 (Aug. 14, 2012) for guidance in preparing for the initial conference call and should be prepared to discuss any proposed changes to

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the Scheduling Order entered with this Decision and any motions the parties anticipate filing during the trial.

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