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571-272-7822

Paper 11
Date: August 25, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

ACANTHA LLC,
Patent Owner.

IPR2020-00684
Patent RE43,008 E

Before TIMOTHY J. GOODSON, JAMES J. MAYBERRY, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAYBERRY, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

NuVasive, Inc. ("Petitioner"), filed a Petition ("Pet.") requesting *inter partes* review of claims 1–5, 10–19, 21, 22, 29–32, 36, and 37 (the "Challenged Claims") of U.S. Patent No. RE43,008 E (Ex. 1001, the "'008 patent"). Paper 2. Patent Owner, Acantha LLC, filed a Preliminary

Response ("Prelim. Resp.") to the Petition. Paper 7. After receiving our authorization to do so (*see* Paper 8), Petitioner filed a Preliminary Reply (Paper 9, "Prelim. Reply") to the Preliminary Response to address issues related to our discretion under 35 U.S.C. § 325(d) and Patent Owner filed a Preliminary Sur-reply (Paper 10, "Prelim. Sur-reply") to the Preliminary Reply.

We have authority under 35 U.S.C. § 314 to determine whether to institute review. *See also* 37 C.F.R. § 42.4(a) (permitting the Board to institute trial on behalf of the Director). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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). For the reasons set forth below, upon considering the Petition, Preliminary Response, Preliminary Reply, Preliminary Sur-reply, and evidence of record, we institute an *inter partes* review.

B. Real Parties in Interest

Petitioner identifies itself as the real party in interest. Pet. 5. Patent Owner identifies itself as the real party in interest. Paper 5, 1.

C. Related Matters

Petitioner identifies *Acantha LLP v. NuVasive, Inc.*, No. 4:19-cv-10656-MFL-EAS (E.D. Mich.) and *Acantha LLP v. Stryker Corp.*, No. 4:19-cv-05604-PJH (N.D. Cal.), as matters related to the '008 patent. Pet. 6. Petitioner also identifies an *inter partes* review petition (IPR2020-00706), filed by Petitioner and challenging additional claims of the '008 patent. *Id.* Petitioner also identifies IPR2016-00329, IPR2016-00333, and IPR2016-00334, proceedings challenging the '008 patent and brought by DePuy Synthes Sales, Inc. *Id.*

Patent Owner agrees with the matters identified by Petitioner and adds *Acantha LLC v. DePuy Orthopaedics, Inc.*, No. 1:15-cv-01257 (E.D. Wis.), "in which the district court entered judgment in favor of Acantha LLC." Paper 5, 1.

D. The '008 Patent

The '008 patent, titled "Orthopedic Implant Assembly," reissued December 6, 2011, from an application filed July 15, 2003. Ex. 1001, codes (54), (45), (22). The '008 patent is a reissue of US 6,261,291 B1, which issued July 17, 2001, from an application filed July 8, 1999. *Id.*, code (64); Ex. 1003. The '008 patent purportedly expired on July 8, 2019. Pet. 9. The first 28 claims of the '008 patent are as originally issued in the '291 patent. Prelim. Resp. 5; Ex. 1001, 7:61–11:9.

The '008 patent is directed "to an orthopedic implant for joining bone segments." Ex. 1001, 1:12–13. We reproduce Figures 1 and 2 from the '008 patent below.

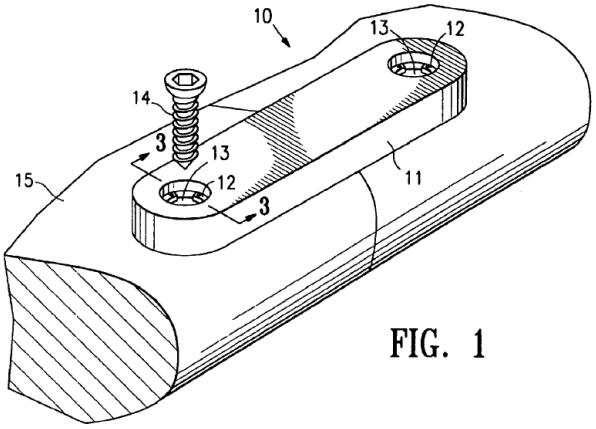


FIG. 1

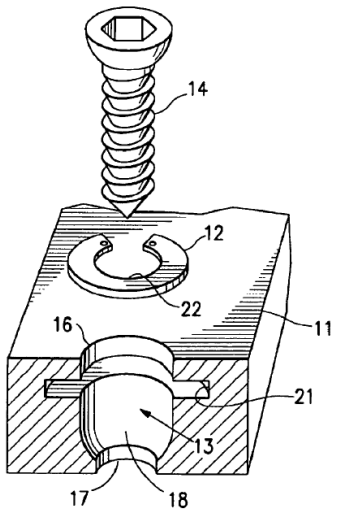


FIG. 2

Figure 1 depicts "an elevational view of an orthopedic implant" of the '008 patent and Figure 2 depicts "an exploded view, partially in section, of

the orthopedic implant assembly shown in F[igure] 1." Ex. 1001, 3:32–35. Orthopedic implant assembly 10 includes stabilizing element 11, biased stopping member 12, and securing element 14. *Id.* at 4:16–20.

Stabilizing element 11 includes two bores 13. Ex. 1001, 4:19. Each bore 13 includes first opening 16 and second opening 17, connected by transverse passageway 18. *Id.* at 4:25–30. Passageway 18 includes groove 21, in which biased stopping member 12 is seated. *Id.* at 4:30–34.

Biased stopping member 12 forms an annular collar with reversibly expandable inner and outer diameters. Ex. 1001, 4:32–34. "Annular collar 12 defines . . . passageway 22." *Id.* at 4:31–32. Collar 12 "is preferably elastically deformable, and formed of titanium, and superelastic or pseudoelastic materials such as [nickel-titanium] alloys." *Id.* at 5:65–67.

Securing element 14 includes an elongated body and integral head. Ex. 1001, 4:45–46.

> The head of
>
> > the securing element is configured to be posteriorly displaceable through the passageway 22 of the collar seated within the groove, from an anterior to a posterior surface of the collar, and retained within a posterior section 25 of the transverse passageway 18 between the posterior surface of the collar 12 and the second, i.e., posterior, opening 17 in the stabilizing element.

Id. at 4:48–55. Figures 5 and 6 of the '008 patent, reproduced below, depict securing element 14 positioned within posterior section 25 of transverse passageway 18.

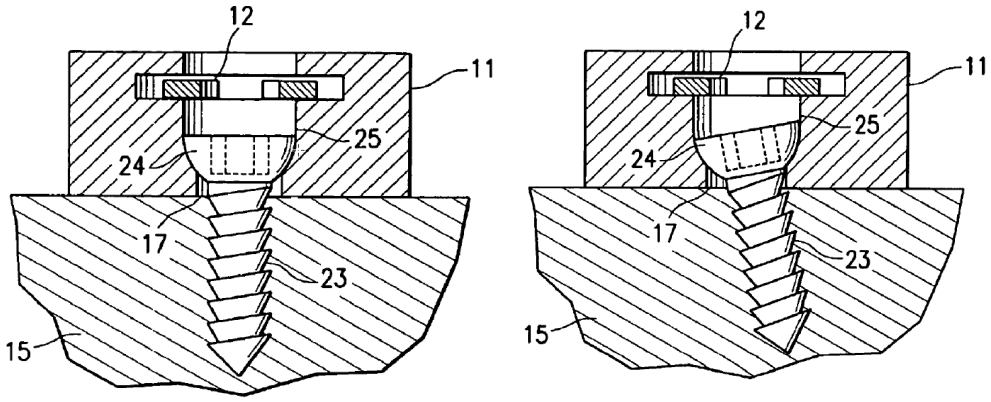


FIG. 5 FIG. 6

Figure 5 depicts "the orthopedic implant assembly [of the embodiment of Figure 1] with the securing element advanced into the posterior section of the transverse passageway of the stabilizing element" and Figure 6 depicts "the orthopedic implant assembly . . ., with the securing element angularly disposed within the patient's bone." *Id.* at 3:46–52.

E. Illustrative Claims

Of the Challenged Claims, claims 1, 21, and 36 are independent claims. Claim 1, reproduced below, is representative.

> 1. An orthopedic implant assembly, comprising
>
> a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;
>
> b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and
>
> c) a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse

passageway between the biased stopping member and the second opening in the stabilizing element.

Ex. 1001, 7:61–8:13. Claim 21 recites a method for attaching an orthopedic implant assembly such as the assembly recited in claim 1. *Id.* at 9:24–63. Claim 36, similarly recites a method for attaching an orthopedic implant assembly such as the assembly recited in claim 1. *Id.* at 11:28–12:2.[1]

F. Prior Art and Asserted Grounds

Petitioner asserts that the Challenged Claims are unpatentable based on three grounds:

Claims Challenged	35 U.S.C. §	References/Basis
1, 2, 4, 10, 12–19, 21, 29, 31, 32, 36	103(a)	Theken,[2] Errico[3]
3, 5, 11, 22, 30, 37	103(a)	Theken, Errico
3, 5, 11, 22, 30, 37	103(a)	Theken, Errico, Farris[4]

Petitioner relies on declaration testimony of Mr. Joseph Errico. Ex. 1002; Ex. 1015 (providing Mr. Errico's curriculum vitae). Patent Owner relies on declaration testimony of Dr. Barton Sachs. Ex. 2016; Ex. 2017 (providing Dr. Sachs's curriculum vitae).

The following subsections provide a brief description of the asserted prior art references.

[1] Challenged Claims 29–32, 36, and 37 were added to the '008 patent during reissue and, as such, appear in the patent printed in italic font. Throughout this decision, we do not use italic font when quoting claim language of these claims.
[2] Theken et al., US 6,228,085 B1, issued May 8, 2001, from an application filed July 14, 1998 (Ex. 1005, "Theken").
[3] Errico et al., WO 96/32071, published October 17, 1996 (Ex. 1006, "Errico").
[4] Farris et al., WO 98/51226, published November 19, 1998 (Ex. 1008, "Farris").

1. Theken

Theken, titled "Bone Fixation System," issued May 8, 2001, from an application filed on July 14, 1998. Ex. 1005, codes (54), (45), (22). Theken is directed "to an internal bone fixation system for the treatment of bone anomalies, such as thoracolumbar spinal instability." *Id.* at 1:5–7. We reproduce Theken's Figures 1 and 10, below.

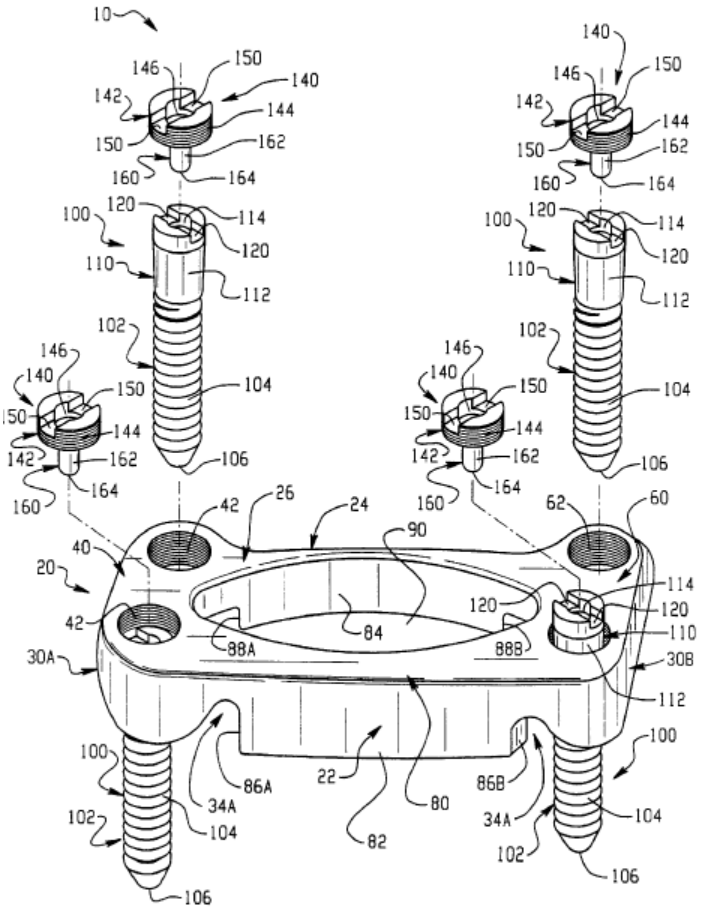


Fig. 1

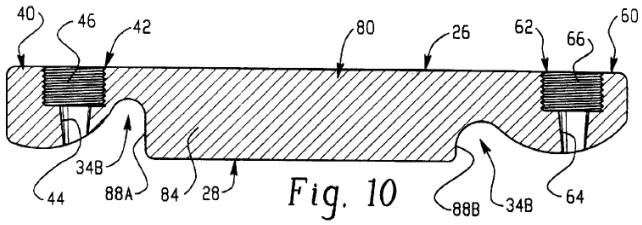


Fig. 10

Figure 1 provides "an exploded perspective view of [an embodiment of Theken's] bone fixation system." Ex. 1005, 2:25–27. Figure 10 depicts "a sectional view of the bone plate." *Id.* at 2:46. Fixation system 10 includes plate 20, bone screws 100, and set screws 140. *Id.* at 3:59–61.

Plate 20 includes openings 42 and 62, which receive bone screws 100 and set screws 140. Ex. 1005, 4:16–18, 4:36–39. These openings include a tapered section (sections 44 and 64) and threaded section (sections 46 and 66). *Id.* at 4:18–20, 4:39–40.

Screw 100 includes threaded portion 102 and head portion 110. Ex. 1005, 6:20–21. Threaded portion 102 engages a vertebral body of a patient. *Id.* at 6:24–26. Head portion 110 includes tapered outer surface 112, which matches taper sections 44 and 64. *Id.* at 6:27–31.

Set screws 140 include head portion 142, which includes threaded outer surface 144, and alignment member 160. Ex. 1005, 6:60–64. Threaded outer surface 144 mates with threaded sections 46 and 66. *Id.* at 6:65–66. During use, alignment member 160 "is inserted into recess 114 of screw 100 to aid in locating set screw 140 and prevent cross-threading." *Id.* at 9:11–14. "[D]riving set screws 140 on top of screws 100 forces screws 100 deeper into tapered section 44, 64, and prevents screws 100 from moving. As a result, the set screws have effectively turned an all-screw construct into an all-bolt construct." *Id.* at 9:22–26.

2. Errico

Errico, titled "A Polyaxial Locking Screw Collar and Plate Assembly," published October 17, 1996. Ex. 1006, codes (54), (43). Errico is directed to an "orthopaedic implant . . . assembly of bone screws, collars, and plates for use in surgical procedures for stabilizing the relative motion

of, or permanently immobilizing, bones." *Id.* at 1, 5–9. We reproduce Errico's Figure 6, below.

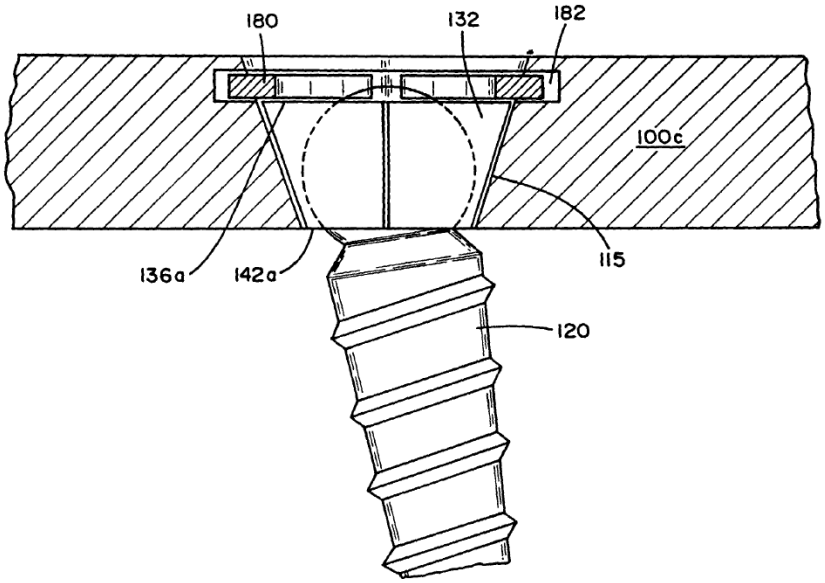


FIG.6

Figure 6 depicts "a side cross-section view of the fully assembled form of" Errico's implant assembly. Ex. 1006, 16, 7–8. This embodiment provides "a retaining ring . . . to further lock the screw and coupling element within the tapered hole. *Id.* at 23, 12–14. Plate 100c includes screw 120, coupling element 132, and snap-ring 180. *Id.* at 23, 25–26.

Annular recess 182 is formed in side wall 115 of tapered hole 110c (shown in Ex. 1006, Fig. 5). Ex. 1006, 23, 14–18. Within annular recess 182 is snap-ring 180. *Id.* at 23, 18–19.

> The undeflected outer diameter of the snap-ring is greater than the diameter of the hole 110c or 112c (so that it will remain in the recess), and is also less than the diameter of the top 136a or 136b of the coupling element 132 or 133, respectively. The inner diameter of the undeflected snap-ring 180 is, however, less than the diameter of the tapered hole, but is greater than the bottom 142a or 142b of the coupling element.

Id. at 23, 19–24. In use, when driving coupling element 132 (or 133) and screw 120,

> the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182. Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).

Id. at 24, 3–10.

3. Farris

Farris, titled "Anterior Cervical Plating System," published November 19, 1998. Ex. 1008, codes (54), (43). Farris is directed to "a plating system for use in the treatment of various spinal pathologies." *Id.* at 1, 6–7. Relevant to this proceeding, Farris includes a plating system that supports using either a fixed angle or variable angle screw. *Id.* at 5, 13–16. Farris states that a benefit of its plating system is "the ability [of the surgeon] to select either a fixed angle or a variable angle screw at any instrumented level and within a single fixation plate." *Id.* at 7, 15–18.

Farris discloses that its fixed and variable angle screws include threaded shanks and spherical heads, which seat into spherical recesses in bores of Farris's orthopedic implant assembly. Ex. 1008, 5:13–19; *see, e.g.*, *id.* at Figs. 4, 5 (depicting fixed and variable angled screws, respectively), Fig. 7 (depicting spherical recess 75). Farris also discloses a locking mechanism (locking assembly 103) for preventing screw backout. *See, e.g.*, *id.* at Figs. 20–22 (depicting locking assembly 103, including locking washer 120).

II. OUR DISCRETION UNDER §§ 325(D) AND 314(A)

A. 35 U.S.C. § 325(d)

Patent Owner contends that we should exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition, applying our precedential decisions in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) ("*Advanced Bionics*") and *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) ("*Becton, Dickinson*"). Prelim. Resp. 12–43. Because the Petitioner filed the Petition prior to *Advanced Bionics* being designated as precedential and Patent Owner provided argument on that case in its Preliminary Response, we authorized Petitioner to file a Preliminary Reply to Patent Owner's Preliminary Response and authorized Patent Owner to file a Preliminary Sur-reply to the Preliminary Reply. Paper 8. For the reasons provided below, we do not exercise our discretion to deny institution under § 325(d).

1. Applicable Framework

Section 325(d) provides that, in determining whether to institute an *inter partes* review, "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." 35 U.S.C. § 325(d) (2018). The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d), specifically:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, Paper 6 at 8.

In applying the two-part framework, we consider several non-exclusive factors from *Becton, Dickinson*, which provide "useful insight into how to apply the framework" (*Advanced Bionics*, Paper 6 at 9): (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[5]; (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 the prior art or arguments. *Becton, Dickinson*, Paper 8 at 17–18. If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, we then review factors (c), (e), and (f), which relate to whether the petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 10.

2. Analysis

For the reasons discussed below, we determine, in evaluating the first part of the *Advanced Bionics* framework, that the same or substantially the same art or arguments were not presented to the Office. We start our

[5] As *Advanced Bionics* explains, "during examination" encompasses both patent prosecution and proceedings before the Board, including prior *inter partes* review proceedings. *Advanced Bionics*, Paper 6 at 10.

analysis with a review of the prosecution history of the '008 patent, as well as the history of the '008 patent before the Board.

a) Prosecution history

The '008 patent is a reissue of US 6,261,291 B1 (the "'291 patent"), which issued July 17, 2001, from an application filed July 8, 1999. Ex. 1003, codes (10), (45), (22). The '291 patent issued after a first office action allowance. Prelim. Resp. 6; Ex. 1016, 68–73 (providing notice of allowability, dated June 16, 2000). The examiner stated that "the primary reason for allowance is that the prior art fails to teach or adequately disclose a biased stopping member that prevents movement of a securing member." Ex. 1016, 70. The examiner initialed an information disclosure statement listing that included, among 29 references, six references by Errico et al. (including US 5,876,402, the "Errico-402" patent[6]).

Patent Owner filed a broadening reissue application on July 15, 2003. Ex. 1001, code (22); Ex. 1004, 724 ("[N]ew claim 29 is broader than issued claims 1 and 23 . . . in several respects."). Patent Owner did not amend original claims 1–28 and added claims 29–105 prior to examination. Ex. 1004, 669–675, 683–689, 727–737.

In the first office action, the examiner rejected certain claims as anticipated by Errico-402 and, relevant to our analysis, identified snap-ring 180 as a stopping member. Ex. 1004, 651–652. The examiner also rejected certain claims as anticipated by Estes.[7] *Id.* at 652–653. The examiner

[6] Errico-402 matured from an application that purports to be a continuation-in-part of the application that matured into US 5,520,690 (US Pat. App. Ser. No. 08/421,087, the "'087 application"). Ex. 1018, 1:5–10. Errico, the reference asserted in this Petition, claims priority to the '087 application. Ex. 1006, code (30).

[7] Estes, US 5,578,034, issued November 26, 1996 (Ex. 2012).

identified allowable subject matter, including the original claims. *Id.* at 652–654.

In response, the Patent Owner proposed "extensive" amendments (Ex. 1004, 643) and added new claims 107–114. Ex. 1004, 515–537. Patent Owner argued that Errico-402 did not disclose an enlarged integral head of a securing member, as Errico-402's coupling member 132 is not an integral head of a securing member. *Id.* at 539–540. Patent Owner also argued that Estes does not disclose "the structure required by these claims." *Id.* at 541.

In the next office action, the examiner rejected certain claims as anticipated by Dill,[8] Hodorek,[9] Richelsoph,[10] and Estes. Ex. 1004, 393–399. The examiner also withdrew some previously identified allowable subject matter. *Id.* at 401.

In response to the rejections, Patent Owner argued that the alleged stopping members identified by the examiner were distinguishable over the claimed stopping member, as the claimed member required a passageway through which the head of a securing member passed. Ex. 1004, 330–336. Patent Owner added claims 115–119. *Id.* at 337.

Next, the examiner rejected certain claims as anticipated by Dill (claims 89–95, 115, and 116) or Campbell[11] (claims 89–95). Ex. 1004, 309–310. As to these rejections, Patent Owner cancelled the rejected independent claims and added new claims 120–126. *Id.* at 274. Patent Owner argued that the alleged stopping members identified by the examiner were

[8] Dill, US 5,118,235, issued June 2, 1992 (Ex. 2013).
[9] Hodorek, US 5,534,032, issued July 9, 1996 (Ex. 2014).
[10] Richelsoph, US 6,017,345, issued January 25, 2000 (not of record). *See* Ex. 1004, 396; Ex. 1001, code (56).
[11] Campbell et al., US 6,258,089 B1, issued July 10, 2001 (Ex. 2008).

distinguishable over the claimed stopping members of the new claims. *Id.* at 274–276.

Next, the examiner rejected certain claims (claims 52, 53, 63–69, and 73) as anticipated by Errico-402. Ex. 1004, 225–226. The rejection identified snap-ring 180 as "a stopping element." *Id.* at 225. Patent Owner amended the claims and argued that Errico-402 does not disclose the required securing member with an enlarged integral head. *Id.* at 198, 200–205.

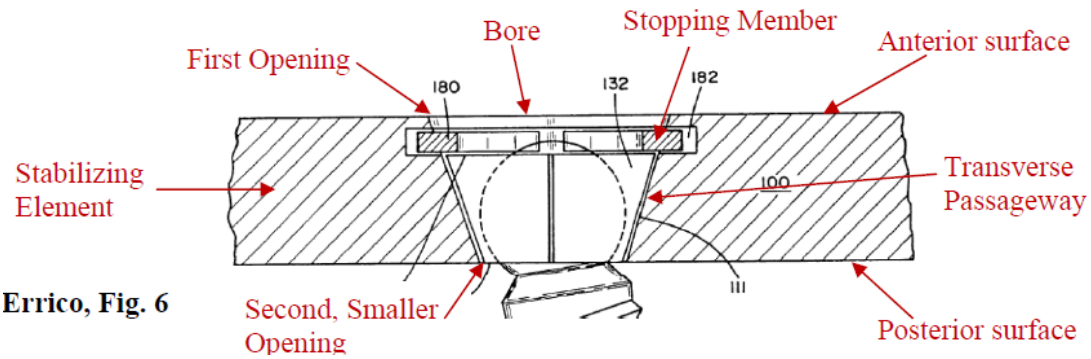
The '008 patent issued with no further art-based rejections. *See* Ex. 1004, 90–155; *see also id.* at 95 (providing claims map for the '008 patent).

b) History of the '008 patent before the Board

In December 2015, DePuy Synthes Sales, Inc. ("DePuy") filed three petitions for *inter partes* review of the '008 patent. Prelim. Resp. 17; *see also* Exs. 2001–2003 (providing the petitions). The three petitions rely on grounds based on Errico-402, as modified by either Koshino[12] or Campbell. Prelim. Resp. 17; Ex. 2001, 5–6; Ex. 2002, 6; Ex. 2003, 6.

For each petition, DePuy provided an annotated version of Errico-402's Figure 6 to illustrate how Errico-402 corresponds to subject matter of a challenged claim of the '008 patent. The annotated figure from Ex. 2001 is reproduced below.

[12] Koshino, US 5,879,389, issued March 9, 1999 (Ex. 2007).



Errico, Fig. 6

Ex. 2001, 21; *see also* Ex. 2002, 23 (providing a similar annotation); Ex. 2003, 24 (same). DePuy argued that snap-ring 180 corresponds to the stopping member of the '008 patent. In each of the three petitions, DePuy proposed to modify Errico-402's securing element to replace coupling element 132 with either Koshino or Campbell's enlarged integral head. Prelim. Resp. 19 ("DePuy argued that it would have been obvious to modify Errico-402's assembly by eliminating the coupling element and replacing the bone screw head with the one-piece, partially curved heads described in Koshino or Campbell"); *see, e.g.*, Ex. 2001, 9–20 (providing DePuy's obviousness position with respect to Errico-402 and Koshino and claims 1–5, 9–22, and 29–37). DePuy characterized its modification as an "obvious choice in design." *See, e.g.*, Prelim. Resp. 19.

In denying institution in each of the three proceedings, the Board determined that DePuy did not provide sufficient reasoning for why a person having ordinary skill in the art would have modified Errico-402 as DePuy proposed. *See, e.g.*, Ex. 2004, 15–16 ("Because Petitioner has not presented sufficient reasoning for why a person of ordinary skill in the art would have made the proposed combination and because Errico[-402] teaches away from such a combination, there is not a reasonable likelihood that Petitioner would prevail."). The Board determined that DePuy's reasoning was not supported by sufficient evidence in the record. *Id.* at 13–14. The Board also

determined that Errico-402 taught away from the proposed modification, as the modification would render Errico-402 inoperable for its intended purpose. *Id.* at 15. Specifically, the Board determined that eliminating Errico-402's coupling element in the manner proposed by DePuy would destroy the ability for Errico-402's screw to be "locked to the plate at any particular angle." *Id.*; *see* Prelim. Resp. 20 ("The Board further found that modifying Errico[-402] as proposed, however desirable, would compromise Errico[-402]'s design goals.").

c) Becton, Dickinson factors (a) and (b)

We now turn to the first part of the *Advanced Bionics* two-part analysis framework.[13] The first two *Becton, Dickinson* factors examine the similarities and material differences between the prior art on which Petitioner relies and the prior art before the Office and the cumulative nature of the references. *Becton, Dickinson*, Paper 8 at 17. Petitioner acknowledges that references "in the same family as Errico" were before the Office. Pet. 9. Petitioner argues, however, that Theken and Farris were not before the Office. *Id.* Petitioner explains that Theken is materially different from other references addressed during prosecution (e.g., Estes, Dill, Hodorek, and Campbell). Specifically, Petitioner argues that Estes includes a screw head that protrudes from the anterior opening of the stabilizing element's bore (Theken's screw head does not protrude above the anterior

[13] Patent Owner argues that "Petitioner fails to address the first part of the *Advanced Bionics* framework" in the Preliminary Reply. Prelim. Sur-reply 1. Although we note that Petitioner did not structure the Preliminary Reply as provided in *Advanced Bionics*, we determine that Petitioner provides sufficient substantive arguments for us to analyze the issue. *See* Prelim. Reply 1–5 (discussing the cumulative nature of the prior art and substance of the arguments made before the Office).

surface of its plate). Prelim. Reply 3–4. Petitioner argues that Dill is not directed to an orthopedic assembly and does not include a stopping member. *Id.* at 4. Petitioner argues that Hodorek's sealing washers are not stopping members. *Id.* Finally, Petitioner argues that Campbell includes a deformable head/rim. *Id.*

Patent Owner argues that Petitioner relies on Theken for the stabilizing element in the same way DePuy relied on Errico-402 for a stabilizing element. Prelim. Resp. 23; *see also id.* at 24 (providing a side-by-side comparison of Theken's and Errico-402's stabilizing element).

Patent Owner argues that "both DePuy and Petitioner here relied upon Errico's 'snap-ring 180' for the teaching of the recited stopping member." Prelim. Resp. 22. Patent Owner argues that "Petitioner simply takes Errico's snap-ring out of Errico's plate and incorporates it into another generic and substantially similar bone plate." *Id.* at 25.

Patent Owner next argues that both DePuy and Petitioner rely on a one-piece screw with an integral head to correspond to the recited securing element. Prelim. Resp. 25; *see id.* at 25–26 (describing DePuy's position of modifying Errico-402 with Koshino's or Campbell's screw).

Patent Owner adds that "Farris provides nothing new that DePuy did not already present to the Board." Prelim. Resp. 26. Patent Owner characterizes Petitioner's reliance on Farris "for its teaching of a bone screw having a spherical head that allows for angular displacement during implantation," which Patent Owner argues DePuy presented with Koshino and Campbell. *Id.*

With respect to prosecution before the Office, Patent Owner argues that the examiner twice rejected "the pending claims" as anticipated by or rendered obvious over Errico-402. Prelim. Resp. 29–30. Patent Owner

recounts that these rejections were overcome by amending the claims to require an enlarged integral portion for the securing member. *Id.* at 30–31. Patent Owner argues that it is undisputed that both the examiner and Petitioner rely on Errico's snap-ring 180 to teach the recited stopping member. *Id.* at 35–36. Patent Owner also argues that Petitioner relies on Theken and Farris for the same elements for which the examiner relied on Errico-402. *Id.* at 36; *see also id.* at 37–38 (comparing the disclosures in Errico-402 and Theken).

Patent Owner adds that the examiner also made rejections based on Estes, Dill, Hodorek, and Campbell. Prelim. Resp. 32–35. Patent Owner argues that the examiner could have proposed a combination that added Errico-402's snap-ring 180 to any of these four references. *Id.* at 40–41.

Patent Owner argues that Farris adds nothing over Errico-402. Prelim. Resp. 41. Patent Owner also argues that, like Farris, Estes and Hodorek each discloses a screw head with a curved posterior surface. *Id.*

In response to the Preliminary Reply, Patent Owner argues that "Petitioner does not dispute that the biased stopping member from Errico applied in its Petition is the ***same art and argument*** from the ***same embodiment*** as applied during prosecution and in the *DePuy* petitions." Prelim. Sur-reply 2.[14] Patent Owner concludes that "[t]hus, the instant Petition raises the same art and argument regarding the biased stopping member that the Office previously considered and rejected." *Id.*

Patent Owner argues that Petitioner does not dispute that Theken's stabilizing element is substantially the same as the stabilizing element from

[14] We address whether the same or substantially the same *arguments* were before the Office in the following subsection.

Errico-402. Prelim. Sur-reply 2. From this allegation, Patent Owner concludes that, with respect to the stabilizing element, substantially the same art was before the Office. *Id.*

Patent Owner argues that Petitioner does not address that the bone screws disclosed in the references considered by the Office and the screws disclosed in Theken and Farris are "just conventional tapered- or curved-head screws." Prelim. Sur-reply 4.

We have considered Patent Owner's arguments and do not find them persuasive, as we find that there are material differences between Theken and Farris and the prior art the Office considered. As an initial point, Patent Owner does not dispute that neither Theken nor Farris was before the Office in previous proceedings. *See* Prelim. Resp. 15–43; Prelim. Sur-reply 1–7.

Next, we find unavailing Patent Owner's arguments that Petitioner relies on Theken and Farris for the same claim elements (except for the stopping member) as the examiner or DePuy in prior interactions with the Office. This fact merely reflects the very nature of any prior art-based ground of unpatentability. To succeed, the proponent of the ground must map each element of a claim to a disclosure in the prior art. So, it is not surprising that Petitioner maps disclosures in Theken to the same elements on which the examiner and DePuy relied in Errico-402. This fact, in and of itself, does not demonstrate that there are no material differences between Theken and Farris and the prior art considered by the Office.

Turning to Theken, we determine that Petitioner relies on express teachings in Theken to support its obviousness position that were not present in other prior art considered by the Office. Among other things, Theken expressly teaches that its set screws "could be replaced by other suitable locking mechanisms." Ex. 1005, 7:33–35. Petitioner relies on this express

suggestion to modify Theken to support Petitioner's obviousness position. *See, e.g.*, Pet. 18–19 ("As Theken expressly directs a POSA to employ other suitable locking mechanisms, a person of ordinary skill in the art would have had good reason to employ other suitable locking mechanisms known to be useful and available at the time."); *id.* at 22 ("Theken indicate[s] that his 'set screw 140 could be replaced by other suitable locking mechanisms.'"); *id.* at 28 ("Theken provides for use of other types of stopping members."); *see also* Ex. 1002 ¶¶ 105–108 (testifying about Theken's express suggestion of replacing its set screws with a different locking mechanism and how Errico's locking mechanism would be suitable).

We do not discern, nor does Patent Owner direct us to evidence of, how DePuy relied on Koshino or Campbell (or Errico-402) expressly to suggest the specific modifications on which DePuy based its obviousness grounds and, more particularly, a suggestion for substituting one locking mechanism for another.

Turning to Farris, we determine that Petitioner uses Farris for a narrow consideration: "Farris provides additional evidence that each of claims 3, 5, 11, 22, 30, and 37 is obvious and provides details regarding implementing an invalidating embodiment of a variable-angle bone screw." Pet. 55. By "additional evidence," the Petition uses Farris's teachings to enhance its position that the combination of Theken and Errico would have been obvious. *See, e.g.*, *id.* at 60 ("As discussed above in Ground 2, Theken and Errico each disclose the head of the securing element having a curved posterior surface. Farris provides additional motivation for the head of the securing element (*e.g.* spherical head 115) to have a curved posterior surface and a minimum outer diameter for both fixed angle and variable angle screws.") (internal citations omitted). Significant to our determination here,

the Petition also relies on Farris's teachings of the advantages of a spinal plating system that allows deploying the bone screws at varying angles. *See* Pet. 55 (referencing Ex. 1008, 3:17–26, 3:27–4:25). Farris explains the need for a plating system with universal application to different pathologies, including the ability for varying degrees of fixation. Ex. 1008, 3:17–23 ("However, even with the more refined plating system designs, there still remains a need for a system that has universal applicability to all pathologies that can be faced by a spinal surgeon in treating the spine."); *see also id.* at 3:35–4:3 ("In cases where a graft is implanted to replace the diseased vertebral body, the presence of a screw capable of some [rotation] ensures continual loading of the graft."); *id.* at 5:13–16 ("The flexibility of the present invention anterior fixation plating system is accomplished by the provision of a fixed angle and a variable angle screw that can be supported within the same screw hole in the plate.").

We do not agree with Patent Owner that Petitioner relies on Farris for the same teachings for which DePuy relied on Koshino and Campbell. We recognize that DePuy does identify a curved posterior surface on the head of Koshino's bone screw (Ex. 2001, 27) and identifies that Koshino's and Campbell's screws can be angularly displaced (e.g., Ex. 2001, 50, 59) and that Petitioner does rely on Farris for teaching the subject matter of claims 11, 22, 30, and 37 (*see* Pet. 61–64). The Petition, however, relies on the combination of Theken and Errico for disclosing a securing element having a curved posterior surface. Pet. 60. Also, in addition to any reliance on the geometry of Farris's screws, the Petition relies on Farris for teaching the advantages of angular displacement of screws and to support a conclusion that a person having ordinary skill in the art would have had a reasonable expectation of success of combining Theken and Errico for Ground 2. *See*

Pet. 55–58. We do not discern, nor does Patent Owner direct us to any argument, that DePuy relied on Koshino or Campbell for teaching the benefits of angular variability in displacing the bone screws. *See, e.g.*, Ex. 2001, 12–20, 52–54; Pet. 55.

Patent Owner argues that the facts here are similar to those in *Advanced Bionics* itself, such that we should arrive at a similar conclusion. Prelim. Sur-reply 5–6. We disagree. In *Advanced Bionics*, the Board determined, on the evidence in that proceeding, that the petitioner relied on the same or substantially the same prior art. *Advanced Bionics*, Paper 6 at 13–19. Here, we determine that express teachings in Theken (suggestion to substitute other stopping members) and Farris (advantages of variable screw displacement) represent material differences over the prior art previously considered by the Office.

For these reasons, we determine that there are material differences between Theken and Farris and the prior art previously considered by the Office. Also, for these same reasons, Theken and Farris are not cumulative to the prior art previously considered by the Office.

d) Becton, Dickinson factor (d)

As part of the first stage of the *Advanced Bionics* framework, we also consider "the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art." *Advanced Bionics*, Paper 6 at 9 n.10, 10. Petitioner argues that the Office never considered Errico "in the manner set forth in this [P]etition," that is, as disclosing a snap-ring stopping member that could serve as a substitute for a stopping member in a different orthopedic assembly. Pet. 9; *see also* Prelim. Reply 2 ("The reissue examiner . . . ***never*** evaluated using Errico's snap-ring

in any other reference, [and] . . . DePuy's IPR petitions never proposed using Errico's snap-ring in a different reference.").

Patent Owner argues that Petitioner's unpatentability position and that of DePuy are the same—using a conventional implant assembly with conventional screws and Errico's snap-ring. Prelim. Sur-reply 4–5. With respect to the securing element, Patent Owner dismisses Petitioner's contention that the Petition proposes modifying Theken with Errico's snap-ring, and not modifying Errico with Theken's screw head—arguing that our precedents are not concerned with labels such as primary and secondary references. *Id.* at 3.

We determine that there is some, but not substantial, overlap in the arguments previously considered by the Office. Significant to our determination is that the Office has not previously been presented with an argument that it would have been obvious to replace a known stopping member, such as Theken's set screws, with Errico's stopping member. *See* Pet. 9; Prelim. Reply 1.

As an initial matter, we recognize that the prior proceedings before the Office have considered conventional orthopedic plates with conventional bone screws. Indeed, as Patent Owner argues, "[o]ne key point of novelty in the ['008] patent is the particular stopping member configuration." Prelim. Resp. 15. Many of the limitations other than the stopping member configuration relate to structures that were, by themselves, known in the implant art. *See, e.g.*, Ex. 1002 ¶ 60 ("At the time of the invention of the '008 patent . . ., the use of plates and screws for joining bones together was well-known."); Ex. 2016 ¶¶ 45–52 (recounting the background of the technology); Ex. 1001, 1:17–18 ("Orthopedic implants used to join bone

segments include rods, plates, and screws."). As such, the arguments directed to a stopping member represent key arguments on patentability.

Petitioner argues that it would have been obvious to modify Theken's orthopedic implant system by replacing its set screw stopping member (referred to as a "locking mechanism") with another type of stopping member. *See* Pet. 18–27 (explaining reasons for why a person having ordinary skill in the art would have made the proposed substitution). One reason on which Petitioner relies is Theken's express suggestion for the substitution of one stopping member for another. *Id.* at 18–19; *see* Ex. 1005, 7:33–35. Petitioner and its expert provide additional reasoning for the substitution. *See* Pet. 23–25; Ex. 1002 ¶ 116.

Petitioner's substitution argument is enhanced by Errico's disclosure, which characterizes its stopping member as "a simple and effective locking mechanism for locking the bone screw to the plate." Ex. 1006, 6:1–2; *see* Pet. 19 (quoting Errico's characterization).

We do not agree with Patent Owner that Petitioner's obviousness position is the same as DePuy's. DePuy's position relied on modifying Errico-402's system to remove the coupling element and modify the head of Errico's screw. *See, e.g.*, Ex. 2004, 13 ("[T]he Petition argues that using a screw head instead of Errico[-402]'s coupling element 'is nothing more than an obvious choice in design, and one that would have been readily contemplated and implemented by a POSA at the time of the invention.'"). The Board did not institute the DePuy proceedings, in part, because it found that Errico-402 favored its particular structure using the coupling element and the proposed modification would render Errico-402 inoperable for its intended purpose. *Id.* at 13–14. That is, the Board determined that DePuy's reasoning was unsupported, in part, because the proposed modification

would have removed coupling element 132, which was key to how Errico-402 achieved its poly-angular screw placement and locking.

Here, Petitioner does not propose to modify Errico at all. Instead, Petitioner proposes to substitute Errico's stopping member structure for Theken's set screws. Theken's orthopedic implant assembly is being modified, not Errico's. Because Petitioner does not propose to modify Errico, we do not face the same issues as the panel in the DePuy proceedings.

Although we agree with Patent Owner that *Advanced Bionics* does not draw any distinction of primary or secondary references, the outlined framework does require us to consider the arguments made before the Office in the previous proceedings. Patent Owner does not assert that DePuy argued, and the Board considered, a modification that relied on the narrow teachings of Errico's snap-ring 180 as a simple and effective locking mechanism, which could have been employed in a different orthopedic implant assembly.

We also determine that Petitioner's arguments were not considered by the Office during prosecution of the original or reissue applications. As we recounted above, no art-based rejections were made in the initial prosecution and, during reissue, the examiner relied on anticipation rejections of a subset of claims and never addressed whether it would have been obvious to employ Errico's snap-ring in a different implant system.

Accordingly, we determine that the arguments in the Petition are not the same or substantially the same as the arguments previously presented to the Office.

e) Conclusion

Because we determine that neither the same or substantially the same art previously was presented to the Office nor the same or substantially the same arguments previously were presented to the Office, we need not address the second stage of the *Advanced Bionics* framework. *See Advanced Bionics*, Paper 6 at 10. We determine that the facts of this proceeding do not support our exercising discretion under 35 U.S.C. § 325(d).

B. 35 U.S.C. § 314(a)

The Board has discretion not to institute an *inter partes* review. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); 37 C.F.R. § 42.108(a) (stating "the Board *may* authorize the review to proceed") (emphasis added); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), "the PTO is permitted, but never compelled, to institute an IPR proceeding").

Patent Owner contends that our precedential decisions in *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential) ("*General Plastic*"), and *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential) ("*NHK Spring*"), "weigh strongly in favor of discretionary denial" of this proceeding. Prelim. Resp. 43. Patent Owner bases its arguments on the prior DePuy petitions and prior district court litigation against DePuy (but not Petitioner). Prelim. Resp. 43–52. For the reasons provided below, we do not agree that exercising our discretion under 35 U.S.C. § 314(a) is appropriate here.

General Plastic provides a non-exhaustive list of factors to consider when multiple petitions address the same patent and, particularly, when one

petition is filed after another petition—a follow-on petition. *General Plastic*, Paper 19 at 15–16. We need address the first of these factors only—*whether the same petitioner previously filed a petition directed to the same claims of the same patent. See General Plastic*, Paper 19 at 9.

The application of the *General Plastic* factors is not limited to the situation where the same petitioner files a follow-on petition. *Valve Corp. v. Electronic Scripting Prods., Inc.*, IPR2019-00062, Paper 11 at 2 (PTAB Apr. 2, 2019) (precedential) ("*Valve Corp.*"). "[W]hen different petitioners challenge the same patent, we consider any relationship between those petitioners when weighing the *General Plastic* factors." *Id.*; *see also id.* at 10 (finding a "significant relationship" between the different parties that filed the petitions at issue). Here, Patent Owner does not allege *any* relationship between Petitioner and DePuy. Indeed, from the record, we discern that the only relationship between these parties is that they both were sued by Patent Owner for infringing the '008 patent. However, Petitioner was served with its complaint *over three years* after the Board denied institution of DePuy's proceedings. Ex. 1013; Ex. 2004. It appears that the only reason that the Petition is a follow-on petition is because the Patent Owner sued Petitioner well after suing DePuy, not because of any actions taken by Petitioner in an attempt to manipulate the *inter partes* review process or gain a tactical advantage over Patent Owner.

Because we find that the Petition is not a "follow-on" petition as contemplated by *General Plastic* and *Valve Corp.*, we do not exercise our discretion to deny institution because of the timing of the Petition.

Second, with respect to *NHK Spring*,[15] Patent Owner asks us to exercise discretion to deny institution because the '008 patent has already been the subject of a jury trial—one that is completed and that did not include Petitioner. Prelim. Resp. 46–52. *NHK Spring* did not address such a fact pattern.

NHK Spring addressed whether the Board should exercise its discretion under 35 U.S.C. § 314(a) to not institute a proceeding because of *parallel* district court litigation involving the challenged patent. *NHK Spring*, Paper 8 at 19–20. The Board has expanded its precedential decision in *NHK Spring* to identify factors we consider in applying *NHK Spring*. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) ("*Fintiv I*"). Our precedential and informative decisions make clear that the Board may exercise discretion to not institute an *inter partes* proceeding in light of the advanced stage of ongoing, parallel litigation. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (PTAB May 13, 2020) (denying institution in light of an ongoing, parallel district court proceeding) (informative) ("*Fintiv II*"); *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 (PTAB June 16, 2020) (applying *Fintiv I* factors in light of ongoing, parallel district court litigation and instituting trial) (informative). These decisions promote efficient use of resources and the integrity of the patent system by avoiding potentially conflicting decisions. *See, e.g.*, *Fintiv I*, Paper 11 at 6 ("[T]he

[15] Patent Owner characterizes our precedential decision in *NHK Spring* as an additional factor to be considered under the *General Plastic* regime. Prelim. Resp. 44. *NHK Spring* does not concern follow-on petitions. *See NHK Spring*, Paper 8 at 19 (distinguishing *General Plastic*).

Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.").

Patent Owner does not direct us to any Board decision, precedential, informative, or otherwise, where the Board exercised its discretion to deny institution of a proceeding under § 314(a) because the subject patent was asserted in a previous, resolved litigation, one not involving the petitioner.[16] Instead, Patent Owner effectively asks us to impute on a later-sued party the consequences of a litigation for which that party had no apparent role. Such a result could incentivize a patent owner to evade the *inter partes* review process by first suing a party who, for whatever reason, may less diligently or effectively defend itself in a litigation, then suing other parties that may have reason to more vigorously defend themselves. Accordingly, under the facts here, we do not expand *NHK Spring* to apply to a long-completed trial that did not involve Petitioner.

We would reach the same result if we apply the factors from *Fintiv I*. These factors include:

> 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
> 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
> 3. investment in the parallel proceeding by the court and the parties;
> 4. overlap between issues raised in the petition and in the parallel proceeding;
> 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
> 6. other circumstances that impact the Board's exercise of discretion, including the merits.

[16] As we indicate below, the previous litigation also did not involve the same grounds as in the Petition.

Fintiv I, Paper 11 at 5–6. Patent Owner argues about the DePuy litigation only and provides no information about the parallel litigation involving Petitioner. So, we evaluate the factors based on the DePuy litigation alone.

Factors (1) and (2) are neutral in this case. There is no court proceeding to stay. DePuy and Patent Owner voluntarily dismissed the case following trial. Ex. 3001.

Factor (3) weighs in favor of discretionary denial. The District Court for the Eastern District of Wisconsin did invest its time in a trial. This factor, however, does not strongly favor denial. Unlike a parallel proceeding, where a court may have to invest additional resources in a proceeding, all effort associated with the DePuy litigation matter is complete.

Factor (4) weighs against discretionary denial. Although we appreciate that DePuy's defense at trial purportedly included an invalidity ground that modified a commercial implant product with Errico-402's snap-ring (*see* Prelim. Resp. 46–48), the ground did not include Theken, with, among other things, its express suggestion for substituting its stopping member. Also, the record in this *inter partes* review proceeding is incomplete as to what was presented to the jury with respect to this ground. In reviewing DePuy's expert's report, the only reason argued in support for the proposed substitution was replacing a two-step process with a one-step process. Ex. 2009 ¶ 712; *see also* Prelim. Resp. 47–48 (identifying this single reason). Petitioner provides additional reasons to support its obviousness position.

Factor (5) weighs strongly against discretionary denial. Petitioner was not a party in the DePuy litigation. Petitioner could not orchestrate its invalidity case before the jury, the case was dismissed prior to any appeal,

and there is no evidence on this record of any relation between Petitioner and DePuy such that Petitioner could have or should have sought to involve itself in such a prior proceeding challenging the '008 patent.

Factor (6) weighs against discretionary denial. As will be evident from our discussion below, we determine, on the current record, that Petitioner has a strong case. Also, there is no chance that our decision would be inconsistent with the results of the DePuy litigation, as the specific grounds addressed in this proceeding were not before that court.

After weighing all of the factors and taking a holistic view of the relevant circumstances of this proceeding, we determine that exercising our discretion to deny institution under 35 U.S.C. § 314(a) because of the DePuy litigation is not warranted. There is no dispute that Petitioner was not part of the DePuy litigation. There is no dispute that the specific grounds in the Petition were not part of the trial. Also, the DePuy litigation is over, and it was dismissed without appeal. *See* Ex. 3001. Because of the differences in grounds, there is no chance for inconsistent results between any decision we reach and the decision reached at trial that could undercut the integrity of the patent system. Similarly, there is no chance of duplicating efforts that would create system inefficiencies.

For the reasons above, we do not exercise our discretion under 35 U.S.C. § 314(a).

III. UNPATENTABILITY

A. Applicable Law

Petitioner's asserted grounds of unpatentability are based on obviousness under 35 U.S.C. § 103(a).

> 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, objective evidence, 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).

"[O]bviousness must be determined in light of *all the facts*, and . . . a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine" teachings from multiple references. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (emphasis added); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) ("The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.").

B. Level of Ordinary Skill in the Art

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). Petitioner contends that a person having ordinary skill in the art of the '008 patent

> would have had: (1) a[n] undergraduate or advanced degree in mechanical engineering, biomechanical engineering, biomedical engineering, or a related field of science, as well as three or more years of related experience in the field of orthopedic implants; or

> (2) would be a practicing orthopedic spinal surgeon with at least five years of experience, as well as some experience in the design of spinal orthopedic implants.

Pet. 11–12 (referencing Ex. 1002 ¶¶ 54–59).

Patent Owner does not expressly provide a definition of the level of ordinary skill in the art. Patent Owner's declarant testifies that "[w]hile I do not necessarily agree that [Petitioner's definition] is the appropriate level of skill in the art, I have assumed for the sake of my analysis in this proceeding that Petitioner's definition is correct." Ex. 2016 ¶ 44.

For the purposes of this Decision, we apply Petitioner's definition. We determine that this definition is consistent with the prior art of record and the skill reflected in the Specification of the '008 patent.

C. Claim Construction

In *inter partes* reviews, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." *See* 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner provides express constructions for the terms "posterior" ("an inner portion of the assembly closer to the bone to which the assembly is attached") and "anterior" ("an outer portion of the assembly farther away from the bone."). Pet. 12. Petitioner also construes the term "collar" to include a discontinuous retaining ring. *Id.* at 12–13. Petitioner construes the term "elastically deformable material" to encompass titanium and the term "superelastic material" to encompass nickel titanium alloys. *Id.* at 13. Finally, Petitioner construes claims 21 and 22 as not requiring "angularly

displacing the head of the securing element after the securing element is positioned within the patient's bone." *Id.* at 13–14.

Patent Owner does not object to Petitioner's constructions of the terms "posterior" and "anterior," and states that we need not expressly construe the other terms addressed by Petitioner to resolve the parties' controversy at this stage of the proceeding. Prelim. Resp. 8–9.

We determine that we need not expressly construe any claim term to resolve the parties' dispute at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

D. Ground 1: Claims 1, 2, 4, 10, 12–19, 21, 29, 31, 32, and 36 as Obvious Over Theken and Errico

Petitioner contends that claims 1, 2, 4, 10, 12–19, 21, 29, 31, 32, and 36 are obvious over Theken and Errico. Pet. 14–47. In the subsections below, we discuss the scope and content of the prior art and any differences between the claimed subject matter and the prior art, on a limitation-by-limitation basis.

1. Independent claims 1, 21, and 36

a) Independent claim 1

(1) Preamble

The preamble of claim 1 recites "[a]n orthopedic implant assembly." Ex. 1001, 7:61. Petitioner contends that "Theken discloses an orthopedic implant assembly," identifying bone fixation system 10. Pet. 27 (referencing Ex. 1005, 4:7–55, 5:59–66, Figs. 1–8, 10; Ex. 1002 ¶ 121).

We determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken discloses the subject matter of the preamble of claim 1. In view of this determination, we need not determine at this

stage of the proceeding whether the preamble is limiting. Patent Owner does not dispute Petitioner's contention with respect to the preamble at this time.

(2) Stabilizing element limitation

Claim 1 also recites "a stabilizing element having an anterior surface, a posterior surface, and at least one bore." Ex. 1001, 7:62–63. Claim 1 requires "the bore hav[e] a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening." *Id.* at 7:63–67.

Petitioner contends that Theken discloses the recited stabilizing element, bone plate 20. Pet. 27. Petitioner contends that lateral side 26 corresponds to the anterior surface and medial side 28 corresponds to the posterior surface. *Id.* Petitioner contends that circular opening 62 corresponds to the recited bore, with a first opening at the top of threaded section 66 and a second opening at the bottom of tapered section 64, with the second opening being smaller than the first opening and a transverse pathway extending between the openings. *Id.* at 27–28 (referencing Ex. 1005, 4:7–55, 5:59–66, Figs. 1–8 and 10; Ex. 1002 ¶ 121 and Table 1)

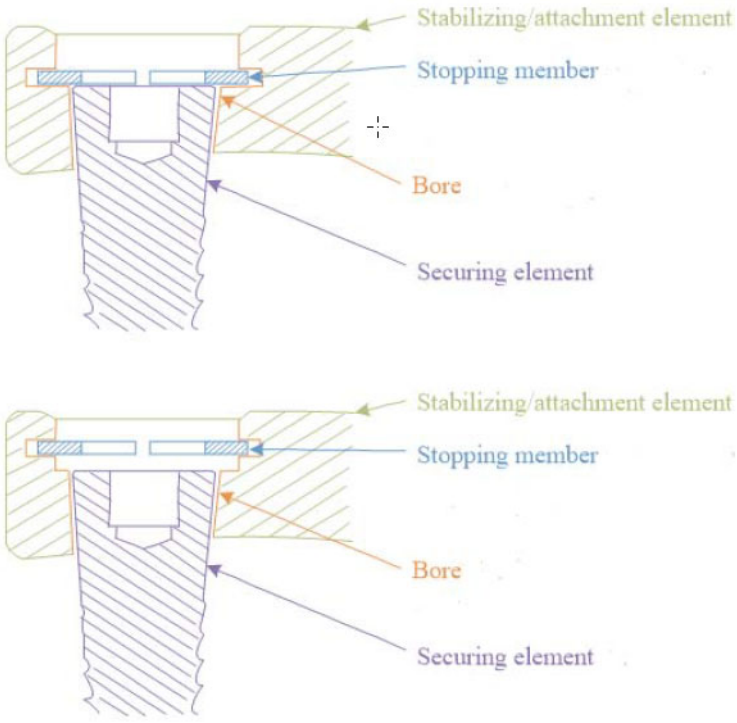
We have reviewed Petitioner's contentions and determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken discloses the subject matter of the stabilizing element limitation of claim 1. Patent Owner does not dispute Petitioner's contention with respect to this limitation at this time.

(3) Subject matter of the biased stopping member limitation

Claim 1 also recites "a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration." Ex. 1001, 8:1–4.

Petitioner contends that Theken's orthopedic implant assembly includes a stopping member, set screws 140. Pet. 28 (referencing Ex. 1005, 3:63–65, 6:60–66, 9:22–24, 9:54–59, Figs. 1–3). Petitioner recognizes that Theken's set screws differ from the recited biased stopping member. *See id.*

Petitioner contends that Errico discloses the recited biased stopping member, snap-ring 180, which defines a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration. Pet. 28 (referencing Ex. 1006, 4:1–5, 6:1–2, 8:13–17, 23:25–24:10, Figs. 5–6); *see also* Ex. 1002 ¶¶ 106–107 (describing Errico's stopping member). Petitioner argues that it would have been obvious to a person having ordinary skill in the art to substitute Errico's snap-ring 180 for Theken's set screws 140. Pet. 22. Petitioner identifies two different implementations for Theken's orthopedic implant assembly as modified by Errico. We reproduce these implementations in images below.



Id. at 25 (referencing Ex. 1002 ¶¶ 111–114). The two images show a stopping member (in blue) within a groove in a bore of Theken's stabilizing element (in green), positioned at the anterior side of a securing element (in purple). The top image shows the stopping member abutting the top of the securing element and the second image shows a gap between the stopping member and the top of the securing element. *Id.* at 25–26.

We have reviewed Petitioner's contentions and determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken, as modified by Errico, discloses the subject matter of the stopping member limitation of claim 1. Patent Owner does not dispute Petitioner's contention with respect to the subject matter of this element at this time. We address Petitioner's reasoning in support of this substitution in the subsection, below.

(4) Reasons for substituting Errico's biased stopping member into Theken

Petitioner reasons that "Theken expressly directs a [person having ordinary skill in the art] to employ other suitable locking mechanisms" and that an artisan of ordinary skill "would have had good reason" to employ a known locking mechanism. Pet. 18–19; *see also* Ex. 1005, 7:33–35 ("It will be appreciated [by a person having ordinary skill in the art] that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms."). Petitioner adds that Errico expressly discloses that its locking mechanism is "a simple and effective locking mechanism for locking the bone screw to the plate." *Id.* at 19. Petitioner explains that "Errico provides prior art evidence confirming a [person having ordinary skill in the art] would have known that a retaining

ring (*e.g.*, snap-ring) is such a suitable locking mechanism." *Id.* at 22 (referencing Ex. 1006, 6:1–2, 23:12–14; Ex. 1002 ¶ 108).

Petitioner contends that additional reasons motivate the proposed substitution. Pet. 23–24. These reasons include (1) avoiding cross-threading of Theken's set screws, (2) eliminating small, slippery screws (reducing "fiddle-factor"), (3) reducing the number of steps to insert the bone screw, because the snap-ring can be preloaded into the stabilizing element, (4) reducing risk of losing a screw in a patient, and (5) minimizing protrusions of a screw above the plate. *Id.* at 24 (referencing Ex. 1002 ¶ 116).

Petitioner contends that a person having ordinary skill in the art would have had a reasonable expectation of success for the proposed substitution. Pet. 22. Petitioner, relying on its declarant's testimony, contends that Errico's snap-ring and annular recess "is a simple, suitable, and inexpensive means to prevent screw back-out in Theken's assembly." *Id.* at 22–23 (referencing Ex.1002 ¶ 110). Mr. Errico testifies that Errico's disclosure supports his opinion. Specifically, because Errico discloses using snap-ring 180 in a way similar to how Theken uses set screws 140 to achieve a similar purpose, a person having ordinary skill in the art would have appreciated that Errico's snap-ring could be employed in Theken with a reasonable expectation of success. Pet. 23; *see also* Ex. 1002 ¶ 115 (listing the disclosures in Theken and Errico that support this opinion).

As Mr. Errico further explains, Errico's snap-ring 180 prevents its coupling element from backing out once the coupling element is positioned posteriorly to the snap-ring because the coupling element's flat head cannot deflect the ring. Ex. 1002 ¶ 107. Theken discloses a screw with a flat head at the upper most point, supporting Mr. Errico's testimony that a person

having ordinary skill in the art would have had a reasonable expectation of success with the proposed substitution in light of Errico's teaching.

Mr. Errico also testifies sizing a snap-ring for head portion 110 of Theken's bone screw 100 would have been within the level of ordinary skill. Pet. 23. Petitioner concludes that the proposed substitution "amounts to nothing more than applying a known technique to a similar device to perform the same function and yield predictable results" and a "simple substitution." *Id.* at 23–24.

Petitioner also contends that the two implementations of its proposed combination would result in "an 'internal bone fixation system for the treatment of bone anomalies.'" Pet. 26 (referencing Ex. 1002 ¶¶ 117–118). As such, the modification renders Theken satisfactory for its intended purpose. *Id.*

Patent Owner argues that a person having ordinary skill in the art would not have been motivated to make the proposed substitution. Prelim. Resp. 52–64.

First, Patent Owner challenges Petitioner's reasoning that the substitution would have been motivated to avoid cross-threading Theken's set screws. Prelim. Resp. 53. Patent Owner argues that Theken solves this problem, by including alignment member 160 on the set screw. *Id.* at 53–54. Patent Owner also argues that, even if cross-threading was a concern, a person having ordinary skill in the art would replace the set screws with alternatives, such as a press fit mechanism or cemented configuration, that Theken expressly discloses. *Id.* at 54–55.

Second, Patent Owner argues that, to address any concerns with "fiddle factor," again, a person having ordinary skill in the art would have

turned to the press fit mechanism or cemented configuration disclosed in Theken. Prelim. Resp. 55.

Third, Patent Owner challenges Petitioner's reasoning of minimizing protrusions, as Theken's set screws do not protrude when installed in plate 20. Prelim. Resp. 56.

Fourth, Patent Owner argues that the proposed modification would not have yielded predictable results. Prelim. Resp. 57. Patent Owner argues that its declarant, Dr. Sachs, opines that Errico discloses using its snap-ring in conjunction with its coupling element and it would not have been predictable to employ the snap-ring without that element. *Id.* at 57–58 (referencing Ex. 2016 ¶¶ 77–79).

Also, Patent Owner argues that Petitioner engages in impermissible hindsight, by abandoning Errico's coupling element and employing only Errico's snap-ring 180. Prelim. Resp. 64–65. Patent Owner argues that the coupling element is what locks the screw to the plate in Errico's orthopedic implant assembly. *Id.*

We have considered Patent Owner's arguments, but do not find them sufficient at this stage of the proceeding to demonstrate a deficiency in Petitioner's position. As an initial matter, we agree with Patent Owner that Theken addresses cross threading of its set screws. We also determine that Petitioner does not adequately explain or support its reasoning concerning minimizing protrusions, particularly in light of Theken's disclosure that its set screws are flush with the anterior surface of plate 20. *See* Ex. 1005, Fig. 2 (depicting set screws 140 flush with anterior surface of plate 20); *see also* Ex. 1002 ¶ 116 (providing, in section "a." as reason (vi), minimizing protrusions above the anterior surface of the plate without any further explanation of how a protrusion would occur).

We do not agree with Patent Owner, on the limited record before us, that a person having ordinary skill in the art would have turned to the press fit mechanism or cement configuration disclosed in Theken rather than Errico's snap-ring stopping member. We read Theken's disclosure of replacing set screws 140 with other suitable locking mechanism to be a broader suggestion to a person having ordinary skill in the art to consider other suitable locking mechanisms. Indeed, in introducing the press fit and cementing alternatives, Theken states that "it should be appreciated that the screws, set screws, and screw and set screw interface formed in plate 20 may take various alternative forms." Ex. 1005, 7:47–49. These alternatives go beyond the suggested alternative embodiment of replacing the set screws with another locking mechanism.

We also determine, on the current record, that Errico's disclosure provides evidence that a person having ordinary skill in the art would have had a reasonable expectation of success in employing Errico's snap-ring and annular groove into plate 20. We do not credit Dr. Sachs's testimony at this stage of the proceeding. First, Dr. Sachs's testimony at paragraph 78 of his declaration is directed to the coupling element for the first embodiment of Errico's orthopedic implant system. *Compare* Ex. 2016 ¶ 78 (citing to Ex. 1006, 7:20–25), *with* Ex. 1006, 7:1–25 (discussing the first embodiment). Similarly, paragraph 79 of his testimony is directed to Errico's second embodiment. Ex. 2016 ¶ 79. These two embodiments do not employ snap-ring 180 as a stopping member. Indeed, as the Board previously found, Errico teaches a complex structure where "the screw can be angulated in countless directions to provide a surgeon flexibility during implantation" and then is locked into place through the "crush locking" Dr. Sachs describes. Ex. 2004, 13–14. This complex structure of coupling

element and spherical-head screw locks the screw to the plate independent of snap-ring 180. *See* Ex. 1006, 7:17–25.

Errico makes clear that its retaining ring, snap-ring 180, is an additional feature to retain and *further* lock the coupling element/screw structure. *See* Ex. 1006, 8:13–17, 23:12–24:10. As Errico teaches, the ring "prevents the coupling element . . . from backing out." *Id.* at 24:7–8; *see, e.g.*, Pet. 19 ("Errico teaches the 'retaining ring . . . snaps back into a retaining position."), 21 ("Errico's snap-ring 180 also prevents the coupling element from backing out of the plate."); Ex. 1002 ¶ 107 (declaring that Errico teaches that snap-ring 180 prevents the coupling element from backing out because the element's flat upper surface cannot deflect the ring). That is, Errico's snap-ring 180 performs the same function as Theken's set screws—preventing screw backout. Errico's coupling element locks the bone screw in the desired orientation. Patent Owner does not adequately explain why a person having ordinary skill in the art would not have had a reasonable expectation of succeeding in having a retaining structure anterior to bone screw 100 in Theken by employing only snap-ring 180 in an annular groove to prevent bone screw 100 from backing out.

Also, because we find, on the limited record before us, that Errico's coupling element functions to lock Errico's non-standard, spherical-head screw and the snap-ring functions to prevent screw backout and provide additional locking, we do not determine that Petitioner's proposed combination is the product of hindsight. Patent Owner does not adequately argue, at this stage of the proceeding, why substituting one structure designed to prevent screw backout with another structure designed for the same purpose, particularly in light of Theken's express suggestion, amounts to hindsight.

Next, Patent Owner argues that "Theken teaches away from substituting its rigid, constrained *locking* mechanisms with a non-rigid 'blocking' mechanism like Errico's snap-ring." Prelim. Resp. 59. Patent Owner argues that "[t]he Board made a similar finding in denying institution of the *DePuy* petitions holding that DePuy's proposed combination would 'render Errico inoperable for its intended purpose.'" *Id.* Patent Owner concludes that "Petitioner's proposed substitution of Theken's set screw with Errico's snap-ring poses the same problem, and should yield the same result." *Id.*

We have considered Patent Owner's arguments, but do not find them sufficient at this stage of the proceeding to demonstrate a deficiency in Petitioner's position. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference . . . would be led in a direction divergent from the path that was taken by the applicant." *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (quoting *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)); *see, e.g.*, *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (holding that, to teach away, the prior art must "criticize, discredit, or otherwise discourage the solution claimed"). Patent Owner does not direct us to any disclosure in Theken that criticizes, discredits, or otherwise discourages substituting a stopping member such as Errico's snap-ring for Theken's set screws.

"Additionally, a reference may teach away from a use when that use would render the result inoperable." *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1381 (Fed. Cir. 2007). As Petitioner argues, the modified configuration of Theken would have still operated as intended—"an 'internal bone fixation system for the treatment of bone anomalies.'" Pet. 26 (citing Ex. 1002 ¶¶ 117–118). We determine, on the current record, that Patent

Owner reads Theken's intended purpose to require a constrained system too narrowly and we agree with Petitioner that the proposed substitution does not render Theken inoperable for its intended purpose—"an internal bone fixation system for the treatment bone anomalies." Ex. 1005, 1:6–7.

Finally, we note that Petitioner contends and Mr. Errico testifies that one of the proposed implementations, where the snap-ring abuts the top of the securing element, would create a constrained system. Pet. 25; Ex. 1002 ¶ 112.

Also, we disagree with Patent Owner's characterization of the Board's decision in the DePuy proceedings. There, the Board found that eliminating Errico's coupling element would render Errico inoperable for its intended purpose because "the coupling element facilitates angulation of the screw relative to the plate prior to full implantation and subsequent locking of the screw to the plate in a given angulation upon full implantation." Ex. 2004, 15. The Board's focus was on Errico's operation and the role the coupling element plays in achieving Errico's "polyaxial coupling of the screw to the plate, whereby a single plate is compatible with a wide range of screw-in angles." *Id.* Indeed, the Board found Errico's complex structure involving the coupling element and a spherical-head screw to allow Errico's screw to "be angulated in countless directions" to be the key feature of Errico's disclosed technology. *Id.* at 13–14. For Petitioner's proposed combination, Errico's operation and its coupling element do not come into play. Petitioner relies on the use of snap-ring 180 to prevent screw backout in a similar way as set screws 140.

For the reasons above, we determine, on the current record, that the Petitioner has made the requisite showing that a person having ordinary skill in the art would have had reasons to combine the teachings of Theken and

Errico as Petitioner proposes to arrive at the stopping member limitation and these reasons are supported by a rational underpinning. *See KSR Int'l Co.*, 550 U.S. at 418 (stating that, to facilitate the analysis of an obviousness position, the proponent should provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

(5) Securing element limitation

Finally, claim 1 recites:

> a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.

Ex. 1001, 8:5–14. Petitioner contends that Theken's bone screw 100 corresponds to the recited securing element. Pet. 29. Petitioner contends that bone screw 100 includes threaded portion 102 (the elongated body) and tapered head portion 110 (integral head). Petitioner contends that tapered head portion 110 has a maximum diameter that is greater than the second opening of the stabilizing element, such that the head is retained between the stopping member and the second opening. *Id.* (referencing Ex. 1005, 4:21–26, 4:42–46, 6:19–31, Figs. 1, 2, 8–11; Ex. 1002 ¶ 123).

Petitioner adds that Errico teaches that the head of the securing element "head should have a diameter larger than the smaller diameter configuration of the biased stopping member so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element." Pet. 29 (referencing Ex. 1002 ¶ 124 and Table 1); *see also* Ex. 1006, 23:12–24:10 (describing

how snap-ring 180 operates to retain Errico's securing element). Petitioner explains that, in light of Errico's express teachings on how its stopping member works in conjunction with its securing element, a person having ordinary skill in the art would have sized the added snap-ring for head portion 110. Pet. 23 ("[S]izing a snap-ring for the head portion 110 of Theken's bone screws 100 would have been routine and well within the skill of the ordinary artisan."); *see also* Ex. 1002 ¶ 110 (testifying that a person having ordinary skill in the art "would have been motivated to—and would have understood how to—adjust the respective dimensions of Theken's tapered screw head portion 110 and Errico's snap-ring 180 to ensure Theken's tapered screw head portion 110 expanded Errico's snap-ring 180 and was retained by Errico's snap-ring 180 during use").

We have reviewed Petitioner's contentions and determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken, as modified by Errico, discloses the subject matter of the securing element limitation of claim 1. Patent Owner does not dispute Petitioner's contention with respect to the subject matter of this limitation at this time.

(6) Conclusion, claim 1

In conclusion, for the reasons provided above, we determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that claim 1 is unpatentable under 35 U.S.C. § 103 over Theken and Errico.

b) Independent claim 21

(1) Preamble

The preamble of claim 21 recites "[a] method of attaching an orthopedic implant assembly to a bone of a patient." Ex. 1001, 9:24–25.

Petitioner contends Theken is directed to the recited method. Pet. 38 (referencing Ex. 1005, 8:34-9:65; Ex. 1002 ¶ 148).

We determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken discloses the subject matter of the preamble of claim 21. In view of this determination, we need not determine at this stage of the proceeding if the preamble is limiting. Patent Owner does not dispute Petitioner's contention with respect to the preamble at this time.

(2) Positioning a stabilizing element step

Claim 21 also recites the step of "positioning a stabilizing element against a surface of the patient's bone," where the stabilizing element is configured as recited in claim 1, including a stopping member as recited in claim 1. Ex. 1001, 9:26–36; *compare id.* at 7:62–8:4 (reciting the stabilizing element and stopping member limitations of claim 1), *with id.* at 9:26–36. Petitioner contends that Theken discloses this step. Pet. 39 (Ex. 1005, 8:33–38, 4:7–55, 5:59–66, Figs. 1–10; Ex. 1002 ¶ 149).

As with claim 1, Petitioner contends that it would have been obvious to substitute Errico's snap-ring 180 in an annular groove for Theken's set screws, which Theken uses to stop screw backout. Pet. 39–40.

We have reviewed Petitioner's contentions and determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken, as modified by Errico, discloses the positioning a stabilizing element step of claim 21. We base this determination, in part, on our analysis of the stabilizing element and stopping member limitations of claim 1, presented above, including our determination that Petitioner has provided reasons, with rational underpinning, for substituting Errico's snap-ring 180 for Theken's set screws.

As we discussed above in connection with our analysis of claim 1, Patent Owner argues that it would not have been obvious to substitute Errico's snap-ring for Theken's set screws. We address these arguments above, in connection with our analysis of claim 1, and we determine that Petitioner has made the requisite showing at this stage of the proceeding.

(3) Providing a securing element step

Claim 21 also recites the step of "providing a securing element," where the securing element is as recited in claim 1. Ex. 1001, 9:37–45; *compare id.* at 8:5–14 (reciting the securing element limitation of claim 1), *with id.* at 9:37–45. Petitioner contends that Theken discloses the providing a securing element step. Pet. 40. Petitioner relies on the same contentions as presented for the securing element limitation of claim 1. *See id.*

We determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken, as modified by Errico, discloses the subject matter of the providing a securing element step of claim 21. Patent Owner does not dispute Petitioner's contentions with respect to the providing a securing element step at this time.

(4) Positioning the body of the securing element step

Claim 21 also recites "positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within the passageway defined by the biased stopping member and thereby displacing the biased stopping member to form the larger diameter configuration passageway defined thereby." Ex. 1001, 9:53–63. Petitioner contends that "Theken discloses positioning the body of the securing element (*e.g.* bone screw 100) in the transverse passageway through the openings 46, 62 and posteriorly advancing the head of the securing element within the transverse passageway from the anterior surface

to the posterior surface of the plate." Pet. 41 (referencing Ex. 1005, 4:35–38, 8:34–37, 8:56–9:1; Ex. 1002 ¶ 152). Petitioner adds that Errico teaches deploying its securing element through the passageway defined by snap-ring 180 and, in doing so, displacing the snap-ring to form a larger diameter configuration passageway through which the securing element passes. *Id.* (referencing Ex. 1006, 8:13–17, 23:27–24:7; Ex. 1002 ¶ 156 & Table 3).

We determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken, as modified by Errico, discloses the subject matter of the providing a securing element step of claim 21. Patent Owner does not dispute Petitioner's contentions with respect to the positioning the body of the securing element step at this time (other than the arguments directed to substituting Errico's snap-ring into Theken's orthopedic implant assembly, which we have addressed above in connection with our analysis of claim 1).

(5) Attaching the stabilizing element step

Finally, claim 21 recites

> attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the biased stopping member so that the passageway defined thereby returns to the smaller diameter configuration, to position the head within a posterior section of the transverse passageway between the biased stopping member and the second opening in the stabilizing element, and to position the body of the securing element within the patient's bone, so that the securing element is attached to the bone and is retained within the posterior section of the transverse passageway of the stabilizing element.

Ex. 1001, 9:53–63. Petitioner contends that Theken discloses attaching its plate 20 to a patient's bone by advancing the head of bone screw 100 and that bone screw 100 is retained within the posterior section of a transverse passageway in plate 20. Pet. 41–42. Petitioner adds that Errico teaches

advancing the head of its securing element (coupling element 132 containing the head of bone screw 120) posteriorly of snap-ring 180. *Id.* at 42.

We determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken, as modified by Errico, discloses the subject matter of the attaching the stabilizing element step of claim 21. Patent Owner does not dispute Petitioner's contentions with respect to the positioning the body of the securing element step at this time (other than the arguments directed to substituting Errico's snap-ring into Theken's orthopedic implant assembly, which we have addressed above in connection with our analysis of claim 1).

(6) Conclusion

In conclusion, for the reasons provided above in our analyses of claims 1 and 21, we determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that independent claim 21 is unpatentable under 35 U.S.C. § 103 over Theken and Errico.

c) Independent claim 36

Claim 36 recites "[a] method of attaching an orthopedic implant assembly to a bone of a patient." Ex. 1001, 11:28–29. Petitioner contends that "[t]he same combination of Theken and Errico discussed above for claims 1 and 21 . . . also renders claim 36 of the '008 patent obvious." Pet. 43.

Petitioner explains how the subject matter of claim 36 is comparable to claims 1 and 21. Pet. 43–44. Petitioner then provides a step-by-step analysis of claim 36. *Id.* at 44–47.

We have reviewed Petitioner's contentions and determine Petitioner has made a sufficient showing, at this stage of the proceeding, that Theken,

as modified by Errico, discloses the subject matter of claim 36. Also, as we determined with respect to claims 1 and 21, Petitioner has provided reasons, with rational underpinning, for substituting Errico's snap-ring 180 for Theken's set screws. Patent Owner does not dispute Petitioner's contentions with respect to claim 36 at this time (other than the arguments directed to substituting Errico's snap-ring into Theken's orthopedic implant assembly, which we have addressed above in connection with our analysis of claim 1).

Accordingly, for the reasons provided above, including in our analyses of claims 1 and 21, we determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that independent claim 36 is unpatentable under 35 U.S.C. § 103 over Theken and Errico.

2. Dependent claims 2, 4, 10, 12–19, 29, 31, and 32

Dependent claims 2, 4, 10, 12–19, 29, 31, and 32 depend, directly or indirectly, from independent claim 1. Ex. 1001, 8:15–11:20. We have reviewed Petitioner's contentions with respect to these dependent claims and determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that claims 2, 4, 10, 12–19, 29, 31, and 32 are unpatentable under 35 U.S.C. § 103 over Theken and Errico. Patent Owner does not provide any arguments directed specifically to any of these dependent claims.

E. Grounds 2 and 3: Claims 3, 5, 11, 22, 30, and 37 as Obvious Over Theken and Errico (Ground 2) or Theken, Errico, and Farris (Ground 3)

Claims 3, 5, 11, and 30 depend, directly or indirectly, from independent claim 1. Ex. 1001, 8:22–11:16. Claim 22 depends from independent claim 21 and claim 37 depends from independent claim 36.

Ex. 1001, 9:64–10:3, 12:3–6. Petitioner contends that each of the claims addressed in these grounds "include[s] limitations related to a variable-angle bone screw." Pet. 47.

With respect to Ground 2, Petitioner contends that Theken suggests that bone screw 100 may be a variable-angle screw. Pet. 48 (referencing Ex. 1005, 6:51–56, 7:57–60; Ex. 1002 ¶¶ 235–238). Petitioner adds that Errico "teaches certain benefits of variable-angle bone screws." *Id.* (referencing Ex. 1006, Abstract, 5:22–25, 6:15–27, 11:11–12:2, 14:3–15:20, Figs. 4a, 4b, 6, 9, 10, 13). Petitioner concludes that, "[i]n view of Theken and Errico, a person of ordinary skill in the art thus would have had good reason to employ variable-angle bone screws in Theken's plate assembly, including the assembly modified to have a snap-ring and annular recess as discussed above in Ground 1." *Id.* at 48–49 (referencing Ex. 1002 ¶¶ 61, 109). We understand Petitioner to reason that, in addition to those reasons for substituting Errico's snap-ring for Theken's set screws provided in conjunction with Petitioner's contentions with respect to claims 1, 21, and 36, Theken and Errico suggest employing the same modification with variable-angle bone screws.

Patent Owner argues that Theken teaches away from Petitioner's proposed modification of using a "'blocking' mechanism like Errico's snap-ring" because Theken employs "constrained *locking* mechanisms." Prelim. Resp. 59; *see also id.* at 59–63 (providing this argument). Patent Owner adds that "this teaching away is especially emphatic for the asserted claims that call for variable angulation." *Id.* at 63. Petitioner argues that Theken (and Petitioner) envisions using spherical-head screws for a variable-angle

embodiment and that Theken would require "a stopping member . . . that actively presses down on or crushes the screw in place." *Id.*[17]

As discussed above in connection with our analysis of claim 1, we determine, for that claim, on the current record and at this stage of the proceeding, that Patent Owner's teaching away argument does not demonstrate a deficiency in Petitioner's position. For the same reasons, we determine that Patent Owner's argument does not demonstrate a deficiency in Petitioner's position with respect to these dependent claims.[18]

With respect to Ground 3, Petitioner asserts that "Theken and Errico also render obvious each of claims 3, 5, 11, 22, 30, and 37 as" presented for Ground 2. Pet. 55. Petitioner adds that "Farris provides additional evidence that each of claims 3, 5, 11, 22, 30, and 37 is obvious and provides details regarding implementing an invalidating embodiment of a variable-angle bone screw." *Id.* (referencing Ex. 1002 ¶ 252). Petitioner explains that Farris's spinal plating systems allow for "different degrees of fixation of a bone screw relative to the plate." *Id.* (referencing Ex. 1008, 3:17–26).

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[17] We do not read Patent Owner's argument to address how, if at all, Farris's teachings, including its locking mechanism, affect this argument. *See, e.g.*, Pet. 56 (discussing Farris's locking mechanism); *see also* Ex. 1008, 24:15–25:26 (discussing *locking* assembly 103, with *locking* washer 120).

[18] Also, because we institute trial in this proceeding and, when we do, we must institute on all challenged claims and grounds, we will address further Patent Owner's contentions with respect to Petitioner's reasoning as to the variable-angle dependent claims on a complete record developed during trial, to the extent Patent Owner continues to dispute such reasoning in its Patent Owner Response. *See* Consolidated Trial Practice Guide 64 (Nov. 2019), available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL ("The Board will not institute on fewer than all claims or all challenges in a petition.").

Petitioner adds that Farris teaches rigid configurations are used to treat tumors or trauma to the spine and semi-rigid configurations are used to treat grafts and degenerative diseases. *Id.*

Petitioner contends that "Farris also teaches fixed angle screws and variable angle screws . . . [with] a spherical head to seat within a spherical recess in [a] bore." Pet. 55–56 (referencing Ex. 1008, 5:8–22). Petitioner adds that Farris teaches that "[a] locking assembly may be used to prevent screw back-out, including a washer seated above the head of the bone screw to lock the screw head in position, the washer residing within a recess in the plate and optionally keyed into notches in the plate." *Id.* at 56 (referencing Ex. 1008, 6:4–31, 20:12–21:7, 21:23–22:3; Ex. 1002 ¶ 253).

Petitioner concludes that "Farris supports the obviousness of the challenged claims by providing an example of a variable angle bone screw contemplated by Theken—*e.g.*, an integral bone screw that has spherical head geometry to allow for angular displacement— and can therefore be used in Theken's plate system." Pet. 57 (citing Ex. 1002 ¶ 254).

We have reviewed Petitioner's contentions with respect to its reasoning for combining the teachings of Theken and Errico, or Theken, Errico, and Farris to arrive at the subject matter of claims 3, 5, 11, 22, 30, and 37 and determine, on the current record, that this reasoning is adequately supported for this stage of the proceeding.

We address Petitioner's contentions with respect to the subject matter of claims 3, 5, 11, 22, 30, and 37 below. We note that Patent Owner has not made any separate arguments, at this stage of the proceeding, with respect to the subject matter of these dependent claims.

1. Claims 3 and 5

Claim 3 depends from claim 1 through claim 2 and recites "wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof." Ex. 1001, 8:22–27. Claim 5 depends from claim 1 through claims 2 and 4 and recites "wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, and which is configured to contact the collar anterior surface and expand the collar as the head is displaced posteriorly through the collar passageway." *Id.* at 8:35–40.

For Ground 2, Petitioner contends that Theken and Errico disclose securing elements with heads having curved posterior surfaces. Pet. 49 (referencing Ex. 1006, 18:14–19:2, 19:13–20, Figs. 2, 6; Ex. 1005, 6:51–56). Petitioner adds that Errico teaches dimensioning the screw head so as to pass through the passageway of snap-ring 180 when inserted, yet retained once the screw is displaced posteriorly through the ring. *Id.* at 49–50.

For Ground 3, Petitioner relies on its contentions with respect to Ground 2 and claims 3 and 5. Pet. 60. Petitioner adds that "Farris provides additional motivation for the head of the securing element (*e.g.* spherical head 115) to have a curved posterior surface and a minimum outer diameter for both fixed angle and variable angle screws." *Id.* (referencing Ex. 1008, 5:8–22, 16:6–8, 17:4–6, 18:33–19:22, 22:29–23:25, 24:3–8, Figs. 18–23; Ex. 1002 ¶¶ 261–263).

We have reviewed Petitioner's contentions with respect to these claims and grounds and determine, on the current record, that the

information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that claims 3 and 5 are unpatentable under 35 U.S.C. § 103 over Theken and Errico, or Theken, Errico, and Farris.

2. Claims 11 and 30

Claim 11 depends from claim 1 through claim 10 and recites "wherein the body of the securing element has a diameter smaller than the second opening in the stabilizing element, and the securing element may be angularly displaced within the transverse passageway and the second opening in the stabilizing element." Ex. 1001, 8:65–9:2. Claim 30 also depends from claim 1 through claim 10 and similarly recites "wherein the body of the securing element has a transverse dimension smaller than the second opening of the stabilizing element, and wherein the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element." *Id.* at 11:12–16.

For Ground 2, Petitioner contends that Theken and Errico disclose "variable screw angulation." Pet. 52 (referencing Ex. 1005, 6:51–56, 7:57–60; Ex. 1006, Abstract, 3:6–20, 5:22–25, 6:15–27, 11:11–12:2, 14:3–15:20, Figs. 4a, 4b, 6, 9, 10, 13). Petitioner contends that Theken's bone screw 100 is dimensioned as recited in claims 11 and 30. *Id.* at 52–53 (referencing Ex. 1005, 6:19–31, 6:24-26, 8:33–38, 8:56–60, Figs. 1–4, 10, 11; Ex. 1002 ¶¶ 245–246 & Table 13).

For Ground 3, Petitioner contends that Farris provides a securing element that may be angularly placed and is dimensioned as recited in claims 11 and 30. Pet. 61 (addressing claim 11 and referencing Ex. 1008, 5:28–6:3, 17:2–6, 24:3–8, Figs. 5, 20–22; Ex. 1002 ¶ 265 & Table 15), 63 (addressing claim 30 and referencing Ex. 1008, 5:28–6:3, 17:2–6, 24:3–8, Figs. 5, 20–22; Ex. 1002 ¶¶ 131, 267 & Table 15).

We have reviewed Petitioner's contentions with respect to these claims and grounds and determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that claims 11 and 30 are unpatentable under 35 U.S.C. § 103 over Theken and Errico, or Theken, Errico, and Farris.

3. Claim 22

Claim 22 depends from claim 21 and recites:

> after the head of the securing element is positioned between the biased stopping member and the second opening in the stabilizing element, the step of longitudinally and angularly displacing the head of the securing element within the transverse passageway, so that the body of the securing element is positioned at an angle within the patient's bone relative to the surface of the bone.

Ex. 1001, 9:64–10:3. For Ground 2, Petitioner contends that Theken and Errico disclose angular displacement of their bone screws. Pet. 53 (referencing contentions with respect to claims 11, 30, and 37). Petitioner contends that "Theken and Errico also disclose longitudinally displacing the head of the securing element . . . in order to secure the securing member within the patient's bone." *Id.*

Petitioner adds that it would have been obvious to a person having ordinary skill in the art to displace longitudinally and angularly the bone screw after the screw is positioned posteriorly of the biased stopping member. Pet. 53 (referencing Ex. 1002 ¶ 248). Petitioner, relying on its declarant's testimony, contends that, in one implementation of its combined orthopedic implant assembly, "the head of the securing element (*e.g.*, bone screw 100) would be longitudinally and angularly displaced within the transverse passageway after the head is positioned [below] the biased

stopping member (*e.g.*, snap-ring 180)." *Id.* at 54 (referencing Ex. 1002 ¶ 248 and Table 13).

For Ground 3, Petitioner contends that Farris discloses the recited step of claim 22. Pet. 62 (referencing Ex. 1008, 5:28–6:3, 24:3–8, Figs. 20–22; Ex. 1002 ¶ 266 and Table 15). Petitioner contends that Farris discloses that, once the securing element is positioned between the stopping member and the second opening of the bore, the screw is longitudinally and angularly displaced into a patient's bone. *Id.*

We have reviewed Petitioner's contentions with respect to claim 22 for Grounds 2 and 3 and determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that claim 22 is unpatentable under 35 U.S.C. § 103 over Theken and Errico, or Theken, Errico, and Farris.

4. Claim 37

Claim 37 depends from claim 36 and recites "wherein the securing member is angularly displaceable within the posterior bore portion so that the securing member may be secured within the patient's bone at an angle relative to a longitudinal axis of the bore." Ex. 1001, 12:3–6. For Ground 2, Petitioner contends that Theken and Errico disclose angularly displaced screws. Pet. 50–51.

Petitioner, relying on its declarant's testimony, concludes that:

> it would have been well within the skill of a person of ordinary skill in the art to employ variable screw angulation in Theken's assembly simply by following Theken's instruction that "the tapered head could be replaced with a spherical head," that "the spherical head would allow variable screw angulation," and that "a screw with a flat or oval head which could be captured" by the set screw (*i.e.*, stopping member) could be used.

Pet. 51 (referencing Ex. 1002 ¶ 243; Ex. 1005, 6:51–56).

For Ground 3, Petitioner contends that Farris discloses angular placement of its bone screws (bone screw 102), so that the screw is secured in a patient's bone at an angle relative to the longitudinal axis of the orthopedic implant assembly's bore. Pet. 64 (referencing Ex. 1008, 5:28–6:3, 24:3–8, Figs. 5, 20–22; Ex. 1002 ¶¶ 161–170, 268, and Table 15).

We have reviewed Petitioner's contentions with respect to claim 37 for Grounds 2 and 3 and determine, on the current record, that the information in the Petition demonstrates a reasonable likelihood Petitioner would prevail in its contention that claim 37 is unpatentable under 35 U.S.C. § 103 over Theken and Errico, or Theken, Errico, and Farris.

IV. CONCLUSION

After considering all the evidence and arguments presently before us, we determine Petitioner has established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. Accordingly, we institute an *inter partes* review on all Challenged Claims and grounds.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–5, 10–19, 21, 22, 29–32, 36, and 37 (the Challenged Claims) of the '008 patent; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this Order.

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