

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

ACANTHA LLC,
Patent Owner.

Case No. IPR2020-00684
Patent No. RE43,008 E

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.
RE43,008E PURSUANT TO 35 U.S.C. §§311-319 AND 37 CFR §42**

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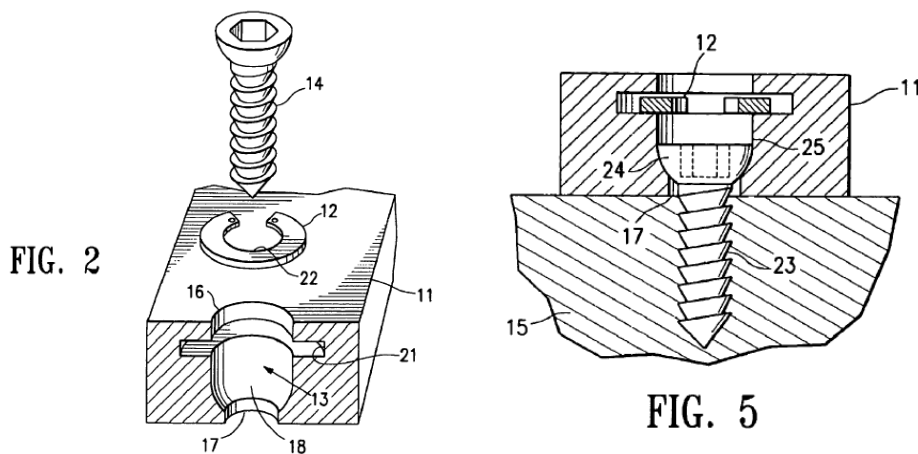
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I. Introduction

NuVasive, Inc. (“Petitioner”) requests *Inter Partes* Review and cancellation of claims 1-5, 10-19, 21-22, and 29-32, 36-37 of U.S. Pat. RE43,008E (“the ’008 patent,” EX1001). This Petition demonstrates there is a reasonable likelihood that at least one of the challenged claims is unpatentable under 35 U.S.C. §103. Indeed, it demonstrates there is a reasonable likelihood that each of the challenged claims is unpatentable under 35 U.S.C. §103.

The ’008 patent is directed to an orthopedic implant assembly comprising a stabilizing element (*i.e.*, a plate for joining bone), a securing element or member (*i.e.*, bone screws) insertable into the bones through bores in the plates, and a stopping member “which inhibits the securing element from loosening or backing out of the bone.” *See, e.g.*, EX1001, Abstract. Figures 2 and 5, reproduced below, depict the assembly comprising a bone screw (securing element 14), biased stopping member (annular collar 12), and plate (stabilizing element 11).



Plates for joining bone, bone screws for securing plates to bones, and stopping members that inhibit the securing elements from loosening or backing out of the bone were well-known in the art and routinely used by orthopedic surgeons well before the critical date for the '008 patent—July 8, 1999. EX1002, ¶¶60-70; EX1001, 1:17-21. EX1002, ¶¶60-70 (discussing EX. 1017, 97-99, 102, FIG. 16; EX1018, 2:57-62; EX1019, 6:1-68, FIGS. 6B-C, 17-18; EX1020, 2:22-27; EX1021, 2:35-43, FIG. 1).

On July 14, 1998, for example, nearly one year before the earliest claimed priority date of the '008 patent, Randall Theken filed the application that became U.S. Patent No. 6,228,085 (“Theken,” EX1005).¹ Theken disclosed and claimed a “bone fixation system” comprising a plate and bone screws for attaching the plate to bones via bores through the plate. EX1005, 4:7-55, 5:59-66, 6:19-31, FIGS. 1-11. Theken also disclosed and claimed in-bore “set screws” to “lock [bone] screws

¹ Theken issued with 33 claims, each one having written description and enablement support in the specification as filed. EX1009, 0007-0053; EX1002, ¶101. For example, issued claims 21 and 22 correspond to as-filed claims 12 and 13, which the examiner indicated contained allowable subject matter in the very first office action. EX1009, 0028-30, 0087, 0121, 0184. The disclosures of Theken relied upon herein are fully supported by the application as-filed.

in position.” EX1005, 3:63-65, 6:60-66, 9:22-24, 9:54-59, FIGS 1-3; EX1002, ¶¶101-04. Theken also provided for using “other suitable locking mechanisms.” EX1005, 7:33-36; EX1002, ¶105.

The “biased stopping member” disclosed and claimed in the ’008 patent also existed in the art, and was well-known in the mechanical arts, for many years before July 8, 1999. EX1002, ¶¶105-07. Independent claims 1 and 21, for example, require a biased stopping member that defines at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration. In practice, the claimed stopping member permits the screw to pass through the bore toward the bone but subsequently prevents the screw from backing out. The claimed stopping member is nothing more than an ordinary retaining ring, also called a snap-ring, the function of which was well-known in July 1999. EX1002, ¶106.

As early as 1995, Joseph P. (“JP”) Errico, a founder of the orthopedic implant company Fastenetix, invented mechanisms for minimizing the possibility that bone screws would back out of plates, including in-bore snap-rings (*i.e.*, biased stopping members). EX1002, ¶¶1-15, 32, 37-38, 65, 69 (discussing biased, canted coil stopping mechanisms that lock a shaft within a bore as disclosed in EX1007). JP Errico realized that snap-rings were effective for minimizing the risk of back-out of bone screws and presented distinct advantages over set screw

stopping members, such as those used in Theken, including the advantages of avoiding cross-threading potential and reducing “fiddle factor.” EX1002, ¶¶39. Set screws were quite small and surgeons had to be very careful not to drop or lose them during the procedure. EX1002, ¶¶16-36, 38. Lost parts not only increased the cost of procedures, but more importantly, they increased patient risk of injury. JP Errico viewed snap-rings as a good design choice for minimizing “fiddle factor” since snap-rings were either integral to the plate to begin with or were preassembled in the plate before surgery. Surgeons could neither cross-thread snap-rings nor drop snap-rings inside patients. *Id.*

Accordingly, on April 9, 1996, JP Errico *et al.* filed International Application No. PCT/US96/04920, which published on October 17, 1996 as International Publication No. WO 1996/032071 (“Errico,” EX1006). Errico disclosed a snap-ring disposed in an annular recess in a bore of a bone plate. EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-14:10, FIGS. 5-6; EX1002, ¶¶46, 66. The snap-ring in Errico is a biased stopping member as disclosed and claimed in the ’008 patent. Although some of JP Errico’s patents were considered during prosecution of the ’008 patent and in three non-instituted IPR petitions filed by an unrelated third party, none of his patents were combined with Theken. EX1002, ¶¶51-52, 73. As JP Errico testifies, it would have been obvious to a person of skill in the art (“POSA”) at the critical date (years after Errico published) to employ a

biased stopping member (*e.g.*, snap-ring in an annular recess) in Theken's orthopedic implant assembly. EX1002, ¶¶71-74, 105-06. As explained below in Grounds 1 and 2, this combination provides compelling evidence that the challenged claims would have been obvious. Neither Theken nor JP Errico's testimony was presented to the Patent Office when it previously considered the challenged claims. The availability of this new evidence now merits another look at these claims and, indeed, demonstrates they are unpatentable.

Ground 3 presents additional evidence that claims 11, 22, 30, and 37 are obvious. International Application No. PCT/US98/09636 by Farris *et al.* was filed on May 12, 1998, and published as International Publication No. WO 1998/051226 ("Farris," EX1008) on November 19, 1998. Farris provides details regarding implementing an embodiment of a variable-angle bone screw compatible with the combination of Theken and Errico. EX1008, FIG. 20-23, 5:28-6:3, 23:35-24:8. EX1002, ¶¶251-260.

For the reasons discussed herein, each of the challenged claims should be found unpatentable and cancelled.

II. Mandatory Notices Under 37 CFR §42.8

A. Real Party-In-Interest Under 37 CFR §42.8(b)(1)

NuVasive, Inc. is the real party-in-interest for this Petition.

B. Related Matters Under 37 CFR §42.8(b)(2)

A complaint asserting infringement of the '008 patent in *Acantha LLP v. NuVasive, Inc.*, Eastern District of Michigan Case No. 4:19-CV-10656-MFL-EAS was served no earlier than March 14, 2019. EX1012-EX1013. The complaint in *Acantha LLP v. Stryker Corporation*, Northern District of California Case No. 4:19-CV-05604-PJH references the '008 patent. Petitioner is filing simultaneously with this Petition a petition for IPR of claims 44-50, 53-54, 59-63, 66, 68-73, 75-78, 80-87, 90-91, 101, and 103-104 of the '008 patent. IPR2020-00706.

In an abundance of caution, Petitioner also identifies the three IPR petitions filed by an unrelated petitioner against the '008 patent. These cases are: *DePuy Synthes Sales, Inc. v. Acantha LLC*, IPR2016-0329; *DePuy Synthes Sales, Inc. v. Acantha LLC*, IPR2016-0333; and *DePuy Synthes Sales, Inc. v. Acantha LLC*, IPR2016-0334. Each of these IPRs was terminated without institution in June 2016.

C. Identification of Counsel (37 CFR §42.8(b)(3)) and Service Information (37 CFR §42.8(b)(4))

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III. Grounds for Standing (37 CFR §42.104(a))

Petitioner certifies that the '008 patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR on the identified grounds.

IV. Identification of Challenge and Statement of Precise Relief Requested

Petitioner challenges claims 1-5, 10-19, 21-22, and 29-32, 36-37 of the '008 patent under 35 U.S.C. §311 and AIA §6, as Petitioner's detailed statement of the reasons for the relief requested sets forth, supported with exhibits, including the Declaration of JP Errico. *See, generally*, EX1002; *see also id.*, ¶99.

Ground	CLAIMS	Obvious under 35 U.S.C. §103
1	1, 2, 4, 10, 12-19, 21, 29, and 31-32, 36	Over Theken (EX1005) in view of Errico (EX1006)
2	3, 5, 11, 22, 30 and 37	Over Theken (EX1005) in view of Errico (EX1006)
3	3, 5, 11, 22, 30 and 37	Over Theken (EX1005) in view of Errico (EX1006) and Farris (EX1008).

Theken is prior art at least under pre-AIA 35 U.S.C. §102(e), Errico is prior art at least under pre-AIA 35 U.S.C. §102(b), and Farris is prior art at least under pre-AIA 35 U.S.C. §102(a). Theken, Errico, and Farris are each from the field of medical devices, and specifically from the field of orthopedic implants for joining bone segments. *See, e.g.*, EX1005, Title (“Bone Fixation System”); EX1006, Abstract (“locking screw plate assembly for immobilization of bones”); EX1008, Title (“Anterior Cervical Plating System”); *see also* EX1002, ¶¶49-53.

V. Summary of the ’008 Patent

The ’008 patent “generally relates to the field of medical devices, and particularly to an orthopedic implant for joining bone segments and methods of use thereof.” EX1001, 1:11-13. The summary of the invention states the invention is directed to an orthopedic implant assembly generally comprising a stabilizing element, a securing element which attaches the stabilizing element to the patient’s bone, and a stopping member in the stabilizing element which defines at least in

part a passageway and which inhibits or prevents the securing element from loosening or backing out of the bone. *Id.*, 1:32-38. The '008 patent has 105 claims. Of the challenged claims in this Petition, claims 1, 21, and 36 are independent. Claim 1 is directed to an orthopedic implant assembly and claims 21 and 36 are directed to a method of attaching the assembly to a patient's bone.

A. Prosecution History

The '008 patent issued from U.S. Appl. 10/620,154 (filed July 15, 2003), and was a Reissue of U.S. Patent No. 6,261,291 (filed July 8, 1999 as U.S. Appl. No. 09/349,519) (the "'291 patent," EX1003). EX1001, cover. July 8, 1999 is thus the earliest claimed priority date for the challenged claims. The '008 patent expired on July 8, 2019.

The Patent Office did not consider Theken or Farris during prosecution of the '008 patent. *See* EX1004. Although the Office considered references in the same family as Errico during prosecution of the '008 patent, the Office did not consider Errico in the manner set forth in this petition or in combination with Theken or Farris. *Id.*

B. Prior IPR Proceedings

Long before Acantha asserted the '008 patent against Petitioner in 2019, Acantha sued an entity unrelated to Petitioner named DePuy Synthes Sales, Inc. That earlier defendant filed three petitions in 2015 challenging claims of the '008

patent. The Board denied those petitions in June 2016. *See* IPR2016-00329, Paper 12; IPR2016-00333, Paper 13; IPR2016-00334, Paper 13.

This Petition is not a serial petition under *General Plastic*. *See* IPR2016-01357, Paper 19, at 1-17 (precedential). Petitioner was not involved in Acantha's litigation with DePuy or in DePuy's IPRs and was not sued for infringement of the '008 Patent until nearly three years after the Board denied DePuy's petitions. *Toshiba America Information Systems, Inc. v. Wallelex Microelectronics Ltd.*, IPR2018-01538, Paper 11, at 19-21 (Mar. 5, 2019) ("Whether it is the same petitioner that is bringing a second petition is at the heart of the *General Plastic* factors."). There is no privity between DePuy and Petitioner, they are not co-defendants in litigation, there is no special relationship (*e.g.*, licensor-licensee) between them to justify considering this a serial petition, the present Petition is the result of Acantha's litigation decision to sue NuVasive years after suing DePuy, and denying institution here based on DePuy's petitions (in which NuVasive had no input) would result in unfair prejudice to NuVasive. *See, e.g., Foursquare Labs, Inc. v. Mimzi, LLC*, IPR2019-01287, Paper 11, at 6-7 (Jan. 14, 2020); *Microsoft Corp. v. Uniloc 2017 LLC*, IPR2019-00973, Paper 7, at 5-6 (Nov. 19, 2019); *Apple, Inc. v. UUSI, LLC d/b/a Nartron*, IPR2019-00358, Paper 12, 13-15 (Aug. 5, 2019); *Microsoft Corp. v. Iron Oak Techs., LLC*, IPR2019-00107, Paper 8, at 53-

55 (May 15, 2019); *Samsung Elecs. Am., Inc. v. Uniloc Luxembourg S.A.*, IPR2017-01797, Paper 8, at 33-34 (Feb. 6, 2018).

NuVasive is filing its Petitions as soon as practicable after Acantha served its Disclosure of Asserted Claims (on March 6, 2020). NuVasive is filing two petitions because it was not practical to challenge all asserted claims within the word limits of a single petition. To maximize efficiency for the parties and the Board, NuVasive's Petitions are tailored to challenging the asserted claims. As set forth in detail below, NuVasive's Petitions rely on prior art (*e.g.*, Theken and Farris) that is different from the art at issue in DePuy's IPRs and that was never previously considered. The previous IPRs presented a conclusory unpatentability theory based on a reference that is related to the asserted Errico reference. The present IPR presents a fundamentally different unpatentability theory using a different primary reference (Theken) and a different additional reference (Farris). Neither combination was ever previously considered. Moreover, unlike in DePuy's IPRs, NuVasive supports its case with the corroborated and detailed expert testimony of JP Errico. For the reasons discussed above, this is not a case appropriate for discretionary denial of institution.

C. Person of Ordinary Skill in the Art

As of July 8, 1999, a POSA in the art of the '008 patent typically would have had: (1) a 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. EX1002, ¶¶54-59.

D. Claim Construction Under 37 CFR §42.104(b)

Claims in IPR are given their ordinary and customary meaning to a POSA at the relevant priority date consistent with the specification. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). This Petition applies the art to the claims using this standard and consistent with the constructions ordered by the district court in the *DePuy* case (EX1014). The meaning of certain claim terms is discussed below. *See* EX1002, ¶¶92-98.

Claims 1, 4, 10, 19, 21, 36, and 37 refer to anterior or posterior surfaces, portions, or sections. The '008 patent defines the term “posterior” to mean “an inner portion of the assembly closer to the bone to which the assembly is attached” and the term “anterior” to mean “an outer portion of the assembly farther away from the bone.” EX1001, 1:44-48; EX1002, ¶95. The petition applies the claim terms posterior and anterior as defined in the specification.

Claims 2, 4, 17-19, 29 refer to a collar or an annular collar. The '008 patent states that FIGS. 1-3 illustrate an embodiment in which the biased stopping

member comprises an annular collar. EX1001, 4:16-44; EX1002, ¶96. At least Figures 2, 3, 3A, and 4A disclose the annular collar (12) as a discontinuous retaining ring/snap-ring. The claimed collar and annular collar thus includes a discontinuous retaining ring/snap-ring.

Claim 17 recites the collar is formed of an elastically deformable material and claim 18 recites a superelastic material. The '008 patent states: “the stopping member 12 is preferably elastically deformable, and formed of titanium, and superelastic or pseudoelastic materials such as NiTi alloys. EX1001, 5:65-67; EX1002, ¶97. The claimed elastically deformable material thus includes titanium and the claimed superelastic material thus includes nickel titanium (Nitinol) alloys.

Claim 22 recites “longitudinally and angularly displacing the head of the securing element” *after* “the head of the securing element is positioned between the biased stopping member and the second opening in the stabilizing element.” EX1001, 9:64-10:3; EX1002, ¶98. Claim 22 depends from claim 21. The '008 patent specification describes this angular displacement of the securing element occurring by tilting the head. EX1001, 5:52-64 (“the securing element is angularly displaceable within the transverse passageway posterior section **25** between the collar **12** and the second opening **17** in the stabilizing element, as illustrated in FIG. 6. The securing element can thus be tilted within the transverse passageway at an angle relative to the transverse passageway longitudinal axis”). As JP Errico

explains, Figure 6 of the '008 patent depicts the body 23 of the securing element that entered the bone 15 at an angle. EX1002, ¶98. Neither claim 21 nor claim 22 requires angularly displacing the head of the securing element after the securing element is positioned within the patient's bone. EX1001, 9:24-10:3.

VI. Ground 1: Claims 1, 2, 4, 10, 12-19, 21, 29, and 31-32, 36 are rendered obvious by Theken in view of Errico under 35 U.S.C. §103

A. Summary of Unpatentability

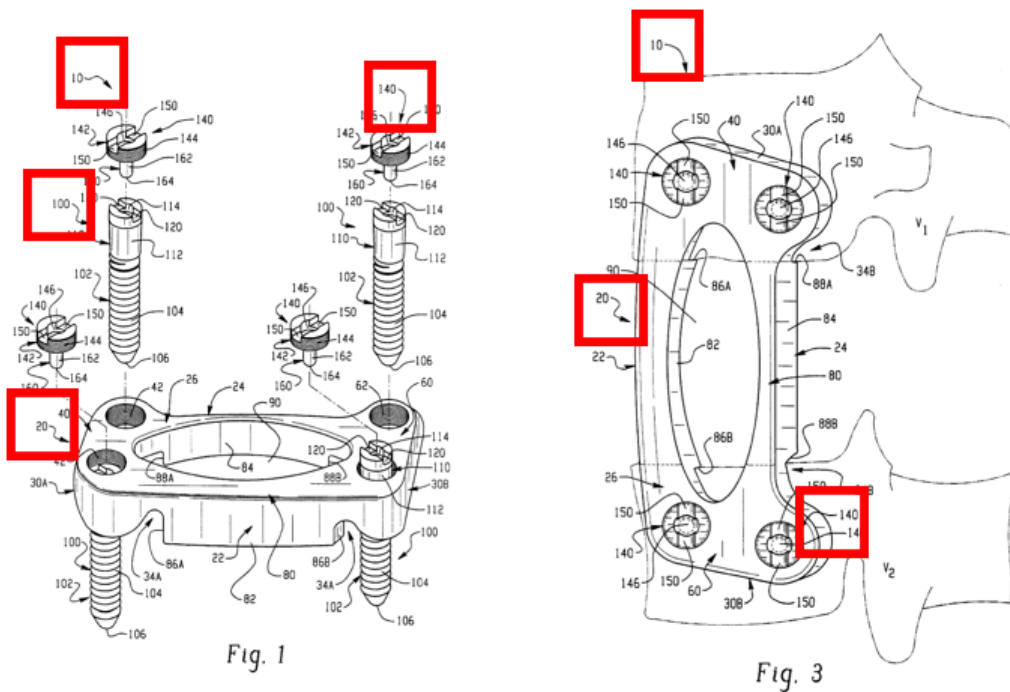
The combination of Theken (EX1005) with Errico (EX1006) discloses all the limitations of claims 1, 2, 4, 10, 12-19, 21, 29, and 31-32, and 36 of the '008 patent, and renders those claims obvious under pre-AIA 35 U.S.C. §103(a).

EX1002, ¶100. Claim 1 is representative and recites:

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.

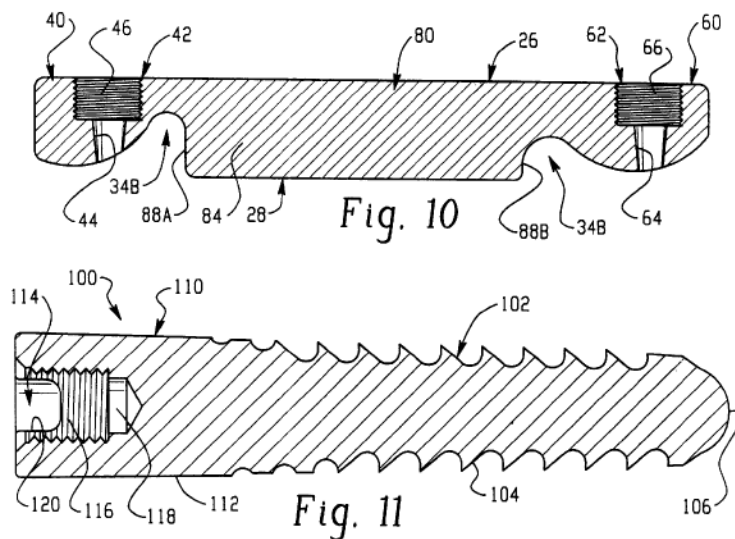
Theken discloses an orthopedic implant assembly in the form of a bone fixation system 10. EX1005, FIGS. 1-14, 2:26-52, 3:54-65. The bone fixation system 10 includes a bone plate 20 (*i.e.*, a stabilizing/attachment element), bone screws 100 (*i.e.*, securing elements), and set screws 140 (*i.e.*, stopping members). *Id.*, 3:57-61. Theken also discloses methods of attaching the bone fixation system 10 to bone. *Id.*, 8:34-9:65; EX1002, ¶101. Figures 1 and 3 are reproduced (with annotations) below.



In Theken, the bone plate 20 (*i.e.*, a stabilizing/attachment element) includes a lateral side 26 (*i.e.*, anterior surface) with a first opening, and a medial side 28 (*i.e.*, a posterior surface) with a second opening. EX1005, 4:7-8, FIGS. 1-6, 10. The medial side 28 (*i.e.*, a posterior surface) contacts the vertebrae. *Id.*, 5:59-66. The bone plate 20 includes a plurality of “generally circular openings 62” (*i.e.*, bores), which are dimensioned to receive “[bone] screw 100 and set screw 140.” *Id.*, 4:36-39 & Figs. 1-2, 5-8, 10.

As shown in FIGS. 8, 10, and 11, each “opening 62 has a tapered section 64 and a threaded section 66” where the “[t]apered section 64 tapers from a first end adjacent to tapered section 66 to a second end terminating at medial side 28” and the “[t]hreaded section 66 includes threads that mate with the threads formed on

set screw 140.” *Id.*, 4:36-49. EX1002, ¶102. Theken thus discloses 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. Theken Figures 10-11 are reproduced below. EX1002, ¶¶101-02.



The bone screws 100 (*i.e.*, securing elements) in Theken each include an integral threaded portion 102 and head portion 110. EX1005, 6:19-21, FIGS. 1-2, 11. The head portion 110 includes a tapered outer surface 112. *Id.*, 6:27-32, FIG. 11. The taper of the head portion 110 and the tapered section 64 of the bore match and the head portion 110 has a maximum diameter greater than the second opening of the bore at the posterior surface. *Id.*, 6:27-32, 4:21-26, 4:42-46, FIGS. 8 and 10. The head portion 110 is retained within the transverse passageway between the set

screw 140 (*i.e.*, stopping member) and the second opening of the bore. *Id.*, FIG. 1 (showing a bottom-left bone screw 100 and dotted line to a set screw 140 that is to be inserted above the bone screw), FIG. 2 (showing bone screws 100 below inserted set screws 140); EX1002, ¶103. Theken thus discloses 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 second opening in the stabilizing element. *Id.*

Theken's bone fixation system 10 as described above includes all elements of the implant assembly recited in independent claims 1, 21, and 36 of the '008 patent except that the type of stopping member used to lock the bone screw to the plate and to prevent it from backing out is different. In Theken, the set screw 140 (*i.e.*, stopping member) is positioned in a threaded section 66 of the opening 62 (*i.e.*, bore) over the head portion 110 of the bone screw 100 such that an anterior surface of the head portion 110 is under (*i.e.*, posterior to) a posterior surface of the set screw 140. EX1005, FIGS. 1-3, 6:60-66. EX1002, ¶¶104-05. Theken discloses "that driving set screws 140 on top of screws 100...prevents screws 100 from moving," such as by "backing out." EX1005, 9:22-24, 9:54-59. Theken teaches that the "set screws 140 could be replaced by other suitable locking mechanisms." EX1005, 7:33-35. 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.

As discussed below, other suitable locking mechanisms were known to be useful and available before July 8, 1999. The use of biased stopping members to lock bone screws to plates and to prevent back-out of bone screws from plates was known to POSAs before the time of the invention. Errico explains that “screw pull-out represents one of the largest risks of implant failure” and thus teaches “locking means” that “locks the screw to the plate” such that, “even if the bone holding the screw fails, the screw will not separate from the plate.” EX1006, 4:1-5.

Errico describes one such locking mechanism: “a simple and effective locking mechanism for locking the bone screw to the plate” (EX1006, 6:1-2), such as a “a retaining ring provided to further lock the screw and coupling element within the tapered hole” of the plate 100 (*Id.*, 23:12-24:10 (discussing snap-ring 180) & FIGS. 5-6); EX1002, ¶106. Errico teaches the “retaining ring expands as the corresponding coupling element is inserted into the hole, and snaps back into a retaining position above the coupling element once the top of the element passes it into the hole.” EX1006, 8:13-17. Errico’s retaining ring (*e.g.*, snap-ring 180) is thus a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter

configuration, the smaller diameter configuration being smaller than the maximum diameter of the head of the securing element. EX1002, ¶106.

For example, Errico discloses an orthopedic implant assembly comprising a bone plate assembly. EX1006, FIG. 5-6, and 23:12-24:10. The bone plate assembly includes a plate 100c (*i.e.*, a stabilizing/attachment element), a screw 120 and tapered coupling element 132 (*i.e.*, collectively a non-integral securing element), and a snap-ring 180 (*i.e.*, a biased stopping member). *Id.*, FIGS. 5-6 and 23:25-26. As shown in FIG. 6 of Errico (reproduced below), the plate 100c includes an anterior surface with a first opening and a posterior surface with a second opening.

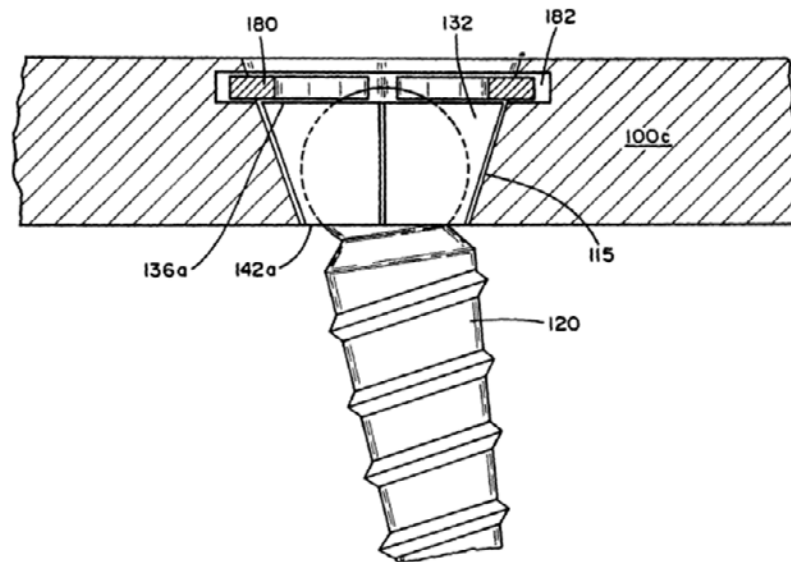


FIG.6

The plate 100c includes a tapered hole 110c (*i.e.*, bore with transverse passageway) that includes a tapered side wall 115 and a posterior section that receives the tapered coupling element 132 (*i.e.*, part of a non-integral securing

element). *Id.*, FIGS. 5-6, 23:12-16, 24:4-5. The tapered coupling element 132, which has a flat upper (*i.e.*, anterior) surface 136a with a maximum diameter greater than the second opening, is retained within a transverse passageway between the snap-ring 180 and the second opening. *Id.*, FIG. 6 (showing a diameter of the surface 136a larger than the bottom opening of the tapered hole 110c), 24:4-5. The tapered side wall 115 further includes an anterior section with an annular recess 182 within which the snap-ring 180 is positioned. *Id.*, FIGS. 5-6, 23:12-19. Errico explains the snap-ring 180 is a retaining ring to “lock the screw and coupling element within the tapered hole” of the plate 100c. *Id.*, 23:12-14, FIGS. 5-6. In addition to locking the coupling element and screw to the plate, Errico’s snap-ring 180 also prevents the coupling element from backing out of the plate. *Id.*, 24:7-10; EX1002, ¶107.

During an implantation procedure, Errico describes that a surgeon inserts both the tapered coupling element 132 and the screw 120 through the tapered hole 110c, and “the tapered exterior surface of the coupling element 132...causes the snap-ring 180 to expand in the recess 182” from a first configuration to a second configuration. EX1006, 23:27-24:4. As Errico further explains, “[o]nce the coupling element 132...is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132...and snaps back to its undeflected state” of the first configuration. *Id.*, 24:4-7. The unexpanded

configuration of Errico's snap-ring 180 prevents the tapered "coupling element 132...from backing out of the plate 100c inasmuch as the flat upper surface 136a...of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open)." *Id.*, 24:7-10. Snap-ring 180 will open (*i.e.*, deform into an expanded configuration) when a tapered shape pushes on the snap-ring 180 during insertion of that tapered shape. *Id.*, 24:9-10. EX1002, ¶107.

As discussed above, Theken indicated that his "set screws 140 could be replaced by other suitable locking mechanisms." EX1005, 7:33-35. Errico provides prior art evidence confirming a POSA would have known that a retaining ring (*e.g.*, snap-ring) is such a suitable locking mechanism. Errico teaches that the snap-ring is "a simple and effective locking mechanism for locking the bone screw to the plate" that "lock[s] the screw and coupling element within the tapered hole" of the plate 100c. EX1006, 6:1-2 and 23:12-14. EX1002, ¶108. As JP Errico explains, a POSA thus would have had good reason with a reasonable expectation of success at the earliest priority date of the '008 patent to use a retaining ring (*e.g.*, snap-ring) and in-bore annular recess to lock Theken's tapered bone screw 100 to Theken's bone plate 20 to prevent Theken's tapered bone screw 100 from backing out. EX1002, ¶109.

As explained by JP Errico, combining Theken and Errico as described above would have had predictable and desirable results: the retention ring (*e.g.*, snap-

ring) and annular recess is a simple, suitable, and inexpensive means to prevent screw back-out in Theken's assembly. EX1002, ¶110. Errico indicates a retention ring would be suitable for Theken's assembly because, like Theken's assembly, Errico's assembly employs a bore (hole 110c) having a tapered profile for receiving a tapered shape of a coupling element; (ii) Errico's snap-ring is designed specifically to be reversibly expanded by a tapered shape to permit the tapered element to move posteriorly to the snap-ring and then retain the tapered element to lock the screw to the plate and to prevent it from separating from the plate (hole 110c), and would similarly retain Theken's screw head 110; and (iii) Errico shows how a bore (hole 110c) can include an annular recess 182 that would similarly be employed in Theken's bore (opening 62). *Id.* As JP Errico explains, sizing 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. *Id.*, ¶110. The claimed invention thus amounts to nothing more than applying a known technique to a similar device to perform the same function and yield predictable results. EX1002, ¶¶110, 115. This is obvious. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

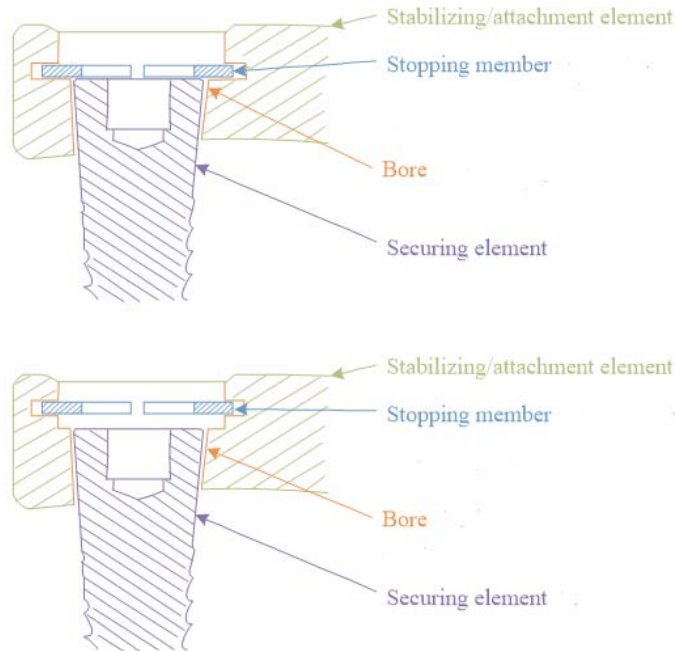
In addition to the motivation for using a retaining ring discussed above, a POSA would have recognized that using a retaining ring in Theken's assembly would have been beneficial because it would make it possible to achieve the same

goal of preventing screw back-out without requiring the use of Theken's set screws. EX1002, ¶116. This amounts to the simple substitution of one known element for another to obtain predictable results, which also is obvious. *See KSR*, 550 U.S. at 416. As discussed above, Errico showed how a snap-ring in an annular recess works with a tapered shape to retain bone screws in an orthopedic assembly and prevent back-out, and a POSA would have expected a snap-ring in an annular recess to successfully perform this function in Theken's assembly. EX1002, ¶116.

As explained by JP Errico, a POSA would have recognized replacing the set screws with the retaining ring was a useful and desirable alternative that would provide the benefits of (i) avoiding cross-threading surgeons encountered when placing set screws in threaded-bores of plates; (ii) reducing "fiddle-factor" by eliminating small, slippery set screws that must be placed in a threaded-bore of a plate with gloved-hands; (iii) reducing the number procedural steps necessary to fully insert a bone screw during time-sensitive surgical procedures by eliminating the step of placing a set screw; (iv) reducing the risk of and liability associated with losing surgical hardware (namely set screws) in the "surgical field" (*i.e.* inside patients) during surgery; and/or (v) minimizing protrusions above the plate that can damage surrounding tissue and cause post-surgical complications and liability. EX1002, ¶116. These benefits provide additional motivation to employ a snap-ring

as a suitable alternative to the set screws of Theken for preventing back out of the bone screws. *Id.*

The illustrations below from JP Errico's declaration are two obvious implementations of a retaining ring (*e.g.*, snap-ring) in Theken:

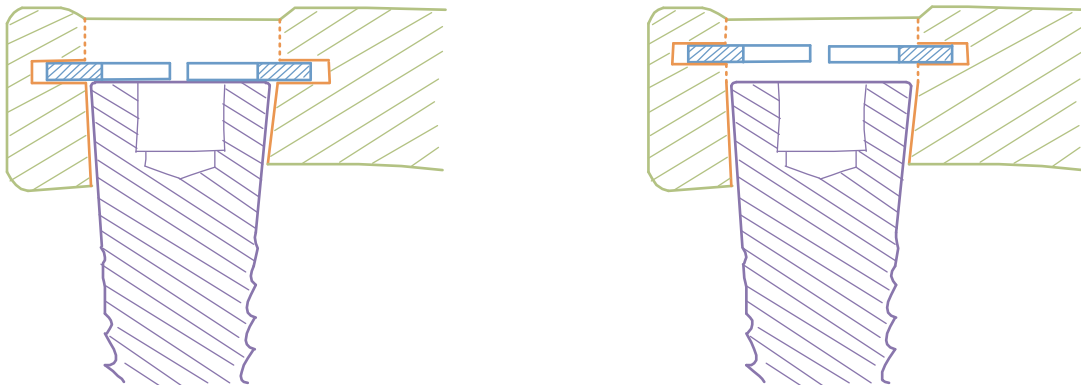


EX1002, ¶¶111-14.

In the first implementation, the annular recess 182 is positioned at the bottom of the threaded section 66. As explained by JP Errico, locating the annular recess 182 at the bottom location was useful to create a constrained system, where the posterior surface of the snap-ring 180 abuts the top of an inserted bone screw 100 to prevent noticeable movement. EX1002, ¶112. In the second implementation, the annular recess 182 is located in the middle of the threaded section 66. As explained by JP Errico, a POSA would have known that this

configuration was useful to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100 to allow for settling after surgery and for different depths of bone screw insertion during surgery. EX1002, ¶113.

Although Theken Figures 8 and 10 depict an annular shoulder 68 at the interface between threaded section 66 and tapered section 64, Theken's plate also could be manufactured such that the tapered section extends from the anterior surface to the posterior surface of the plate, as illustrated by JP Errico below:



EX1002, ¶114. As explained by JP Errico, a POSA would have recognized this implementation with a uniform contour to be desirable for various reasons, including, ease and robustness of manufacture and ease of use. *Id.*

As explained by JP Errico, employing a snap-ring and annular recess in Theken leaves Theken's bone fixation system quite satisfactory for its intended purpose, which is to provide an "internal bone fixation system for the treatment of bone anomalies." EX1002, ¶¶117-18; EX1005, 1:4-7, Abstract. Theken contemplates embodiments for achieving the intended purpose of treating bone

anomalies, including an embodiment that locks the bone screw 100 to the plate 20 by material deformation of the bone screw 100 and/or the hole in the plate 20 (EX1005, 7:53-56), and an embodiment that locks the bone screw 100 to the plate 20 with the set screw 140. (*Id.*, 9:22:26 and 9:55-59). Moreover, Theken expressly teaches that the “set screws 140 could be replaced by other suitable locking mechanisms.” EX1005, 7:33-35. Using a snap-ring in an annular recess in Theken’s bone fixation system supports Theken’s intended purpose of treating bone anomalies as set forth above. EX1002, ¶118.

B. Claim 1 is Obvious Over Theken in View of Errico

The combination of Theken and Errico as discussed above renders claim 1 of the ’008 patent obvious. EX1002, ¶¶119-27. Theken discloses an orthopedic implant assembly (*e.g.*, bone fixation system 10). EX1005, 4:7-55, 5:59-66, FIGS. 1-8 and 10; EX1002, ¶121.

1. Claim Limitation 1.a): The claimed “stabilizing element”

Theken discloses the orthopedic implant assembly (*e.g.*, bone fixation system 10) comprises a stabilizing element (*e.g.* bone plate 20) having an anterior surface (*e.g.* lateral side 26), a posterior surface (*e.g.* medial side 28), and at least one bore (*e.g.* circular openings 62), the bore having a first opening (*e.g.* at top of a threaded section 66) in the anterior surface, a second opening (*e.g.* at bottom of a tapered section 64) in the posterior surface smaller than the first opening, and a

transverse passageway extending from the first opening to the second opening.

EX1005, 4:7-55, 5:59-66, FIGS. 1-8 and 10; EX1002, ¶121 & Table 1.

2. *Claim Limitation 1.b): The claimed “biased stopping member”*

With respect to claim element 1(b), Theken discloses the orthopedic implant assembly comprises a stopping member (*e.g.* set screws 140). EX1005, 3:63-65, 6:60-66, 9:22-24, 9:54-59, FIGS. 1-3. Theken provides for use of other types of stopping members. *Id.*, 7:33-35 (“It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.”); EX1002, ¶122. Errico discloses a biased stopping member (*e.g.* retaining ring/snap-ring 180) defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration. EX1006, 4:1-5, 6:1-2, 8:13-17, 23:25-24, FIGS 5-6. Errico also discloses a head (*e.g.* tapered coupling element 132) having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member (*e.g.* snap-ring 180) so that the head (coupling element 132) is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element. *Id.*, 6:1-2, 23:12-24:10, FIGS. 5-6. EX1002, ¶¶122 & 124 & Table 1.

3. Claim Limitation 1.c): The claimed “securing element”

Theken discloses the orthopedic implant assembly comprises a securing element (*e.g.* bone screw 100) having an elongated body (*e.g.* threaded portion 102), and a head (*e.g.* tapered head portion 110) at one end of the body and integral therewith, the head (*e.g.* tapered head portion 110) having a maximum diameter greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element. EX1005, 4:21-26, 4:42-46, 6:19-31, FIGS. 1-2, 8-11 (the head portion 110 has a taper that matches the taper of the tapered section 64 of the plate, such that the top of the head portion 110 has a maximum diameter that is greater than the second opening at the bottom of the tapered section 64 of the plate 20); EX1002, ¶123. Errico discloses the 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. *See* element 1.b) above; EX1002, ¶124 & Table 1.

Accordingly, Theken in view of Errico discloses each and every element of claim 1 and claim 1 as a whole would have been obvious.

C. Each of Claims 2, 4, 10, 12-19, 29, and 31-32 of the '008 patent is Obvious Over Theken in View of Errico

The combination of Theken and Errico discussed above for claim 1 renders each of claims 2, 4, 10-19, 29, 31-32 of the '008 patent obvious as a whole. For each claim below, the rationales for combining Theken and Errico with respect to the parent claim(s) of that claim also apply to that claim.

1. Claim 2:

Claim 2 depends from claim 1. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 1, also satisfies the limitations of claim 2. Specifically, that same combination provides a biased stopping member (*e.g.* retaining ring/snap-ring 180) comprising a collar defining a passageway, enlargeable from an unexpanded inner diameter to an expanded inner diameter, wherein the head of the securing element has a maximum diameter greater than the unexpanded inner diameter of the collar and less than the expanded inner diameter of the collar. *See, e.g.*, EX1006, FIGS. 5-6, 8:13-17, 23:12-24:10. EX1002, ¶¶119-27, 128-29 & Table 2. Theken in view of Errico thus discloses each and every element of claim 2 and claim 2 as a whole would have been obvious.

2. Claim 4:

Claim 4 depends from claim 2. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1

and 2, also satisfies the limitations of claim 4. Specifically, that same combination provides a bore that has a groove (*e.g.* annular recess 182) in an anterior portion of the transverse passageway having a diameter and a height, and wherein the collar (*e.g.* snap-ring 180) is a reversibly expandable annular collar seated in the groove, the collar having an expanded outer diameter, and an unexpanded outer diameter which is less than the diameter of the groove and greater than a diameter of the transverse passageway. *See, e.g.*, EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6.

EX1002, ¶¶119-27, 130 & Table 2. Theken in view of Errico thus discloses each and every element of claim 4 and claim 4 as a whole would have been obvious.

3. *Claim 10:*

Claim 10 depends from claim 1. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 1, also satisfies the limitations of claim 10. Specifically, that same combination provides a head of the securing element that is longitudinally displaceable within the transverse passageway between a posterior surface of the biased stopping member and the second opening in the posterior surface of the stabilizing element. As discussed above in Section VI.A, in one obvious implementation of the combination, the annular recess 182 is placed at the middle of Theken's threaded section 66 to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100. As explained by JP Errico, a POSA would have

known this was useful to allow for settling after surgery and for different depths of bone screw insertion during surgery. EX1002, ¶113. In this implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20). EX1002, ¶¶113, 119-27, 131 & Table 2. Accordingly, Theken in view of Errico discloses each and every element of claim 10 and claim 10 as a whole would have been obvious.

4. *Claim 12:*

Claim 12 depends from claim 1. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 1, also satisfies the limitations of claim 12. Specifically, that same combination provides a stabilizing element (*e.g.* plate 20) that includes at least two bores (*e.g.* openings 42 and 62). *See, e.g.*, EX1005, 3:62, 4:4-7, 4:16-18, 4:35-38 & FIGS 1-3, 5-8, 10. EX1002, ¶¶119-27, 132 & Table 2. Theken in view of Errico thus discloses each and every element of claim 12 and claim 12 as a whole would have been obvious.

5. *Claim 13:*

Claim 13 depends from claim 1. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 1,

also satisfies the limitations of claim 13. Specifically, that same combination provides a stabilizing element (*e.g.* plate 20) that is configured to conform to and extend between at least two bone segments (*e.g.* vertebral bodies V_1 and V_2). *See, e.g.*, EX1005, 3:65-66, 5:34-36, 5:59-64, FIGS. 3-4. EX1002, ¶¶119-27, 133 & Table 2. Accordingly, Theken in view of Errico discloses each and every element of claim 13 and claim 13 as a whole would have been obvious.

6. *Claim 14:*

Claim 14 depends from claim 13. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1 and 13, also satisfies the limitations of claim 14. Specifically, that same combination provides a stabilizing element (*e.g.* plate 20) that has a curved surface (*e.g.* surface at notches 34A, 34B). *See, e.g.*, EX1005, 5:34-36, 5:59-6:7, FIG. 4. EX1002, ¶¶119-27, 134 & Table 2. Accordingly, Theken in view of Errico discloses each and every element of claim 14 and claim 14 as a whole would have been obvious.

7. *Claim 15:*

Claim 15 depends from claim 1. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 1, also satisfies the limitations of claim 15. Specifically, that same combination provides a stabilizing element (*e.g.* plate 20) that is selected from the group

consisting of rods and plates. *See, e.g.*, EX1005, 3:59-61, FIGS. 1-10. EX1002, ¶¶119-27, 135 & Table 2. Theken in view of Errico thus discloses each and every element of claim 15 and claim 15 as a whole would have been obvious.

8. *Claim 16:*

Claim 16 depends from claim 1. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 1, also satisfies the limitations of claim 16. Specifically, that same combination provides a securing element (*e.g.* bone screws 100) that is selected from the group consisting of screws and nails. *See, e.g.*, EX1005, 3:59-60, 6:19-34, FIGS. 1-2 and 11. EX1002, ¶¶119-27, 136 & Table 2. Theken in view of Errico thus discloses each and every element of claim 16 and claim 16 as a whole would have been obvious.

9. *Claim 17:*

Claim 17 depends from claim 2. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1 and 2, also satisfies the limitations of claim 17. Specifically, that same combination provides a collar (*e.g.* snap-ring 180) that is formed of an elastically deformable material. That the snap-ring 180 is formed of an elastically deformable material is evidenced by its disclosed range of motion from inward deformation to outward deformation. *See, e.g.*, EX1006, 8:14-17 (“each retaining ring expands as the

corresponding coupling element is inserted into the hole, and snaps back into a retaining position about the coupling element once the top of the element passes it into the hole.”), 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”), 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”), and 24:5-7 (“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”); EX1002, ¶¶119-27, 129, 137-139 & Table 2. Moreover, both Theken and Errico teach making the orthopedic assembly from titanium. EX1005, 7:37-41 (screws and set screws); EX1006, 17:20-18:2 (plate). It thus would have been obvious to employ a collar that is formed of titanium, an elastically deformable material. Accordingly, Theken in view of Errico renders obvious claim 17 as a whole.

10. Claim 18:

Claim 18 depends from claim 2. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1, 2, and 17, also satisfies the limitations of claim 18. Specifically, that same combination provides a collar (*e.g.* snap-ring 180) that is formed of a material selected from the group consisting of titanium and superelastic material. That the snap-ring 180 is formed of an elastic material is evidence by its disclosed range of motion from inward deformation to outward deformation. EX1006, 8:14-17,

23:26-27, 24:3-4, 24:5-7. Moreover, both Theken and Errico teach making the orthopedic assembly from titanium. EX1005, 7:37-41 (screws and set screws); EX1006, 17:20-18:2 (plate). It thus would have been obvious to employ a collar that is formed of titanium, an elastically deformable material. EX1002, ¶¶97, 140-41.

Using particular types of elastic material, such as superelastic materials, is a simple design choice. EX1002, ¶¶119-27, 129, 141-42 & Table 2. Indeed, Superelastic nickel-titanium alloys were known to have good potential for clinical use in orthopedic surgery. EX1002, ¶¶141-42 (discussing EX1010, 481-88; EX1011, 451-57 (describing superelasticity of nickel-titanium alloys “that could be very useful in surgical applications” and appear “to have good potential for clinical use” and are “potentially very useful in orthopedic surgery”). It thus would have been obvious for the retaining ring/snap-ring to be formed of a material selected from the group consisting of titanium and superelastic material.

Accordingly, Theken in view of Errico renders obvious claim 18 as a whole.

11. Claim 19:

Claim 19 depends from claim 2. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1 and 2, also satisfies the limitations of claim 19. Specifically, that same combination provides a collar (*e.g.* snap-ring 180) that has a posterior surface perpendicular to a

longitudinal axis of the transverse passageway. *See, e.g.*, EX1006, FIG. 6 (snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the transverse passageway between the top and bottom of Errico's plate 100c and, when combined with Theken, the lateral side 26 and the medial side 28 of Theken's plate 20); EX1002, ¶¶119-27, 129, 143 & Table 2. Theken in view of Errico thus discloses each and every element of claim 19 and claim 19 as a whole would have been obvious.

12. Claim 29:

Claim 29 depends from claim 4. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1, 2, and 4, also satisfies the limitations of claim 29. Specifically, that same combination provides a collar (*e.g.* snap-ring 180) that has a height less than the height of the groove (*e.g.* annular recess 182). *See, e.g.*, EX1006, FIGS. 5-6. EX1002, ¶¶119-27, 130, 144 & Table 2. Theken in view of Errico thus discloses each and every element of claim 29 and claim 29 as a whole would have been obvious.

13. Claim 31:

Claim 31 depends from claim 10. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1 and 10, also satisfies the limitations of claim 31. Specifically, that same

combination provides a stabilizing element (*e.g.* plate 20) that is selected from the group consisting of rods and plates. *See, e.g.*, EX1005, 3:59-61, FIGS. 1-10.

EX1002, ¶¶119-27, 131, 145 & Table 2. Accordingly, Theken in view of Errico discloses each and every element of claim 31 and claim 31 as a whole would have been obvious.

14. Claim 32:

Claim 32 depends from claim 10. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 1 and 10, also satisfies the limitations of claim 32. Specifically, that same combination provides a securing element (*e.g.*, bone screw 100) that is selected from the group consisting of screws and nails. *See, e.g.*, EX1005, 3:59-60, 6:19-34, FIGS. 1-2 and 11. EX1002, ¶¶119-27, 131, 146 & Table 2. Theken in view of Errico thus discloses each and every element of claim 32 and claim 32 as a whole would have been obvious.

D. Claim 21 is Obvious Over Theken in View of Errico

The combination of Theken and Errico discussed above also renders claim 21 of the '008 patent obvious. EX1002, ¶¶147-60. With respect to the preamble to claim 21, Theken is directed to a method of attaching an orthopedic implant assembly to a bone of a patient. EX1005, 8:34-9:65. EX1002, ¶148. As discussed above in Section VI.A, it would have been obvious for a POSA to use a retaining

ring/snap-ring and in-bore annular recess to prevent back-out of the screw in Theken's orthopedic implant assembly such that the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring and being retained by the snap-ring. EX1002, ¶¶115-118, 147-48 & Table 3.

1. Claim Limitation 21a: The claimed "positioning a stabilizing element" step.

As discussed above for claim element 1.a), Theken discloses positioning a stabilizing element (*e.g.* plate 20) against a surface of the patient's bone, the stabilizing element having an anterior surface (*e.g.* lateral side 26), a posterior surface (*e.g.* medial side 128), and at least one bore (*e.g.* opening 62), 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. EX1005, 8:33-38, 4:7-55, 5:59-66, FIGS. 1-10, in particular FIGS. 3-4. EX1002, ¶¶149. Theken also discloses a stopping member (*e.g.* set screw 140) within the bore. *Id.*, 3:63-65, 6:60-66, 9:22-24, 9:54-59, FIGS. 1-3, 7:33-35. EX1002, ¶¶150 & Table 3. As discussed above with respect to claim element 1.b), it would have been obvious to employ a biased stopping member (*e.g.*, snap-ring 180 such as disclosed in Errico (EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-14:10)) that defines at least in part a reversibly expandable

passageway having a smaller diameter configuration and a larger diameter configuration.

2. Claim Limitation 21b: The claimed “providing a securing element” step

As discussed above for claim element 1.c), Theken discloses providing a securing element (*e.g.* bone screw 100) having an elongated body (*e.g.* threaded portion 102), and a head (*e.g.* tapered head portion 110) at one end of the body and integral therewith, the head (*e.g.* tapered head portion 110) having a maximum diameter greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the stopping member (*e.g.* set screw 140) and the second opening in the stabilizing element. EX1006, 4:21-26, 4:42-46, 6:19-31, FIGS. 1-2, 8-11; EX1002, ¶151. As discussed above for claim 1, it would have been obvious in view of Errico for the maximum diameter of a head of the securing element (*e.g.* head 110 of bone screw 100 in Theken) to be greater than the smaller diameter configuration of the passageway defined by the biased stopping member (*e.g.*, snap-ring 180 such as disclosed in Errico) so that the head is retained within a transverse passageway between the biased stopping member and the second opening in a stabilizing element. EX1006, 8:13-17, 24:1-10, FIG. 6; EX1002, ¶155 & Table 3.

3. *Claim Limitation 21c: The claimed “positioning the body of the securing element” step*

As discussed above in Section VI.A-B, 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. EX1005, at 4:35-38, 8:34-37, 8:56-9:1. EX1002, ¶152. Errico discloses posteriorly advancing a head (*e.g.* tapered coupling element 132) of a securing element (*e.g.* coupling element 132 attached to bone screw 120) within the passageway defined by the biased stopping member (*e.g.* snap-ring 180) and thereby displacing the biased stopping member (*e.g.* snap-ring 180) to form the larger diameter configuration passageway defined thereby. EX1006, 8:13-17, 23:27-24:7. EX1002, ¶156 & Table 3.

4. *Claim Limitation 21d: The claimed “attaching the stabilizing element to the bone” step*

As discussed above in Section VI.A-B, Theken discloses attaching the stabilizing element (*e.g.* plate 20) to the bone by advancing the head (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) posteriorly of the stopping member (*e.g.* set screw 140, inserted later), to position the head (*e.g.* tapered head portion 110) within a posterior section (*e.g.* tapered section 64) of the transverse passageway (*e.g.* opening 62) between the stopping member (*e.g.* set

screw 140) and the second opening in the stabilizing element (*e.g.* plate 20), and to position the body of the securing element (*e.g.* bone screw 100) within the patient's bone, so that the securing element (*e.g.* bone screw 100) is attached to the bone and is retained within the posterior section (*e.g.* tapered section 64) of the transverse passageway of the stabilizing element (*e.g.* plate 20). EX1006, 4:35-38, 8:56-9:1. EX1002, ¶153. Errico discloses attaching a stabilizing element (*e.g.* plate 100c) to a bone by advancing the head (*e.g.* tapered coupling element 132) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) posteriorly of the biased stopping member (*e.g.* snap-ring 180) so that the passageway defined thereby returns to the smaller diameter configuration. EX1006, 8:13-17, 24:4-10, FIG. 6. As a result, the head (*e.g.* tapered coupling element 132) is positioned within a posterior section of the transverse passageway (*e.g.* hole 110c) between the biased stopping member (*e.g.* snap-ring 180) and the second opening in the stabilizing element (*e.g.* plate 100c), the body of the securing element is positioned within the patient's bone, and the securing element is retained within the posterior section of the transverse passageway of the stabilizing element. *Id.*, 23:9-24:10, FIG. 6. EX1002, ¶157 & Table 3.

For the reasons discussed, Theken in view of Errico discloses each and every element of claim 21 and claim 21 as a whole would have been obvious.

E. Claim 36 is Obvious Over Theken in View of Errico

The same combination of Theken and Errico discussed above for claims 1 and 21 in Sections VI.A-B and VI.D also renders claim 36 of the '008 patent obvious. EX1002, ¶¶161-70 & Table 4. The preamble of claim 36 is identical to the preamble to claim 21 and is disclosed for the same reasons discussed above for claim 21. Claim element 36.a) of providing the claimed securing member (*e.g.* Theken bone screw 100), attachment member (*e.g.* Theken plate 20), and stopping member (*e.g.* Errico snap-ring 180) is obvious over Theken in view of Errico for the same reasons providing the securing element, stabilizing element, and biased stopping member and of claims 1 and 21 are obvious, as discussed above for claims 1 and 21. The first and second configurations of the stopping member of claim element 36.a)[iii] correspond for purposes of the prior art analysis with the larger diameter configuration and smaller diameter configuration, respectively, of the biased stopping member of claim element 21.a). EX1002, ¶¶163, 166, & Table 4.

Claim element 36.b) of positioning the attachment member with at least a part of the posterior surface against a surface of the patient's bone is obvious for the same reason positioning the stabilizing element against a surface of the patient's bone (claim element 21.a)) is obvious, as discussed above. Claim element 36.c) of attaching the securing member to the patient's bone as claimed in its

entirety is obvious over Theken in view of Errico for the same reasons provided above that claim elements 21.b)-d) are obvious. With respect to the combination of Theken and Errico asserted in this Ground, there is no patentable distinction between claims 21 and 36 EX1002, ¶¶162-69 & Table 4.

Illustrative disclosures from the prior art are cited below. With respect to the preamble to claim 36, Theken is directed to a method of attaching an orthopedic implant assembly to a bone of a patient. EX1005, 8:34-9:65.

1. Claim Limitation 36.a): The claimed “providing” step

Theken discloses providing a securing member (*e.g.* bone screw 100) with an elongated body (*e.g.* threaded portion 102) and an enlarged integral portion (*e.g.* tapered head portion 110) having a maximum transverse dimension. *Id.*, 4:21-26, 4:42-46, 6:19-31, FIGS. 1-2, 8-11. Theken further discloses an attachment member (*e.g.* plate 20) which has an anterior surface (*e.g.* lateral side 26) and a posterior surface (*e.g.* medial side 28) and which has at least one bore (opening 62) extending through the attachment member from the anterior surface to the posterior surface and is configured to receive the securing member (*e.g.* bone screw 100), the bore having an anterior bore portion (*e.g.* section 66 of the opening 62), and a posterior bore portion (*e.g.* tapered section 64 of the opening 62) with at least one transverse dimension smaller than a transverse dimension of the anterior bore

portion and smaller than the maximum transverse dimension of the enlarged integral portion of the securing member. *Id.*, 4:7-65, 5:59-66, FIGS. 1-8, 10.

Theken uses a stopping member (*e.g.*, set screws 140) to prevent screw back-out and states that “set screws 140 could be replaced by other suitable locking mechanisms.” *Id.*, 3:63-65, 6:60-66, 7:33-35, 9:22-24, 9:54-59, FIGS. 1-3,. EX1002, ¶163 & Table 4. Errico discloses a suitable stopping member (*e.g.* snapping 180) which has a first configuration (*e.g.* expanded configuration) which allows passage of an enlarged integral portion (*e.g.* tapered coupling element 132) of the securing member (*e.g.* coupling element 132 attached to bone screw 120) and has a second configuration (*e.g.* unexpanded configuration) that reduces a transverse dimension of a bore (*e.g.* hole 110c) that is smaller than a maximum transverse dimension (*e.g.* top surface 136) of the enlarged integral portion (*e.g.* tapered coupling element 132) in order to retain the enlarged integral portion (*e.g.* tapered coupling element 132) within a posterior bore portion of an attachment member (*e.g.* plate 20), wherein the stopping member has an anterior surface and a posterior surface. EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-24:10, FIGS. 5-6. EX1002, ¶166 & Table 4.

Theken in view of Errico thus discloses providing the securing member, attachment member, and stopping member as recited in claim element 36.a).

2. *Claim Limitation 36.b): The claimed “positioning the attachment member” step*

Theken discloses positioning the attachment member (*e.g.* plate) with at least part of the posterior surface (*e.g.* medial side 28) thereof against a surface of the patient's bone (*e.g.* vertebral bodies V₁ and V₂). *Id.*, 3:65-66, 5:34-36, 8:33-38, FIGS. 3-4. EX1002, ¶164 & Table 4.

3. *Claim Limitation 36.c): The claimed “attaching” step*

Theken discloses attaching the securing member (*e.g.* plate 20) to the patient's bone by advancing the securing member (*e.g.* bone screw 100) within the bore (*e.g.* opening 62) of the attachment member (*e.g.* plate 20) until the enlarged integral portion (*e.g.* tapered head portion 110) of the securing member (*e.g.* bone screw 100) passes a location for stopping member (*e.g.* section 66 of the opening 62) and is disposed in the posterior bore portion (*e.g.* tapered section 64 of the opening 62), wherein a stopping member (*e.g.* set screw 140) retains the enlarged integral portion (*e.g.* tapered head portion 110) within the posterior bore portion (*e.g.* tapered section 64) below a posterior surface of the stopping member (*e.g.* set screw 140). *Id.*, 4:33-38, 8:56-9:1, FIGS. 1-2. EX1002, ¶165 & Table 4. Errico discloses attaching the securing member (*e.g.* plate 100c) to the patient's bone by advancing the securing member (*e.g.* coupling element 132 attached to bone screw 120) within the bore (*e.g.* hole 110c) of the attachment member (*e.g.* plate 100c) until the enlarged portion (*e.g.* tapered coupling element 132) of the securing

member (*e.g.* coupling element 132 attached to bone screw 120) passes the stopping member (*e.g.* snap-ring 180) thereby displacing the stopping member (*e.g.* snap-ring 180) to the first configuration (*e.g.* expanded configuration) and is disposed in the posterior bore portion, the stopping member (*e.g.* snap-ring 180) then returning to the second configuration (*e.g.* unexpanded configuration) to retain the enlarged portion (*e.g.* tapered coupling element 132) of the securing member within the posterior bore portion below the posterior surface of the stopping member (*e.g.* snap-ring 180). EX1002, ¶167 & Table 4.

For the reasons discussed, Theken in view of Errico discloses each and every element of claim 36 and claim 36 as a whole would have been obvious.

VII. Ground 2: Claims 3, 5, 11, 22, 30 and 37 are rendered obvious by Theken in view of Errico under 35 U.S.C. §103

A. Summary of Unpatentability

The combination of Theken (EX1005) in view of Errico (EX1006) discloses all the limitations of claims 3, 5, 11, 22, 30 and 37 of the '008 patent, and renders those claims obvious under pre-AIA 35 U.S.C. 103(a). EX1002, ¶233. Each of claims 3, 5, 11, 22, 30 and 37 ultimately depends from a claim (claims 1, 2, 4, 10, 21, or 36) rendered obvious by the combination of Theken and Errico discussed above in Section VI, which discussion applies equally here. EX1002, ¶234. Each of the claims also include limitations related to a variable-angle bone screw. EX1002, ¶234.

As discussed above in Ground 1, one obvious embodiment of the combination of Theken and Errico is a fixed-angle bone screw and plate assembly with a snap-ring and annular recess. EX1002, ¶109. Theken also contemplates using variable-angle bone screws. In discussing its integral bone screw 100, Theken specifically discloses that screw 100 “may have other suitable geometries” that “would allow variable screw angulation,” such as by replacing the tapered head with “a spherical head.” EX1005, 6:51-56, 7:57-60; EX1002, ¶235. Theken thereby suggests that its integral bone screws 100 may be variable-angle bone screws. EX1002, ¶¶236-38.

Errico also teaches certain benefits of variable-angle bone screws. *See, e.g.*, EX1006, Abstract (“bone screws (120) may be inserted at a variety of angles), 3:6-20 (screw plate assemblies may “permit screws to be entered into the bone at angles other than 90 degrees”), 5:22-25 (desired screw insertion angle may depend on fracture type and bone anatomy), 6:15-27 (teaching variable-angle screws with semi-spherical head and locking the screw at the desired angle), 11:11-12:2 (same and specifying “the head of the screw is loosely retained” during insertion to permit angular displacement of the screw within the bore “relative to the bottom opening of the socket portion”), 14:3-15:20 (disclosing various means of fastening the plate to the bone via variable-angle screws, including using an annular flange and a channel), FIGS. 4a-b, 6, 9-10, 13. In 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. EX1002, ¶109; *see also id.*, ¶61 (discussing EX1017, 97, Table 3).

B. Each of Claims 3 and 5 is Obvious Over Theken in View of Errico

Claim 3 depends from claim 1 via claim 2 and claim 5 depends from claim 1 via claims 2 and 4. Each of claims 1-2 and 4 is obvious for the reasons discussed in Ground 1 above.

Each of claims 3 and 5 requires 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. Claim 3 requires the curved posterior surface be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof. Claim 5 requires the curved posterior surface is configured to contact the collar anterior surface and expand the collar away as the head is displaced posteriorly through the collar passageway.

Theken and Errico each disclose a head of the securing element having a curved posterior surface. EX1006, 18:14-19:2, 19:13-20, FIGS. 2, 6 (integral spherical head portion 122 of screw 120); EX1005, 6:51-56 (tapered head may be replaced with spherical or oval head). Errico discloses that the minimum transverse dimension of the posterior surface of a head (*e.g.* coupling element 132) of the

securing element should be smaller than unexpanded inner diameter of the collar, which configures it to expand the collar by contacting the collar at an anterior surface of the collar and deforming the collar away from the longitudinal axis of the collar passageway as the head is displaced posteriorly through the collar passageway. EX1006, 8:13-17, 23:12-24:10 & FIGS 5-6. EX1002, ¶¶239-41 & Table 12. An embodiment of the same combination of Theken and Errico discussed above for claims 1-2 and 4 in which the head has a curved posterior surface satisfying the requirements of each of claims 3 and 5 thus would have been obvious. EX1002, ¶¶239-41 & Table 12.

C. Each of Claims 11, 22, 30 and 37 is Obvious Over Theken in View of Errico.

Claims 11 and 30 depend from claim 1 via claim 10, claim 22 depends from claim 21, and claim 37 depends from claim 36. Each of claims 1, 10, 21, and 36 is obvious for the reasons discussed in Ground 1 above.

1. Claim 37

Claim 37 requires “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.” As discussed above, Theken suggests that its integral bone screws 100 may be variable-angle bone screws (EX1005, 6:51-56, 7:57-60) and Errico teaches certain benefits of variable-angle bone screws. *See, e.g.*, EX1006, Abstract, 3:6-20, 5:22-25, 6:15-27,

11:11-12:2, 14:3-15:20, FIGS. 4a-b, 6, 9-10, 13; EX1002, ¶¶109, 235. These disclosures of “variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion,” teach “the securing member is angularly displaceable within the posterior bore portion so that the bone screw may be secured with the patient’s bone at an angle relative to the longitudinal axis of the bore,” as required by claim 37 EX1002, ¶¶242-49. This disclosure is sufficient to render claim 37 obvious as a whole. EX1002, ¶244 & Table 13.

As JP Errico explains, 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. EX1002, ¶243; EX1005, 6:51-56.

2. Claims 11 and 30

Claim 30 requires “the body of the securing element has a transverse dimensions 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.” Claims 11 requires “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.” Theken and Errico’s disclosures of “variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion” discussed above for claim 37 (EX1005, 6:51-56, 7:57-60; EX1006, Abstract, 3:6-20, 5:22-25, 6:15-27, 11:11-12:2, 14:3-15:20, FIGS. 4a-b, 6, 9-10, 13) teach that “the securing element may be angularly displaced within the transverse passageway and the second opening in the stabilizing element,” as required by claim 11, and that “the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element,” as required by claim 30. EX1002, ¶¶242-49.

With respect to the remaining recitations of claims 11 and 30, Theken discloses that the body of the securing element (*e.g.*, bone screw 100) has a diameter smaller than the second opening in the stabilizing element (*e.g.*, plate 20), as required by claim 11, and has a transverse dimension smaller than the second opening of the stabilizing element (*e.g.*, plate 20), as required by claim 30, including along the length of the threaded portion 102 and at the rounded tip 106. EX1005, 6:19-31, 8:33-38, 8:56-60, FIGS. 1-4, 10-11; EX1002, ¶¶245-46 & Table 13. Indeed, Theken discloses that the securing element (*e.g.*, bone screw 100) extends from the second opening to be screwed into the vertebral body. *E.g.*,

EX1005, 6:24-26, 8:56 FIGS. 1-3. Theken in view of Errico thus renders each of claims 11 and 30 obvious as a whole.

3. Claim 22

Claim 22 requires “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.” Theken and Errico disclose the angular displacement element of claim 22 for the same reasons they disclose the angular displacement elements of claims 11, 30, and 37, as discussed above. Theken and Errico also disclose longitudinally displacing the head of the securing element (*e.g.*, bone screw 100) in order to secure the securing member within the patient’s bone. *See, e.g.*, EX1005, 6:24-26, 8:56; EX1006, 5:3-4. Theken in view of Errico thus disclose this element.

Claim 22 also requires the longitudinal and angular displacement occur *after* the head of the securing element (*e.g.*, bone screw 100) is positioned between the biased stopping member (*e.g.*, snap-ring 180) and the second opening in the stabilizing element (*e.g.*, plate 20). This too would have been obvious in view of Theken and Errico. EX1002, ¶¶247-48, Table 13. As discussed above in Section VI.A and for claim 10 in Section VI.C, the annular recess 182 is placed at the

middle of Theken's threaded section 66 so there is a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100. As explained by JP Errico, a POSA would have known this was useful to allow for settling after surgery and for different depths of bone screw insertion during surgery. EX1002, ¶248. In this implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the biased stopping member (*e.g.*, snap-ring 180) and the second opening in the stabilizing element (*e.g.*, plate 20). EX1002, ¶248 & Table 13. As JP Errico explains, when combined with the variable-angle bone screws suggested by Theken, 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 between the biased stopping member (*e.g.*, snap-ring 180) and the second opening 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, as required by claim 22. EX1002, ¶248 & Table 13. Theken in view of Errico thus renders obvious claim 22 as a whole. EX1002, ¶249.

VIII. Ground 3: Claims 3, 5, 11, 22, 30 and 37 are rendered obvious by Theken in view of Errico and Farris under 35 U.S.C. §103

A. Summary of Unpatentability

The combination of Theken (EX1005) in view of Errico (EX1006) in further view of Farris (EX1008) discloses all the limitations of claims 3, 5, 11, 22, 30 and

37 of the '008 patent, and renders those claims obvious under pre-AIA 35 U.S.C. 103(a). EX1002, ¶250. Each of claims 3, 5, 11, 22, 30 and 37 depends from a claim (claims 2, 4, 10, 21, or 36) rendered obvious by the combination of Theken and Errico discussed above in Section VI, which discussion applies equally here. EX1002, ¶251. Each of the claims also include limitations related to a variable-angle bone screw. EX1002, ¶251. Theken and Errico also render obvious each of claims 3, 5, 11, 22, 30, and 37 as discussed above in Section VII, which discussion also applies equally here.

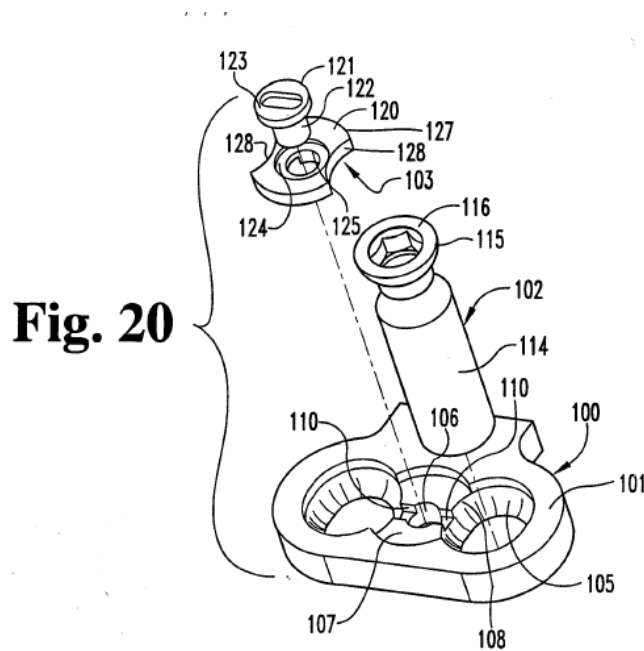
Farris provides additional evidence that each of claims 3, 5, 11, 22, 30, and 37 is obvious and provides details regarding implementing an invalidating embodiment of a variable-angle bone screw. EX1002, ¶252. Farris discloses that spinal plating systems with “different degrees of fixation of a bone screw relative to the plate are more advantageous for treating certain pathologies as opposed to other pathologies.” EX1008, 3:17-26. Farris teaches that spinal plates using bone screws in a rigid fashion are preferable for treatment of tumors or trauma to the spine and that using bone screws in a semi-rigid fashion are preferable for grafts and for the treatment of degenerative diseases of the spine. *Id.*, 3:27-4:25.

Farris also teaches fixed angle screws and variable angle screws, each having a threaded shank for screwing into the vertebra, a spherical head to seat within a spherical recess in the bore, and an intermediate portion that resides in

the screw hole when the screw is fixed to the plate. EX1008, 5:8-22. The intermediate portion of the fixed angle screw “has an outer diameter sized for a close fit” within the adjacent screw hole so that the screw “is prevented from rotating or pivoting within the screw hole” whereas the intermediate portion of the variable angle bone screw “has an outer diameter that is significantly smaller” than the diameter of the adjacent screw hole so that “the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” *Id.*, 5:22-6:3; *see also id.*, 15:17-16:1, 16:24-17:26, 18:33-20:11, 21:8-22, 22:29-23:26, FIGS 18-19. Farris teaches this variable angle screw permits angulation of 20 degrees from the axis of the recess and the bore. *Id.*, 23:9-11. 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.*, 6:4-31; *see also id.*, 20:12-21:7, 21:23-22:3, EX1002 ¶253.

Farris also discloses an orthopedic implant assembly 100. EX1008, FIG. 20-23, and 23:33-25:26. EX1002, ¶252. Farris’s plate assembly 100 includes a plate 101 (*i.e.*, a stabilizing/attachment element), one-piece bone screws 102 (*i.e.*, integral securing elements), and a locking assembly 103 (*i.e.*, a stopping member) to “lock the bone screw within the plate.” EX1008, 23:35-24:3, FIGS. 20-23.

EX1002, ¶252. The plate 101 includes a spherical recess 105 in a posterior section of a bore to receive a spherical head of the bone screw. EX1008, 24:3-4. EX1002, ¶252. The bone screw can be similar to other variable-angle bone screws described in Farris. EX1008, 24:6-8. EX1002, ¶¶252-53. Farris's spherical screw head is used with a curved/spherical recess in a posterior section of a bore. EX1008, 24:3-4, FIGS. 20-22; EX1002, ¶252-53. Farris Figure 20 is reproduced below.

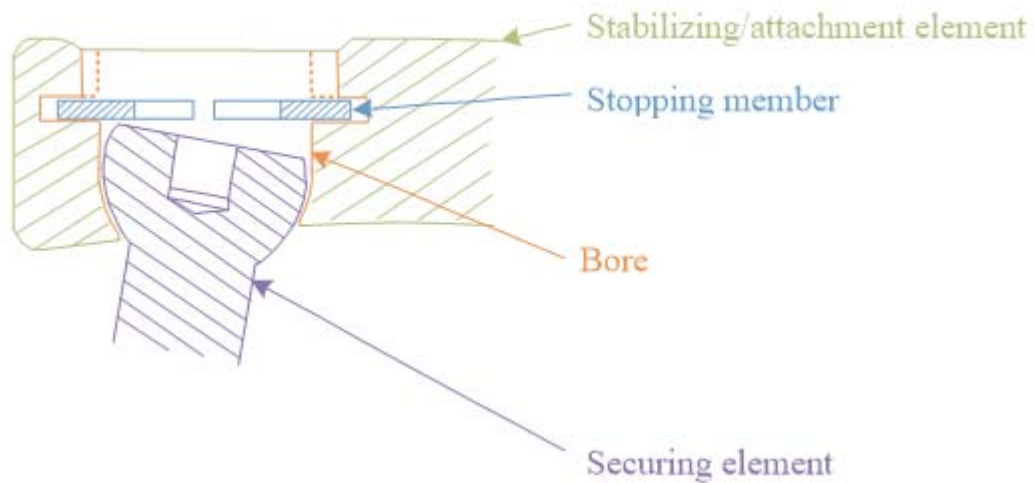


Farris supports the obviousness of the challenged claims by providing an example of a variable angle bone screw contemplated by Theken—*e.g.*, an integral bone screw that has spherical head geometry to allow for angular displacement—and can therefore be used in Theken's plate system. EX1002, ¶254. Additionally, the curved posterior bore section of Farris is compatible for use in a posterior bore

section of the bore in Theken. EX1002, ¶255. Farris thus confirms that a POSA at the time of the invention of the '008 patent would have had good reason with a reasonable expectation of success to use a variable-angle bone screw in a posterior bore section of Theken's plate. EX1002, ¶255.

Farris's teachings regarding variable-angle bone screws also confirm that a POSA would have had good reason with a reasonable expectation of success to employ a snap-ring, as taught in Errico, to lock a variable angle bone screw in place in the posterior bore section of Theken's plate. EX1002, ¶255. As discussed above, Farris discloses locking the variable angle bone screw in place using a washer that resides in a recess in the plate. EX1002, ¶¶253. As JP Errico explains, a POSA would have been motivated to, and would have understood how to, adjust the respective dimensions of the screw head, snap-ring, and bore to ensure the spherical screw head expanded the snap-ring, was subsequently retained by the snap-ring, and could still be angularly displaced within a posterior section of the bore. EX1002, ¶255. Combining the teachings of Theken, Errico, and Farris as described above and as illustrated below would provide a bone fixation system that offers variable-angle insertion of bone screws that are locked to a plate by a snap-ring. EX1002, ¶¶256-60.

An obvious implementation showing a bone fixation system of the combination of Theken, Errico, and Farris is shown below. EX1002, ¶256.



EX1002, ¶256.

By virtue of the relative positions of the posterior surface of the snap-ring and the top-most part of the bone screw head for different angles of insertion, longitudinal movement of the bone screw head within the posterior section of the bore is available, which Farris taught was advantageous for, *e.g.*, treating degenerative disease. EX1008, 3:17-4:25; EX1002, ¶256. Alternatively, material deformation of the bone screw head and/or bore (*e.g.* EX1005, 7:53-56) would provide a constrained bone fixation system Farris taught was useful for treating traumatic injury. EX1008, 3:17-4:25; EX1002, ¶256.

The asserted combination of Ground 3 renders obvious each of claims 1, 2, 4, 10, 12-19, 21, 29, 31-32, and 36 for the same reasons discuss above in Ground 1. Ground 3 also renders each of claim 3, 5, 11, 22, 30, and 37 obvious for the reasons discussed above in Ground 2 and the reasons discussed below.

B. Each of Claims 3, 5, 11, 22, 30 and 37 is Obvious Over Theken in View of Errico in further view of Farris

1. Claims 3 and 5

Claim 3 depends from claims 1 and 2. Claim 5 depends from claims 1, 2, and 4. Claims 1-2 and 4 are obvious as discussed in Grounds 1-2. The rationales discussed above in Section VIII.A for combining Farris with Theken and Errico apply to claims 3 and 5. EX1002, ¶¶261-63.

As discussed above in Ground 2, Theken and Errico each disclose the head of the securing element having a curved posterior surface. EX1006, 18:14-19:2, 19:13-20, FIGS. 2, 6; EX1005, 6:51-56. 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. *See, e.g.*, EX1008, 5:8-22, 16:6-8, 17:4-6, 18:33-19:22, 22:29-23:25, 24:3-8, FIGS. 18-23; EX1002, ¶¶261-63. As discussed above, Errico discloses that the minimum outer diameter should be smaller than the unexpanded inner diameter of the collar, which configures it to expand the collar by contacting the collar at an anterior surface of the collar and deforming it outward as the head is displaced posteriorly through the collar passageway. EX1006, 8:13-17, 23:12-24:10 & FIGS 5-6.

Each of claims 3 and 5 thus is rendered obvious by the combination of Theken, Ericsson, and Farris. EX1002, ¶¶261-63 & Table 14.

2. *Claim 11:*

Claim 11 depends from claim 10, which is discussed above in Section VI. Claim 10 is obvious for the reasons discussed above in Ground 1. The rationales discussed above in Section VIII.A for combining Farris with the combination of Theken and Errico from Grounds 1 and 2 apply to claim 11. EX1002, ¶264-65.

Regarding the limitations of claim 11, Farris provides a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a body that has a diameter (*e.g.* diameter of an intermediate portion) smaller than a second opening in a stabilizing element (*e.g.* opening at bottom of recess 105 in Farris's plate 101), and that may be angularly displaced within a transverse passageway and a second opening in a stabilizing element. *See, e.g.*, EX1008, 24:3-6, FIG. 20-22, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (The "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate."); EX1002, ¶265 & Table 15. Accordingly, Theken in view of Errico and Farris discloses each and every element of claim 11 and claim 11 as a whole would have been obvious.

3. *Claim 22:*

Claim 22 depends from claim 21, which is discussed above in Section VI. Claim 21 is obvious for the reasons discussed above in Ground 1. The rationales

discussed above in Section VIII.A for combining Farris with the combination of Theken and Errico discussed above in Ground 1 and 2 apply to claim 22. EX1002, ¶266.

Regarding the limitations of claim 22, Farris comprises a step, after a head of a securing element (*e.g.* spherical head of a bone screw 102 having similar features from other disclosed bone screws) is positioned between a stopping member (*e.g.* locking assembly 103) and a second opening (*e.g.* opening at bottom of recess 105) in a stabilizing element (*e.g.* plate 101), 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. *See, e.g.*, EX1008, 24:3-6, FIG. 20-22, 24:6-8, 5:28-6:3 (the “relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.”) EX1002, ¶266 & Table 15.

Just as for claim 10, Errico’s annular recess 182 is placed at the middle of Theken’s bore section 66 to allow for longitudinal displacement of a bone screw between the stopping member and the posterior hole of the bore. EX1002, ¶131, 266 & Table 15. This semi-rigid system would advantageously allow settling as desired for certain surgeries. *Id.* Accordingly, Theken in view of Errico and Farris

discloses each and every element of claim 22 and claim 22 as a whole would have been obvious.

4. *Claim 30:*

Claim 30 depends from claim 10, which is discussed above in Section VI. Claim 10 is obvious for the reasons discussed above in Ground 1. The rationales discussed above in Section VIII.A for combining Farris with the combination of Theken and Errico discussed in Grounds 1 and 2 above apply to claim 30. EX1002, ¶267.

Regarding the limitations of claim 30, Farris comprises a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a body that has a transverse dimension (*e.g.* diameter of an intermediate portion) smaller than the second opening of the stabilizing element (*see e.g.* opening at bottom of recess 105 in Farris's plate 101), and wherein the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element. *See, e.g.*, EX1008, 24:3-6, FIG. 20-22, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (the "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate."); EX1002, ¶131, 267 & Table 15. Accordingly, Theken in view of Errico

and Farris discloses each and every element of claim 30 and claim 30 as a whole would have been obvious.

5. *Claim 37:*

Claim 37 depends from claim 36, which is discussed above in Section VI. Claim 36 is obvious for the reasons discussed above in Ground 1. The rationales discussed above in Section VIII.A for combining Farris with the combination of Theken and Errico discussed in Grounds 1 and 2 apply to claim 37. EX1002, ¶268.

Regarding the limitations of claim 37, Farris comprises a securing member (*e.g.* bone screw 102 having similar features from other disclosed bone screws) that is angularly displaceable within a posterior bore portion (*see e.g.* opening at bottom of recess 105 in Farris's plate 101) so that the securing member may be secured within the patient's bone at an angle relative to a longitudinal axis of the bore. *See, e.g.*, EX1008, 24:3-6, FIG. 20-22, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (the "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate."); EX1002, ¶161-70, 268 & Table 15. Accordingly, Theken in view of Errico and Farris discloses each and every element of claim 37 and claim 37 as a whole would have been obvious.

IX. Conclusion

Petitioner respectfully requests that the Board institute a Trial and that it cancel claims 1-5, 10, 11-19, 21-22, 29-32, and 36-37 of the '008 patent as unpatentable for the reasons stated in this Petition.

Respectfully submitted:

/ Michael T. Rosato /

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Dated: March 13, 2020

X. Certificate of Compliance

Pursuant to 37 CFR §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 13,867 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a).

Dated: March 13, 2020

By:

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182
Attorney for Petitioner

XI. Payment of Fees under 37 C.F.R. §42.103

The required fees are submitted herewith. If any additional fees are due at any time during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 23-2415.

XII. Appendix - List of Exhibits

Exhibit No.	Exhibit Name
1001	U.S. Patent No. RE43,008
1002	Declaration of Joseph P. Errico
1003	U.S. Patent No. 6,261,291
1004	File History for U.S. Patent No. RE43,008
1005	U.S. Patent No. 6,228,085 to Theken <i>et al.</i>
1006	International Publication No. WO 1996/032071 to Errico <i>et al.</i>
1007	U.S. Patent No. 5,082,390 to Balsells
1008	International Publication No. WO 1998/051226 to Farris <i>et al.</i>
1009	File History for U.S. Patent No. 6,228,085
1010	Ryhanen, J. <i>et al.</i> , <i>In vivo biocompatibility evaluation of nickel-titanium shape memory metal alloy: muscle and perineural tissue responses and capsule membrane thickness</i> , 41 J. Biomed. Mater. Res. 481-88 (Sep. 1998).
1011	Ryhanen, J. <i>et al.</i> , <i>Biocompatibility of nickel-titanium shape memory metal and its corrosion behavior in human cell cultures</i> , 35 J. Biomed. Mater. Res. 451-57 (Jun. 1997).
1012	Complaint from <i>Acantha LLP v. NuVasive, Inc.</i> , Eastern District of Michigan Case No. 4:19-CV-10656-MFL-EAS.
1013	Docket Entry No. 4 from <i>Acantha LLP v. NuVasive, Inc.</i> , Eastern District of Michigan Case No. 4:19-CV-10656-MFL-EAS.
1014	Claim Construction Order from <i>Acantha LLC v. DePuy Synthes Sales, Inc.</i> , Eastern District of Wisconsin Case No. 15-c-1257-WCG.
1015	Curriculum Vitae for Joseph P. Errico.

1016	File History for U.S. Patent No. 6,261,291
1017	Baskin et al., "Techniques of Anterior Cervical Plating," by (EX1017) 1 Operative Techniques in Neurosurgery 90-102 (June 1998)
1018	U.S. Patent No. 5,876,402 to Errico et al.
1019	U.S. Patent No. 5,411,348 to Peter J. Balsells
1020	U.S. Patent No. 5,904,683 to Pohndorf et al.
1021	U.S. Patent No. 4,488,543 to Alain Tornier

CERTIFICATE OF SERVICE OF THE PETITION

Pursuant to 37 CFR §§42.6(e) and 42.105, this is to certify that I caused to be served a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. RE43,008 (and accompanying Exhibits 1001-1021) by overnight courier (Federal Express or UPS), on this 13th day of March, 2020, on the Patent Owner at the correspondence address of record as follows:

Attn: Maryellen Hank
Anthony Venturino
Vorys, Sater, Seymour and Pease LLP
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Washington, DC 20006
202-467-8800

And at other address also likely to effect service:

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27725 Stansbury Blvd, Suite 125
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248-353-8620

Dated: March 13, 2020

By:

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