

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

ACANTHA LLC,
Patent Owner.

Case No. IPR2020-00706
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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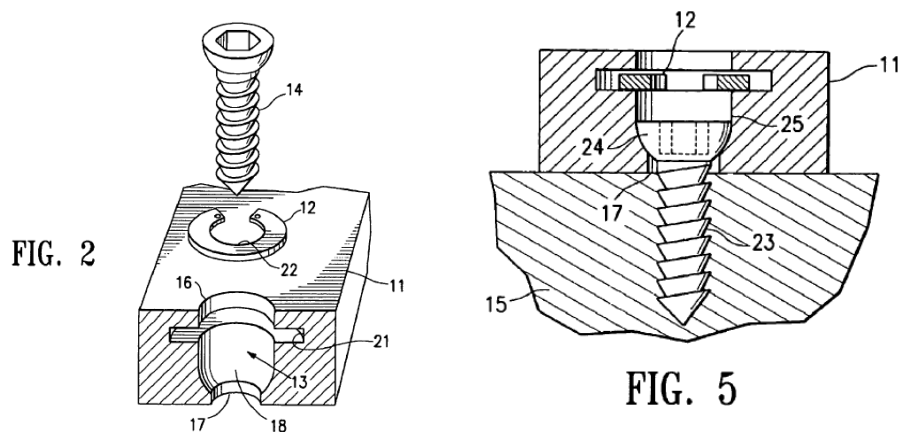
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I. Introduction

NuVasive, Inc. (“Petitioner”) requests *Inter Partes* Review and cancellation of claims 44-50, 53-54, 59-63, 66, 68-73, 75-78, 80-87, 90-91, 101, and 103-104 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 (discussing EX1017, 97-99, 102, FIG. 16, Table 3; 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 in position.” EX1005, 3:63-65, 6:60-66, 9:22-24, 9:54-59, FIGS 1-3; EX1002,

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.

¶¶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 44, 59, and 101 require a biased stopping member that has a larger configuration that allows passage of the securing element into the posterior bore portion and a smaller configuration to facilitate retention of the securing element below the posterior surface of the stopping member. 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. EX1002, *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 ordinary 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, this combination provides compelling evidence the challenged claims are 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 2 demonstrates that claims 62-63 and 87 are obvious over Theken and Errico in further view of International Publication No. WO 1998/051226 ("Farris," EX1008). Farris published on November 19, 1998, from International Application No. PCT/US98/09636, filed on May 12, 1998. Claims 62-63 and 87 recite posterior geometries or relative dimensions that facilitate angular displacement of the securing member within the bore. Theken and Errico each teach using spherical head geometries to permit "variable screw angulation," Errico teaches certain benefits of variable-angle bone screws, and Farris provides details about how to implement a variable-angle bone screw by using the claimed posterior geometries and relative dimensions. EX1002, ¶¶251-60. Theken and Errico in further view of Farris render each of claims 62-63 and 87 obvious.

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 1-5, 10, 12-21, 29, and 31-37 of the '008 patent. IPR2020-00684.

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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Please direct all correspondence to lead counsel and back-up counsel at the contact information above. Petitioner consents to electronic mail service at the email addresses above. A power of attorney accompanies this Petition.

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 44-50, 53-54, 59-63, 66, 68-73, 75-78, 80-87, 90-91, 101, and 103-104 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	44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101, and 103-104	Over Theken (EX1005) in view of Errico (EX1006)
2	62-63 and 87	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 44, 59, and 101 are independent. They are directed to an orthopedic implant or attachment assembly.

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 44, 59, and 101 and certain dependent claims refer to anterior or posterior surfaces or portions. 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 47-50, 68-73, 80-82, and 103 refer to a 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; EX100, ¶96. At least Figures 2, 3, 3A, and 4A disclose the annular collar (12) as a discontinuous retaining ring/snap-ring. The claimed collar thus includes a discontinuous retaining ring/snap-ring.

Claim 68 recites the collar is formed of an elastically deformable material and claim 69 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.

VI. Ground 1: Claims 44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101, and 103-104 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 44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101,

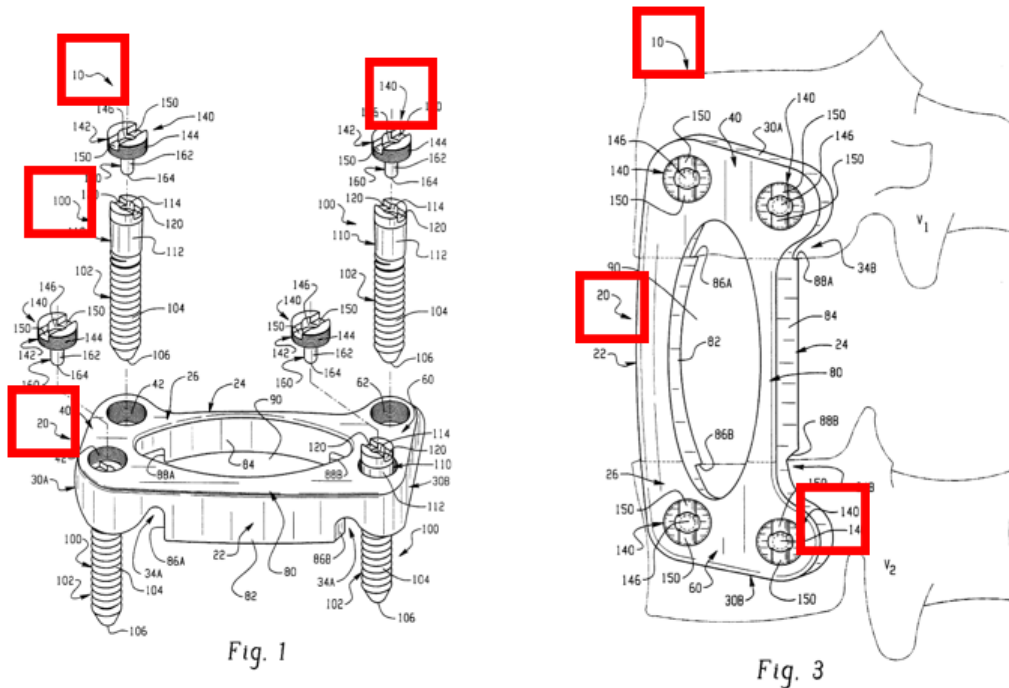
and 103-104 of the '008 patent, and renders those claims obvious under pre-AIA 35 U.S.C. §103(a). EX1002, ¶100. Claim 44 is representative and recites:

44. An orthopedic implant assembly, comprising

- a. a stabilizing element having an anterior surface, a posterior surface, and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface and the bore having an anterior bore portion with a transverse dimension and a posterior bore portion which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion;
- b. a securing element which is configured to be slidably disposed within the bore of the stabilizing element and which has an elongated body and an enlarged integral portion with a maximum transverse dimension; and
- c. a stopping member which is at least partially disposed within the bore of the stabilizing element, which has a posterior stopping surface, a first configuration within the bore allowing passage of the securing element into the posterior bore portion with the enlarged integral portion of the securing element disposed in the posterior bore portion posterior to the stopping member and a second configuration within the bore which has smaller transverse dimensions than the first configuration and smaller than the maximum transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion of the stabilizing element; and wherein the enlarged integral portion of the securing element is retained below the posterior surface

of the stopping member.

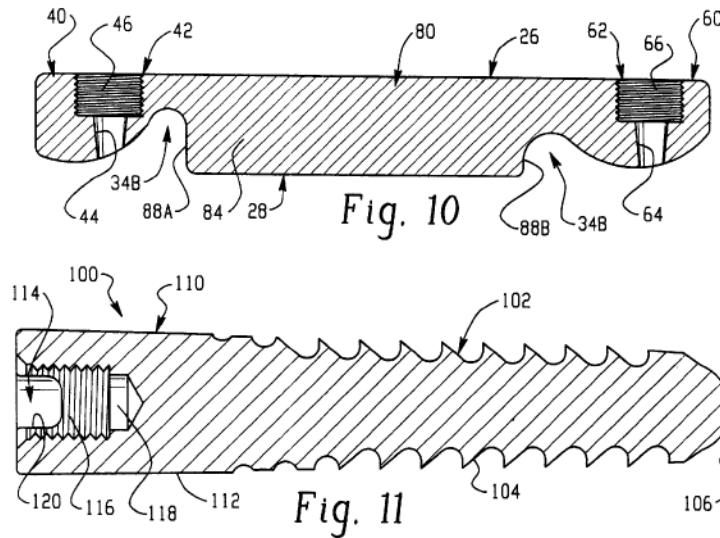
Theken discloses an orthopedic implant assembly in the form of a bone fixation system 10. EX1005, FIGS. 1-14, 2:26-52, 3:54-65. The bone fixation system 10 includes a bone plate 20 (*i.e.*, a stabilizing/attachment element/member), bone screws 100 (*i.e.*, securing elements), and set screws 140 (*i.e.*, 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/member) 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.” EX1005, 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 threaded 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.” EX1005, 4:36-49. EX1002, ¶102. Theken thus discloses a stabilizing element having an anterior surface, a posterior surface, and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface and the bore having an anterior bore portion with a transverse dimension and a posterior bore portion which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion. EX1002, ¶¶101-02. Theken Figures 10-11 are reproduced below.



The bone screws 100 (*i.e.*, securing elements) in Theken each include an elongated threaded portion 102 integral with an enlarged head portion 110. EX1005, 6:19-21, FIGS. 1-2, 11. The head portion 110 includes a tapered outer surface 112. EX1005, 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 transverse dimension greater than the second opening of the bore at the posterior surface. EX1005, 6:27-32, 4:21-26, 4:42-46, FIGS. 8 and 10. The head portion 110 is retained within the bore between the set screw 140 (*i.e.*, stopping member) and the second opening of the bore. EX1005, 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 which is configured to be slidably

disposed within the bore of the stabilizing element and which has an elongated body and an enlarged integral portion having a maximum transverse dimension. *Id.*

Theken's bone fixation system 10 as described above includes all elements of the implant assembly recited in independent claims 44, 59, 98, and 101 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 which is at least partially disposed within the bore of the stabilizing element, which has a posterior stopping surface, a first configuration within the bore allowing passage of the securing element into the posterior bore portion with the enlarged integral portion of the securing element disposed in the posterior bore portion posterior to the stopping member and a second configuration within the bore which has smaller transverse dimensions than the first configuration and smaller than the maximum transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the

enlarged integral portion of the securing element within the posterior bore portion of the stabilizing element; and wherein the enlarged integral portion of the securing element is retained below the posterior surface of the stopping member. 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). EX1006, 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.

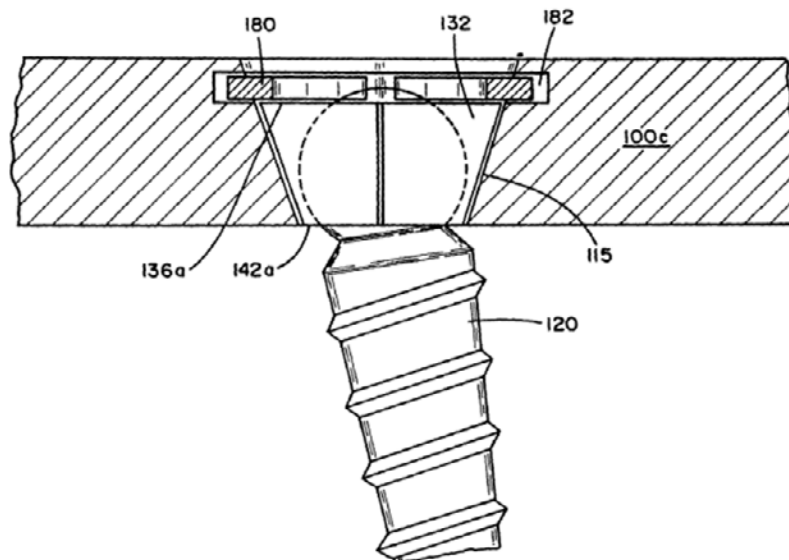


FIG.6

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). EX1006, 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 transverse dimension greater than the second opening, is retained within a bore between the snap-ring 180 and the second opening. EX1006, FIG. 6 (showing a transverse dimension 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. EX1006, 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. EX1006, 23:12-14 and 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. EX1006, 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. EX1006, 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”). EX1006, 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. EX1006, 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).

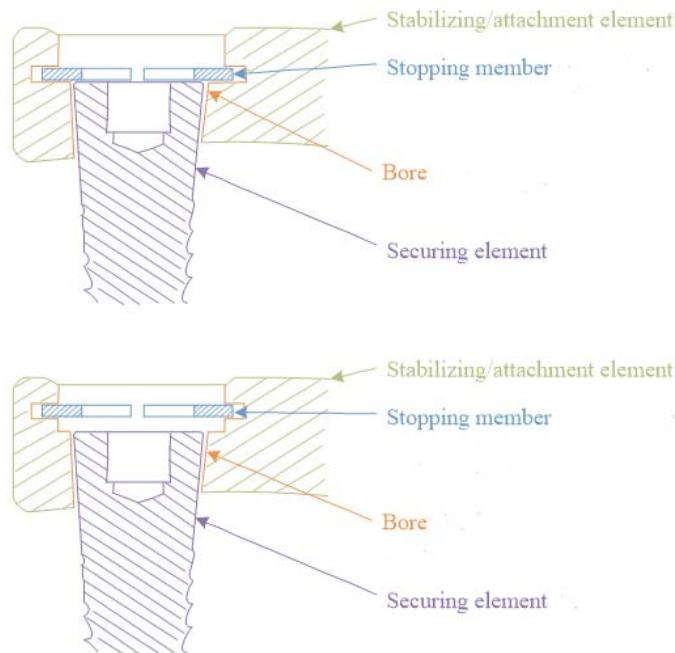
In addition to the motivation for using a retaining ring discussed above, a POSA would have recognized that using a retaining ring in Theken’s assembly would have been beneficial because it would make it possible to achieve the same goal of preventing screw back-out without requiring the use of Theken’s 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:

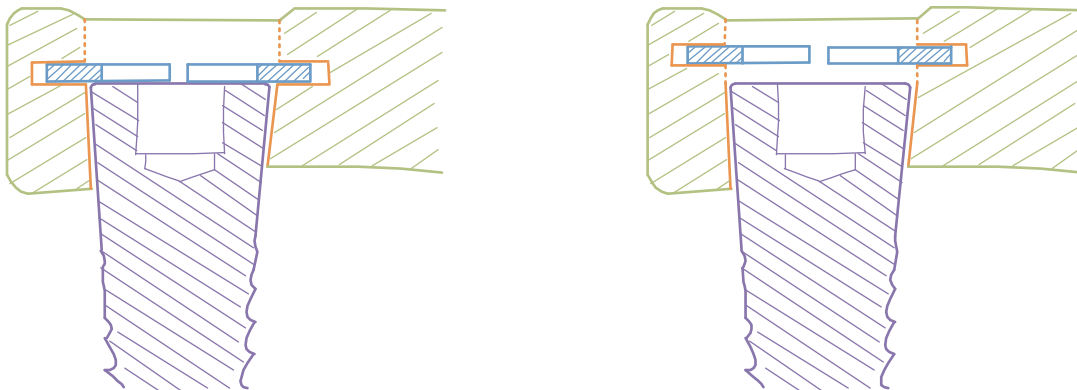


EX1002, ¶¶111-14.

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. (EX1005, 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 44 is Obvious Over Theken in View of Errico

The combination of Theken and Errico as discussed above renders claim 44 obvious. EX1002, ¶¶171-79. 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, ¶172.

1. Claim Limitation 44.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) extending through the stabilizing element from the anterior surface to the posterior surface and the bore having an anterior bore portion with a transversion dimension (*e.g.* at top of a threaded section 66 near the anterior surface) and a posterior bore portion (*e.g.* at bottom of a tapered section 64 near the posterior surface) with a transverse dimension smaller than the transverse dimension of the anterior bore portion. EX1005, 4:7-55, 5:59-66, FIGS. 1-8 and 10; EX1002, ¶173 & Table 5.

2. Claim Limitation 44.b: The claimed “securing element”

Theken discloses the orthopedic implant assembly comprises a securing element (*e.g.* bone screw 100) which is configured to be slidably disposed within the bore (*e.g.* opening 62) of the stabilizing element (*e.g.* plate 20) and which has an elongated body (*e.g.* threaded portion 102), and an enlarged integral portion (*e.g.* tapered head portion 110) with a maximum transverse dimension. EX1005, 4:21-46, 6:19-31, FIGS. 1-2 (showing the slidable disposition of screw 100), 8-11 (showing features of screw 100, including the head portion 110 has a taper than matches the taper of the tapered section 64 of the plate, such that the top of the

head portion 110 has a maximum transverse dimension); EX1002, ¶¶174 & Table 5.

3. Claim Limitation 44.c: The claimed “stopping member”

Theken discloses the orthopedic implant assembly comprises a stopping member (*e.g.* set screws 140) which is at least partially disposed within the bore of the stabilizing element to facilitate retention of the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) within the posterior bore portion (*e.g.* tapered section 64) of the stabilizing element (*e.g.* plate 20), wherein the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) is retained below the posterior surface of the stopping member (set screw 140). EX1005, 3:63-65, 4:63-65, 6:60-66, 7:33-35, 9:22-24, 9:54-59, FIGS. 1-3; EX1002, ¶175 & Table 5. Theken provides for use of other types of stopping members. EX1005, 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, ¶175.

Errico discloses a stopping member (*e.g.* snap-ring 180) which is at least partially disposed within a bore (*e.g.* hole 110c) of a stabilizing element (*e.g.* plate 100c), which has a posterior stopping surface, a first (*e.g.* expanded) configuration within the bore (*e.g.* hole 110c) allowing passage of a securing element (*e.g.* coupling element 132 attached to bone screw 120) into the posterior bore portion

with an enlarged portion (*e.g.* tapered coupling element 132) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) disposed in a posterior bore portion posterior to the stopping member (*e.g.* snap-ring 180) and a second (*e.g.* unexpanded) configuration within the bore (*e.g.* hole 110c) which has smaller transverse dimensions than the first configuration and smaller than the maximum transverse dimension of the enlarged integral portion (*e.g.* tapered coupling element 132) to facilitate retention of the enlarged integral portion (*e.g.* tapered coupling element 132) within the posterior bore portion of the stabilizing element (*e.g.* plate 100c), wherein the enlarged integral portion (*e.g.* tapered coupling element 132) is retained below the posterior surface of the stopping member (*e.g.* snap-ring 180). EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-24:10, FIGS 5-6; EX1002, ¶176 & Table 5.

For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 44 and claim 44 as a whole would have been obvious.

C. Each of Claims 45-50 and 53-54 is Obvious over Theken in View of Errico

The combination of Theken and Errico discussed above for claim 44 also renders each of claims 45-50 and 53-54 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 45:

Claim 45 depends from claim 44. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 44, also satisfies the limitations of claim 45. Specifically, that same combination provides a stopping member (*e.g.* snap-ring 180) that is configured to prevent the back-out of the securing element through the bore of the stabilizing element. *See, e.g.*, EX1006, 8:13-17, 23:12-24:10; EX1002, ¶¶180-81 & Table 6. Theken's tapered head portion 110 is inserted into a bore in the same manner as Errico's tapered coupling element 132, and would be prevented from backing out in the same manner as Errico's tapered coupling element 132. *Id.* For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 45 and claim 45 as a whole would have been obvious.

2. Claim 46:

Claim 46 depends from claim 44. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 44, also satisfies the limitations of claim 46. Specifically, that same combination provides a stopping member (*e.g.* snap-ring 180) that is biased to the second (*e.g.* unexpanded) configuration. *See, e.g.*, EX1006, 8:13-17, 23:12-24:10; EX1002, ¶182 & Table 6. For the reasons discussed above, Theken in view of Errico

discloses each and every element of claim 46 and claim 46 as a whole would have been obvious.

3. Claim 47:

Claim 47 depends from claim 46. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 44 and 46, also satisfies the limitations of claim 47. Specifically, that same combination provides a stopping member (*e.g.* snap-ring 180) that comprises a biased collar having a passageway therethrough. *See, e.g.*, EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6; EX1002, ¶183 & Table 6. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 47 and claim 47 as a whole would have been obvious.

4. Claim 48:

Claim 48 depends from claim 47. The plate of the orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 44, 46, and 47, also satisfies the limitations of claim 48. Specifically, that same combination provides a bore that has a groove (*e.g.* annular recess 182) in an anterior portion thereof configured to receive the biased collar (*e.g.* snap-ring 180), and wherein the biased collar (*e.g.* snap-ring 180) is configured to be reversibly expandable when seated in the groove (*e.g.* annular recess 182). *See, e.g.*, EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6; EX1002, ¶184 &

Table 6. Errico shows an annular recess 182 that is positioned in an anterior section of Errico's hole 110c. *Id.*, FIG. 6. In the proposed combination, the annular recess 182 is similarly positioned in the anterior portion (*e.g.* section 66) of Theken's bore (*e.g.* opening 62). *Id.* For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 48 and claim 48 as a whole would have been obvious.

5. *Claim 54:*

Claim 54 depends from claim 44. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 44, also satisfies the limitations of claim 54. Specifically, that same combination provides an enlarged integral portion of a securing element that is configured to be longitudinally displaceable within the posterior bore portion of the bore of the stabilizing element. EX1002, ¶185 & Table 6. In one obvious implementation of the combination, the annular recess 182 is placed at the middle of Theken's threaded section 66 and the inserted bone screw 100 is driven down into the tapered section 64 of the opening 62 to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100 that allows for settling after certain surgeries. *Id.* 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). *Id.*

For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 54 and claim 54 as a whole would have been obvious.

6. Claims 49-50 and 53

Claim 50 depends from claim 49, which depends from claim 44 via claims 46-48. Claim 53 depends directly from 44. Each of claims 44-48 is obvious for the reasons discussed above.

Each of claims 49-50 and 53 requires the enlarged integral portion of the securing element has a curved posterior surface. Claim 49 requires that the curved posterior surface is configured to expand the collar as the enlarged integral portion is displaced posteriorly through the collar passageway. Claim 50 requires that the curved posterior surface has a minimum transverse dimension smaller than a transverse dimension of the passageway of the unexpanded collar and which is configured to contact an anterior surface of the collar and deform the collar away from the longitudinal axis of the collar passageway as the enlarged integral portion is displaced posteriorly through the collar passageway.

Theken and Errico each disclose an enlarged integral portion 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 of screw 100 may be replaced with spherical or oval head). Errico discloses that the minimum transverse dimension of the posterior surface of an enlarged portion (*e.g.* coupling element 132) of the securing element should be smaller than the transverse dimension of the passageway of the unexpanded 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 enlarged portion is displaced posteriorly through the collar passageway. EX1006, 8:13-17, 23:12-24:10 & FIGS 5-6; EX1002, ¶187. An embodiment of the same combination of Theken and Errico discussed above for claim 44 but in which the enlarged integral portion has a curved posterior surface satisfying the requirements of each of claims 49-50 and 53 thus would have been obvious. EX1002, ¶¶186-88 & Table 7.

D. Claim 59 is Obvious over Theken in View of Errico

The combination of Theken and Errico discussed above in Section VI.A renders obvious claim 59 as a whole. EX1002, ¶¶100-18, 189-97 & Table 8. Theken is directed to an orthopedic implant assembly. EX1005, 3:54-65, 8:34-9:65, FIGS. 1-14.

1. Claim Limitation 59a: The claimed “securing element”

Theken discloses an elongated securing element (*e.g.* bone screw 100) having an enlarged integral portion (*e.g.* tapered head portion 110) with a length,

an anterior surface, a posterior surface and a transverse dimension. EX1005, 6:20-31, FIG. 11; EX1002, ¶191 & Table 8.

2. Claim Limitation 59b: The claimed “attachment element”

Theken discloses an attachment element (*e.g.* plate 20) that has 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) extending from the anterior surface (*e.g.* lateral side 26) to the posterior surface (*e.g.* medial side 128) that is configured to receive the securing element (*e.g.* bone screw 100), and that includes 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) that has a transverse dimension that is smaller than the transverse dimension of the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) to facilitate retention of the enlarged integral portion (*e.g.* tapered head portion 110) within the posterior bore portion (*e.g.* tapered section 64). EX1005, 4:7-8, 4:35-48, FIGS. 1-2 and 8; EX1002, ¶192 & Table 8.

3. Claim Limitation 59c: The claimed “stopping member”

Theken discloses a stopping member (*e.g.* set screw 140) which has a posterior stopping surface that is configured to engage with the anterior surface (*e.g.* top) of the enlarged integral portion (*e.g.* head portion 110) of the securing member (*e.g.* bone screw 100). EX1005, 4:63-65, FIGS. 1-2. Theken provides for

use of other types of stopping members. *Id.*, 7:33-35; EX1002, ¶193. Errico discloses a biased stopping member (*e.g.* snap-ring 180) which has a posterior stopping surface, a first configuration (*e.g.* unexpanded configuration) which extends within a bore (*e.g.* hole 110c) of an attachment member (*e.g.* plate 100c), the first configuration is elastically deformed to a second configuration (*e.g.* expanded configuration) as an enlarged portion (*e.g.* tapered coupling element 132) of a securing member (*e.g.* coupling element 132 attached to bone screw 120) passes into a posterior bore portion of the bore (*e.g.* hole 110c), the biased stopping member (*e.g.* snap-ring 180) returning to the first configuration (*e.g.* unexpanded configuration) upon passage of the enlarged portion (*e.g.* tapered coupling element 132) into the posterior bore portion, the posterior stopping surface of the biased stopping member (*e.g.* snap-ring 180) configured to engage with an anterior surface (*e.g.* top surface 136) of the enlarged portion (*e.g.* tapered coupling element 132) facilitating retention of the enlarged portion (*e.g.* tapered coupling element 132) within the posterior bore portion of the attachment member (*e.g.* plate 100c). EX1006, 6:1-2, 8:13-17, 23:12-24:10, FIGS. 5-6; EX1002, ¶194 & Table 8.

For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 59 and claim 59 as a whole would have been obvious. EX1002, ¶¶195-97.

E. Each of Claims 60-61, 66, 68, 69, 70-73, 75-78, 80-86, and 90-91 is Obvious Over Theken in View of Errico

The combination of Theken and Errico discussed above for claim 44 renders each of claims 60-61, 66, 68, 69, 70-72, 75-78, 80-86, and 90-91 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.

4. Claim 60:

Claim 60 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 60. Specifically, that same combination provides a first configuration (*e.g.* unexpanded configuration) of the stopping member (*e.g.* snap-ring 180) that has inner transverse dimensions that are smaller than transverse dimensions of the enlarged integral portion of the securing member to facilitate retention of the enlarged integral portion of the securing member within the posterior bore portion and a second configuration (*e.g.* expanded configuration) of the stopping member that has inner transverse dimensions that are greater than transverse dimensions of the enlarged integral portion of the securing member to allow passage of the enlarged integral portion of the securing member into the posterior bore portion. *See, e.g.*, EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6; EX1002, ¶¶198-99 & Table 9. The snap-ring 180 operates by enlarging from an unexpanded inner diameter to an expanded inner diameter as

a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded inner diameter after the tapered coupling element 132 passes through the snap-ring 180. *Id.* Theken's tapered head portion 110 is inserted into a bore in the same manner as Errico's tapered coupling element 132, and would pass through the snap-ring 180 in the same manner as Errico's tapered coupling element 132. EX1002, ¶199. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 60 and claim 60 as a whole would have been obvious.

5. Claim 61:

Claim 61 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59, also satisfies the limitations of claim 61. Specifically, that same combination provides a securing element (*e.g.* bone screw 100) having an enlarged integral portion (*e.g.* tapered head portion 110) and being slidably disposed within the bore (*e.g.* opening 62). *See, e.g.*, EX1005, 4:35-48, 8:65-9:1, FIGS. 1-2 (showing the slidable disposition of screws 100); EX1002, ¶200 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 61 and claim 61 as a whole would have been obvious.

6. *Claim 66:*

Claim 66 depends from claim 61. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 61, also satisfies the limitations of claim 66. 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, ¶201 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 16 and claim 16 as a whole would have been obvious.

7. *Claim 71:*

Claim depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 71. Specifically, that same combination provides a biased stopping member (*e.g.* snap-ring 180) that is a collar having at least in part a passageway enlargeable from a first inner dimension (*e.g.* unexpanded dimension) to a second inner dimension (*e.g.* expanded dimension) by the passage of the enlarged integral portion of the securing member therethrough. *See, e.g.*, EX1006 at FIGS. 5-6, 8:13-17, 23:12-24:10; EX1002, ¶202 & Table 9. For the reasons discussed above, Theken in view of Errico

discloses each and every element of claim 71 and claim 71 as a whole would have been obvious.

8. *Claim 68:*

Claim 68 depends from claim 71. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 71, also satisfies the limitations of claim 68. Specifically, that same combination provides the collar (*e.g.* snap-ring 180) is formed of an elastically deformable material. EX1002, ¶203 & Table 9. 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, 8:13-17 (“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.”), 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, ¶¶138, 203 & Table 9. 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, ¶203 & Table 9. For the reasons discussed above, Theken in view of Errico renders obvious claim 68 as a whole.

9. Claim 69:

Claim 69 depends from claim 71. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 71, also satisfies the limitations of claim 69. Specifically, that same combination makes it obvious for the collar (*e.g.* snap-ring 180) to be formed of a material selected from the group consisting of titanium and superelastic material. EX1002, ¶204 & Table 9. 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, 8:13-17, 23:26-27, 24:3-7. 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, ¶204.

Using particular types of elastic material, such as superelastic materials, is a simple design choice. EX1002, ¶¶138, 204. Indeed, Superelastic nickel-titanium alloys were known to have good potential for clinical use in orthopedic surgery. EX1002, ¶¶62, 138 (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. EX1002, ¶204 & Table 9.

For the reasons discussed above, Theken in view of Errico renders obvious claim 69 as a whole.

10. Claim 70:

Claim 70 depends from claim 71. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 70, also satisfies the limitations of claim 70. Specifically, that same combination provides the collar (*e.g.* snap-ring 180) has a posterior surface perpendicular to a longitudinal axis of the bore. *See, e.g.*, EX1006, FIG. 6 (snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the bore extending through Errico’s plate 100c and, when combined with Theken, the lateral side 26 and the medial side 28 of Theken’s plate 20); EX1002, ¶205 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 70 and claim 70 as a whole would have been obvious.

11.Claim 72:

Claim 72 depends from claim 71. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 71, also satisfies the limitations of claim 72. Specifically, that same combination provides the bore has a groove (*e.g.* annular recess 182) in an anterior portion (*e.g.* section 66) of Theken's bore (*e.g.* opening 62), which groove receives the collar (*e.g.* snap-ring 180). *See, e.g.*, EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6; EX1002, ¶206 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 72 and claim 72 as a whole would have been obvious.

12.Claim 73

Claim 73 depends from claim 71 and further recites limitations regarding a curved posterior surface identical to those discussed above for claims 49-50 and 53. An embodiment of the same combination of Theken and Errico discussed above for claim 71 in which the enlarged integral portion has a curved posterior surface satisfying the requirements of each of claim 73 thus would have been obvious in view of the disclosures of Theken and Errico. EX1002, ¶207.

As discussed above for claims 49-50 and 53, Theken and Errico each disclose an enlarged integral portion of the securing element having a curved posterior surface (EX1006, 18:14-19:2, 19:13-20, FIGS. 2, 6; EX1005, 6:51-56),

and Errico discloses the posterior surface of an enlarged portion of a securing element (*e.g.* coupling element 132) configured to expand the collar by contacting the collar at an anterior surface of the collar and expanding the collar away from the longitudinal axis of the collar passageway as the enlarged portion is displaced posteriorly through the collar passageway. EX1006, 8:13-17, 23:12-24:10 & FIGS 5-6; EX1002, ¶207 & Table 9. Claim 73 is thus also obvious over Theken and Errico.

13. Claim 75:

Claim 75 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 75. Specifically, that same combination provides the attachment member (*e.g.* plate 20) 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, ¶208 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 75 and claim 75 as a whole would have been obvious.

14. Claim 76:

Claim 76 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 76. Specifically, that same

combination provides the attachment member (*e.g.* plate 20) is configured to conform to and extend between at least two bone segments (*e.g.* vertebral bodies V₁ and V₂). *See, e.g.*, EX1005, 3:65-66, 5:34-36, 5:59-64, FIGS. 3-4; EX1002, ¶209 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 76 and claim 76 as a whole would have been obvious.

15. Claim 77:

Claim 77 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 77. Specifically, that same combination provides the attachment member (*e.g.* plate 20) has a concave posterior surface. *See, e.g.*, EX1005, 5:34-36, 5:59-6:7, FIGS. 1-4, 10 (showing concave posterior surface formed by the notches 34A and 34B); EX1002, ¶210 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 77 and claim 77 as a whole would have been obvious.

16. Claim 78:

Claim 78 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 78. Specifically, that same combination provides the attachment member (*e.g.* plate 20) is selected from the

group consisting of rods and plates. *See, e.g.*, EX1005, 3:59-61, FIGS. 1-10; EX1002, ¶211 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 78 and claim 78 as a whole would have been obvious.

17.Claim 80:

Claim 80 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 80. Specifically, that same combination provides the stopping element comprises a biased collar (*e.g.* snap-ring 180). *See, e.g.*, EX1006, 8:13-17, 23:18-19, FIGS. 5-6; EX1002, ¶212 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 80 and claim 80 as a whole would have been obvious.

18.Claim 81:

Claim 81 depends from claim 80. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 80, also satisfies the limitations of claim 81. Specifically, that same combination provides the biased collar (*e.g.* snap-ring 180) is elastically deformable to the second configuration. *See, e.g.*, EX1006, 8:13-17, 23:27-24:10, FIGS. 5-6; EX1002, ¶213 & Table 9. For the reasons discussed above, Theken in

view of Errico discloses each and every element of claim 81 and claim 81 as a whole would have been obvious.

19.Claim 82:

Claim 82 depends from claim 81. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 81, also satisfies the limitations of claim 82. Specifically, that same combination provides the biased collar (*e.g.* snap-ring 180) that extends at least partially within the bore of the stabilizing element (*e.g.* plate 20). *See, e.g.*, EX1006, 23:16-19, FIGS. 5-6; EX1002, ¶214 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 82 and claim 82 as a whole would have been obvious.

20.Claim 83:

Claim 83 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 83. Specifically, that same combination provides the stopping member (*e.g.* snap-ring 180) is a biased stopping member that reduces a transverse configuration of the anterior bore portion to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member. *See, e.g.*, EX1006, 24:4-10 (“In its undeflected state it prevents the coupling element 132 (or 133) from backing out

of the plate 100c”), FIG. 6; EX1002, ¶215 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 83 and claim 183 as a whole would have been obvious.

21. Claim 84:

Claim 84 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 84. Specifically, that same combination provides the biased stopping member (*e.g.* snap-ring 180) that resiliently returns (*e.g.* snaps) to the first configuration (*e.g.* unexpanded state) after passage of the enlarged portion of the securing member. *See, e.g.*, EX1006, 23:27-24:10 (“Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”), FIG. 6; EX1002, ¶216 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 84 and claim 84 as a whole would have been obvious.

22. Claim 85:

Claim 85 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 85. Specifically, that same

combination provides the posterior bore portion that has a length sufficiently greater than the length of the enlarged integral portion of the securing element so that the enlarged integral portion of the securing element is longitudinally displaceable within the posterior bore portion when retained therein.

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 system 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 bore 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, ¶217 & Table 9. Accordingly, Theken in view of Errico discloses each and every element of claim 85 and claim 85 as a whole would have been obvious.

23.Claim 86:

Claim 86 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 86. Specifically, that same

combination provides the elongated securing element (*e.g.* bone screw 100) has an enlarged integral portion (*e.g.* head portion 110) with a length, a posterior surface (*e.g.* tapered surface 112) and a transverse dimension and a shaft (*e.g.* threaded portion 102) extending from the enlarged integral portion configured to be secured within bone. *See, e.g.*, EX1005, FIG. 11, 6:19-34; EX1002, ¶218 & Table 9.

The combination of Theken and Errico also provides the attachment element (*e.g.* plate 20) has an anterior surface (*e.g.* later side 26) and a posterior surface (*e.g.* medial side 28) and has at least one bore (*e.g.* opening 62) extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element (*e.g.* bone screw 100), the bore having an anterior bore portion (*e.g.* section 66), a posterior bore portion (*e.g.* section 64) having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing element to retain the enlarged integral portion of the securing element within the posterior bore portion. EX1005, 4:7-8, 4:35-48, FIG. 8, FIGS. 1-2 (showing claimed retention); EX1002, ¶218 & Table 9.

The combination of Theken and Errico also provides the stopping member that defines in part a passageway in the posterior bore portion, where the posterior bore portion (*e.g.* section under Errico's snap-ring 180) is longer than the length of the enlarged integral portion (*e.g.* head portion 110) of the securing element (*e.g.* bone screw 100) to allow longitudinal displacement of the enlarged integral portion

of the securing element within the posterior bore portion. 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 (*i.e.* Theken's head portion 110 of the bone screw 100) is longitudinally displaceable within a bore between the posterior surface of the biased stopping member (*i.e.* snap-ring 180) and the second opening in the posterior surface of the stabilizing element (*i.e.* Theken's plate 20). EX1002, ¶218 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 86 and claim 86 as a whole would have been obvious.

24. Claim 90:

Claim 90 depends from claim 86. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 59 and 86, also satisfies the limitations of claim 90. Specifically, that same combination provides the second configuration of the stopping member (*e.g.* snap-ring 180) has a transverse dimension that is larger than the transverse dimension of the stopping member in the first configuration. *See, e.g.*, EX1006, 8:13-17, 23:27-

24:10, FIGS. 5-6; EX1002, ¶219 & Table 9. Accordingly, Theken in view of Errico discloses each and every element of claim 90 and claim 90 as a whole would have been obvious.

25. Claim 91:

Claim 91 depends from claim 59. The orthopedic attachment assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 59, also satisfies the limitations of claim 91. Specifically, that same combination provides the posterior stopping surface of the stopping member (*e.g.* snap-ring 180) is perpendicular to the longitudinal axis of a bore. *See, e.g.*, EX1006, FIG. 6; EX1002, ¶220 & Table 9. For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 91 and claim 91 as a whole would have been obvious.

F. Claim 101 is Obvious over Theken in View of Errico

The combination of Theken and Errico discussed above in Section VI.A renders obvious claim 101 as a whole. EX1002, ¶¶100-18, 221-29 & Table 10. Theken is directed to an orthopedic implant assembly. EX1005, 3:54-65, FIGS. 1-14.

1. Claim Limitation 101a: The claimed “stabilizing element”

Theken discloses a stabilizing element (*e.g.* plate 20) 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) extending through the stabilizing element (*e.g.* plate 20) from the anterior surface to the posterior surface with an anterior bore portion (*e.g.* section 66) which has a transverse dimension, a posterior bore portion (*e.g.* tapered section 64) which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion. EX1005, 4:7-55, 5:59-66, FIGS. 1-8, 10; EX1002, ¶223 & Table 10.

2. Claim Limitation 101b: The claimed “securing element”

Theken discloses a securing element (*e.g.* bone screw 100) having an elongated body (*e.g.* threaded portion 102) and an enlarged integral portion (*e.g.* tapered head portion 110) having an anterior surface (*e.g.* top). EX1005, 4:21-46, 6:91-31, FIGS. 1-2, 8-11; EX1002, ¶224 & Table 10.

3. Claim Limitation 101c: The claimed “stopping member”

Theken discloses a stopping member (*e.g.* set screw 140) which has a posterior stopping surface (*e.g.* bottom) positioned to engage the anterior surface (*e.g.* top) of the securing element (*e.g.* bone screw 100) and prevent the securing element (*e.g.* bone screw 100) from backing out of the posterior bore portion (*e.g.* tapered section 64) and to facilitate retention of the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) within the posterior bore portion (*e.g.* tapered section 64). EX1005, 3:63-65, 4:63-65, 6:60-66, 7:33-35, 9:22-24, 9:54-59, FIGS. 1-3; EX1002, ¶225 & Table 10.

Errico discloses a biased stopping member (*e.g.* snap-ring 180) which has a posterior stopping surface, which has a first configuration within an anterior bore portion that has a first transverse dimension and is elastically deformable to a second configuration within the anterior bore portion that has a second transverse dimension larger than the first transverse dimension that allows an enlarged portion (*e.g.* tapered coupling element 132) of a securing element (*e.g.* coupling element 132 attached to bone screw 120) to pass into a posterior bore portion posterior to the biased stopping member (*e.g.* snap-ring 180), the biased stopping member (*e.g.* snap-ring 180) returning to the first configuration so that the posterior surface of the stopping member (*e.g.* snap-ring 180) is positioned to engage an anterior surface (*e.g.* upper surface 136a) of the enlarged portion (*e.g.* coupling element 312) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) and to prevent the securing element (*e.g.* coupling element 132 attached to bone screw 120) from backing out of the posterior bore portion and to facilitate retention of the enlarged portion (*e.g.* coupling element 312) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) within the posterior bore portion. EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-24:10, FIGS. 5-6; EX1002 ¶226 & Table 10.

G. Each of Claims 103-104 is Obvious over Theken in View of Errico

1. Claim 103:

Claim 103 depends from claim 101. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claim 101, also satisfies the limitations of claim 103. Specifically, that same combination provides a biased stopping member (*e.g.* snap-ring 180) that comprises a collar. *See, e.g.*, EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6. EX1002 ¶230-31 & Table 11. Theken in view of Errico thus discloses each and every element of claim 103 and claim 103 as a whole would have been obvious.

2. Claim 104:

Claim 104 depends from claim 103. The orthopedic implant assembly rendered obvious by the combination of Theken and Errico, as discussed above for claims 101 and 103, also satisfies the limitations of claim 104. Specifically, that same combination provides the biased collar (*e.g.* snap-ring 180) disposed in part within a recess (*e.g.* annular recess 182) of the stabilizing element. *See, e.g.*, EX1006, 23:16-19, 23:26-27, 24:3-4, FIGS. 5-6; EX1002, ¶232 & Table 11. In the combination, the annular recess 182 is similarly positioned in part with an annular recess in Theken's bore (*e.g.* opening 62). *Id.* For the reasons discussed above, Theken in view of Errico discloses each and every element of claim 104 and claim 104 as a whole would have been obvious.

VII. Ground 2: Claims 62-63, and 87 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 62-63, 67, and 87 of the '008 patent, and renders those claims obvious under pre-AIA 35 U.S.C. 103(a). EX1002, ¶250. Each of claims 62-63 and 87 ultimately depends from a claim (claims 59, 61, and/or 86) 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 includes, or depends from a claim that includes, limitations related to the following concepts: (i) a variable angle screw having transverse dimensions proximate the posterior bore portion small enough to permit angular displacement of the screw within the bore; or (ii) using a curved surface in a posterior section of a bore to facilitate angulation of the securing member within the posterior bore portion. EX1002 ¶251.

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, ¶252. Theken thereby suggests that its integral bone screws 100 may be variable-angle bone screws.

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.

Farris details how to implement a variable-angle bone screw by (i) making a portion of the securing member posterior to the enlarged integral portion have a transverse dimensions sufficiently smaller than the transverse dimensions of the

posterior bore portion or opening in the posterior bore portion so the securing member may be angularly displaced within the bore (as required by claims 62 and 87, respectively); and (ii) using a curved surface in a posterior section of a bore to facilitate angulation of the securing member within the posterior bore portion (as required by claim 63). EX1002, ¶251.

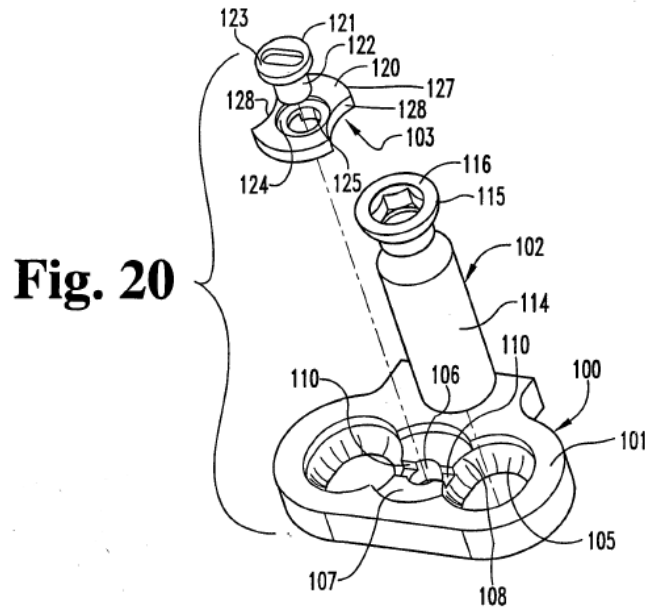
Farris discloses that spinal plating systems with “different degrees of fixation of a bone screw relative to the plate are more advantageous for treating certain pathologies as opposed to other pathologies.” EX1008, 3:17-26. Farris teaches that spinal plates using bone screws in a rigid fashion are preferable 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.

Farris also discloses an orthopedic attachment 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.

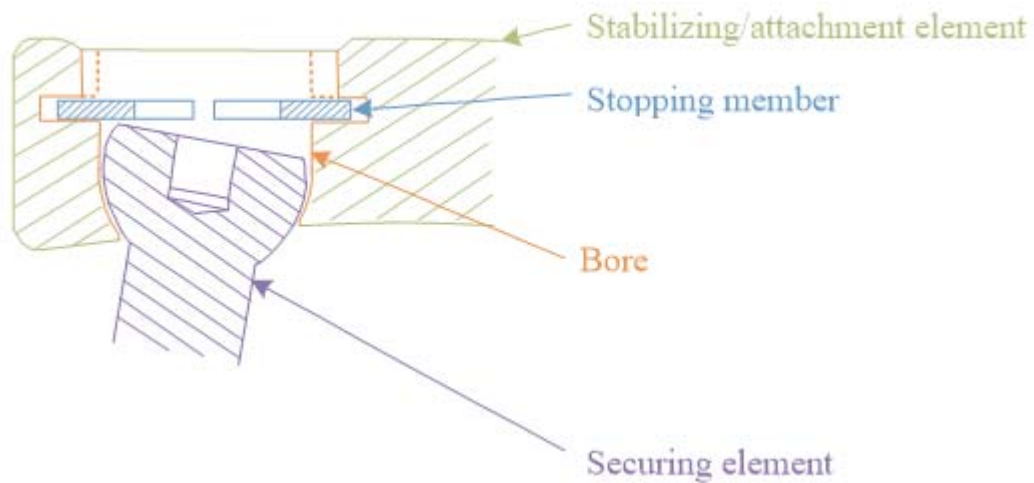
EX1008, 24:3-4, FIGS. 20-22; EX1002, ¶252-53. Farris Figure 20 is reproduced below.



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 was 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 2 renders obvious each of claims 44-48, 54, 59-61, 66, 68-72, 75-78, 80-87, 90-91, 101, and 103-104 for the same reasons discuss above in Ground 1. Ground 2 also renders each of claims 62-63 and 87 obvious for the reasons discussed above and the reasons discussed below.

B. Each of Claims 62-63 and 87 is Obvious Over Theken in View of Errico in further view of Farris

1. Claim 62:

Claim 62 depends from claim 61, which is discussed above in Section VI. Claim 61 is obvious for the reasons discussed above in Ground 1. The rationales discussed above for combining Farris with the combination of Theken and Errico apply to claim 62. EX1002, ¶¶200, 269 & Table 15.

Regarding the limitations of claim 62, Farris provides a securing member (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a portion posterior to an enlarged integral portion that has transverse dimensions (*e.g.* diameter of an intermediate portion below spherical head of bone screw) sufficiently smaller than the transverse dimensions of the posterior bore portion (*see e.g.* opening at bottom of recess 105 in Farris's plate 101) so the securing member may be angularly displaced within the bore. *See, e.g.*, EX1008 at 24:3-8, FIGS. 20-22, 24:6-8, 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, ¶269 & Table 15. Accordingly, Theken in view of Errico and Farris discloses each and every element of claim 62 and claim 62 as a whole would have been obvious.

2. *Claim 63:*

Claim 63 depends from claim 62, discussed above, which depends from claim 61, which is discussed above in Section VI. Claim 62 is obvious for the reasons discussed above. The rationales discussed above for combining Farris with the combination of Theken and Errico apply to claim 63. EX1002, ¶270.

Regarding the limitations of claim 63, Farris comprises a posterior surface of an enlarged integral portion of a securing member (*e.g.* spherical surface of spherical head of variable-angle bone screw) that is configured at least in part to conform to a posterior surface of a posterior bore portion (*e.g.* spherical recess) to facilitate angulation of the securing member within the posterior bore portion. *See, e.g.*, EX1008, 24:3-8 (“a spherical recess 105 to receive the spherical head 115 of the bone screw.”), FIGS. 20-22, 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, ¶270 & Table 15.

Theken in view of Errico and Farris thus discloses each and every element of claim 63 and claim 63 as a whole would have been obvious.

3. *Claim 87:*

Claim 87 depends from claim 86, discussed above, and which depends from claim 59, which is discussed above in Section VI. Claims 59 and 86 are obvious

for the reasons discussed above. The rationales discussed above for combining Farris with the combination of Theken and Errico apply to claim 87. EX1002, ¶271.

Regarding the limitations of claim 87, 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) that has a portion posterior to the enlarged integral portion that has a transverse dimension (*e.g.* diameter of an intermediate portion) smaller than a transverse dimension of an opening in the posterior bore portion (*see e.g.* opening at bottom of recess 105 in Farris's plate 101) to provide angular displacement of the securing element within the posterior bore portion. *See, e.g.*, EX1008, 24:3-8, FIGS. 5, 20-22, FIG. 5, 17:2-6, 5:28-6:3. EX1002, ¶271 & Table 15. Theken in view of Errico and Farris thus discloses each and every element of claim 87 and claim 87 as a whole would have been obvious.

VIII. Conclusion

Petitioner respectfully requests that the Board institute a Trial and that it cancel claims 44-50, 53-54, 59-63, 66, 68-73, 75-78, 80-87, 90-91, 101, and 103-104 of the '008 patent as unpatentable for the reasons stated in this Petition.

Respectfully submitted:

Dated: March 13, 2020

/ Michael T. Rosato /

Michael T. Rosato, Lead Counsel

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ROSATI

Attorney for Petitioner

IX. 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 13,956 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

X. 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.

XI. 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 et al.
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. et al., <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. et al., <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
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Dated: March 13, 2020

By:

/ Michael T. Rosato /
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