

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEPUY SYNTHES SALES, INC.
Petitioner

v.

ACANTHA LLC
Patent Owner

Patent No. RE43,008

Filing Date: July 15, 2003

Issue Date: December 6, 2011

Title: ORTHOPEDIC IMPLANT ASSEMBLY

Inter Partes Review No.: IPR2016-00334

**THIRD PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. RE43,008
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §42.100 *et seq.***

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I. INTRODUCTION

DePuy Synthes Sales, Inc. (“Petitioner” or “DePuy”) petitions for *Inter Partes* Review (“IPR”) under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1, et seq. and seeks the cancellation of claims 59-91 (the “challenged claims”) of U.S. Patent No. RE43,008 to Talaber, *et al.* (“the ’008 patent”) (Ex. 1001), which has been assigned to Acantha LLC (“Patent Owner” or “Acantha”). For all the reasons set forth herein, DePuy asserts that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. DePuy respectfully requests that this Petition be granted.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. 37 C.F.R. § 42.8(b)(1): Real-Party-In-Interest

DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. are affiliates of Johnson & Johnson and are the Real-Parties-In-Interest. Additionally, Patent Owner asserts that DePuy Synthes, Inc., Johnson & Johnson, Synthes, Inc., Synthes USA, LLC, DePuy Orthopaedics, Inc. and DePuy Spine, LLC are also Real-Parties-In-Interest.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

The ’008 patent has been asserted against Petitioner in a litigation pending before the United States District Court for the Eastern District of Wisconsin styled as *Acantha LLC v. DePuy Synthes Sales, Inc., et al.*, Civil Action No. 1:15-cv-01257. Additionally, DePuy is concurrently filing two separate petitions for *inter*

partes review challenging claims 1-5, 9-22 and 29-37, and 44-54 and 101-105 of the '008 Patent, respectively. Petitioner is not aware of any other judicial or administrative proceeding or matter that would affect, or be affected by, a decision in this proceeding.

**C. 37 C.F.R. § 42.8(b)(3): Lead and Back-Up Counsel
37 C.F.R. § 42.8(b)(4): Service Information**

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III. MANDATORY FILINGS UNDER 37 C.F.R. §§ 42.10(b) and 43.63(e)

Concurrently filed herewith is the required power of attorney designating counsel and an Exhibit List.

IV. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

The Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 501432 (Customer ID No. 362327-030053) for the fee required by 37 C.F.R. § 42.15(a) for this Petition, and further authorizes payment for any additional fees to be charged to this Deposit Account.

V. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '008 patent is eligible for IPR, and Petitioner is not barred or estopped from requesting an IPR on the grounds identified herein. In accordance with 35 U.S.C. § 315(b), the present petition is being filed within one year of the service date of the original complaint filed in United States District Court alleging that the Petitioner is infringing the '008 patent, as referenced in Section II.B, above.

VI. BACKGROUND

A. The '008 Patent

The '008 patent is generally directed to an orthopedic implant assembly for joining bone segments and methods of use thereof. More specifically, all of the challenged claims of the '008 patent are directed to an assembly including a stabilizing member (bone plate) with at least one through-hole, a securing member (bone screw), and a stopping member (such as a flexible snap-ring or c-ring) positioned inside an annular groove in the through-hole for the purpose of preventing the securing member from backing out of the bone. The '008 patent includes 105 claims. Claims 1, 21, 23, 28, 36, 38, 43, 44, 55, 59, 92, 98 and 101 are the independent claims of the '008 patent.

B. Prosecution History And Priority Date Of The '008 Patent Claims

The '008 patent issued on December 6, 2011 from U.S. Reissue Application 10/620,154 (“the '154 application”), filed on July 15, 2003. The '008 patent is a

reissue of U.S. Patent No. 6,261,291 (“the ’291 patent), filed on July 8, 1999 and issued on July 17, 2001. The ’291 patent issued without a single office action and had a total of twenty-eight (28) claims, of which three were independent.

The Patent Owner added over seventy (70) claims during the reissue prosecution. During that prosecution, the ’154 application received four separate office actions rejecting certain claims as anticipated by various prior art references. Every substantive prior art rejection of an independent claim was based solely on anticipation under 35 U.S.C. § 102. While the Examiner did make two obviousness rejections, both of these rejections were directed to a single dependent claim limitation (relating to the collar being formed of titanium or a superelastic material), and in both rejections, the Examiner relied on single-reference obviousness only. Ex. 1002 at 083, 339. At no point during the prosecution of the ’154 application did the Examiner consider any *combination* of references, nor did the Examiner consider any obviousness rejections at all for the vast majority of the claim limitations.

VII. IDENTIFICATION OF CHALLENGE UNDER 37 C.F.R. § 42.104(b)

A. 37 C.F.R. § 42.104(b)(1): Identification of Relief Requested

Petitioner requests the institution of an IPR for, and cancellation of, claims 59-91 of the ’008 patent.

B. 37 C.F.R. § 42.104(b)(2): Identification of Prior Art and Specific Grounds For Challenge of Claims

1. Prior Art References

An IPR trial is requested in view of the following prior art references:

- U.S. Patent No. 5,876,402 to Errico, et al. (“Errico”) (Ex. 1003), filed on March 29, 1996 and issued on March 2, 1999. Errico qualifies as prior art under 35 U.S.C. § 102(a) and/or (e)(2) because it is a U.S. patent that was filed and issued on or before the earliest priority date of the ’008 patent.
- U.S. Patent No. 5,879,389 to Koshino (“Koshino”) (Ex. 1004), filed on April 1, 1996 and issued on March 9, 1999. Koshino qualifies as prior art under 35 U.S.C. § 102(a) and/or (e)(2) because it is a U.S. patent that was filed and issued on or before the earliest priority date of the ’008 patent.
- U.S. Patent No. 6,258,089 to Campbell et al. (“Campbell”) (Ex. 1005), filed on May 19, 1999, and issued July 10, 2001. Campbell qualifies as prior art under 35 U.S.C. § 102(e)(2) because it is a U.S. patent that was granted from an application filed on or before the earliest priority date of the ’008 patent.

2. Specific Grounds For Challenge Of Claims

The following table identifies the specific statutory grounds and the prior art references establishing the challenged claims of the ’008 patent are unpatentable:

Ground	35 U.S.C.	Challenged '008 Patent Claims	Basis for Rejection of Challenged Claims
1	§ 103	59-91	Errico in view of Koshino or Campbell

C. 37 C.F.R. § 42.104(b)(3): Claim Construction

DePuy submits that the claim term “orthopedic attachment assembly” should be construed as “an assembly for attachment to one or more bones.” DePuy’s proposed construction is supported by the specification of the ’008 patent. *See* Ex. 1001 at 1:11-13 (“This invention generally relates to the field of medical devices, and particularly to an orthopedic implant for joining bone segments and methods of use thereof.”); *id.* at 1:32-35 (“This 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...”); *id.* at 7:40-42 (“The assembly of the invention is suitable for use in a variety of medical procedures, including securing fractured bone segments or vertebrae following disk removal.”). DePuy’s proposed construction is also supported by express statements made by Patent Owner during prosecution of the ’008 patent. Ex. 1002 at 356 (“In the present application, applicants have used the terms orthopedic attachment or orthopedic implant continuously throughout the specification and clearly describes a fundamental characteristic of the invention, namely an assembly for attachment to one or more bones.”).

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purposes of this review, Petitioner construes the remaining claim language such that the claims are given their broadest reasonable interpretation in light of the specification of the '008 patent.

D. 35 U.S.C. § 42.104(b)(4): How the Construed Claims Are Unpatentable

An explanation of how claims 59-91 of the '008 patent are unpatentable, including identification of where each claimed limitation is found in the prior art, is set forth below in Section IX.

E. 35 U.S.C. § 42.104(b)(5): Identification of Supporting Evidence

Per 37 C.F.R. § 42.6(d), copies of the references supporting the grounds for this Petition are filed herewith. Also filed herewith is the declaration of Bret A. Ferree, M.D. (Ex. 1006, "Ferree Decl.") under 37 C.F.R. § 1.68, which explains what the prior art would have conveyed to a person of ordinary skill in the art ("POSA") and the reasons that would have motivated a POSA to make the cited combinations.

VIII. STATE OF THE ART AND LEVEL OF SKILL IN THE ART AT THE TIME OF THE PRIORITY DATE OF THE '008 PATENT

A POSA is presumed to be aware of all pertinent art and is a person of ordinary creativity. As of July 8, 1999, a POSA with respect to orthopedic devices for attachment to bone would have had knowledge of bone plates (including cervical bone plates), bone screws, the potential for bone screw back-out, the

potential complications related to bone screw back-out, as well as various mechanisms for preventing bone screw back-out. Ferree Decl. at ¶ 20. A POSA as of July 8, 1999 would typically have had at least a Bachelors of Science in Mechanical, Biomechanical or Biomedical engineering, or a related field of science, as well as five to ten years of related experience in the field of orthopedic implants; or would be a practicing orthopedic surgeon with at least five years of experience, as well as some experience in the design of orthopedic implants. *Id.* at ¶ 19.

At the time of the invention of the '008 patent, the use of plates and screws for attachment to bones, including vertebral bones, was known. *Id.* at ¶ 21. It was also known that bone screw back-out from orthopedic implants, especially vertebral implants, was a potential problem associated with such surgeries, and it was known that there was a desire to prevent bone screw back-out. *Id.* at ¶ 22. Various mechanisms to mechanically prevent screw back-out, including snap-rings and/or c-rings, were also known. *Id.* at ¶ 23. It was also known at the time of the invention of the '008 patent that orthopedic implants, including spinal implants, were preferably designed to include the minimum number of components necessary to achieve the intended purpose. *Id.* at ¶ 24. Finally, it was also known that bone plates, especially spinal plates, should be designed with the minimum possible profile to avoid disruption with surrounding anatomy. *Id.* at ¶ 25.

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '008 PATENT IS UNPATENTABLE

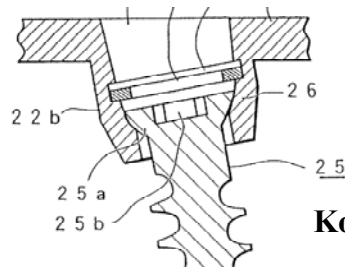
As detailed in the discussion and claim charts below, the prior art references identified below demonstrate that all of the limitations of claims 59-91 of the '008 patent were known in the prior art at the time of invention. The inventions claimed in the '008 patent are “[t]he combination of familiar elements according to known methods” that “do[] no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The claims of the '008 patent are no more than “the predictable use of prior art elements according to their established functions.” *Id.* at 417.

A. Ground 1: Claims 59-91 Of The '008 Patent Are Obvious Over Errico In View Of Koshino Or Campbell.

1. Summary Of The Prior Art

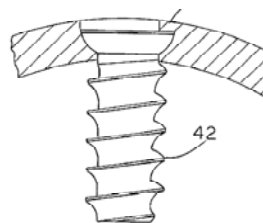
Errico discloses a polyaxial locking screw plate assembly for fixation to, and immobilization of, vertebral bones. Ex. 1003 at Abstract. As shown in Figure 6 below, the assembly includes a plate having an upper (anterior) portion and a lower (posterior) portion. *Id.* The plate has at least one tapered hole into which a bone screw can be inserted, wherein the posterior opening of the hole is smaller than the anterior opening of the hole. *Id.* at Abstract, Fig. 6. The upper (anterior) part of the hole includes an annularly recessed channel in which a snap-ring is disposed. *Id.* The assembly also includes a coupling element surrounding the head of the screw. *Id.* The coupling element has an axial taper which matches the taper of the

the hole, the flexible stopper ring is inserted into the annular groove to prevent the screw from backing out. *Id.* at 13:7-11.



Koshino, Fig. 6

Campbell discloses a cervical plate and fixation system, designed to be attached to the spine with fixation screws, and designed to prevent loosening of the device after implantation. Ex. 1005 at 1:12-15; 2:10-26. As shown in Figure 22 below, the orthopedic implant device of Campbell includes an upper (anterior) portion and a lower (posterior) portion. *E.g., id.* at Figs. 20, 22. The plate has at least one hole into which a bone screw can be inserted, wherein the posterior opening of the hole is smaller than the anterior opening of the hole. *Id.* The bone screw is inserted through the hole until the head of the screw engages the matching, inner posterior surface of the hole. *Id.* at 6:44-54. Once the screw is fully seated in the hole, a retaining feature is plastically deformed over the head of the screw to prevent the screw from backing out. *Id.* at 6:55-65.



Campbell, Fig. 22

Errico was cited during prosecution of the '008 patent and was used to reject certain claims in Office Actions dated September 8, 2006 (Ex. 1002 at 81) and August 10, 2010 (*id.* at 510). Campbell was of record during prosecution of the '008 patent and was also used to reject certain claims in an Office Action dated December 7, 2009 (*id.* at 427). Koshino was also of record during prosecution of the '008 patent, but was not used as the basis for any rejection. Importantly, the Examiner never considered Errico in combination with Koshino or Campbell. In fact, the Examiner never considered Errico in *any* obviousness combinations. However, as explained below, it would have been obvious to a POSA, in light of Koshino or Campbell, to modify the invention of Errico to arrive at the invention of the '008 patent. The arguments presented herein are thus different from the arguments considered by the Examiner during the prosecution of the '008 patent. *See, e.g., Kamada, Ltd. v. Grifols Therapeutics Inc.*, IPR2014-00899, Decision – Institution of *Inter Partes* Review, Paper No. 8 at 22-23 (P.T.A.B. December 18, 2014) (finding that the petition’s challenges, based on a “combination” of references, were different than those at issue in a co-pending reissue proceeding, which were based only on the same primary references “without any of the additional references”).

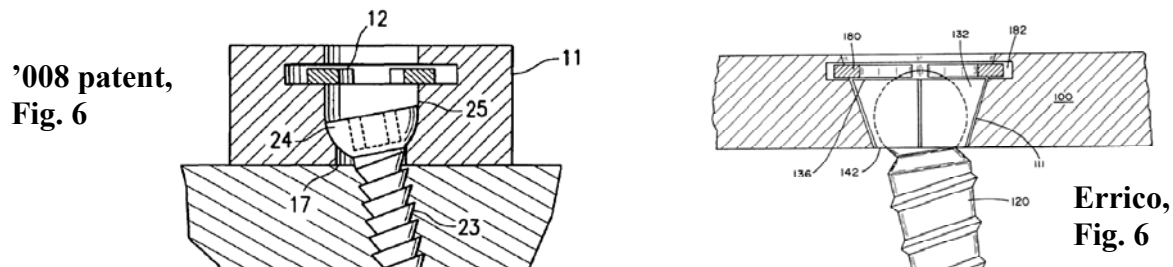
The only distinction that Patent Owner made with respect to Errico during the prosecution of the '008 patent related to Errico’s use of a coupling element

rather than an “integral” screw head. *E.g.*, Ex. 1002 at 122-23; 555. DePuy submits that these arguments should not have prevailed in the first instance. Moreover, they are certainly insufficient to overcome the combination of Koshino or Campbell with Errico as presented herein because Koshino and Campbell both disclose the allegedly missing screw head.

2. It Would Have Been Obvious To A POSA At The Time Of The Invention Of The '008 Patent To Combine The Teachings Of Errico And Koshino or Campbell

The challenged claims of the '008 patent and Errico are both directed to an orthopedic implant device (such as a plate) to be attached to human bone. Both describe attachment of the implant device to the bone by a separate securing device, most commonly a bone screw. Both disclose an implant device that contains one or more through-holes (or bores), with an anterior opening to allow the screw to be inserted into the bore, and a smaller, posterior opening that allows the shaft of the screw to pass through, but prevents the head of the screw from passing through the bottom of the implant device. Both also disclose a mechanism for preventing the screw from backing out of the bone after implantation. As the mechanism for preventing screw back-out, both the challenged claims of the '008 patent and Errico describe a flexible collar or snap-ring (stopping member), that sits in an annular groove located in an anterior portion of the bore. Both disclose that the stopping member expands as the screw passes through the bore, and then snaps

back to its closed position after the screw passes through. A comparison of the figures of the '008 patent and Errico readily demonstrates the similarity of the two designs:



The *only* difference between the challenged claims of the '008 patent and Errico is that the claimed invention of the '008 patent uses the head of the screw itself to expand the stopping member and provide a surface to prevent the screw from backing out, whereas Errico includes an extra part – a coupling element that surrounds the screw head – to perform these same functions. As explained below, such a difference is nothing more than an obvious choice in design, and one that would have been readily contemplated and implemented by a POSA at the time of the invention, for both mechanical and clinical reasons, with a reasonable expectation of success. Ferree Decl. at ¶¶ 38-39.

From a mechanical standpoint, it was known in the orthopedic industry at the time of the filing of the '008 patent that it was desirable for orthopedic implants to be limited to the minimum number of components necessary. *Id.* at ¶ 40. There are many reasons for this, such as cost of manufacturing, inventory, ease of use, crevice corrosion, and simplicity of surgery. *Id.*

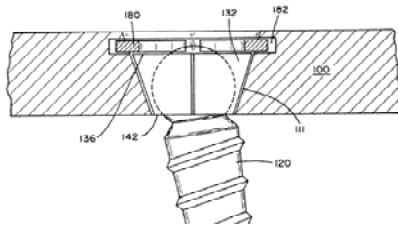
A POSA would have had a clinical reason to modify Errico as well. Bone plates of the type described in, for example, the '008 patent and Errico, are often placed very close to critical anatomy, such as the esophagus or major blood vessels. *Id.* at ¶ 42; *see also* Ex. 1003 at 2:39-3:6. For this reason, a POSA would understand that it is critical for the bone plate to have as thin a profile as possible. Ferree Decl. at ¶ 42. The coupling element in Errico, however, requires more space in the bore, and thus necessarily increases the profile (thickness) of the plate. *Id.* at ¶ 43.

These design considerations for bone fixation plates were well known in the field, and were succinctly described in a prior art reference, which issued well before the '008 patent was filed:

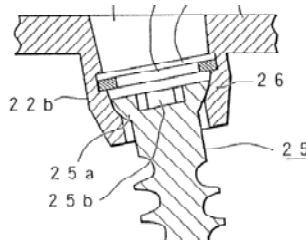
All of the foregoing prior art systems suffer from several undesirable drawbacks. First, the addition of intricately machined componentry makes most of these systems expensive and difficult to manufacture. Second, since some of these prior art systems rely on a threaded connection to maintain the bone screws in a secure position, such locking systems are still subject to the problem of screw back out and may therefore be unreliable. Finally, most of the foregoing systems, by their nature, result in an increased profile or bulk which, in many surgical applications, is undesirable. What is therefore needed is a bone fixation system including a

mechanism for preventing screw backout without increasing the profile or bulk of the fixation system. Such a system should ideally be easy and inexpensive to manufacture.

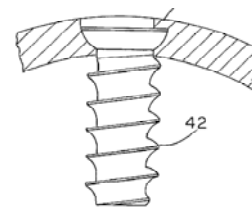
U.S. Pat. No. 5,578,034 (Ex. 1008) at 2:10-23; Ferree Decl. at ¶ 44. Accordingly, a POSA at the time of the invention of the '008 patent would have been motivated to improve upon the Errico invention by reducing the total number of components of the implant, and by minimizing the profile of the bone plate. Ferree Decl. at ¶ 45. A POSA would readily recognize that the first and most logical way to achieve *both* improvements would be to remove the coupling element from the Errico invention and to utilize a screw head of the type disclosed in Koshino or Campbell (*Id.*):



Errico, Fig. 6



Koshino, Fig. 6



Campbell, Fig. 22

It would have been obvious to a POSA that the partially curved head of the Koshino or Campbell bone screws could be used for the same purpose of expanding the stopping member of Errico without the need for an additional coupling element. *Id.* at ¶ 46. As can be seen above, the diameter of the Koshino and Campbell screw heads are larger than the opening of the stopping member, and

thus would necessarily expand the stopping member if used with the Errico device. *Id.* In fact, it would have been obvious to a POSA that essentially any typical bone screw could have been used for this purpose with a reasonable expectation of success. *Id.* Indeed, the only design requirements necessary to achieve the desired result here are that the screw head have a posterior surface that is curved or tapered, and a diameter that is larger than the diameter of the undeflected stopping member. *Id.* Such a configuration will predictably expand the flexible stopping member of Errico as the screw head passes through, and prevent the screw from backing out. *Id.*

Further, not only would such a modification reduce the number of components of the implant, but by removing the coupling element and employing a hemi-spherical screw head, such as that shown in Koshino or Campbell, it would result in a screw head with a smaller anterior-to-posterior dimension. *Id.* at ¶ 47. This would permit a thinner bone plate with a reduced profile, thus achieving the additional improvement of causing less potential for interference with nearby, critical anatomical structures. *Id.*

Nothing in the disclosure of Errico would have dissuaded a POSA from making the simple combination described herein. *Id.* at ¶ 48. In addition to causing the stopping member to expand and being captured posterior to the stopping member, Errico explains that the coupling element also permits the screw

to be inserted at multiple angles, and ultimately will “crush lock” the head of the screw when fully seated, fixing the angle of the screw. *See* Ex. 1003 at 4:32-35; 5:5-7. A POSA would have understood, however, that the screw can be inserted at multiple angles and the head can be effectively captured posterior to the stopping member without a “coupling element.” Ferree Decl. at ¶ 48. For example, other patents directed to similar constructs used a design that did not utilize a separate coupling element around the head of the screw. (*See, e.g.*, Ex. 1005 and International Application Publication No. WO 99/21502 (Ex. 1014), which describe bone plates that include a mechanism for preventing screw back-out and permit the screw to be inserted at multiple angles, but do not utilize a separate coupling member.) Thus, a POSA would understand that a design without a coupling element would be just as effective as — and readily substitutable for — a configuration that does. Ferree Decl. at ¶ 49.

This is illustrated by the fact that, during prosecution of a related European patent application (which claims priority to the '291 patent), the Examiner repeatedly rejected similar claims in view of the combination of Errico in view of Koshino, finding that the use of an integral screw head in place of the head/coupling element structure of Errico was not inventive:

The examining division is still of the opinion that the integration of the securing element of D1 [Errico] falls within the scope of the customary practice. It is noted

that D2 [Koshino], D3 and the remaining document of the search report all show integral securing elements which allow for angular adjustment. If the skilled person would feel the need to have a more simple system, which need is quite obvious due to the complicated mounting procedure, he would call back the well known integral securing elements and substitute them to the one used in D1 [Errico].

Ex. 1015 at 7. The Examiner maintained this rejection, and Patent Owner was ultimately required to amend the claims. *Id.* at 16 (“alternative (i) is not regarded as involving inventive step over D1 [Errico] since the only distinguishing feature is ‘the head being integral with the body’ which is regarded as [a] normal design option”).

Finally, a POSA would have reason to combine the teachings of Errico with Koshino or Campbell to accomplish these goals, as each reference teaches orthopedic implant assemblies to be attached to the bone with a bone screw. *Id.* at ¶ 50. More specifically, each of Errico, Koshino and Campbell expressly addresses the same primary problem — the prevention of the bone screw backing out of the implant assembly after implantation. Ex. 1003 at 4:1-3 (“It is still further an object of the present invention to provide a screw plate assembly having a retaining means for preventing screw pull-out”); Ex. 1004 at 3:62-66 (“[W]ith a medical substituting element for hard tissues and an artificial joint of this invention,

the slip-off prevention member can prevent the fixation screw from spontaneously rotating and moving back outside after the element is mounted on hard tissues.”); Ex. 1005 at 2:10-13 (“[I]t is an object of the present invention to provide a cervical plate and fixation system in which bone screws or other fasteners are more securely retained and less likely to work loose...”). As the Supreme Court stated:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

KSR, 550 U.S. at 421. Here, the prior art establishes that there was a design need to solve the problem of screw back-out in orthopedic implants. Additionally, given the nature of the device and the relevant mechanical and clinical considerations, there were a finite number of possible solutions. Ferree Decl. at ¶ 51. In light of these same considerations, the most logical and predictable solution that a POSA would have pursued upon reviewing Errico, Koshino and Campbell would be to

remove the Errico coupling member and employ the screw head of either Koshino or Campbell with the Errico device. *Id.*¹

For all of the above reasons, a POSA would have been motivated to modify the Errico device, and would have understood that the teachings of Koshino or Campbell are applicable to improving the orthopedic implant device disclosed in Errico. *Id.* at ¶ 52. Such a simple improvement – using the Koshino or Campbell screw head with the Errico device – is the result of ordinary skill and common sense. *See Belden Inc. v. Berk-Tek LLC*, Nos. 2014-1575, 1576, 2015 U.S. App. LEXIS 19307, at *16 (Fed. Cir. Nov. 5, 2015) (affirming Board’s finding of obviousness where circumstances involved “a simple point in a mechanical field and one very close piece of prior art”).

¹ Although the discussion herein pertains to modifying the Errico device by substituting the screw head disclosed in Koshino, a POSA would have similarly understood that the Koshino device could be modified by substituting the pre-inserted, expandable c-ring configuration disclosed in Errico, with the same reasonable expectation of success. Ferree Decl. at ¶ 53. A POSA would have been motivated to make such a modification, for example, to eliminate the additional step required in Koshino of inserting the stopping member after the screw has been seated (thus simplifying the surgical procedure). *Id.*

3. Independent Claim 59 Of The '008 Patent Is Obvious In View Of Errico And Koshino Or Campbell

The combination of Errico and either of Koshino or Campbell discloses all of the limitations of claim 59. With respect to the preamble, Errico, Koshino and Campbell each disclose an “orthopedic attachment assembly.” Ex. 1003 at 1:15-16; Ex. 1004 at 1:5-13, 1:22-30; Ex. 1005 at 1:12-15.

(a) Independent Claim 59, Element 59(a)

With respect to claim element 59(a), each of Errico, Koshino and Campbell discloses an elongated securing element (bone screw) with an enlarged integral portion with a length, an anterior surface, a posterior surface, and a transverse dimension:

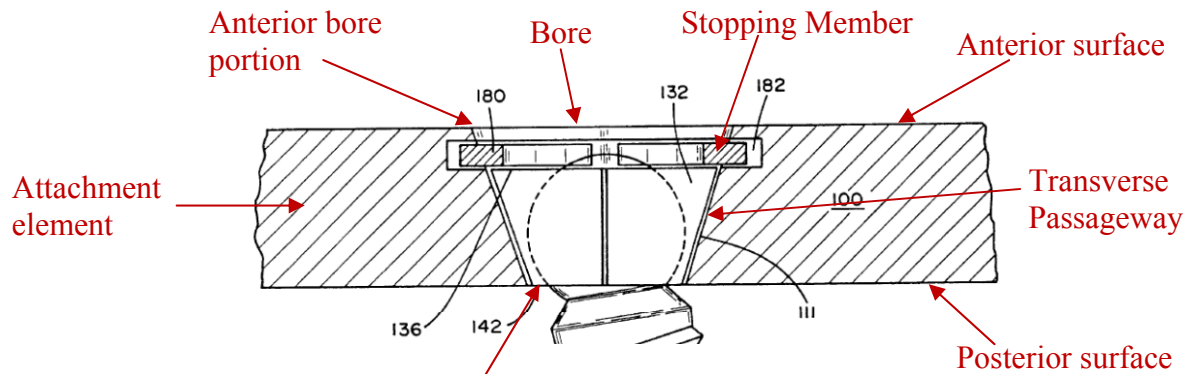


'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
59a) an elongated securing element having an enlarged integral portion with a length, an anterior surface, a posterior surface and a transverse dimension;	<u>Errico</u> : “The screw 120 comprises a head portion 122, a neck 124, and a shaft 126.” Ex. 1003 at 6:16-17; <i>see also id.</i> at Fig. 4. <u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 3b. <u>Campbell</u> : <i>See</i> Ex. 1005 at Fig. 8.

(b) Independent Claim 59, Element 59(b)

With respect to claim element 59(b), Errico discloses an attachment element (a plate) that has an anterior (top) surface, a posterior (bottom) surface,² and at least one bore extending through the plate from the anterior surface to the posterior surface that is configured to receive the securing element; and the bore has an anterior bore portion and a posterior bore portion, wherein the posterior bore portion has a transverse dimension that is smaller than the transverse dimension of the enlarged integral portion of the securing element. *See* Ex. 1003 at Abstract; *see also id.* at Fig. 6 (rotated 90° and annotated):

² The '008 patent defines the “anterior surface” as the surface furthest from the bone, and the “posterior surface” as the surface closest to the bone. Ex. 1001 at 1:44-48. Errico defines the “top surface” (surface 108) as the surface furthest from the bone, and the “bottom surface” as the surface closest to the bone. Ex. 1003 at 5:53-54; Fig. 3a. Accordingly, all citations to the “top” surface of Errico correspond to the “anterior” surface of the '008 patent, and all citations to the “bottom” surface of Errico correspond to the “posterior” surface of the '008 patent.



Posterior bore portion with transverse dimension smaller than transverse dimension of enlarged integral portion of securing element

Errico also discloses that the plate is designed to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion.

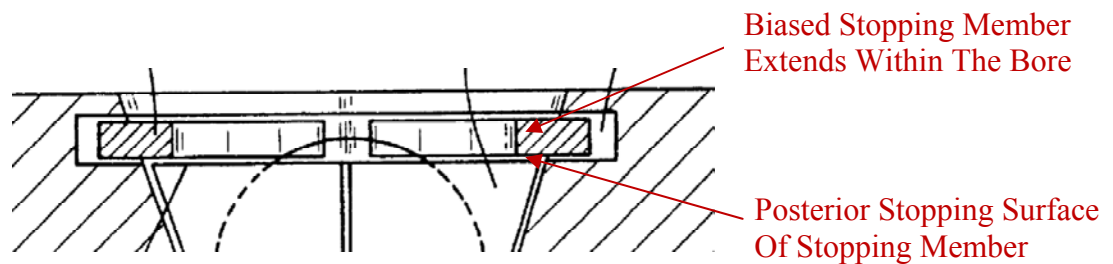
Id. at 4:47-50; 7:47-51; Fig. 6.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
59b) an attachment element which has an anterior surface and a posterior surface and which has at least one bore extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element, the bore having an anterior bore portion, and a posterior bore portion, the posterior bore portion having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the enlarged integral portion of the securing member within the	<u>Errico</u> : “The plate 100 comprises upper and lower portions 102, 104 respectively, and a top surface 108 and a bottom surface (not shown).... A pair of holes 110, having a smooth tapered inner surface 111, extend fully through the upper portion 102 of the plate. A second pair of holes 112 having a tapered inner surface 111 as well, are disposed in the lower portion 104 of the plate 100. Each of the holes 110,112 is ideally suited for receiving therethrough a bone screw for affixing the plate to the vertebral bodies.” Ex. 1003 at 5:53-67; <i>see also id.</i> at Fig. 6. “The screw 120 comprises a head portion 122, a neck 124, and a shaft 126.” <i>Id.</i> at 6:16-17; <i>see also id.</i> at Fig. 4; “The head portion 122 of the screw 120 comprises a semi-spherical shape, which has a recess in it.” <i>Id.</i> at 6:26-27; “After the coupling

<p>posterior bore portion; and</p>	<p>element passes through it, however, the ring snaps back into its undeflected shape which fits loosely in the recessed channel, and extends radially inward to block the element from backing out of the hole.” <i>Id.</i> at 4:47-50.</p> <p><u>Koshino</u>: “The fixation screw 6 is a right-handed screw as described above, and has a flat head as shown in FIG. 3(b).” Ex. 1004 at 11:30-31; Fig. 3(b); “Next, each fixation screw 25 is inserted into the through hole unit 23 formed in the projection 22b and threaded into the tibia, until the head 25a of the fixation screw 25 abuts against the screw stopper 26” <i>Id.</i> at 12:65–13:4; “With the stopper ring 20 being fitted in the groove 24, even if the fixation screw 25 once threaded into the hard tissues (tibia) is spontaneously rotated and moved back outside, this motion is stopped by the stopper ring 20 and the fixation screw 25 cannot be moved back outside.” <i>Id.</i> at 13:15-19; Fig. 6.</p> <p><u>Campbell</u>: “At this stage, retaining feature 40 is plastically deformed to move a medial region 102 radially inwardly, to a closed position in which the retaining member overlies head 46 of the fastener. Retaining feature 40, when in the closed position, engages head 46 to prevent any substantial retraction or movement of fastener 24 in the anterior direction, substantially maintaining head 46 against section 34 of the aperture, which in turn maintains posterior surface 28 of the plate against the bony material. This overcomes any tendency in fastener 24 to work loose when the fastener and plate are subject to shock, vibration or other disturbance.” Ex. 1005 at 6:55-65; Fig. 22.</p>
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(c) Independent Claim 59, Element 59(c)

With respect to claim element 59(c), Errico discloses a biased stopping member which has a posterior stopping surface and a first configuration that extends within the bore. *See id.* at Fig. 6 (below) and 6:6-8 (“[T]he inner diameter of the undeflected snap-ring 180 is less than the diameter of the tapered hole.”).



Errico further discloses a stopping member that is elastically deformed from the first, smaller diameter configuration to a second, larger diameter configuration as the enlarged portion of the securing element passes into the posterior portion of the bore. *Id.* at 4:64-66 (“Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation”); *id.* at 4:43-46 (“The discontinuity in the element permits the ring to be ... expanded to permit the tapered coupling element to slide through it into the hole.”); *id.* at 6:10-12 (“The ring 180 can, however, be deflected inward or outward”); *see also id.* at 7:43-47; Fig. 6. Errico also discloses that, once the enlarged integral portion of the securing element passes through the stopping member and into the posterior bore portion, the stopping member returns to the first, smaller diameter configuration and facilitates retention of the enlarged integral portion of the securing member

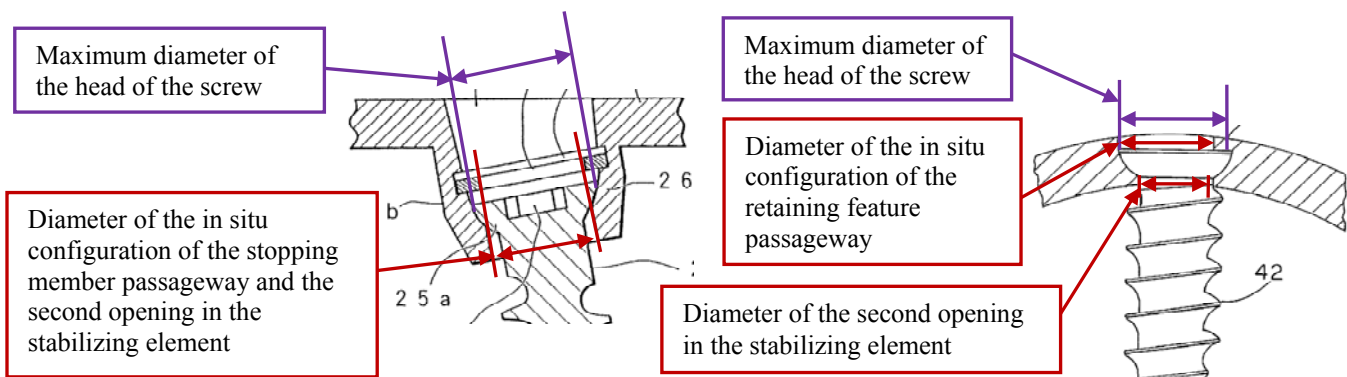
within the posterior bore portion of the attachment member. *Id.* at 4:47-50 (“After the coupling element passes through it, however, the ring snaps back into its undeflected shape which fits loosely in the recessed channel, and extends radially inward to block the element from backing out of the hole.”); *id.* at 4:64-5:2 (“Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation (which is narrower than the diameter of the top of the coupling element), therein preventing the coupling element from backing out by interference.”); *see also id.* at 7:47-55; Fig 6.

Finally, each of Errico, Koshino and Campbell discloses that the posterior stopping surface of the biased stopping member is configured to engage with the anterior surface of the enlarged integral portion of the securing member.” *See* Ex. 1003 at Figs. 4-6 and 7:51-55 (“In its undeflected state it [the snap-ring] prevents the coupling element 132 from backing out of the plate 100 inasmuch as the flat upper surface 136 of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open.)”); Ex. 1004 at Fig. 6 and 13:15-19 (“With the stopper ring 20 being fitted in the groove 24, even if the fixation screw 25 once threaded into the hard tissues (tibia) is spontaneously rotated and moved back outside, this motion is stopped by the stopper ring 20 and the fixation screw 25 cannot be moved back outside.”); Ex. 1005 at Fig. 22 and 6:58-63 (“Retaining feature 40, when in the closed position, engages head 46 to

prevent any substantial retraction or movement of fastener 24 in the anterior direction, substantially maintaining head 46 against section 34 of the aperture, which in turn maintains posterior surface 28 of the plate against the bony material.”).

With respect to the remainder of claim 59, it would have been obvious for a POSA to use the head of the screw and/or its enlarged integral portion, as opposed to a separate coupling element, to perform the function of expanding the stopping member and/or preventing back-out of the screw for all of the reasons explained above. This is further confirmed by Dr. Ferree, a spinal surgeon with nearly 25 years of experience both in spinal surgery and in the design and development of spinal implants. Ferree Decl. at ¶¶ 1-7, 61; Ex. 1013. In modifying Errico in such a way, the diameter of the enlarged integral portion of the screw would be (1) greater than the posterior opening in the attachment member (so that the screw would not simply go all the way through the opening); (2) smaller than the larger diameter configuration of the passageway defined by the biased stopping member (so that the screw could pass through the stopping member); and (3) greater than the smaller diameter configuration of the passageway defined by the biased stopping member (so that the screw could not back out of the assembly). Ferree Decl. at ¶ 62. These dimensional relationships are standard, and Koshino and Campbell each disclose a screw having a head with the required limitations. *Id.*

The screw heads in Koshino and Campbell are designed specifically for the purpose of retaining the head of the screw within the longitudinal area defined by the posterior surface of the stopping member and the smaller, posterior bore opening. *Id.* at ¶ 63 As can be seen in Figure 6 of Koshino and Figure 22 of Campbell, the maximum diameter of the head of the screw is greater than both the passageway defined by the stopping member, and the second opening in the stabilizing element:



As explained above, it would have been obvious for a POSA to configure the Errico device with the screw head of Koshino or Campbell. Ferree Decl. at ¶¶ 39-52. Such a combination would result in the same dimensional relationships described above. As such, the combination of Errico and either of Koshino or Campbell discloses all of the limitations of claim 59 of the '008 patent.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
59c) a biased stopping member which has a posterior stopping surface, a first configuration which extends within the bore that is elastically deformed to a	Errico: "Within this annular recess 182 is provided a discontinuous '7/8ths' snap-ring 180. ... The ring 180 can, however, be deflected inward or outward" Ex. 1003 at 6:2-12; "During the implantation

second configuration as the enlarged portion of the securing member passes into the posterior bore portion, the biased stopping member returning to the first configuration upon passage of the enlarged integral portion into the posterior bore portion, the posterior stopping surface of the biased stopping member configured to engage with the anterior surface of the enlarged integral portion of the securing member facilitating retention of the enlarged portion of the securing member within the posterior bore portion of the attachment member.

procedure, the screw 120 and the coupling element 132 are inserted through the hole. Once the bottom 142 of the coupling element 132, respectively, seats in the top of the hole 110 or 112, and begins to travel into it, the tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182. Once the coupling element 132 is fully seated in the hole 110, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 from backing out of the plate 100 inasmuch as the flat upper surface 136 of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” *Id.* at 7:41-55; *see also id.* at Figs 3b, 4 and 6.

Koshino: “The fixation screw 6 is a right-handed screw as described above, and has a flat head as shown in FIG. 3(b).” Ex. 1004 at 11:30-31; Fig. 3(b); “Next, each fixation screw 25 is inserted into the through hole unit 23 formed in the projection 22b and threaded into the tibia, until the head 25a of the fixation screw 25 abuts against the screw stopper 26” *Id.* at 12:65–13:4; “With the stopper ring 20 being fitted in the groove 24, even if the fixation screw 25 once threaded into the hard tissues (tibia) is spontaneously rotated and moved back outside, this motion is stopped by the stopper ring 20 and the fixation screw 25 cannot be moved back outside.” *Id.* at 13:15-19; Fig. 6.

Campbell: “At this stage, retaining feature 40 is plastically deformed to move a medial region 102 radially inwardly, to a closed

	position in which the retaining member overlies head 46 of the fastener. Retaining feature 40, when in the closed position, engages head 46 to prevent any substantial retraction or movement of fastener 24 in the anterior direction, substantially maintaining head 46 against section 34 of the aperture, which in turn maintains posterior surface 28 of the plate against the bony material. This overcomes any tendency in fastener 24 to work loose when the fastener and plate are subject to shock, vibration or other disturbance.” Ex. 1005 at 6:55-65; Fig. 22.
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For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 54-64), Petitioner has shown a reasonable likelihood of proving that claim 59 of the '008 patent is obvious over Errico in view of Koshino or Campbell.

4. Dependent Claims 60-91 Of The '008 Patent Are Obvious In View Of Errico And Koshino Or Campbell

Claims 60-91 all depend, directly or indirectly, from claim 59, which is discussed above and which discussion is incorporated into each of the following dependent claims.

(a) Dependent Claim 60

As shown in the table below, claim 60 includes limitations that are identical to, or substantially the same as, those found in claim 59(c):

Claim 60	Claim 59(c)
60. The attachment assembly of claim 59 wherein the first configuration of the stopping member has inner transverse dimensions that are smaller than	59c) a biased stopping member which has . . . a first configuration which extends within the bore . . . , the biased stopping member returning to the first

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	configuration upon passage of the enlarged integral portion into the posterior bore portion, the posterior stopping surface of the biased stopping member configured to engage with the anterior surface of the enlarged integral portion of the securing member facilitating retention of the enlarged portion of the securing member within the posterior bore portion of the attachment member.
and the second configuration of the stopping member 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.	59c) a biased stopping member . . . that is elastically deformed to a second configuration as the enlarged portion of the securing member passes into the posterior bore portion

Although claim 59(c) does not expressly recite the dimensional relationships stated in claim 60, these dimensional requirements are implicit in the limitations of claim 59(c), which are discussed above at section IX.A.3(c). For example, claim 59(c) recites that the second configuration of the stopping member allows the screw head to pass through. In order for the screw head to pass, however, the transverse dimension of the second configuration must be greater than the diameter of the screw head, which is the limitation recited in claim 60. Ferree Decl. at ¶ 68. Similarly, claim 59(c) recites that the first configuration of the stopping member retains the screw head in the posterior bore portion after it has passed through the stopping member. In order for the stopping member to do so, the transverse

dimension of the first configuration must be smaller than the diameter of the screw head, which is the limitation recited in claim 60. *Id.* Accordingly, for all of the reasons discussed above with respect to claim 59(c), the combination of Errico and Koshino or Campbell discloses all of the limitations of claim 60.

(b) Dependent Claim 61

Errico discloses that the securing element (screw) is slidably disposed within the bore of the attachment member. *See* Ex. 1003 at 4:55-56.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
61. The attachment assembly of claim 59 wherein the securing element having an enlarged integral portion is slidably disposed within the bore.	<p><u>Errico</u>: “With the plate in place, the screws are inserted through the holes and into the vertebral bodies.” Ex. 1003 at 4:55-56; <i>see also id.</i> at 7:41-47, Figs 4 and 6.</p> <p><u>Koshino</u>: “A combination of the stopper ring 20, groove 24, and fixation screw 25 is preferably arranged so as to leave a desired amount of gap between the bottom surface of the stopper ring 20 and the top surface of the fixation screw 25.” Ex. 1004 at 13:11-14.</p> <p><u>Campbell</u>: “Fasteners 24a-24d are secured within their respective apertures 30a-30d, turned inwardly or in the posterior direction by using drive tool 56. Each of the bone screws or fasteners is turned inwardly, causing shank 42 to penetrate the osseous material of the vertebra to a depth sufficient to (1) bring spherical surface 48 of head 46 into engagement with spherical section 34 of the aperture, and (2) bring posterior surface 28 into contiguous engagement with the bony material. Thus, each fastener becomes nested within its associated aperture while urging the cervical plate against the bony</p>

	material.” Ex. 1005 at 6:42-52; Fig. 22.
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(c) Dependent Claims 62 and 87

As shown in the table below, claims 62 and 87 contain limitations that are substantially the same:

Claim 62	Claim 87
62. The attachment assembly of claim 61 wherein a portion of the securing member posterior to the enlarged integral portion has transverse dimensions sufficiently smaller than the transverse dimensions of the posterior bore portion so the securing member may be angularly displaced within the bore.	87. The orthopedic attachment assembly of claim 86 wherein the securing element has a portion posterior to the enlarged integral portion that has a transverse dimension smaller than a transverse dimension of an opening in the posterior bore portion to provide angular displacement of the securing element within the posterior bore portion.

The combination of Errico and Koshino or Campbell discloses all of the limitations of claims 62 and 87. As shown in Figure 6 of Errico, the body of the securing element (bone screw) posterior to the enlarged integral portion has a transverse dimension smaller than the transverse dimension of the posterior bore portion of the stabilizing element (thus allowing the body of the screw to pass through and attach to the bone), and the screw is angularly displaced within the posterior bore portion. Ex. 1003 at Fig. 6; *see also id.* at 6:51-54; *see also* Ex. 1004 at Fig. 6; Ex. 1005 at Fig. 29.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
62. The attachment assembly of claim 61 wherein a portion of the	<u>Errico</u> : “While it is preferable that the diameter of the shaft 126 be less than the

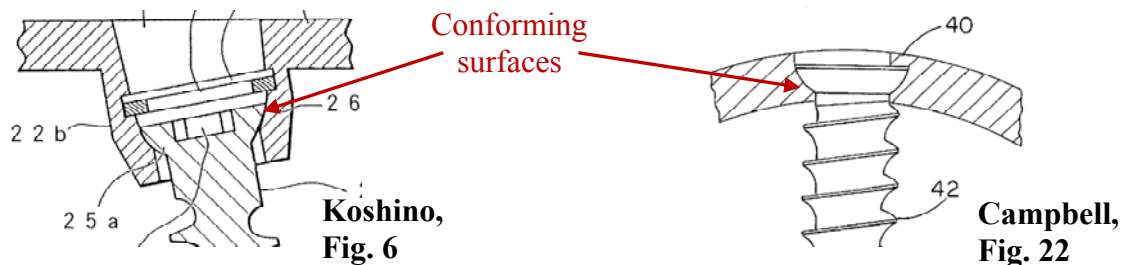
'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
securing member posterior to the enlarged integral portion has transverse dimensions sufficiently smaller than the transverse dimensions of the posterior bore portion so the securing member may be angularly displaced within the bore.	radius of the semi-spherical head 122, it is also preferable that the neck 124 of the screw 120 be narrower than the widest portion of the shaft 126. This preferable dimension permits the screw to be inserted at a variety of angles while still permitting the specific coupling element to be screwed into the appropriate hole 110 or 112 of the plate 100 and remain coupled to the head 122.” Ex. 1003 at 6:49-57; <i>see also id.</i> at Fig. 6.
87. The orthopedic attachment assembly of claim 86 wherein the securing element has a portion posterior to the enlarged integral portion that has a transverse dimension smaller than a transverse dimension of an opening in the posterior bore portion to provide angular displacement of the securing element within the posterior bore portion.	<p><u>Koshino</u>: <i>See</i> Ex. 1004 at Fig. 6.</p> <p><u>Campbell</u>: <i>See</i> Ex. 1005 at Figs. 22, 25, 29; 8:24-28. “[I]t is readily apparent that the head can be pivoted about any number of transverse axes (transverse with respect to the longitudinal screw extension) so that the fastener can assume a variety of non-perpendicular orientations relative to the plate.”</p>

(d) Dependent Claims 63 and 67

As shown in the table below, claims 63 and 67 contain limitations that are substantially the same:

Claim 63	Claim 67
63. The attachment assembly of claim 62 wherein the posterior surface of the enlarged integral portion of the securing member is configured at least in part to conform to the posterior surface of the posterior bore portion to facilitate angulation of the securing member within the posterior bore portion.	67. The attachment assembly of claim 61 wherein a posterior surface of the posterior bore portion is configured to conform at least in part to the posterior surface of the enlarged integral portion of the securing member so as to facilitate angular displacement within the posterior bore portion.

The combination of Errico and Koshino or Campbell discloses all of the limitations of claims 63 and 67. Errico discloses placement of the securing element at an angle. *See, e.g.*, Ex. 1003 at 6:51-54 (“[I]t is also preferable that the neck 124 of the screw 120 be narrower than the widest portion of the shaft 126. This preferable dimension permits the screw to be inserted at a variety of angles. . . .”) and Fig. 6; *see also* Ex. 1005 at 8:24-28 (“[I]t is readily apparent that the head can be pivoted about any number of transverse axes (transverse with respect to the longitudinal screw extension) so that the fastener can assume a variety of non-perpendicular orientations relative to the plate.”) and Figs. 28-29. Koshino and Campbell both disclose a screw head with a posterior portion that conforms to a posterior surface of the posterior portion of the bore:



For all of the reasons explained above (section IX.A.2), it would have been obvious to a POSA to use the screw head configuration of Koshino or Campbell in place of the screw head/coupling element configuration of Errico. Ferree Decl. at ¶¶ 39-52. This is especially so considering that Errico discloses that the coupling element includes a tapered external surface designed to conform to the interior

tapered surface of the holes of the plate. Ex. 1003 at 6:62-67 (“The coupling element 132 comprises a tapered cylindrical socket having a smooth external surface 134. The taper of the surface 134 is designed to mate with the interior tapered surface 111 of the holes 110 or 112 of the plate 100”); Ferree Decl. at ¶ 74.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
63. The attachment assembly of claim 62 wherein the posterior surface of the enlarged integral portion of the securing member is configured at least in part to conform to the posterior surface of the posterior bore portion to facilitate angulation of the securing member within the posterior bore portion.	<u>Errico</u> : “While it is preferable that the diameter of the shaft 126 be less than the radius of the semi-spherical head 122, it is also preferable that the neck 124 of the screw 120 be narrower than the widest portion of the shaft 126. This preferable dimension permits the screw to be inserted at a variety of angles while still permitting the specific coupling element to be screwed into the appropriate hole 110 or 112 of the plate 100 and remain coupled to the head 122.” Ex. 1003 at 6:49-57; <i>see also id.</i> at Fig. 6. “The coupling element 132 comprises a tapered cylindrical socket having a smooth external surface 134. The taper of the surface 134 is designed to mate with the interior tapered surface 111 of the holes 110 or 112 of the plate 100, so that the coupling element 132 may be seated into the plate 100.” <i>Id.</i> at 6:62-67.
67. The attachment assembly of claim 61 wherein a posterior surface of the posterior bore portion is configured to conform at least in part to the posterior surface of the enlarged integral portion of the securing member so as to facilitate angular displacement within the posterior bore portion.	<u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6. <u>Campbell</u> : <i>See</i> Ex. 1005 at Figs. 22, 25, 29; 8:24-28 “[I]t is readily apparent that the head can be pivoted about any number of transverse axes (transverse with respect to the longitudinal screw extension) so that the fastener can assume a variety of non-perpendicular orientations relative to the plate.”

(e) Dependent Claims 64-65

Similarly, with respect to claims 64 and 65, Koshino and Campbell disclose a posterior bore portion that is curved in shape. *See* Ex. 1004 at Fig. 6 and Ex. 1005 at Fig. 22 (pictured above). Although Figure 6 of Koshino and Figure 22 of Campbell are cross-section views, when rotated 360°, these curved posterior bore portions form a bowl-shaped, hemispherical zone, as claimed by claims 64 and 65. Ferree Decl. at ¶ 75.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
64. The attachment assembly of claim 63 wherein the posterior surface of the posterior bore portion has a bowl shape.	<u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6. <u>Campbell</u> : <i>See</i> Ex. 1005 at Fig. 22.
65. The attachment assembly of claim 64 wherein the bowl-shaped posterior surface of the posterior bore portion at least in part is a hemispherical zone.	<u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6. <u>Campbell</u> : <i>See</i> Ex. 1005 at Fig. 22.

(f) Dependent Claim 66

Errico discloses a securing element that is a screw. *Id.* at 6:13-16.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
66. The attachment assembly of claim 61 wherein the securing member is selected from the group consisting of screws and nails.	<u>Errico</u> : “Referring now to FIG. 4, a screw of a type which is ideally suited for coupling the plates of this invention to vertebral bodies (or long bones in other embodiments) is shown....” Ex. 1003 at 6:13-16.

(g) Dependent Claim 68

Errico discloses that the stopping member (collar) is formed of an elastically deformable material. *E.g.*, Ex. 1003 at 4:65-67.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
68. The attachment assembly of claim 71 wherein the collar is formed of an elastically deformable material.	<u>Errico</u> : “[T]he ring elastically contracts back to its undeflected conformation...” Ex. 1003 at 4:65-67. “Once the coupling element 132 is fully seated in the hole 110, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 and snaps back to its undeflected state.” <i>Id.</i> at 7:47-51.

(h) Dependent Claim 69

Errico discloses that the bone plate may be formed of titanium, and explains that a particular titanium material has enhanced fatigue endurance. *Id.* at 5:46-52 (“Materials which would be suitable for such applications include titanium alloys and steels. A specific titanium material which has been utilized in implants of the prior art include ASTM F-136 titanium alloy (Ti 6AL-4V). This material has enhanced mechanical properties including fatigue endurance and tensile strength, as compared with pure titanium.”). To the extent that Errico does not expressly disclose the use of titanium for the stopping member (as opposed to the plate), or the use of a “superelastic” material, it would have been obvious to a POSA to do so, since it has been held to be within the general skill of a POSA to select a known material on the basis of its suitability for the intended use as an obvious design

choice. *See, e.g., In re Leshin*, 277 F.2d 197, 199 (C.C.P.A. 1960); *see also* Ferree Decl. at ¶ 78.

Here, given that the stopping member disclosed in Errico is intended to be elastically deformable, and given that Errico teaches that the plate may be made from a titanium material with enhanced fatigue endurance, it would have been obvious to a POSA to select a superelastic material or a similar titanium for the stopping member as well. Ferree Decl. at ¶ 79. Indeed, during the prosecution of the '008 patent, the Examiner came to the same conclusion (Ex. 1002 at 83-84; 339), and the applicant never contended that this conclusion was incorrect, arguing only that this claim was not obvious because the claim it depends from was not obvious. (Ex. 1002 at 124; 359).³

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
69. The attachment assembly of claim 71 wherein the collar is formed of a material selected from the group consisting of titanium and superelastic material.	<u>Errico</u> : “Materials which would be suitable for such applications include titanium alloys and steels.” Ex. 1003 at 5:46-48; “Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation....” <i>Id.</i> at 4:64-67.

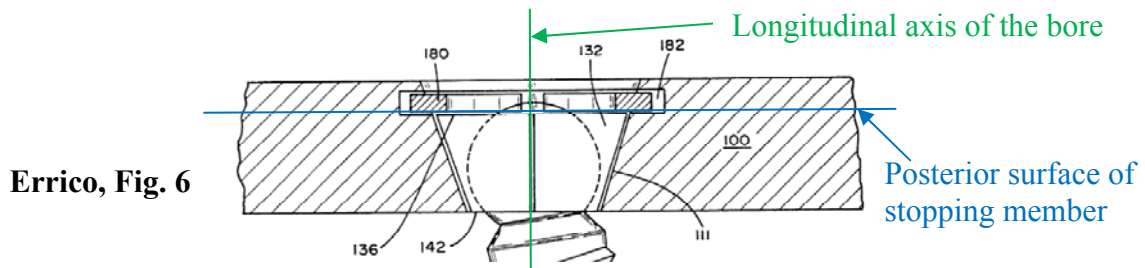
³ As noted above in Section VI.B, this was the only obviousness rejection made by the Examiner during prosecution.

(i) Dependent Claims 70 and 91

As shown in the table below, claims 70 and 91 contain limitations that are substantially the same:

Claim 70	Claim 91
70. The attachment assembly of claim 71 wherein the collar has a posterior surface perpendicular to a longitudinal axis of the bore extending through the attachment member.	91. The assembly of claim 59 wherein the posterior stopping surface of the stopping member is perpendicular to the longitudinal axis of the bore.

Errico discloses all of the limitations of claims 70 and 91. As shown below, Errico discloses a device wherein the stopping member has a posterior surface (blue line) that is perpendicular to a longitudinal axis of the bore (green line):



'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
70. The attachment assembly of claim 71 wherein the collar has a posterior surface perpendicular to a longitudinal axis of the bore extending through the attachment member.	<u>Errico</u> : See Ex. 1003 at Fig. 6.
91. The assembly of claim 59 wherein the posterior stopping surface of the stopping member is perpendicular to the longitudinal axis of the bore.	

(j) Dependent Claim 71

Errico discloses a stopping member that is a collar having at least in part a passageway enlargeable from a first inner dimension to a second inner dimension. Ex. 1003 at Fig. 6; 6:10-11 (“The ring 180 can, however, be deflected inward or outward”). Errico further discloses that the collar passageway is enlargeable by the passage of the enlarged integral portion of the securing member therethrough. *See, e.g., id.* at 7:41-51. Further, Koshino and Campbell disclose a securing member (bone screw) wherein the integral head of the screw has a maximum diameter greater than the smaller inner diameter of the collar. Ex. 1004 at Fig. 6; 13:15-19; Ex. 1005 at Fig. 22. As explained above, it would have been obvious for a POSA to configure the Errico device with the screw head of either Koshino or Campbell, rather than using a separate coupling element. Ferree Decl. at ¶¶ 39-52. When so configured, the enlarged integral portion of the securing member would expand or enlarge the collar passageway as it passes through, thus also resulting in a device with all of the limitations of claim 71. Ferree Decl. at ¶ 82.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
71. The attachment assembly of claim 59 wherein the biased stopping member is a collar having at least in part a passageway enlargeable from a first inner dimension to a second inner dimension by the passage of the enlarged integral portion of	<u>Errico</u> : “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel.” Ex. 1003 at 4:62-64; “During the implantation procedure, the screw 120 and the coupling element 132 are inserted through the hole. Once the bottom 142 of the coupling element 132,

the securing member therethrough.	respectively, seats in the top of the hole 110 or 112, and begins to travel into it, the tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182.” <i>Id.</i> at 7:41-47; <i>see also id.</i> at Figs. 4 and 6. <u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6. <u>Campbell</u> : <i>See</i> Ex. 1005 at Fig. 22.
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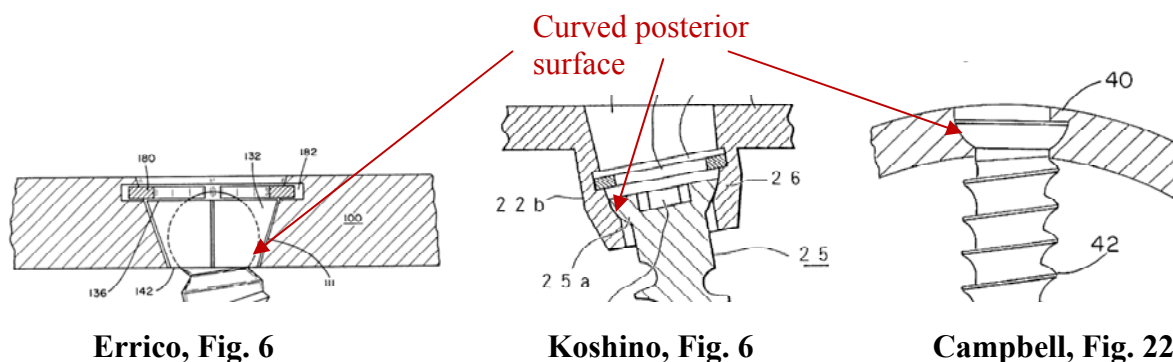
(k) Dependent Claim 72

Errico discloses a groove in the bore that receives the collar (stopping member). *See id.* at Fig. 6; 6:1-4.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
72. The attachment assembly of claim 71 wherein the bore has a groove which receives the collar.	<u>Errico</u> : “[E]ach of the holes 110 or 112 includes an annular recessed channel 182. Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180.” Ex. 1003 at 6:1-4; Fig. 3b.

(l) Dependent Claim 73

Each of Errico, Koshino and Campbell discloses a securing element (screw) wherein the enlarged integral portion of the screw has a curved posterior surface:



Errico further discloses that the head of the screw is configured with a separate coupling element that is designed to contact the collar's anterior surface and expand the collar as the head of the screw is displaced posteriorly through the passageway. *Id.* at 4:62-64 (“As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel.”); 7:41-47 (“Once the bottom 142 of the coupling element 132, respectively, seats in the top of the hole 110 or 112, and begins to travel into it, the tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182.”). Although Errico does not expressly disclose using the head of the screw itself to expand the collar, for all of the reasons described above, it would have been obvious to configure the Errico device with the screw head of Koshino or Campbell, each of which has a minimum head diameter that is smaller than, and a maximum head diameter that is larger than, the unexpanded inner diameter of the collar. Ex. 1004 at Fig. 6; Ferree Decl. at ¶ 85. When so configured, the screw would pass through the opening of the collar, and the head of the screw would contact the anterior surface of the collar, thus causing it to expand, as required by claims 73. Ferree Decl. at ¶ 85.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
73. The attachment assembly of claim 71 wherein the enlarged integral portion of the securing member has a curved posterior	<u>Errico</u> : “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel.” Ex. 1003 at 4:62-

surface which is configured to contact an anterior surface of the collar and expand the collar as the enlarged integral portion of the securing member is displaced posteriorly through the collar passageway.	64; “During the implantation procedure, the screw 120 and the coupling element 132 are inserted through the hole. Once the bottom 142 of the coupling element 132, respectively, seats in the top of the hole 110 or 112, and begins to travel into it, the tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182.” <i>Id.</i> at 7:41-47; <i>see also id.</i> at Figs. 4 and 6. <u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6. <u>Campbell</u> : <i>See</i> Ex. 1005 at Fig. 22.
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(m) Dependent Claim 74

With respect to claim 74, although Errico, Koshino and Campbell do not expressly disclose a collar with an anterior surface that tapers inwardly toward the collar passageway, such a configuration would have been a simple and obvious design choice. Ferree Decl. at ¶ 86. Such tapers are well known and a POSA would have understood that such a tapered collar could be used to help facilitate entry of the bone screw into the transverse passageway, and to facilitate expansion of the collar as the screw passes through. *Id.* Indeed, Errico expressly discloses the benefits of using a tapered surface with respect to the coupling element. *See, e.g.,* Ex. 1003 at 7:45-47 (“[T]he tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182.”). It would have been obvious for a POSA to use the tapered configuration of the Errico coupling element with the anterior surface of the collar as well to facilitate insertion. Ferree Decl. at ¶ 86; *see also Belden*, 2015 U.S. App. LEXIS 19307, at *16. (“In the

circumstances here, involving a simple point in a mechanical field and one very close piece of prior art, the Board was entitled to rely on its own reading of [the prior art reference] — supported by the Petition’s observations about it — to find [w]hat a skilled artisan would have understood”).

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
74. The attachment assembly of claim 73 wherein the anterior surface of the collar tapers inwardly toward the collar passageway.	<u>Errico</u> : “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180. ... The ring 180 can, however, be deflected inward or outward” Ex. 1003 at 6:2-12; <i>see also id.</i> at 7:40-51, Figs. 3b, 6.

(n) Dependent Claim 75

Errico discloses an attachment member with at least two bores. *Id.* at 5:61-65.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
75. The attachment assembly of claim 59 wherein the attachment member includes at least two bores.	<u>Errico</u> : “A pair of holes 110, having a smooth tapered inner surface 111, extend fully through the upper portion 102 of the plate. A second pair of holes 112 having a tapered inner surface 111 as well, are disposed in the lower portion 104 of the plate 100.” Ex. 1003 at 5:61-65.

(o) Dependent Claims 76-78

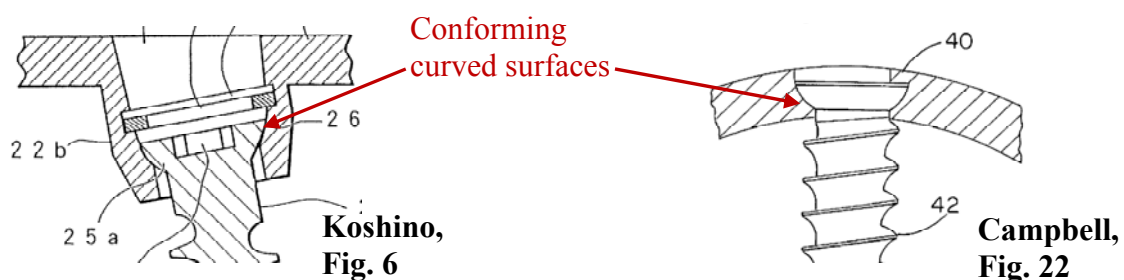
With respect to claims 76 and 77, Errico discloses an attachment member that is configured to conform to and extend between at least two bone segments, and wherein the bottom, or posterior, surface is concave. *Id.* at 5:55-60. With

respect to claim 78, Errico discloses an attachment member that is a bone plate. *Id.* at 5:41-60.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
76. The attachment assembly of claim 59 wherein the attachment member is configured to conform to and extend between at least two bone segments.	<u>Errico</u> : “A slight curvature may be imparted to the plate 100 so that it may grossly conform to the cylindrical morphology of the bones (i.e., vertebral bodies) which it couples. The curvature would correspondingly be such that the top surface 108 would be convex surface, and the bottom surface would be concave.” Ex. 1003 at 5:55-60.
77. The attachment assembly of claim 59 wherein the posterior surface of the attachment member is at least in part a concave surface.	
78. The attachment assembly of claim 59 wherein the attachment member is selected from the group consisting of rods and plates.	<u>Errico</u> : “The plate 100 may be constructed of any suitably biocompatible material....” Ex. 1003 at 5:43-44; <i>see also id.</i> at Fig. 3a.

(p) Dependent Claim 79

Koshino and Campbell both disclose a screw head with a posterior portion that is curved to conform to a curved posterior surface of the posterior portion of the bore:



For all of the reasons explained above (section IX.A.2), it would have been obvious to a POSA to use the screw head configuration of Koshino or Campbell in

place of the screw head/coupling element configuration of Errico. Ferree Decl. at ¶¶ 39-52. This is especially so considering that Errico discloses that the coupling element includes a tapered external surface designed to conform to the interior tapered surface of the holes of the plate. Ex. 1003 at 6:62-67 (“The coupling element 132 comprises a tapered cylindrical socket having a smooth external surface 134. The taper of the surface 134 is designed to mate with the interior tapered surface 111 of the holes 110 or 112 of the plate 100...”); Ferree Decl. at ¶ 89.

’008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
<p>79. The attachment assembly of claim 59, wherein</p> <p>a) the enlarged integral portion of the elongated securing member has a curved posterior surface; and</p> <p>b) the posterior bore portion has a curved posterior surface configured to conform at least in part to part of the curved posterior surface of the enlarged integral portion of the securing member received by the bore.</p>	<p><u>Errico</u>: “The coupling element 132 comprises a tapered cylindrical socket having a smooth external surface 134. The taper of the surface 134 is designed to mate with the interior tapered surface 111 of the holes 110 or 112 of the plate 100, so that the coupling element 132 may be seated into the plate 100.” Ex. 1003 at 6:62-67.</p> <p><u>Koshino</u>: See Ex. 1004 at Fig. 6.</p> <p><u>Campbell</u>: See Ex. 1005 at Fig. 22.</p>

(q) Dependent Claims 80-81

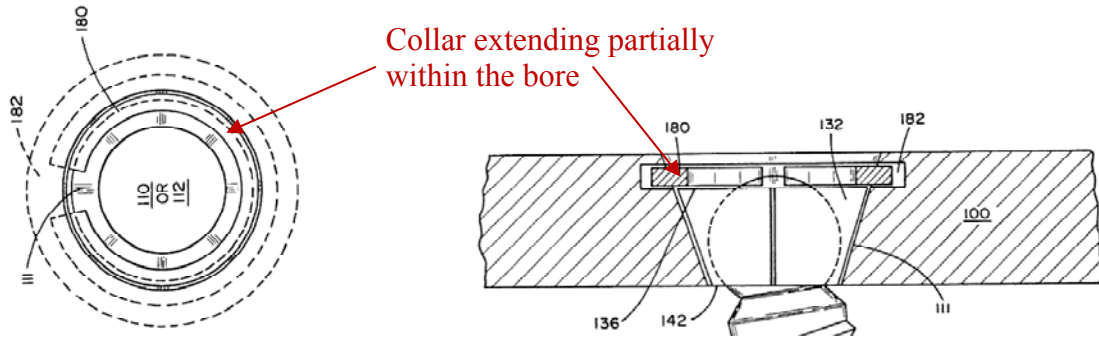
With respect to claims 80 and 81, Errico discloses a stopping element that comprises a biased collar and that is elastically deformable to the second configuration. See Ex. 1003 at 6:2-12; *see also id.* at 7:40-51 (“During the

implantation procedure, the screw 120 and the coupling element 132 are inserted through the hole. Once the bottom 142 of the coupling element 132, respectively, seats in the top of the hole 110 or 112, and begins to travel into it, the tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182. Once the coupling element 132 is fully seated in the hole 110, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 and snaps back to its undeflected state.”); *see also id.* at Figs. 3b, 6.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
80. The assembly of claim 59 wherein the stopping element comprises a biased collar.	<u>Errico</u> : “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180. ... The ring 180 can, however, be deflected inward or outward” Ex. 1003 at 6:2-12; <i>see also id.</i> at 7:40-51, Figs. 3b, 6.
81. The assembly of claim 80 wherein the biased collar is elastically deformable to the second configuration.	<u>Errico</u> : “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel. Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation (which is narrower than the diameter of the top of the coupling element), therein preventing the coupling element from backing out by interference.” Ex. 1003 at 4:62-5:2; <i>see also id.</i> at 4:42-46.

(r) Dependent Claim 82

Errico discloses a collar that extends at least partially within the bore of the stabilizing element. *See* Ex. 1003 at Fig. 3b and 6:



See also *id.* at 6:6-8.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
82. The assembly of claim 81 wherein the biased collar extends at least partially within the bore of the stabilizing element.	<u>Errico</u> : “[T]he ring snaps back into its undeflected shape which fits loosely in the recessed channel, and extends radially inward to block the element from backing out of the hole.” Ex. 1003 at 4:47-50; <i>see also id.</i> at Figs. 3b and 6; “The undeflected outer diameter of the snap-ring is greater than the diameter of the hole 110 or 112 (so that it will remain in the recess), and the inner diameter of the undeflected snap-ring 180 is less than the diameter of the tapered hole.” <i>Id.</i> at 6:4-8.

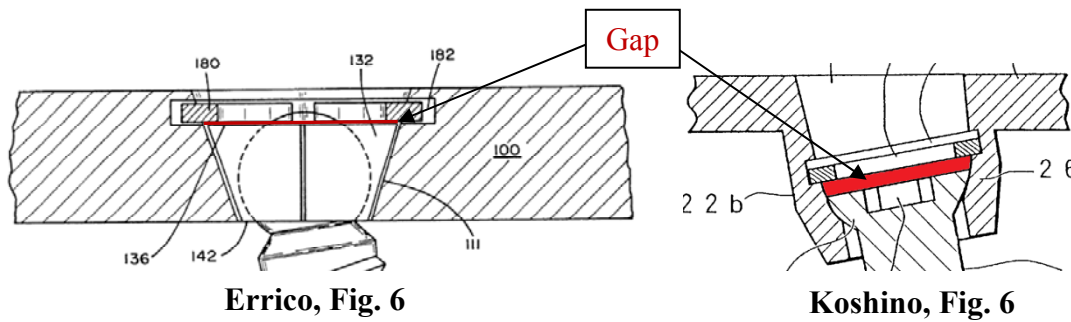
(s) Dependent Claims 83-84

With respect to claims 83 and 84, the biased stopping member of Errico resiliently returns to its first configuration after passage of the head of the screw, and it reduces a transverse configuration of the anterior bore portion to retain the head of the securing member within the posterior bore portion of the attachment member. Ex. 1003 at 4:47-50, 4:62–5:2, 6:4-8, Figs. 3b and 6.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
83. The attachment assembly of claim 59, wherein the stopping member is a biased stopping member which 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.	<u>Errico</u> : “[T]he ring snaps back into its undeflected shape which fits loosely in the recessed channel, and extends radially inward to block the element from backing out of the hole.” Ex. 1003 at 4:47-50; <i>see also id.</i> at Figs. 3b and 6; “The undeflected outer diameter of the snap-ring is greater than the diameter of the hole 110 or 112 (so that it will remain in the recess), and the inner diameter of the undeflected snap-ring 180 is less than the diameter of the tapered hole.” <i>Id.</i> at 6:4-8.
84. The attachment assembly of clam [sic] 59 wherein the biased stopping member resiliently returns to the first configuration after passage of the enlarged integral portion of the securing member.	<u>Errico</u> : “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel. Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation (which is narrower than the diameter of the top of the coupling element), therein preventing the coupling element from backing out by interference.” Ex. 1003 at 4:62–5:2; <i>see also id.</i> at 6:2-12, 7:40-51, Figs. 3b, 6.

(t) Dependent Claim 85

As can be seen in Figure 6 of both Errico and Koshino, the length of the posterior bore portion is greater than the length of the enlarged integral portion of the securing element, resulting in a gap between the posterior surface of the collar and the head of the screw/coupling member (colored in red), and thus allowing the head of the screw, and its enlarged integral portion, to be longitudinally displaceable within the posterior bore portion of the attachment member:



See also Ex. 1003 at 7:41-47; Ex. 1004 at 13:11-14. Indeed, a POSA would have understood that the Errico device would necessarily be designed such that there is a gap between the stopping member and the coupling element. Ferree Decl. at ¶ 93. Such a design would be required to ensure that the coupling element would pass below the stopping member, thus allowing the stopping member to retract to its undeflected position, and allowing the device to work for its intended function (*i.e.*, retaining the screw head/coupling member below the stopping member). *Id.*

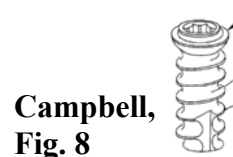
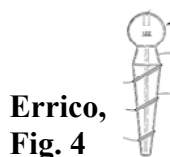
Further, a POSA would have understood that modifying Errico to remove the coupling element and employ the screw head of Koshino or Campbell would also result in the head of the screw being longitudinally displaceable between the posterior surface of the stopping member and the second opening in the stabilizing element, as expressly recognized in Koshino. Ex. 1004 at 13:11-14 (“A combination of the stopper ring 20, groove 24, and fixation screw 25 is preferably arranged so as to leave a desired amount of gap between the bottom surface of the stopper ring 20 and the top surface of the fixation screw 25.”); see also Ferree Decl.

at ¶ 94. Such a configuration would allow the placement of the screw at an angle, as contemplated by both the '008 Patent and Errico. Ferree Decl. at ¶ 94.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
85. The orthopedic attachment assembly of claim 59 wherein the posterior bore portion 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.	<p><u>Errico</u>: “During the implantation procedure, the screw 120 and the coupling element 132 are inserted through the hole. Once the bottom 142 of the coupling element 132, respectively, seats in the top of the hole 110 or 112, and begins to travel into it, the tapered exterior surface of the coupling element 132 causes the snap-ring 180 to expand into the recess 182.” Ex. 1003 at 7:41-47; <i>see also id.</i> at Figs 4 and 6.</p> <p><u>Koshino</u>: “A combination of the stopper ring 20, groove 24, and fixation screw 25 is preferably arranged so as to leave a desired amount of gap between the bottom surface of the stopper ring 20 and the top surface of the fixation screw 25.” Ex. 1004 at 13:11-14.</p> <p><u>Campbell</u>: <i>See</i> Ex. 1005 at Fig. 22.</p>

(u) Dependent Claim 86

With respect to claim 86, element 86(a), each of Errico, Koshino and Campbell discloses an elongated securing element that has an enlarged integral portion with a length, a posterior surface and a transverse dimension, and a shaft extending from the enlarged integral portion configured to be secured within bone:



See also Ex. 1003 at 4:53-55; Ex. 1004 at 3:38-39; Ex. 1005 at 4:57-60.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
<p>86. The orthopedic attachment assembly of claim 59 wherein,</p> <p>a) the elongated securing element has an enlarged integral portion with a length, a posterior surface and a transverse dimension and a shaft extending from the enlarged integral portion configured to be secured within bone;</p>	<p><u>Errico</u>: “The screw 120 comprises a head portion 122, a neck 124, and a shaft 126.” Ex. 1003 at 6:16-17; <i>see also id.</i> at Fig. 4.</p> <p>“Once the screw has been inserted into the bone....” <i>Id.</i> at 4:57.</p> <p>“[P]re-drilled holes are formed in the bones at the desired angle, into which the screws are to be inserted.” <i>Id.</i> at 4:53-55.</p> <p><u>Koshino</u>: “[T]he fixation screw inserted into the through hole unit is threaded into hard tissues....” Ex. 1004 at 3:38-39; <i>see also id.</i> at Fig. 3b.</p> <p><u>Campbell</u>: “Each of the fasteners extends through one of four apertures in the cervical plate, and further penetrates the osseous material (one of the vertebrae) to anchor the cervical plate.” Ex. 1005 at 4:57-60; <i>see also id.</i> at Fig. 8.</p>

As shown in the table below, claim 86(b) includes limitations that are identical to, or substantially the same as, those found in claim 59(b):

Claim 86(b)	Claim 59(b)
86b) the attachment element has an anterior surface and a posterior surface and has at least one bore extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element, the bore having an anterior bore portion, a posterior bore portion 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	59b) an attachment element which has an anterior surface and a posterior surface and which has at least one bore extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element, the bore having an anterior bore portion, and a posterior bore portion, the posterior bore portion having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing element to

within the posterior bore portion; and	facilitate retention of the enlarged integral portion of the securing member within the posterior bore portion; and
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Accordingly, for all of the reasons discussed above with respect to claim 59(b), the combination of Errico and Koshino or Campbell discloses all of the limitations of claim 86(b).

Similarly, as shown in the table below, claim 86(c) contains limitations that are identical to, or substantially the same as, those found in claim 85.

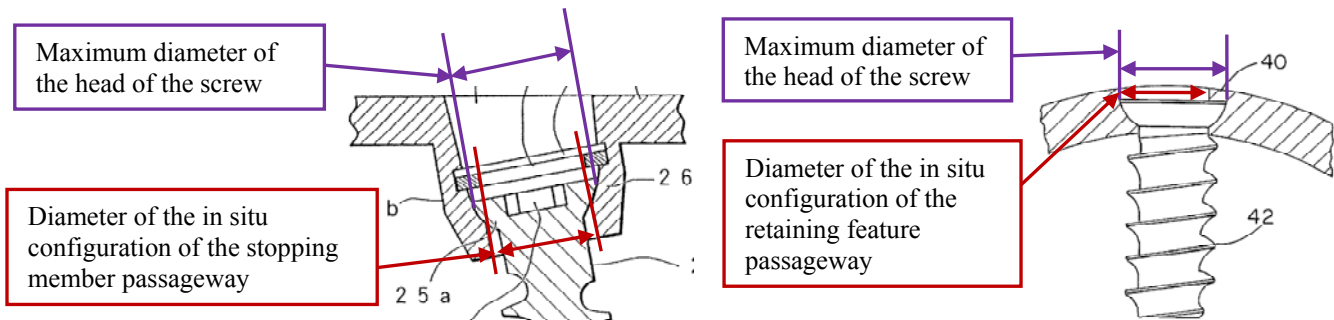
Claim 86(c)	Claim 85
86c) the stopping member defines in part a passageway in the posterior bore portion, said posterior bore portion being longer than the length of the enlarged integral portion of the securing element to allow longitudinal displacement of the enlarged integral portion of the securing element within the posterior bore portion.	85. The orthopedic attachment assembly of claim 59 wherein the posterior bore portion 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.

Accordingly, for all of the reasons discussed above with respect to claim 85, the combination of Errico and Koshino or Campbell discloses all of the limitations of claim 86(c).⁴

⁴ As can be seen, for example, in Figure 6 of Errico, the posterior surface of the stopping member “defines in part a passageway” (*i.e.*, the upper boundary of the passageway) in the posterior bore portion.

(v) Dependent Claim 88

Errico discloses that the enlarged integral portion of the securing element has a maximum transverse dimension greater than the second (smaller) transverse dimension of the stopping member. *See* Ex. 1003 at Fig. 6. Additionally, as explained above, it would have been obvious for a POSA to configure the Errico device with the screw head of Koshino or Campbell. Ferree Decl. at ¶¶ 39-52. In modifying Errico in such a way, the diameter of the enlarged integral portion of the screw would be (1) greater than the posterior opening in the stabilizing element (so that the screw would not simply go all the way through the bore); (2) smaller than the larger diameter configuration of the passageway defined by the stopping member (so that the screw could pass through the stopping member); and (3) greater than the smaller diameter configuration of the passageway defined by the stopping member (so that the screw could not back out of the assembly). *Id.* at ¶ 98. These dimensional relationships are standard, and Koshino and Campbell each disclose a screw having a head with the required limitations. *Id.* As can be seen in Figure 6 of Koshino and Figure 22 of Campbell, the maximum diameter of the head of the screw is greater than the smaller transverse dimension of the stopping member:



As such, the combination of Errico and either of Koshino or Campbell discloses all of the limitations of claim 88.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
88. The orthopedic attachment assembly of claim 87 wherein the enlarged integral portion of the securing element has a maximum transverse dimension which is greater than the second transverse dimension of the stopping member.	<p><u>Errico</u>: “The screw 120 comprises a head portion 122, a neck 124, and a shaft 126.” Ex. 1003 at 6:16-17; <i>see also id.</i> at Fig. 4; “The head portion 122 of the screw 120 comprises a semi-spherical shape, which has a recess in it.” <i>Id.</i> at 6:26-27.</p> <p><u>Koshino</u>: “The fixation screw 6 is a right-handed screw as described above, and has a flat head as shown in FIG. 3(b).” Ex. 1004 at 11:30-31; Fig. 3(b); “With the stopper ring 20 being fitted in the groove 24, even if the fixation screw 25 once threaded into the hard tissues (tibia) is spontaneously rotated and moved back outside, this motion is stopped by the stopper ring 20 and the fixation screw 25 cannot be moved back outside.” <i>Id.</i> at 13:15-19; Fig. 6.</p> <p><u>Campbell</u>: “At this stage, retaining feature 40 is plastically deformed to move a medial region 102 radially inwardly, to a closed position in which the retaining member overlies head 46 of the fastener.... This overcomes any tendency in fastener 24 to work loose when the fastener and plate are subject to shock, vibration or other disturbance.” Ex. 1005 at 6:55-65; Fig. 22.</p>

(w) Dependent Claim 89

With respect to claim 89, although Errico, Koshino and Campbell do not expressly disclose a screw head with a tapered posterior surface configured to expand the stopping member upon passage therethrough, such a configuration would have been a simple and obvious design choice. Ferree Decl. at ¶ 99. Indeed, Errico expressly discloses a tapered coupling member surrounding the head of the screw, designed for this precise purpose (to facilitate expansion of the stopping member as it passes through). Ex. 1003 at 4:62-64. It would have been obvious for a POSA to use the screw head configuration of Koshino or Campbell with the Errico implant device and to employ this tapered configuration directly to the posterior surface of that screw head. Ferree Decl. at ¶ 99; *see also Belden*, 2015 U.S. App. LEXIS 19307, at *16. (“In the circumstances here, involving a simple point in a mechanical field and one very close piece of prior art, the Board was entitled to rely on its own reading of [the prior art reference]—supported by the Petition’s observations about it—to find [w]hat a skilled artisan would have understood”).

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
89. The orthopedic attachment assembly of claim 88 wherein the enlarged integral portion of the securing element has a tapered posterior surface configured to expand the stopping member	<u>Errico</u> : “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel.” Ex. 1003 at 4:62-64.

upon the passage therethrough.	<u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6. <u>Campbell</u> : <i>See</i> Ex. 1005 at Fig. 22.
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(x) Dependent Claim 90

Errico discloses a stopping member wherein the second configuration of the stopping member has a transverse dimension that is larger than the transverse dimension of the stopping member in first configuration. Ex. 1003 at 4:43-46 (“The discontinuity in the element permits the ring to be ... expanded to permit the tapered coupling element to slide through it into the hole.”); *id.* at 4:47-50 (“After the coupling element passes through it, however, the ring snaps back into its undeflected shape which fits loosely in the recessed channel, and extends radially inward to block the element from backing out of the hole.”); *id.* at 4:64-5:2 (“Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation (which is narrower than the diameter of the top of the coupling element), therein preventing the coupling element from backing out by interference.”); *see also id.* at 7:47-55; Figs 3b and 6.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
90. The orthopedic attachment assembly of claim 86 wherein the second configuration of the stopping member has a transverse dimension that is larger than the transverse dimension of the stopping member in the first configuration.	<u>Errico</u> : “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180. ... The ring 180 can, however, be deflected inward or outward” Ex. 1003 at 6:2-12; <i>see also id.</i> at Figs. 3b, 6.

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 65-100), Petitioner has shown a reasonable likelihood of proving that each of claims 60-91 is obvious over Errico in view of Koshino or Campbell.

X. CONCLUSION

Claims 59-91 of the '008 patent are rendered obvious over the combination of Errico and Koshino or Campbell. Petitioner has established a reasonable likelihood of prevailing on these grounds, and prompt and favorable consideration of this Petition is respectfully requested.

RESPECTFULLY SUBMITTED,
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Dated: December 14, 2015

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that the above-captioned “THIRD PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE43,008 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §42.100 *et seq.*,” including its supporting evidence (Exhibits 1001 — 1015), was served in its entirety on December 14, 2015, upon the following attorney of record via Express Mail:

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Additionally, courtesy copies of the foregoing have been served via Express Mail on the following:

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