

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.: IPR2016-00333

**SECOND 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 44-54 and 101-105 (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 59-91 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 44-54 and 101-105 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	44-54 and 101-105	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 implant 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 44-54 and 101-105 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

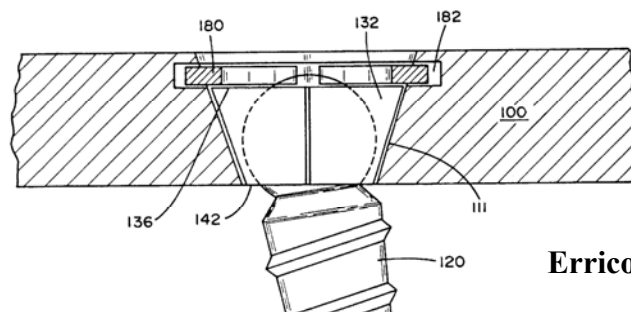
As detailed in the discussion and claim charts below, the prior art references identified below demonstrate that all of the limitations of claims 44-54 and 101-105 of the '008 patent were known in the prior art at the time of invention. The inventions claimed in the '008 patent are “[t]he combination 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 44-54 and 101-105 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

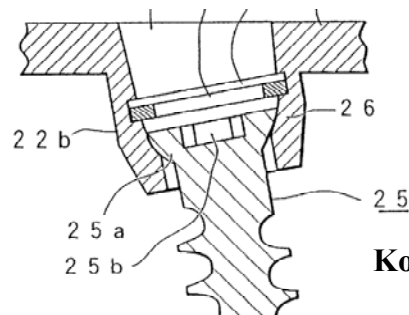
hole. *Id.* The bone screw (with coupling element on the head of the screw) is inserted through the hole in the plate until the coupling element engages and expands the snap-ring. *Id.* Once the coupling element and bone screw pass through the snap-ring, the snap-ring contracts to its undeflected position and prevents the screw from backing out of the hole. *Id.*



Errico, Fig. 6

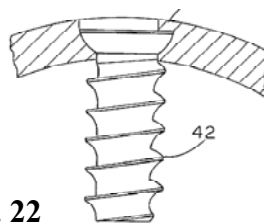
Koshino discloses an orthopedic implant device, such as a bone fixation plate, designed to be attached to the bone with fixation screws, and designed to prevent loosening of the device after implantation. Ex. 1004 at 1:5-13, 22; 3:23-25. As shown in Figure 6 below, the orthopedic implant device of Koshino includes an upper (anterior) portion and a lower (posterior) portion. *E.g., id.* at Figs. 2, 6 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 upper (anterior) part of the hole includes an annularly recessed channel in which a c-ring, called a stopper ring, is disposed. *Id.*; 12:43-48. 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 12:65-13:1. Once the screw is fully seated in

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”).

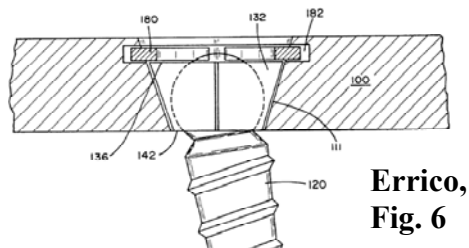
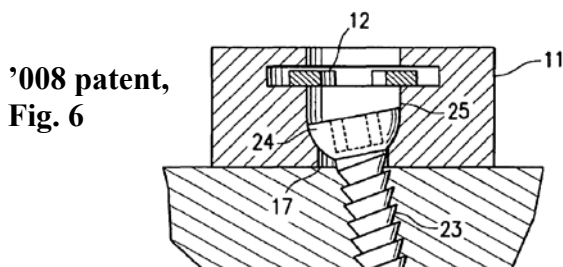
The only distinction that Patent Owner made with respect to Errico during the prosecution of the '008 patent related to Errico’s use of a coupling element

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.*

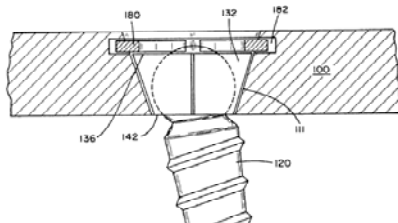
A POSA would have had a clinical reason to modify Errico as well. Bone plates of the type described in, for example, the '008 patent and Errico, are often placed very close to critical anatomy, such as the esophagus or major blood vessels. *Id.* at ¶ 42; *see also* Ex. 1003 at 2:39-3:6. For this reason, 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:

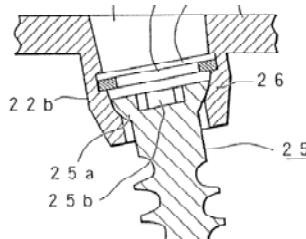
All of the foregoing prior art systems suffer from several undesirable drawbacks. First, the addition of intricately machined componentry makes most of these systems expensive and difficult to manufacture. Second, since some of these prior art systems rely on a threaded connection to maintain the bone 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.

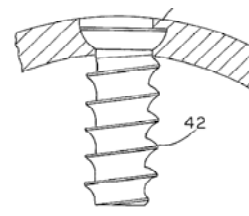
U.S. Pat. No. 5,578,034 (Ex. 1008) at 2:10-23; Ferree Decl. at ¶ 44. Accordingly, a POSA at the time of the invention of the '008 patent would have been motivated to improve upon the Errico invention by reducing the total number of components of the implant, and by minimizing the profile of the bone 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 (“with 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 or Campbell, 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 44 Of The '008 Patent Is Obvious In View Of Errico And Koshino Or Campbell

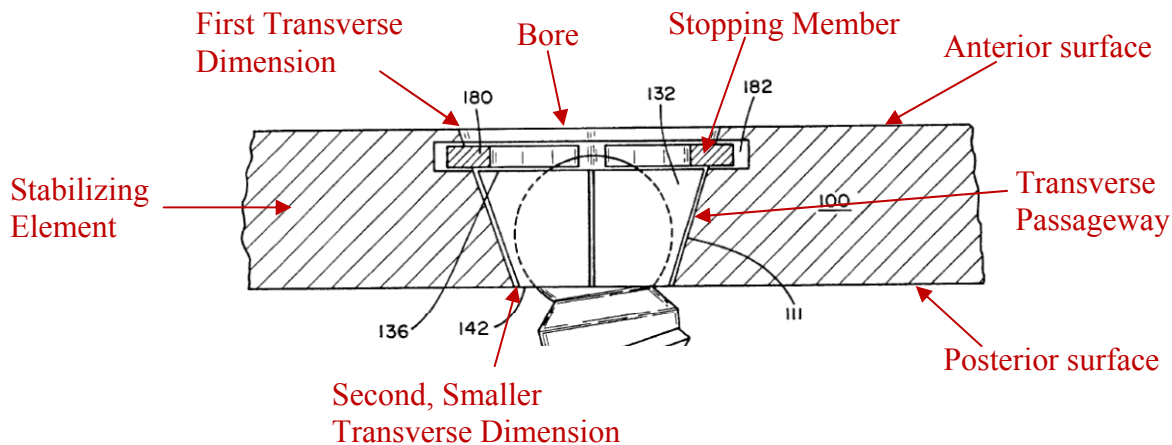
The combination of Errico and either of Koshino or Campbell discloses all of the limitations of claim 44. With respect to the preamble, Errico, Koshino and Campbell each disclose an “orthopedic implant assembly.” Ex. 1003 at 1:15-16; Ex. 1004 at 1:5-13, 1:22-30; Ex. 1005 at 1:12-15.

(a) Independent Claim 44, Element 44(a)

With respect to claim element 44(a), Errico discloses a stabilizing element (a plate) that has an anterior (top) surface, a posterior (bottom) surface,² and at least one bore from the anterior surface to the posterior surface with a first transverse dimension in the anterior bore portion (*i.e.*, the anterior opening of the bore) and a second, smaller transverse dimension in the posterior bore portion (*i.e.*, the posterior opening of the bore). *See* Ex. 1003 at Abstract; *see also id.* at Fig. 6

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.

(rotated 90° and annotated):



'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
44a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface and the bore having an anterior bore portion with a transverse dimension and a posterior bore portion which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion;	<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.

(b) Independent Claim 44, Element 44(b)

With respect to claim element 44(b), each of Errico, Koshino and Campbell discloses a securing element (bone screw) with an elongated body and an enlarged integral portion with a maximum transverse dimension:



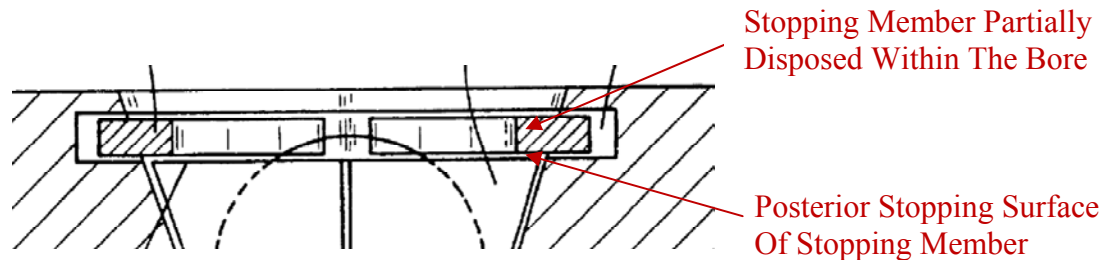
Errico further discloses that the screw is slidably disposed within the bore of the stabilizing element. Ex. 1003 at 4:55-56 (“With the plate in place, the screws are inserted through the holes and into the vertebral bodies”).

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
44b) a securing element which is configured to be slidably disposed within the bore of the stabilizing element and which has an elongated body and an enlarged integral portion with a maximum transverse dimension; and	<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>“Next, pre-drilled holes are formed in the bones at the desired angle, into which the screws are to be inserted. With the plate in place, the screws are inserted through the holes and into the vertebral bodies Continued screwing down causes the bottom of the coupling element to advance into the hole, passing through the retaining ring.” <i>Id.</i> at 4:53-62.</p> <p><u>Koshino</u>: <i>See</i> Ex. 1004 at Fig. 3b.</p> <p><u>Campbell</u>: <i>See</i> Ex. 1005 at Fig. 8.</p>

(c) Independent Claim 44, Element 44(c)

With respect to claim element 44(c), Errico discloses a stopping member that is at least partially disposed within the bore of the stabilizing element and has a posterior stopping surface. *See id.* at Fig. 6 (below); *see also* Ex. 1003 at 6:6-8

(“[T]he inner diameter of the undeflected snap-ring 180 is less than the diameter of the tapered hole.”).

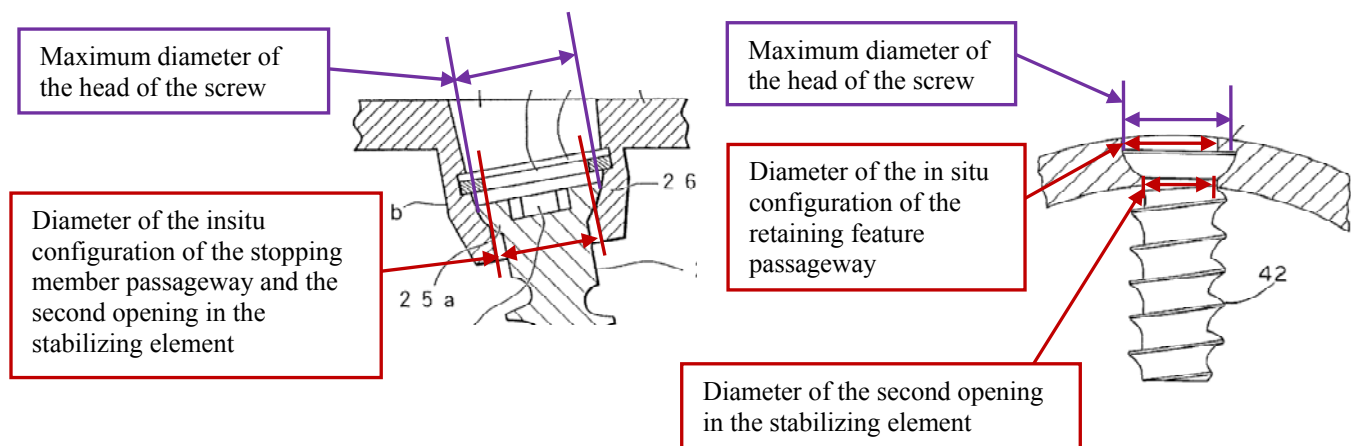


Errico further discloses a stopping member that is reversibly expandable and has a first, larger diameter configuration and a second, smaller diameter configuration. *Id.* at 6:10-12 (“The ring 180 can, however, be deflected inward or outward”). Errico discloses that the first configuration of the stopping member allows passage of the securing element into the posterior portion of the bore. *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.”); *see also id.* at 7:43-47; Fig. 6. Errico also discloses that the second configuration of the stopping member has a smaller transverse dimension than the first configuration, and facilitates retention of the enlarged integral portion of the securing member within the posterior bore portion, posterior to the stopping 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.”); *see also id.* at 7:47-51; Fig. 6. Once the securing element has passed through the stopping

member, the enlarged integral portion of the securing member is disposed and retained in the posterior bore portion posterior to the stopping member. *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 7:51-55; Fig 6.

With respect to the remainder of claim element 44(c), to the extent the claim so requires, 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, 60; 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 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 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 stopping member (so that the screw could not back out

of the assembly). Ferree Decl. at ¶ 61. 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 ¶ 62. 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 44 of the '008 patent.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
<p>44c) a stopping member which is at least partially disposed within the bore of the stabilizing element, which has a posterior stopping surface, a first configuration within the bore allowing passage of the securing element into the posterior bore portion with the enlarged integral portion of the securing element disposed in the posterior bore portion posterior to the stopping member and a second configuration within the bore which has smaller transverse dimensions than the first configuration and smaller than the maximum transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion of the stabilizing element; and wherein the enlarged integral portion of the securing element is retained below the posterior surface of the stopping member.</p>	<p><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; “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. 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).” <i>Id.</i> at 7:41-55; <i>see also id.</i> at Figs 3b, 4 and 6.</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</p>

	<p>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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For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 54-63), Petitioner has shown a reasonable likelihood of proving that claim 44 of the '008 patent is obvious over Errico in view of Koshino or Campbell.

4. Dependent Claims 45-54 Of The '008 Patent Are Obvious In View Of Errico And Koshino Or Campbell

Claims 45-54 all depend, directly or indirectly, from claim 44, which is discussed above and which discussion is incorporated into each of the following dependent claims.

(a) Dependent Claim 45

Errico discloses a stopping member that is configured to prevent the screw from backing-out of the stabilizing element. Ex. 1003 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.”), 7:51-52 (“In its undeflected state [the snap-ring] prevents the coupling element 132 from backing out of the plate 100”), and Fig. 6; *see also id.* 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”).

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
45. The assembly of claim 44 wherein the stopping member is configured to prevent the back-out of the securing element through the bore of the stabilizing element.	<u>Errico</u> : “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).” Ex. 1003 at 7:47-55; <i>see also id.</i> at Fig. 6; 4:47-50; 4:1-4.

(b) Dependent Claims 46-47

With respect to claims 46 and 47, Errico discloses a biased stopping member that is capable of expanding from, and contracting back to, its undeflected state

after the screw head moves through the opening (passageway) of the stopping member. *See* Ex. 1003 at 6:2-12:

Within this annular recess 182 is provided a discontinuous “7/8ths” snap-ring 180. 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. This permits the snap-ring 180 to protrude as an annular flange into the hole 110 or 112 in its undeflected state. The ring 180 can, however, be deflected inward or outward so as to entirely seat within the annular channel, or be removed entirely from the hole.

See also id. at 7:40-51, Figs. 3b, 6.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
46. The assembly of claim 44 wherein the stopping member is biased to the second 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 7:40-51, Figs. 3b, 6.
47. The assembly of claim 46 wherein the stopping member comprises a biased collar having a passageway therethrough.	<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.

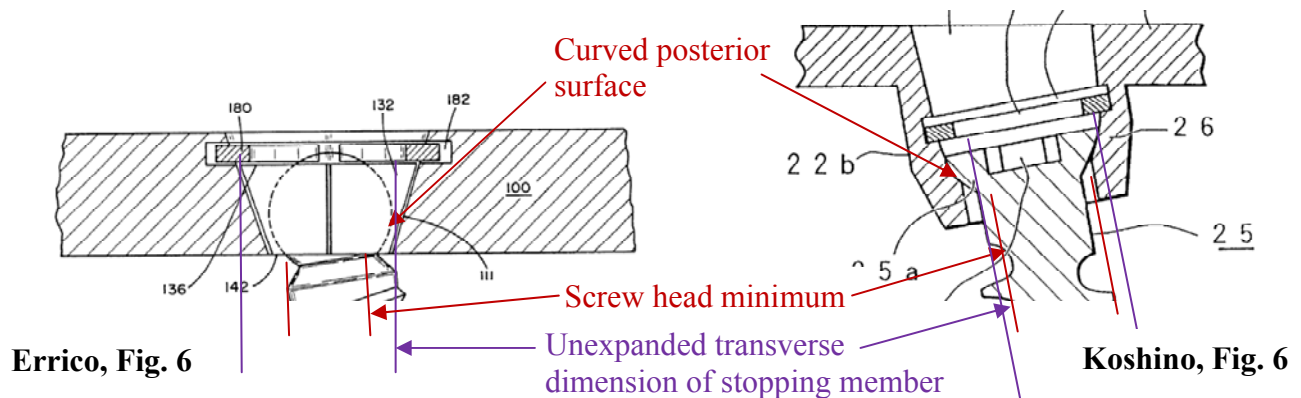
(c) Dependent Claim 48

Errico discloses a groove in an anterior portion of the bore that is configured to receive the biased collar (stopping member). *See id.* at Fig. 6 (showing groove in the anterior portion of the bore) and at 6:1-4 (“Referring also to FIG. 3b, each 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”). Errico also discloses an annular collar that is reversibly expandable when seated in the groove. *Id.* at 6:7-12 “This permits the snap-ring 180 to protrude as an annular flange into the hole 110 or 112 in its undeflected state. The ring 180 can, however, be deflected inward or outward so as to entirely seat within the annular channel, or be removed entirely from the hole.”); *see also id.* at Fig. 3b.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
48. The assembly of claim 47 wherein the bore has a groove in an anterior portion thereof configured to receive the biased collar, and wherein the biased collar is configured to be reversibly expandable when seated in the groove.	<u>Errico</u> : “each 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. 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. This permits the snap-ring 180 to protrude as an annular flange into the hole 110 or 112 in its undeflected state. The ring 180 can, however, be deflected inward or outward so as to entirely seat within the annular channel, or be removed entirely from the hole.” Ex. 1003 at 6:1-12; Fig. 3b.

(d) Dependent Claims 49-50

With respect to claims 49 and 50, Errico and Koshino each disclose a securing element (screw) wherein the head of the screw has a curved posterior surface and which has a minimum transverse dimension smaller than the unexpanded transverse dimension of the collar:



Additionally, if the screw head of Campbell were employed with the Errico device, the combination would similarly result in a device wherein the head of the screw has a curved posterior surface and which has a minimum transverse dimension smaller than the unexpanded transverse dimension of the collar. Ferree Decl. at ¶ 69.

Errico 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 (*i.e.*, deflect the collar away from a longitudinal axis of the collar passageway) as the head of the screw is displaced posteriorly through the passageway. Ex. 1003 at 4:60-64 ("Continued screwing down causes the bottom

of the coupling element to advance into the hole, passing through the retaining ring. As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel”); *see also id.* at 7:41-47; Fig. 6. 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 ¶ 70. 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 49 and 50.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
49. The assembly of claim 48 wherein the curved posterior surface of the enlarged integral portion of the securing element is configured to expand the collar as the enlarged integral portion of the securing element is displaced posteriorly through the collar passageway.	<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, 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;

	<p><i>see also id.</i> at Figs. 4 and 6.</p> <p><u>Koshino</u>: <i>See</i> Ex. 1004 at Fig. 6.</p> <p><u>Campbell</u>: <i>See</i> Ex. 1005 at Fig. 22.</p>
<p>50. The assembly of claim 49 wherein the curved posterior surface of the enlarged integral portion of the securing element has a minimum transverse dimension smaller than a transverse dimension of the passageway of the unexpanded collar, and which is configured to contact an anterior surface of the collar and deflect the collar away from a longitudinal axis of the collar passageway as the enlarged integral portion of the securing element is displaced posteriorly through the collar passageway.</p>	<p><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, 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.</p> <p><u>Koshino</u>: <i>See</i> Ex. 1004 at Fig. 6.</p> <p><u>Campbell</u>: <i>See</i> Ex. 1005 at Fig. 22.</p>

(e) Dependent Claim 51

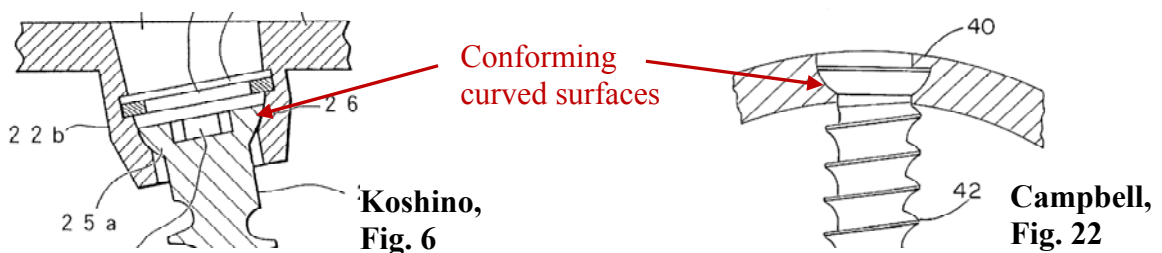
With respect to claim 51, although Errico, Koshino and Campbell do not expressly disclose a collar with an anterior surface that tapers toward the collar passageway, such a configuration would have been a simple and obvious design choice. Ferree Decl. at ¶ 71. Such tapers are well known and a POSA would 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 (“the 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 ¶ 71; *see also Belden*, Nos. 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)
51. The assembly of claim 50 wherein the collar has an anterior surface which tapers 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.

(f) Dependent Claim 52

Koshino and Campbell disclose a posterior portion of the bore that is curved to conform to the curved posterior surface of the head of the screw. Ex. 1004 at Figs 2, 6; Ex. 1005 at Fig. 22:



It would have been obvious for a POSA to employ either of these configurations to the Errico device. Ferree Decl. at ¶ 72. This is especially so considering that Errico also discloses a posterior portion of the transverse passageway that is designed to conform to the surface of the screw head coupling element. 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”).

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
52. The assembly of claim 51 wherein the posterior bore portion has a curved posterior surface that is configured to receive at least in part the curved posterior surface of the enlarged integral portion of the securing element.	<u>Koshino</u> : See Ex. 1004 at Fig. 6. <u>Campbell</u> : See Ex. 1005 at Fig. 22.

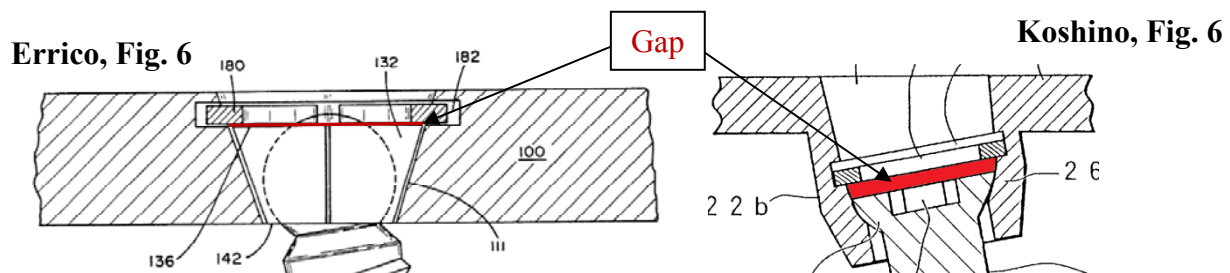
(g) Dependent Claim 53

Each of Errico, Koshino and Campbell disclose a screw that has an enlarged integral portion with a curved posterior surface. Ex. 1003 at Fig. 6; Ex. 1004 at Fig. 6; Ex. 1005 at Fig. 22.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
53. The assembly of claim 44 wherein the enlarged integral portion of the securing element has a curved posterior surface.	<u>Errico</u> : See Ex. 1003 at Figs. 4, 6. <u>Koshino</u> : See Ex. 1004 at Fig. 6. <u>Campbell</u> : See Ex. 1005 at Fig. 22.

(h) Dependent Claim 54

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



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 ¶ 74. 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 ¶ 75. Such a configuration would allow the placement of the screw at an angle, as contemplated by both the ’008 Patent and Errico. *Id.*

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
54. The assembly of claim 44 wherein the enlarged integral portion of the securing element is configured to be longitudinally displaceable within the posterior bore portion of the bore of the stabilizing element.	<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>

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 64-75), Petitioner has shown a reasonable likelihood of proving that each of claims 45-54 is obvious over Errico in view of Koshino or Campbell.

5. Independent Claim 101 Of The '008 Patent Is Obvious In View Of Errico And Koshino or Campbell

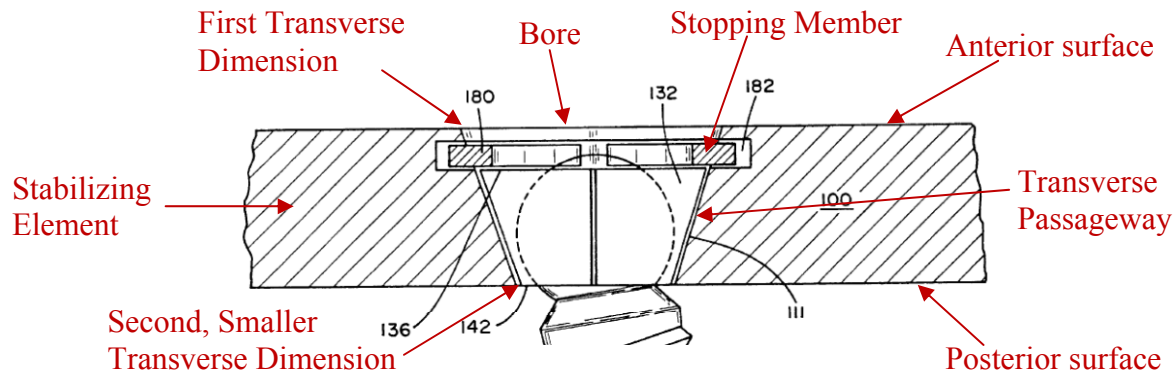
The combination of Errico and either of Koshino or Campbell discloses all of the limitations of claim 101, which is in all material respects identical to claim 44.³ With respect to the preamble, Errico, Koshino and Campbell each disclose an “orthopedic implant assembly.” Ex. 1003 at 1:15-16; Ex. 1004 at 1:5-13, 1:22-30; Ex. 1005 at 1:12-15.

(a) Independent Claim 101, Element 101(a)

With respect to claim element 101(a), Errico discloses a stabilizing element (a plate) that has an anterior (top) surface, a posterior (bottom) surface, and at least one bore from the anterior surface to the posterior surface with a first transverse dimension in the anterior bore portion (*i.e.*, the anterior opening of the bore) and a second, smaller transverse dimension in the posterior bore portion (*i.e.*, the

³ The primary difference between claim 44 and claim 101 is that, in claim 44, the “first” configuration of the stopping member is the larger diameter configuration, and the “second” configuration is the smaller diameter configuration; whereas in claim 101, the “first” configuration of the stopping member is the smaller diameter configuration and the “second” configuration is the larger diameter configuration.

posterior opening of the bore). *See* Ex. 1003 at Abstract; *see also id.* at Fig. 6 (rotated 90° and annotated):



'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
101a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface with an anterior bore portion which has a transverse dimension, a posterior bore portion which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion;	<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.

(b) Independent Claim 101, Element 101(b)

Each of Errico, Koshino and Campbell discloses a securing element (bone screw) with an elongated body and an enlarged integral portion with an anterior surface:

**Errico,
Fig. 4**



**Koshino,
Fig. 3b**



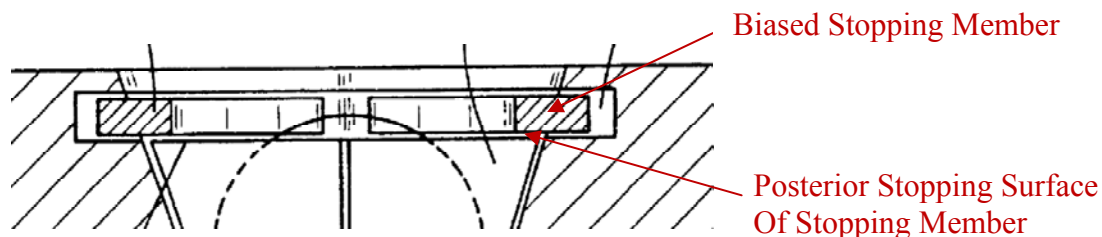
**Campbell,
Fig. 8**



'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
101b) a securing element having an elongated body and an enlarged integral portion having an anterior surface; and	<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.

(c) Independent Claim 101, Element 101(c)

Errico discloses a biased stopping member that has a posterior stopping surface. *See* Ex. 1003 at Fig. 6 (below); *see also id.* at 6:2-4 (“Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180.”).



Errico further discloses a stopping member that is elastically deformable and has a first, smaller diameter configuration and a second, larger diameter configuration. *Id.* at 6:10-12 (“The ring 180 can, however, be deflected inward or outward”); 4:64-67 (“Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation”). Errico discloses that the second configuration of the stopping member allows passage of

the enlarged integral portion of the securing element into the posterior portion of the bore posterior to the biased stopping member. *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.”); *see also id.* at 7:43-47; Fig. 6. Errico also discloses that the stopping member returns to the first configuration, which has a smaller transverse dimension than the second configuration, and facilitates retention of the enlarged integral portion of the securing element within the posterior bore portion. *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.”); *see also id.* at 7:47-51; Fig. 6.

Once the securing element has passed through the stopping member, the posterior surface of the stopping member is positioned to engage the anterior surface of the securing element to prevent the securing element from backing out of the posterior bore portion. *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 7:51-55 (“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.”); *see also id.* at Fig 6.

With respect to the remainder of claim element 101(c), to the extent the claim so requires, 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. See Ferree Decl. at ¶¶ 1-7, 83; 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 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 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 ¶ 84. 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.*

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, 85. 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 101 of the '008 patent.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
101c) a biased stopping member which has a posterior stopping surface, which has a first configuration within the anterior bore portion that has a first transverse dimension and is elastically deformable to a second configuration within the anterior bore portion that has a second transverse dimension larger than the first transverse dimension that allows the enlarged integral portion of the securing element to pass into the posterior bore portion posterior to the biased stopping member, the biased stopping member returning to the first configuration so that the posterior surface of the stopping member is positioned to engage the anterior surface of the securing element and prevents the	<p><u>Errico</u>: “Continued screwing down causes the bottom of the coupling element to advance into the hole, passing through the retaining ring. 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 4:60-5:2. <i>See also id.</i> at 7:41-55.</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</p>

<p>securing element from backing out of the posterior bore portion and to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion.</p>	<p>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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For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 76-85), Petitioner has shown a reasonable likelihood of proving that claim 101 of the ’008 patent is obvious over Errico in view of Koshino or Campbell.

6. Dependent Claims 102-105 Of The ’008 Patent Are Obvious In View Of Errico And Koshino or Campbell

Claims 102-105 all depend, directly or indirectly, from claim 101, which is discussed above and which discussion is incorporated into each of the following dependent claims.

(a) Dependent Claim 102

Errico discloses a biased stopping member (*e.g.*, Ex. 1003 at 4:42-46; 6:2-12) that elastically returns from the first configuration back to the second configuration. *Id.* at Figs. 3b and 6; *id.* at 4:62 – 5:2 (“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.”).

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
102. The orthopedic implant assembly of claim 101 wherein the biased stopping member elastically returns from the first configuration back to the second configuration.	<u>Errico</u> : “Once the coupling element fully passes the retaining snap-ring, the ring elastically contracts back to its undeflected conformation.” Ex. 1003 at 4:64-67.

(b) Dependent Claim 103

Errico discloses a biased stopping member that comprises a collar. *See* Ex. 1003 at 6:2-12:

Within this annular recess 182 is provided a discontinuous “7/8ths” snap-ring 180. 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

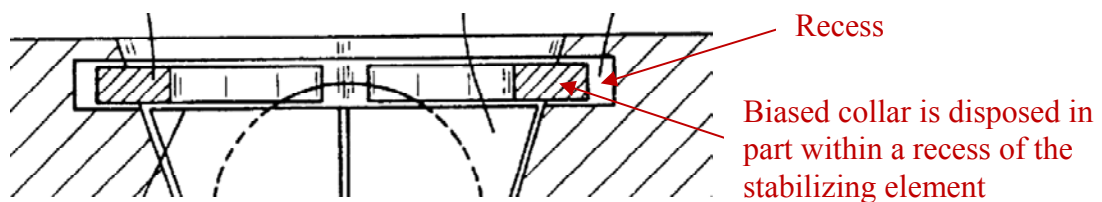
snap-ring 180 is less than the diameter of the tapered hole. This permits the snap-ring 180 to protrude as an annular flange into the hole 110 or 112 in its undeflected state. The ring 180 can, however, be deflected inward or outward so as to entirely seat within the annular channel, or be removed entirely from the hole.

See also id. at Figs. 3b and 6.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
103. The assembly of claim 101 wherein the biased stopping member comprises a collar.	<u>Errico</u> : “each 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; Figs. 3b and 6.

(c) Dependent Claim 104

Errico discloses a biased collar that is disposed in part within a recess of the stabilizing element. *See* Ex. 1003 at Fig. 6:



See also id. at 6:4-8 (“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”); *see also id.* at Fig. 3b.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
104. The assembly of claim 103 wherein the biased collar is disposed in part within a recess of the stabilizing element.	<u>Errico</u> : “each 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. 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. Ex. 1003 at 6:1-8; Figs. 3b and 6.

(d) Dependent Claim 105

Errico discloses a bore with a groove configured to slidably receive a biased collar. *See* Ex. 1003 at 4:43-45 (“The discontinuity in the element permits the ring to be radially compressed for insertion in the channel”); *see also id.* at Figs. 6 and 3b. Errico explains that the stopping element is radially compressed, and then slides into the bore for insertion into the groove (channel). *Id.* At 4:43-45.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004) or Campbell (Ex. 1005)
105. The assembly of claim 104 wherein the recess is a groove configured to slidably receive the biased collar.	<u>Errico</u> : “The discontinuity in the element permits the ring to be radially compressed for insertion in the channel” Ex. 1003 at 4:43-45; Fig. 6.

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 86-91), Petitioner has shown a reasonable likelihood of proving that each of claims 102-105 is obvious over Errico in view of Koshino or Campbell.

X. CONCLUSION

Claims 44-54 and 101-105 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,
Jones Day

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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 “SECOND 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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