

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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

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*Inter Partes* Review No.: IPR2016-00329

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**FIRST 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 1-5, 9-22, and 29-37 (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 44-54 and 101-105, 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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Petitioner consents to email service at: cpgriffith@jonesday.com and kluchesi@jonesday.com.

**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 1-5, 9-22, and 29-37 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:

<b>Ground</b>	<b>35 U.S.C.</b>	<b>Challenged ’008 Patent Claims</b>	<b>Basis for Rejection of Challenged Claims</b>
1	§ 103	1-5, 9-22, and 29-37	Errico in view of Koshino

Ground	35 U.S.C.	Challenged '008 Patent Claims	Basis for Rejection of Challenged Claims
2	§ 103	36-37	Errico in view of 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 1-5, 9-22, and 29-37 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**

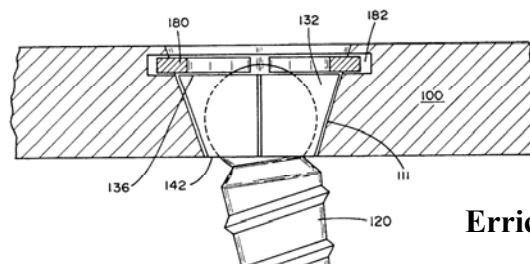
As detailed in the discussion and claim charts below, the prior art references identified below demonstrate that all of the limitations of claims 1-5, 9-22, and 29-37 of the '008 patent were known in the prior art at the time of invention. The inventions claimed in the '008 patent are “[t]he combination 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 1-5, 9-22, and 29-37 Of The '008 Patent Are Obvious Over Errico In View Of Koshino.**

#### **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

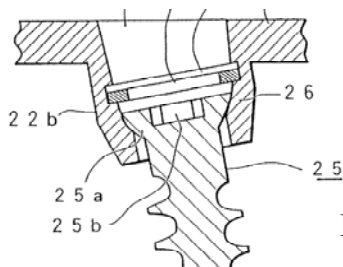
hole. *Id.* The bone screw (with coupling element on the head of the screw) is inserted through the hole in the plate until the coupling element engages and expands the snap-ring. *Id.* Once the coupling element and bone screw pass through the snap-ring, the snap-ring contracts to its undeflected position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

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). 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. 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, 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”).

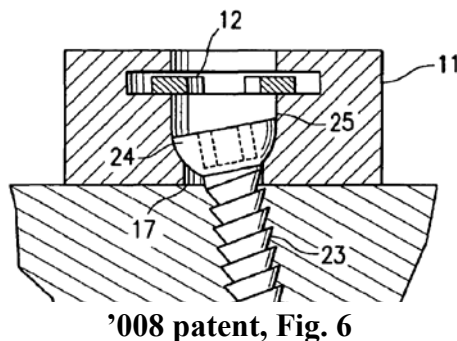
The only distinction that Patent Owner made with respect to Errico during the prosecution of the '008 patent related to Errico's use of a coupling element rather than an "integral" screw head. *E.g.*, Ex. 1002 at 122-23; 555. DePuy submits that these arguments should not have prevailed in the first instance. Moreover, they are certainly insufficient to overcome the combination of Koshino with Errico as presented herein because Koshino discloses the allegedly missing integral 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**

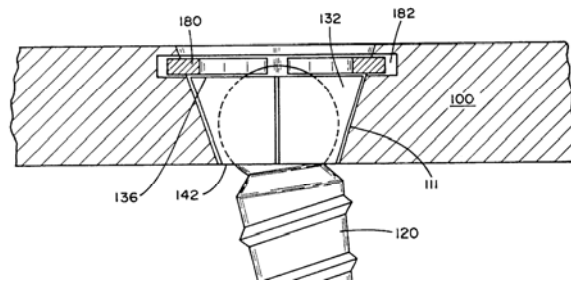
The challenged claims of the '008 patent and Errico are both directed to an orthopedic implant device (such as a plate) to be attached to human bone. Both describe attachment of the implant device to the bone by a separate securing device, most commonly a bone screw. Both disclose an implant device that 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:



'008 patent, Fig. 6



Errico, Fig. 6

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 ¶¶ 37-38.

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. Ferree Decl. at

¶ 39. There are many reasons for this, such as cost of manufacturing, inventory, ease of use, crevice corrosion, and simplicity of surgery. *Id.*

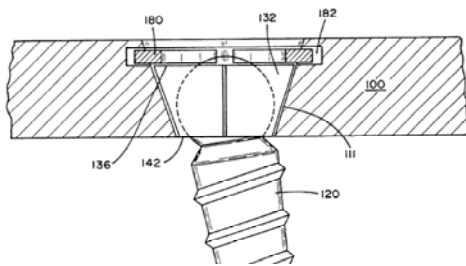
A POSA would have had a clinical reason to modify Errico as well. Bone plates of the type described in, for example, the '008 patent and Errico, are often placed very close to critical anatomy, such as the esophagus or major blood vessels. *Id.* at ¶ 41; *see also* Ex. 1003 at 2:39-3:6. For this reason, a POSA would understand that it is critical for the bone plate to have as thin a profile as possible. Ferree Decl. at ¶ 41. The coupling element in Errico, however, requires more space in the bore, and thus necessarily increases the profile (thickness) of the plate. *Id.* at ¶ 42.

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:

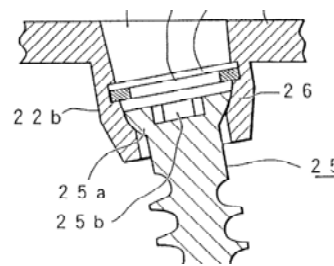
All of the foregoing prior art systems suffer from several undesirable drawbacks. First, the addition of intricately machined componentry makes most of these systems expensive and difficult to manufacture. Second, since some of these prior art systems rely on a threaded connection to maintain the bone 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 ¶ 43. 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 ¶ 44. 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 (*id.*):



**Errico, Fig. 6**



**Koshino, Fig. 6**

It would have been obvious to a POSA that the partially curved head of the Koshino bone screw could be used for the same purpose of expanding the stopping member of Errico without the need for an additional coupling element. *Id.* at ¶ 45. As can be seen above, the diameter of the Koshino screw head is 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, it would result in a screw head with a smaller anterior-to-posterior dimension. *Id.* ¶ 46. 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 ¶ 47. 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 ¶ 47. 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 ¶ 48.

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 same combination asserted here – 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 to accomplish these goals, as both references teach orthopedic implant assemblies to be attached to the bone with a bone screw. *Id.* at ¶ 49. More specifically, both Errico and Koshino expressly address 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”). 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 ¶ 50. In light of these same considerations, the most logical and predictable solution that a POSA would have pursued upon reviewing Errico and Koshino would be to remove the Errico coupling member and employ the screw head of Koshino with the Errico device. *Id.*<sup>1</sup>

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<sup>1</sup> 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-

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 are applicable to improving the orthopedic implant device disclosed in Errico. *Id.* at ¶ 51. Such a simple improvement — using the Koshino 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”).

### **3. Independent Claim 1 Of The ’008 Patent Is Obvious In View Of Errico And Koshino**

The combination of Errico and Koshino discloses all of the limitations of claim 1 of the ’008 patent. With respect to the preamble, Errico and Koshino both disclose an “orthopedic implant assembly.” Ex. 1003 at 1:15-16; Ex. 1004 at 1:5-

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(continued...)

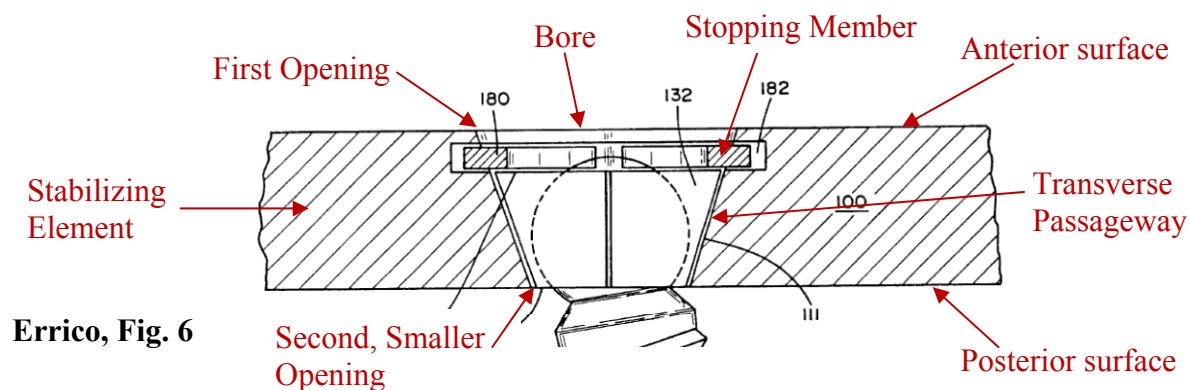
inserted, expandable c-ring configuration disclosed in Errico, with the same reasonable expectation of success. Ferree Decl. at ¶ 52. A POSA would have been motivated to make such a modification, for example, to eliminate the additional step required in Koshino of inserting the stopping member after the screw has been seated (thus simplifying the surgical procedure). *Id.*



13, 1:22-30.

**(a) Independent Claim 1, Element 1(a)**

With respect to claim element 1(a), Errico discloses a stabilizing element (a plate) that has an anterior (top) surface and a posterior (bottom) surface,<sup>2</sup> and at least one bore with a first opening in the anterior surface and a second, smaller opening in the posterior surface, and a transverse passageway extending between the openings. *See* Ex. 1003 at Abstract; *see also id.* at Fig. 6 (rotated 90° and annotated):



<sup>2</sup> 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.

<b>'008 Patent Claim</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
1a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;	<u>Errico</u> : “The plate 100 comprises upper and lower portions 102, 104 respectively, and a top surface 108 and a bottom surface.... 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 1, Element 1(b)**

With respect to claim element 1(b), Errico discloses a stopping member. *See above; see also id.* at 6:2-4. The stopping member of Errico includes a passageway (*see above; see also id.* at Fig. 3b) that is reversibly expandable and has a smaller diameter configuration and a larger diameter configuration. *Id.* at 6:10-12 (“The ring 180 can, however, be deflected inward or outward”).

<b>'008 Patent Claim</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
1b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and	<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) Independent Claim 1, Element 1(c)**

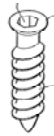
With respect to claim element 1(c), both Errico and Koshino disclose a securing element (bone screw) with an elongated body and an integral head at one

end of the screw:

**Errico,  
Fig. 4**



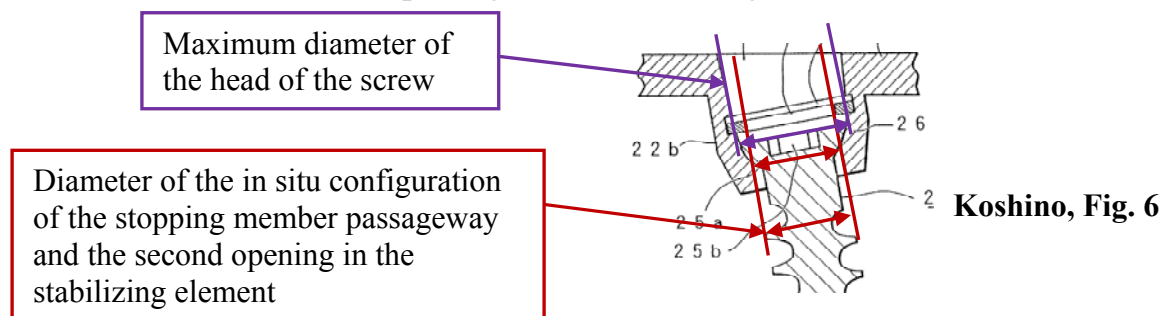
**Koshino,  
Fig. 3b**



Errico also discloses that the head of the screw is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element. *See id.* at Fig. 6, annotated above; *see also 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”). In this regard, while Figure 6 of Errico shows some portion of the head of the screw that is not within the transverse passageway, Figure 5 shows a coupling member wherein the entire head of the screw is retained within the coupling member. Because the coupling member of Errico is retained entirely within the transverse passageway, a POSA would understand that Figures 5 and 6 of Errico discloses this limitation. Ferree Decl. at ¶ 58. Koshino also discloses that the head of the screw is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element. *See Ex. 1004 at Fig. 6.*

With respect to the remainder of claim element 1(c), it would have been obvious for a POSA to use the head of the screw, as opposed to a separate coupling device, to perform the function of expanding the stopping member and/or preventing back-out of the screw for all of the reasons explained above (section IX.A.2). 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, 59; Ex. 1013. In modifying Errico in such a way, the diameter of the head of the screw would be (1) greater than the second opening in the stabilizing element (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 ¶ 60. These dimensional relationships are standard, and Koshino discloses a screw having a head with the required limitations. *Id.* The screw head in Koshino is designed specifically for the purpose of retaining the head of the screw within the longitudinal area defined by the stopping member and the smaller, posterior bore opening. *Id.* at ¶ 61. As can be seen in Figure 6 of Koshino, the 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. Ferree Decl. at ¶¶ 38-51. Such a combination would result in the same dimensional relationships described above. As such, the combination of Errico and Koshino discloses all of the limitations of claim 1(c) of the '008 patent.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
1c) a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.	<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 130 in it.” <i>Id.</i> at 6:26-27. <i>See also id.</i> at Fig. 5 and Fig. 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 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>

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 53-62), Petitioner has shown a reasonable likelihood of proving that claim 1 of

the '008 patent is obvious over Errico in view of Koshino.

**4. Dependent Claims 2-5, 9-20, And 29-35 Of The '008 Patent Are Obvious In View Of Errico And Koshino**

Claims 2-5, 9-20, and 29-35 all depend, directly or indirectly, from claim 1, which is discussed above and which discussion is incorporated into each of the following dependent claims.

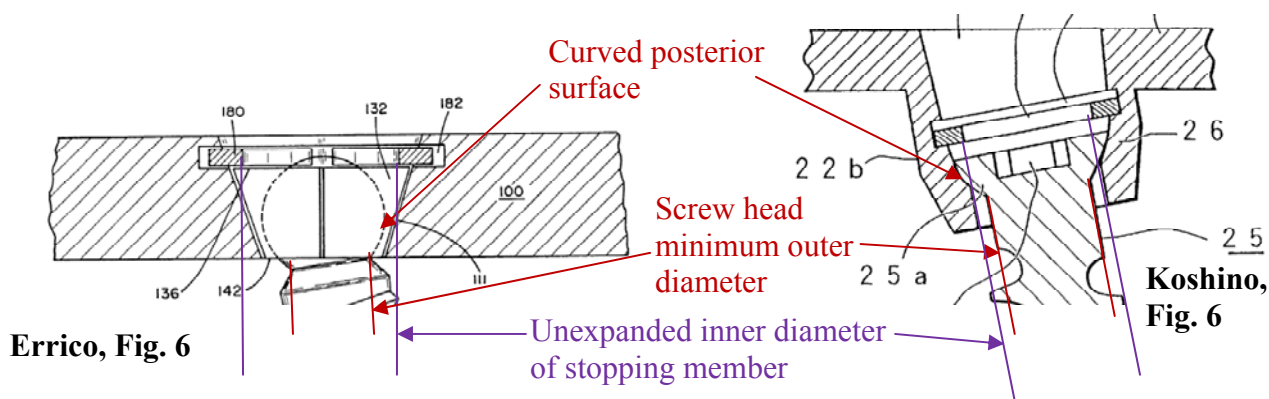
**(a) Dependent Claim 2**

Errico discloses a stopping member comprising a collar that defines a passageway that is enlargeable from an unexpanded inner diameter to an expanded inner diameter. Ex. 1003 at Fig. 6; 6:10-11. Errico also discloses the use of a separate coupling element around the head of the screw, such that the screw head and coupling element together have a maximum diameter that is greater than the unexpanded inner diameter of the stopping member, yet smaller than the expanded inner diameter of the stopping member. *See, e.g., id.* at 7:41-51. Koshino discloses a securing member (bone screw) wherein the integral head of the screw has a maximum diameter greater than the unexpanded inner diameter of the stopping member. Ex. 1004 at Fig. 6; 13:15-19. As explained above, it would have been obvious for a POSA to configure the Errico device with the screw head of Koshino, rather than using a separate coupling element, thus resulting in a device with all of the limitations of claim 2. Ferree Decl. at ¶¶ 38-51; 65-66.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
2. The assembly of claim 1 wherein the biased stopping member comprises a collar defining a passageway, enlargeable from an unexpanded inner diameter to an expanded inner diameter, wherein the head of the securing element has a maximum diameter greater than the unexpanded inner diameter of the collar and less than the expanded inner diameter of the collar.	<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; <i>see also</i>, Figs. 3b, 6; <i>see also id.</i> at 7:41-51.</p> <p><u>Koshino</u>: “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. 1004 at 13:15-19; <i>see also id.</i> at Fig. 6.</p>

### (b) Dependent Claim 3

Errico and Koshino each disclose a screw that has a head with a curved posterior surface that has a minimum outer diameter that is smaller than the unexpanded inner diameter of the stopping member:

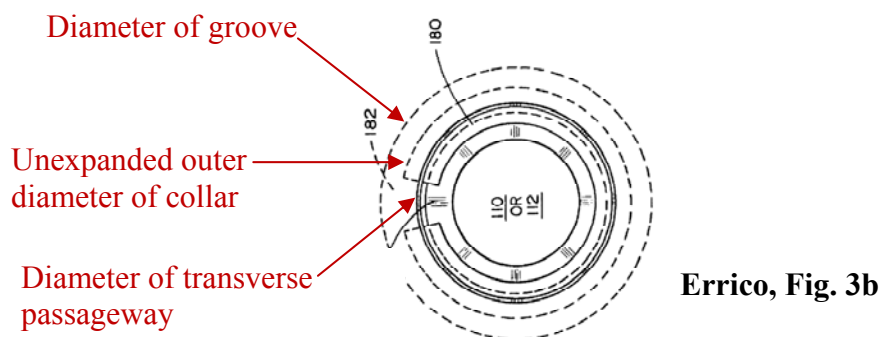


'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
3. The assembly of claim 2 wherein the head of the securing element has a curved posterior surface which has a minimum	<u>Errico</u> : “During the implantation procedure, the screw 120 and the coupling element 132 are inserted through the hole. Once the bottom 142 of the coupling element 132,

outer diameter smaller than the unexpanded inner diameter of the collar, configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof.	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.” Ex. 1003 at 7:41-51; <i>see also id.</i> at Figs 4 and 6. <u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6.
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### (c) Dependent Claim 4

Errico discloses a groove in an anterior portion of the transverse passageway. Ex. 1003 at Fig. 6; 6:1-2. Errico also discloses an annular collar that is reversibly expandable (*id.* at 6:2-12), and that has an unexpanded outer diameter which is less than the diameter of the groove and greater than a diameter of the transverse passageway. *See id.* at Fig. 3b:



Errico, Fig. 3b

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
4. The assembly of claim 2 wherein the bore has a groove in an anterior portion of the transverse passageway having a diameter and a height, and	<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. The undeflected outer diameter of the snap-ring



wherein the collar is a reversibly expandable annular collar seated in the groove, the collar having an expanded outer diameter, and an unexpanded outer diameter which is less than the diameter of the groove and greater than a diameter of the transverse passageway.	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.
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**(d) Dependent Claim 5**

Errico discloses a securing element wherein the head of the screw has a curved posterior surface and which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar. *See id.* at Fig. 6. Errico also discloses that the head of the screw is configured with a separate collar that is designed to contact the stopping member anterior surface and expand the stopping member as the head of the screw is displaced posteriorly through the passageway. *Id.* at 4:62-64; 7:41-47; Fig. 6. Although Errico does not expressly disclose using the head of the screw itself to expand the stopping member, for all of the reasons described above, it would have been obvious to configure the Errico device with the screw head of Koshino, 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 stopping member. Ex. 1004 at Fig. 6; Ferree Decl. at ¶ 70. When so configured, the screw would pass through the opening of the stopping member, and the head of

the screw would contact the anterior surface of the stopping member, thus causing it to expand, as required by Claim 5.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
5. The assembly of claim 4 wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, and which is configured to contact the collar anterior surface and expand the collar as the head is displaced posteriorly through the collar passageway.	<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. <u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6.

### (e) Dependent Claim 9

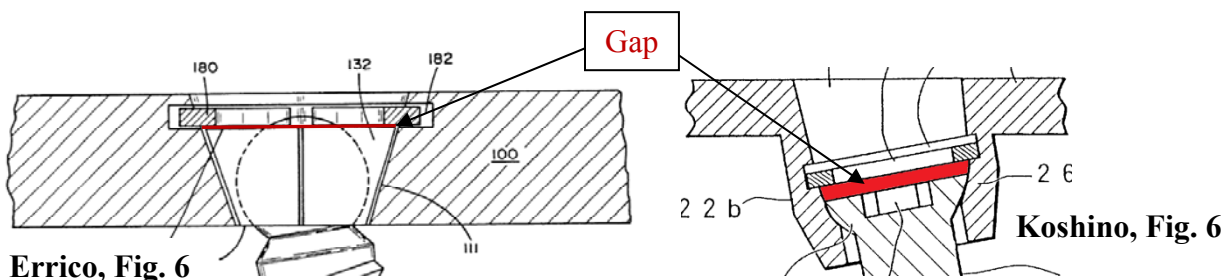
Koshino discloses a posterior portion of the transverse passageway that is curved to conform to the curved posterior surface of the head of the screw. Ex. 1004 at Figs 2, 6. It would have been obvious for a POSA to employ this configuration to the Errico device. Ferree Decl. at ¶ 72. This is especially 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 member. *Id.*; Ex. 1003 at 6:62-67.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
9. The assembly of claim 3 wherein a posterior portion of the	<u>Errico</u> : “The coupling element 132 comprises a tapered cylindrical socket

transverse passageway is curved to conform to the curved posterior surface of the head.	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. <u>Koshino</u> : See Ex. 1004 at Fig. 6.
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**(f) Dependent Claim 10**

As can be seen in Figure 6 of both Errico and Koshino, the devices include a gap between the posterior surface of the stopping member and the head of the screw/coupling member (colored in red), thus allowing the head of the screw to be longitudinally displaceable between a posterior surface of the stopping member and the second opening in 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 ¶ 73. 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 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; *see also* Ferree Decl. at ¶ 74. 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 ¶ 74.

'008 Patent Claim	Errico (Ex. 1003) and Koshino (Ex. 1004)
10. The assembly of claim 1 wherein the head of the securing element is longitudinally displaceable within the transverse passageway between a posterior surface of the biased stopping member and the second opening in the posterior surface of the stabilizing element.	<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. 4-6.</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; Fig. 6.</p>

### (g) Dependent Claims 11-16

With respect to claim 11, as shown in Figure 6 of Errico, the body of the securing element (bone screw) has a diameter smaller than the second opening in the stabilizing element (thus allowing the body of the screw to pass through and

attach to the bone), and the screw is angularly displaced. Ex. 1003 at Fig. 6; *see also id.* at 6:49-57; *see also* Ex. 1004 at Fig. 6. With respect to claim 12, Errico discloses a stabilizing element with at least two bores. Ex. 1003 at 5:61-65. With respect to claims 13 and 14, Errico discloses a stabilizing element that is configured to conform to and extend between at least two bone segments, and that has a curved surface. *Id.* at 5:55-58. With respect to claim 15, Errico discloses a stabilizing element that is a bone plate. *Id.* at 5:43-44. With respect to claim 16, Errico discloses a securing element that is a screw. *Id.* at 6:13-16.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004)
11. The assembly of claim 10 wherein the body of the securing element has a diameter smaller than the second opening in the stabilizing element, and the securing element may be angularly displaced within the transverse passageway and the second opening in the stabilizing element.	<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. <u>Koshino</u> : <i>See</i> ex. 1004 at Fig. 6.
12. The assembly of claim 1 wherein the stabilizing element 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.
13. The assembly of claim 1 wherein the stabilizing element is	<u>Errico</u> : “A slight curvature may be imparted to the plate 100 so that it may grossly

<b>'008 Patent Claims</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
configured to conform to and extend between at least two bone segments.	conform to the cylindrical morphology of the bones (i.e., vertebral bodies) which it couples.” Ex. 1003 at 5:55-58.
14. The assembly of claim 13 wherein the stabilizing element has a curved surface.	<u>Errico</u> : “A slight curvature may be imparted to the plate 100...” Ex. 1003 at 5:55-56.
15. The assembly of claim 1 wherein the stabilizing element 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.
16. The assembly of claim 1 wherein the securing element 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.

#### **(h) Dependent Claims 17-18**

With respect to claims 17 and 18, Errico discloses that the coupling device is formed of an elastically deformable material. *E.g.*, Ex. 1003 at 4:64-67. Further, with respect to claim 18, Errico also discloses that the plate may be formed of titanium, and explains that a particular titanium material has enhanced fatigue endurance. *Id.* at 5:41-52. To the extent that Errico does not expressly disclose the use of titanium for the stopping member, 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). Here, given that the stopping member 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 material for the stopping member as well. Ferree Decl at ¶ 77. Indeed, during the prosecution of the '008 patent, the Examiner came to the same conclusion (Ex. 1002 at 83-84; 339), and Patent Owner 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).<sup>3</sup>

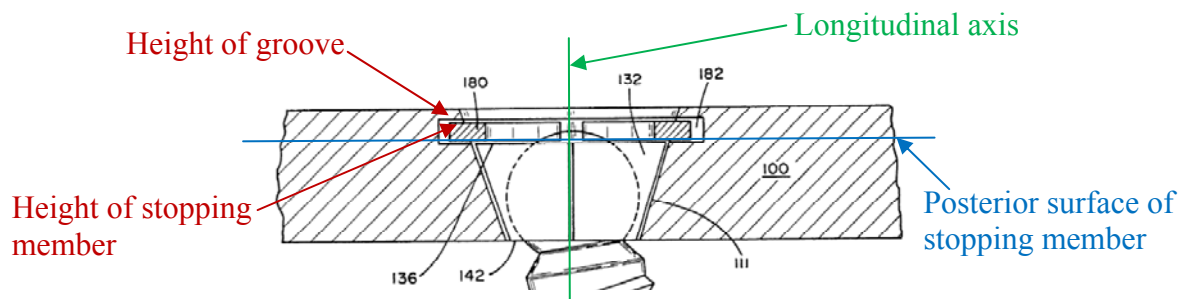
'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004)
17. The assembly of claim 2 wherein the collar is formed of an elastically deformable material.	<u>Errico</u> : “Once the coupling element 132 is fully seated in the hole 110, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 and snaps back to its undeflected state.” Ex. 1003 at 7:47-51; “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.
18. The assembly of claim 2 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.

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

### (i) Dependent Claims 19-20 and 29

With respect to claim 19, 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 transverse passageway (green line). As also shown below, with respect to claim 20 (and claim 29, which is identical to claim 20), the stopping member has a height less than the height of the groove:



'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004)
19. The assembly of claim 2 wherein the collar has a posterior surface perpendicular to a longitudinal axis of the transverse passageway.	<u>Errico</u> : See Ex. 1003 at Fig. 6.
20/29. The assembly of claim 4 wherein the collar has a height less than the height of the groove.	<u>Errico</u> : See Ex. 1003 at Fig. 6.

### (j) Dependent Claims 30-35

As shown in the table below, claims 30, 31, 32, 34, and 35 include limitations that are identical to, or substantially the same as, those found in claims 11, 15, 16, 12, and 13, respectively:

Claims 30, 31, 32, 34, and 35	Claims 11, 15, 16, 12, and 13
30. The assembly of claim 10 wherein the body of the securing element has a	11. The assembly of claim 10 wherein the body of the securing element has a



transverse dimension smaller than the second opening of the stabilizing element, and wherein the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element.	diameter smaller than the second opening in the stabilizing element, and the securing element may be angularly displaced within the transverse passageway and the second opening in the stabilizing element.
31. The assembly of claim 10 wherein the stabilizing element is selected from the group consisting of rods and plates.	15. The assembly of claim 1 wherein the stabilizing element is selected from the group consisting of rods and plates.
32. The assembly of claim 10 wherein the securing element is selected from the group consisting of screws and nails.	16. The assembly of claim 1 wherein the securing element is selected from the group consisting of screws and nails
34. The assembly of claim 1 wherein the stabilizing element includes at least two bores.	12. The assembly of claim 1 wherein the stabilizing element includes at least two bores.
35. The assembly of claim 1 wherein the stabilizing element is configured to conform to and extend between at least two bone segments.	13. The assembly of claim 1 wherein the stabilizing element is configured to conform to and extend between at least two bone segments.

Accordingly, for all of the reasons discussed above with respect to claims 11-13 and 15-16 in section IX.A.4.(g) above, Errico discloses all of the limitations of claims 30-32 and 34-35. With respect to claim 33, Errico discloses a bone plate wherein the bottom, or posterior, surface is concave. Ex. 1003 at 5:55-60.

<b>'008 Patent Claim</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
33. The assembly of claim 13 wherein the stabilizing element has a concave posterior surface.	<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.

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 63-80), Petitioner has shown a reasonable likelihood of proving that each of claims 2-5, 9-20, and 29-35 of the '008 patent is obvious over Errico in view of Koshino.

**5. Claims 21 and 22 Of The '008 Patent Are Obvious In View Of Errico And Koshino**

Claim 21 is a method claim, and is directed to a method of using the claimed orthopedic implant assembly.

**(a) Independent Claim 21, Elements 21(a)-(c)**

As shown in the table below, claim elements 21(a)-(c) are generally directed to method steps using the orthopedic implant assembly defined by the combination of claims 1, 2, and 5:

<b>Claim Elements 21(a)-(c)</b>	<b>Claims 1, 2, and 5</b>
21a) positioning a stabilizing element against a surface of the patient's bone, the stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening, and a biased stopping member within the bore and defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration;	1a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;  1b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and
21b) providing a securing element	1c) a securing element having an

having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element;	elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.
21c) positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within the passageway defined by the biased stopping member and thereby displacing the biased stopping member to form the larger diameter configuration passageway defined thereby; and	<p>2. The assembly of claim 1 wherein the biased stopping member comprises a collar defining a passageway . . .</p> <p>5. The assembly of claim 4 wherein the head of the securing element . . . is configured to contact the collar anterior surface and expand the collar as the head is displaced posteriorly through the collar passageway</p>

Accordingly, for all of the same reasons discussed above with respect to claim 1 (section IX.A.3), claim 2 (section IX.A.4.(a)), and claim 5 (section IX.A.4.(d)), as well as the citations relating to claim 21(a)-(c) in the claim chart below, the combination of Errico and Koshino discloses all of the limitations of claim elements 21(a)-(c).

<b>'008 Patent Claims</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
21a) positioning a stabilizing element against a surface of the patient's bone, the stabilizing element having an anterior surface, a posterior surface, and at	<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

<p>least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening, and a biased stopping member within the bore and defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration;</p>	<p>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.</p> <p>“The first step in the process of implanting this invention is to position the plate against the vertebral bodies and to align the entry points for the screws.” <i>Id.</i> at 4:51-53;</p> <p>“Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180... The ring 180 can, however, be deflected inward or outward ....” <i>Id.</i> at 6:2-12. <i>See also id.</i> at Fig. 6.</p>
<p>21b) providing a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element;</p>	<p><u>Errico</u>: “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.” Ex. 1003 at 4:55-62; “The screw 120 comprises a head portion 122, a neck 124, and a shaft 126.” <i>Id.</i> at 6:16-17; 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. <i>See also id.</i> at Fig. 5 (showing a coupling member that completely encompasses the head of the screw) and Fig. 6 (showing a coupling member completely retained within the transverse passageway).</p> <p><u>Koshino</u>: “Into the through hole unit, a fixation screw is inserted for mounting the medical substituting element to hard tissues.” Ex. 1004 at 6:3-4; “As the fixation screw inserted into the through hole unit continues to be threaded into the hard tissues, the screw</p>

	<p>stopper and the head of the fixation screw abut against each other to restrict the threading of the fixation screw.” <i>Id.</i> at 6:11-14. “The fixation screw 6 is a right-handed screw as described above, and has a flat head as shown in FIG 3(b).” <i>Id.</i> at 11:30-31; Fig 3b; “Particular examples of the slip-off prevention member to be enumerated are ... a ring stopper ....” <i>Id.</i> at 6:30-34; “The stopper ring shown in FIG. 5 has a holding unit 20a at each end of a cut-portion of a C-shaped concentric stopper ring .... Therefore, the diameter of the stopper ring 20 can be made smaller easily.” <i>Id.</i> at 12:25-33; Fig. 5.</p>
<p>21c) positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within the passageway defined by the biased stopping member and thereby displacing the biased stopping member to form the larger diameter configuration passageway defined thereby; and</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; Fig. 6.</p>

**(b) Independent Claim 21, Element 21(d)**

Errico discloses a method of attaching a stabilizing element to the bone by advancing the securing element (and thus its head) posteriorly of the stopping member. Ex. 1003 at 4:51-5:2. Once the head of the screw passes through the passageway defined by the stopping member, the passageway returns to its smaller

diameter configuration, thus retaining the head of the screw within the posterior section of the transverse passageway of the stabilizing element and attaching the stabilizing element to the bone. *Id.*; *see also id.* at 7:47-55 and Figs. 5-6.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004)
<p>21d) attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the biased stopping member so that the passageway defined thereby returns to the smaller diameter configuration, to position the head within a posterior section of the transverse passageway between the biased stopping member and the second opening in the stabilizing element, and to position the body of the securing element within the patient's bone, so that the securing element is attached to the bone and is retained within the posterior section of the transverse passageway of the stabilizing element.</p>	<p><u>Errico</u>: “The first step in the process of implanting this invention is to position the plate against the vertebral bodies and to align the entry points for the screws. 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. Once the screw has been inserted into the bone, at the desired angle, the coupling element, via its rotationally free mating of the socket to the inserted screw, is realigned so that it seats into the hole. 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 ...).” Ex. 1003 at 4:51–5:2.</p> <p>“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</p>

	element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” <i>Id.</i> at 7:47-55; <i>see also id.</i> at Figs. 5 and 6.
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**(c) Dependent Claim 22**

Claim 22 depends from claim 21 and adds the additional step of inserting the screw at an angle relative to the surface of the bone. Errico and Koshino both disclose inserting the screw at a variety of different angles relative to the surface of the bone. Ex. 1003 at 6:49-57; *see also id.* at Fig. 6; *see also* Ex. 1004 at Fig. 6. Given the dimensional relationship between the screw head and the bore shown in Figure 6 of Koshino (*e.g.*, gaps between the top of the screw head and the stopping member, and between the screw shaft and the posterior opening of the bore), it would have been obvious to a POSA that the screw head of Koshino could be inserted at a variety of different angles relative to the longitudinal axis of the bore. Ferree Decl. at ¶ 84.

<b>'008 Patent Claims</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
22. The method of claim 21 including, after the head of the securing element is positioned between the biased stopping member and the second opening in the stabilizing element, the step of longitudinally and angularly displacing the head of the securing element within the transverse passageway, so that the body of the securing element is positioned at an angle within the	<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.

<b>'008 Patent Claims</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
patient's bone relative to the surface of the bone.	<u>Koshino</u> : See Ex. 1004 at Fig. 6.

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 81-84), Petitioner has shown a reasonable likelihood of proving that each of claims 21 and 22 is obvious over Errico in view of Koshino.

## **6. Claims 36 and 37 Of The '008 Patent Are Obvious In View Of Errico And Koshino**

Similar to claim 21 above, claim 36 is a method claim directed to a method of using the claimed orthopedic implant assembly.

### **(a) Independent Claim 36, Element 36(a)**

As shown in the table below, claim element 36(a) is generally directed to the orthopedic implant assembly defined by the combination of Claims 1-2:

<b>Claim Element 36(a)</b>	<b>Claims 1-2</b>
a) providing a securing member with an elongated body and an enlarged integral portion having a maximum transverse dimension,	1c) a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter . . .
an attachment member which has an anterior surface and a posterior surface and which has at least one bore extending through the attachment member from the anterior surface to the posterior surface and is configured to receive the securing member, the bore having an anterior bore portion, and a posterior bore portion with at least one transverse dimension smaller than a transverse dimension of the	<p>1a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;</p> <p>1c) a securing element . . . , the head having a maximum diameter . . . greater than the second opening in the stabilizing</p>



anterior bore portion and smaller than the maximum transverse dimension of the enlarged integral portion of the securing member, and	element . . .
a stopping member which has a first configuration which allows passage of the enlarged integral portion of the securing member and has a second configuration that reduces a transverse dimension of the bore that is smaller than the maximum transverse dimension of the enlarged integral portion of the securing member in order to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member wherein the stopping member has an anterior surface and a posterior surface;	<p>1b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and</p> <p>2. The assembly of claim 1 wherein the biased stopping member comprises a collar defining a passageway, enlargeable from an unexpanded inner diameter to an expanded inner diameter, wherein the head of the securing element has a maximum diameter greater than the unexpanded inner diameter of the collar and less than the expanded inner diameter of the collar.</p> <p>1c) a securing element . . . , the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member . . . so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.</p>

Accordingly, for all of the same reasons discussed above with respect to claim 1 (section IX.A.3) and claim 2 (section IX.A.4.(a)), as well as the citations relating to claim 36(a) in the claim chart below, the combination of Errico and Koshino discloses all of the limitations of Claim 36(a), with one exception. Claim 36(a) adds the additional limitation that the stopping member has an anterior

surface and a posterior surface. Figure 6 of Errico plainly discloses a stopping member with an anterior surface and a posterior surface. Ex. 1003 at Fig. 6.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004)
36a) providing a securing member with an elongated body and an enlarged integral portion having a maximum 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; Fig. 4.
an attachment member which has an anterior surface and a posterior surface and which has at least one bore extending through the attachment member from the anterior surface to the posterior surface and is configured to receive the securing member, the bore having an anterior bore portion, and a posterior bore portion with at least one transverse dimension smaller than a transverse dimension of the anterior bore portion and smaller than the maximum transverse dimension of the enlarged integral portion of the securing member, and	<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.
a stopping member which has a first configuration which allows passage of the enlarged integral portion of the securing member and has a second configuration that reduces a transverse dimension of the bore that is smaller than the maximum transverse dimension of the enlarged integral portion of the securing member in order to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member wherein the	<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; “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel.” <i>Id.</i> at 4:62-64; Fig. 6; “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

stopping member has an anterior surface and a posterior surface;	the coupling element from backing out by interference.” <i>Id.</i> at 4:64–5:2. <u>Koshino</u> : “Particular examples of the slip-off prevention member to be enumerated are ... a ring stopper ....” Ex. 1004 at 6:30-34; “The stopper ring shown in FIG. 5 has a holding unit 20a at each end of a cut-portion of a C-shaped concentric stopper ring .... Therefore, the diameter of the stopper ring 20 can be made smaller easily.” <i>Id.</i> at 12:25-33; Fig. 5; Fig 6.
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**(b) Independent Claim 36, Elements 36(b)-(c)**

With respect to claim element 36(b), Errico discloses positioning the attachment member with at least part of the posterior surface against a surface of the patient’s bone. *See* Ex. 1003 at 4:51-53 and 5:55-60. With respect to claim element 36(c), Errico discloses attaching a bone screw to the bone wherein the screw is advanced through the bore of the bone plate; as the head of the screw passes through the stopping member, the stopping member is displaced to a larger-diameter configuration allowing the head of the screw to pass through; once the head of the screw is disposed in the posterior portion, the stopping member returns to its smaller-diameter configuration, thus retaining the head of the screw in the posterior bore portion below the posterior portion of the stopping member. *See* Ex. 1003 at 4:51-5:2, 7:41-55, and Figs. 5-6. Additionally, although claim 36 does not explicitly require the head of the screw itself to expand the stopping member as the screw passes through, for all of the reasons describe above (section IX.A.2), it

would have been obvious to a POSA to employ the screw head configuration of Koshino to the implant assembly of Errico. Ferree Decl. at ¶¶ 38-52, 89.

'008 Patent Claims	Errico (Ex. 1003) and Koshino (Ex. 1004)
36b) positioning the attachment member with at least part of the posterior surface thereof against a surface of the patient's bone; and	<u>Errico</u> : "The first step in the process of implanting this invention is to position the plate against the vertebral bodies and to align the entry points for the screws." Ex. 1003 at 4:51-53; <i>see also id.</i> at 5:55-60.
36c) attaching the securing member to the patient's bone by advancing the securing member within the bore of the attachment member until the enlarged integral portion of the securing member passes the stopping member thereby displacing the stopping member to the first configuration and is disposed in the posterior bore portion, the stopping member then returning to the second configuration to retain the enlarged integral portion within the posterior bore portion; and wherein the enlarged integral portion of the securing member is retained within the posterior bore portion below the posterior surface of the stopping member.	<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. 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 7:41-55; <i>see also id.</i> at Figs. 5-6.</p> <p><u>Koshino</u>: "Into the through hole unit, a fixation screw is inserted for mounting the medical substituting element to hard tissues." Ex. 1004 at 6:3-4; "As the fixation screw inserted into the through hole unit continues to be threaded into the hard tissues, the screw stopper and the head of the fixation screw abut against each other to restrict the</p>

	<p>threading of the fixation screw.” <i>Id.</i> at 6:11-14; “Particular examples of the slip-off prevention member to be enumerated are ... a ring stopper ....” <i>Id.</i> at 6:30-34; “The stopper ring shown in FIG. 5 has a holding unit 20a at each end of a cut-portion of a C-shaped concentric stopper ring .... Therefore, the diameter of the stopper ring 20 can be made smaller easily.” <i>Id.</i> at 12:25-33; “In this state, the stopper ring 20 is inserted into the through hole unit 23 and fitted into the groove 24. With the stopper ring 20 being fitted into the groove 24, a slip-out prevention of the fixation screw 25 is ensured.” <i>Id.</i> at 13:7-11; Fig. 5; Fig 6.</p>
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The primary difference between the assembly described in claim 21 (and claim 1) and that described in claim 36 (and claim 37) is that claims 1 and 21 require the entire head of the screw to be retained within the transverse passageway, whereas claims 36 and 37 require only that the “enlarged integral portion” of the screw be retained within the transverse passageway. This difference is inconsequential for purposes of this ground because both Errico and Koshino disclose that both the “enlarged integral portion,” as well as the entirety of the head of the screw, are retained within the transverse passageway. *See, e.g.*, Ex. 1003 at Fig. 5 (showing a coupling member that completely encompasses the head of the screw) and Fig. 6 (showing a coupling member completely retained within the transverse passageway); and Ex. 1004 at Fig. 6.

**(c) Dependent Claim 37**

Claim 37 depends from claim 36 and adds the additional step of inserting the screw at an angle relative to the longitudinal axis of the bore. Errico and Koshino both disclose inserting the screw at a variety of different angles relative to the longitudinal axis of the bore. Ex. 1003 at 6:49-57; *see also id.* at Fig. 6; *see also* Ex. 1004 at Fig. 6; *see also* Ferree Decl. at ¶ 92.

<b>'008 Patent Claims</b>	<b>Errico (Ex. 1003) and Koshino (Ex. 1004)</b>
37. The method of claim 36 wherein the securing member is angularly displaceable within the posterior bore portion so that the securing member may be secured within the patient's bone at an angle relative to a longitudinal axis of the bore.	<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. <u>Koshino</u> : <i>See</i> Ex. 1004 at Fig. 6.

For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 85-92), Petitioner has shown a reasonable likelihood of proving that each of claims 36 and 37 is obvious over Errico in view of Koshino.

**B. Ground 2: Claims 36 and 37 Of The '008 Patent Are Obvious Over Errico In View Of Campbell**

As noted above, the primary difference between the assembly described in independent claim 1 (and its dependent claims) and that described in claim 36 (and claim 37) is that claim 1 requires the entire head of the screw to be retained within

the transverse passageway, whereas claims 36 and 37 require only that the “enlarged integral portion” of the screw be retained within the transverse passageway. Ground 2 asserts Campbell as an additional secondary reference for claims 36 and 37 because, although Campbell primarily discloses a screw where only a portion of the head is retained within the transverse passageway, Campbell discloses that the “enlarged integral portion” of the screw head is retained within the transverse passageway (*e.g.*, Ex. 1005 at Fig. 22).

### **1. Summary of Prior Art**

The disclosure of Errico is described above in section IX.A.1. 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. 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.

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 555). A discussion of the Patent Office's use of Errico, and Patent Owner's attempt to distinguish Errico, is included above in Section IX.A.1. Campbell was also of record during prosecution of the '008 patent, and was also used to reject certain claims in an Office Action dated December 7, 2009. Importantly, although Errico and Campbell were both before the Examiner, the Examiner never considered Errico in combination with Campbell. As explained below, it would have been obvious to a POSA, in light of Campbell, to modify the invention of Errico to reach 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*, IPR2014-00899, Paper No. 8 at 22-23.

**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 Campbell**

The reasons why a POSA would have been motivated to combine the teachings of Errico and Koshino are described above in section IX.A.2. These same reasons are equally applicable to the combination of Errico and Campbell. Ferree Decl. at ¶ 95. A POSA would have reason to combine the teachings of Errico with Campbell to accomplish the goals described above (*e.g.*, reducing the



number of components of the implant and reducing the profile of the bone plate), as both references teach orthopedic implant assemblies to be attached to the bone with a bone screw. *Id.* at ¶ 96. A POSA would readily recognize that the first and most logical way to achieve the stated improvements would be to remove the coupling device from the Errico invention and to implement the configuration of the screw head disclosed in Campbell. *Id.* at ¶ 97. First, it would have been obvious to a POSA that the partially curved head of the Campbell bone screw (*see* Ex. 1005 at Fig. 22) could be used for the same purpose of expanding the stopping member without the need for an additional coupling device component. Ferree Decl. at ¶ 98. Further, not only would such a modification reduce the number of components of the implant, but by removing the coupling member and employing a hemi-spherical screw head, such as that shown in Campbell, it would achieve the additional improvement of reducing the profile of the bone plate, thus causing less potential for interference with nearby, critical anatomical structures. *Id.* at ¶ 99.

More specifically, both Errico and Campbell are directed to cervical bone plates to be used in spinal surgery; and, as with Koshino and Errico, Campbell expressly addresses the same primary problem — the prevention of the bone screw backing out of the implant assembly after implantation. 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...”). For all of the above reasons, as well as those described above with respect to the combination of Errico and Koshino, a POSA would have understood that the teachings of Campbell are applicable to improving the orthopedic implant device disclosed in Errico. Ferree Decl. at ¶¶ 95-101.

### **3. Claims 36 and 37 Of The '008 Patent Are Obvious In View Of Errico And Campbell**

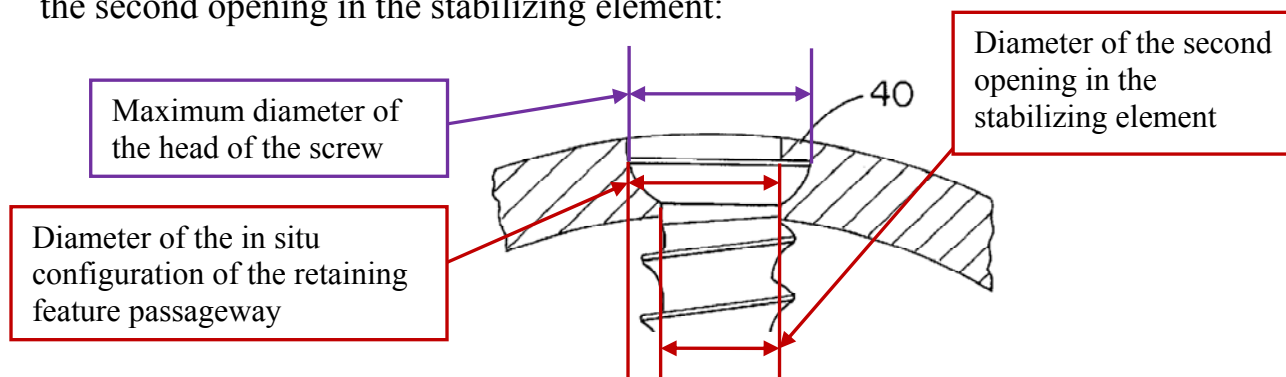
Claim 36 is a method claim directed to a method of using the claimed orthopedic implant assembly.

#### **(a) Independent Claim 36, Element 36(a)**

As shown above in Section IX.A.6(a), claim element 36(a) is generally directed to the orthopedic implant assembly defined by the combination of claims 1-2. For all of the same reasons discussed in Sections IX.A.3 and IX.A.4(a) above with respect to claims 1-2, as well as the citations relating to claim 36(a) in the claim chart below, the combination of Errico and Campbell discloses all of the limitations of claim 36(a), with one exception. Claim 36(a) adds the additional limitation that the stopping member has an anterior surface and a posterior surface. Figure 6 of Errico plainly discloses a stopping member with an anterior surface and a posterior surface. Ex. 1003 at Fig. 6.

Although the discussion above relating to claims 1-2 addresses the combination of Errico and Koshino, the same arguments and analysis are applicable to the combination of Errico and Campbell. For example, as with

Koshino, Campbell discloses a screw having a head with the required limitations. The screw head in Campbell is designed specifically for the purpose of retaining the enlarged integral portion of the head of the screw within the longitudinal area defined by the retaining feature and the smaller, posterior bore opening. As can be seen in Figure 22 of Campbell, the diameter of the head of the screw is greater than both the smaller configuration passageway defined by the retaining feature 40, and the second opening in the stabilizing element:



Similarly, Campbell discloses a securing member (bone screw) wherein the enlarged integral portion of the head of the screw has a maximum diameter greater than the opening defined by the retaining feature. 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 Campbell, rather than using a separate coupling element. Ferree Decl. at ¶¶ 38-52.

'008 Patent Claims	Errico (Ex. 1003) and Campbell (Ex. 1005)
36a) providing a securing member with an elongated body and an enlarged integral portion having a maximum 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; Fig. 4.

<p>an attachment member which has an anterior surface and a posterior surface and which has at least one bore extending through the attachment member from the anterior surface to the posterior surface and is configured to receive the securing member, the bore having an anterior bore portion, and a posterior bore portion with at least one transverse dimension smaller than a transverse dimension of the anterior bore portion and smaller than the maximum transverse dimension of the enlarged integral portion of the securing member, and</p>	<p><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.</p>
<p>a stopping member which has a first configuration which allows passage of the enlarged integral portion of the securing member and has a second configuration that reduces a transverse dimension of the bore that is smaller than the maximum transverse dimension of the enlarged integral portion of the securing member in order to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member wherein the stopping member has an anterior surface and a posterior surface;</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; “As the tapered surface of the coupling element advances, the retaining ring spreads apart, expanding into the annular recessed channel.” <i>Id.</i> at 4:62-64; Fig. 6; “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.” <i>Id.</i> at 4:64 – 5:2.</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</p>

	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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**(b) Independent Claim 36, Elements 36(b)-(c)**

With respect to claim element 36(b), Errico discloses positioning the attachment member with at least part of the posterior surface against a surface of the patient’s bone. *See* Ex. 1003 at 4:51-53 and 5:55-60. With respect to claim element 36(c), Errico discloses attaching a bone screw to the bone wherein the screw is advanced through the bore of the bone plate; as the head of the screw passes through the stopping member, the stopping member is displaced to a larger-diameter configuration allowing the head of the screw to pass through; once the head of the screw is disposed in the posterior portion, the stopping member returns to its smaller-diameter configuration, thus retaining the head of the screw in the posterior bore portion below the posterior portion of the stopping member. *See* Ex. 1003 at 4:51-5:2, 7:41-55, and Figs. 5-6. Additionally, although claim 36 does not explicitly require the head of the screw itself to expand the stopping member as the screw passes through, for all of the reasons described immediately above, as well

as those described above in section IX.A.2, it would have been obvious to a POSA to employ the screw head configuration of Campbell to the implant assembly of Errico, which would necessarily expand the stopping member as the screw passes through. Ferree Decl. at ¶ 109.

'008 Patent Claims	Errico (Ex. 1003) and Campbell (Ex. 1005)
36b) positioning the attachment member with at least part of the posterior surface thereof against a surface of the patient's bone; and	<u>Errico</u> : "The first step in the process of implanting this invention is to position the plate against the vertebral bodies and to align the entry points for the screws." Ex. 1003 at 4:51-53; <i>see also id.</i> at 5:55-60.
36c) attaching the securing member to the patient's bone by advancing the securing member within the bore of the attachment member until the enlarged integral portion of the securing member passes the stopping member thereby displacing the stopping member to the first configuration and is disposed in the posterior bore portion, the stopping member then returning to the second configuration to retain the enlarged integral portion within the posterior bore portion; and wherein the enlarged integral portion of the securing member is retained within the posterior bore portion below the posterior surface of the stopping member.	<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. 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 7:41-55; <i>see also id.</i> at Figs. 5-6.</p> <p><u>Campbell</u>: "After the openings are drilled and tapped, cervical plate 22 is placed with posterior surface 28 in contact with the vertebrae. Fasteners 24a-24d are secured within their respective apertures 30a-30d, turned inwardly or in the posterior direction</p>

	<p>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.... 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.” <i>Id.</i> Ex. 1005 at 6:40-65; Figs. 20; 22.</p>
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**(c) Dependent Claim 37**

Claim 37 depends from claim 36 and adds the additional step of inserting the screw at an angle relative to the longitudinal axis of the bore. Errico and Campbell both disclose inserting the screw at a variety of different angles relative to the longitudinal axis of the bore. Ex. 1003 at 6:49-57; *see also id.* at Fig. 6; Ex. 1005 at 8:22-37; Figs. 28-29.

<b>'008 Patent Claims</b>	<b>Errico (Ex. 1003) and Campbell (Ex. 1005)</b>
37. The method of claim 36	<u>Errico</u> : “While it is preferable that the

<p>wherein the securing member is angularly displaceable within the posterior bore portion so that the securing member may be secured within the patient's bone at an angle relative to a longitudinal axis of the bore.</p>	<p>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.</p> <p><u>Campbell</u>: “Bone screw or fastener 132 is shown with its longitudinal extension substantially perpendicular to cervical plate 118. However, it 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.” Ex. 1005 at 8:22-28.</p>
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For at least these reasons, and as explained by Dr. Ferree (Ferree Decl. at ¶¶ 93-111), Petitioner has shown a reasonable likelihood of proving that each of claims 36 and 37 is obvious over Errico in view of Campbell.

## **X. CONCLUSION**

Claims 1-5, 9-22 and 29-37 of the '008 patent are rendered obvious over the combination of Errico and Koshino. Claims 36 and 37 of the '008 patent are also rendered obvious over the combination of Errico and 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 “FIRST 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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