

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,

Petitioner,

v.

ACANTHA LLC,

Patent Owner.

Patent No. RE43,008 E

DECLARATION OF JOSEPH P. ERRICO

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I, Joseph P. (“JP”) Errico, hereby declare and state as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I am currently a Board Member of electroCore Inc., a company focused on non-invasive vagus nerve stimulation therapy of multiple conditions in neurology and rheumatology. I co-founded electroCore in 2005. I served as the Chief Executive Officer of the company from 2008 through 2016, after which I served as the Chief Science & Strategy Officer and CEO of electroCore until 2019.

2. From 2001 through 2004, I co-founded SpineCore, LLC, which, in 2003, converted into SpineCore, Inc (hereinafter “SpineCore”). I served as the Chief Executive Officer and a Board Member of SpineCore from its founding to its sale to Stryker Spine in August of 2004. From 2004 through 2007, I served as the General Manager of the Motion Preservation Unit of Stryker Spine, which was the group within Stryker Spine responsible for the assets previously developed within SpineCore.

3. In 2003, I co-founded K2 Medical, Inc., having invested a significant portion of the intellectual property portfolio from which the company’s initial products were derived.

4. From 1995 through 2001, I co-founded a number of private companies for the purposes of developing intellectual property in the field of orthopedics. These companies licensed patents that have resulted in FDA

approved and FDA cleared products commercialized by several Fortune 500 companies that have licensed these patents from my companies.

5. I am a named inventor on several hundred patents in the US and other jurisdictions. I am still an active inventor, and have filed hundreds of patent applications as an inventor. Many of my patents disclose and claim orthopedic implants. Many of my patented orthopedic implants include bone screws and/or plates for various orthopedic applications, including implants for the spine, hip, or knee.

6. Over the past 25 years, products based on patented technology I invented have generated more than \$10 billion in sales to date.

7. Medical-device companies I co-founded have delivered over \$500 million in liquidity events to their investors.

8. I received my undergraduate degree in aeronautical engineering from the Massachusetts Institute of Technology (MIT) in 1990.

9. In 1993, I graduated and received a Juris Doctorate (JD) degree from Duke University School of Law.

10. In 1993, I also graduated and received a Master of Science degree in mechanical engineering and materials science from Duke University School of Engineering.

11. I am an attorney, having been admitted to the Pennsylvania and District of Columbia (D.C.) Bars (PA – inactive, D.C. – active).

12. I am a registered patent agent. My Registration No. is 38,131. I am also the author of a treatise on international intellectual property law.

13. A copy of my curriculum vitae is attached as EX1015.

14. At many of the companies I co-founded, I worked closely with and co-invented technology with my uncle, Thomas J. Errico, MD. I have had a close working relationship with Dr. Errico since 1994. Over this time period, Dr. Errico was (i) the Chief of the Division of Spine Surgery in the Department of Orthopedics at NYU Langone Medical Center and NYU Langone Orthopedic Hospital, (ii) a tenured Professor of Orthopedic and Neurological Surgery at NYU School of Medicine, and (iii) one of the most prolific inventors in the field of spinal implants. My close working relationship with Dr. Errico has given me deep understanding of different market opportunities for serving the different needs and preferences of spine surgeons throughout the world, especially in the area of medical device implants for treatment of various spinal conditions.

15. In 1994, Dr. Errico and I founded our first company, Fastenetix, LLC, to provide innovative spine technologies. Fastenetix provided novel spinal-implant assemblies, including plates and bone screws to join and stabilize vertebral bones.

16. Screws were (and still are) used to affix plates to two or more bones or bone fragments such that the plate spans the separation between the bones or fragments to hold them in stable relative positions so that the bones can grow together and fuse into one rigid structure. In some assemblies the bones or fragments thereof are simply held closely together, however, in the field of spinal orthopedics, it is often necessary to place a piece of cadaveric bone, artificial bone-like material, or even the patient's own bone harvested from a distal donor site, between adjacent vertebral bones to serve as a conduit for the new bone to grow.

17. In the mid-1990s, plate-and-screw implant assemblies for joining vertebral bones included plates with bores and bone screws inserted into bones through the bores in the plates. At the time, there were different types of plate-and-screw implants, for example: (1) fixed-angle vs. variable-angle insertion of screws through plates into bone; (2) constrained vs. unconstrained fixation of screws to plates and plates to bone; and (3) bicortical vs. unicortical screws.

18. A fixed-angle system only allowed insertion of screws through bores into bone at one, fixed angle between the screw and the plate. A variable-angle system allowed the surgeon to choose the angle at which to insert the screw into the bone through the plate from various possible angles between the screw and the plate. Each system offered different advantages and were preferred by different surgeons or for different surgeries.

19. A constrained system fixes, or locks, the screw to the plate in some manner. A constrained system is intended to prohibit noticeable movement of the plate relative to the bone. An unconstrained system allows for some small movement of the plate relative to the bone to allow for natural post-operative positional adjustment, referred to as “settling.”

20. Many bones, including vertebral bones, have a relatively soft and porous inner portion, referred to as cancellous bone, which is surrounded by a much harder and denser cortical bone at the surface. Screws are typically inserted into bone and extend into the inner portion, with some extending through to the far cortical region at the other side of the bone. Unicortical screws rely on the strong engagement of their threading with the cortical bone at the point of insertion. Bicortical screws, however, are designed to include a feature, typically associated with the threading of the screw, such that when the screw is inserted through the near surface of the bone, this feature engages with both the cortex at the insertion point and the cortical bone at the far side of the bone.

21. The development and use of bicortical screws was one of many attempts to enhance the gripping strength of screws, as the failure of the screws to remain firmly positioned relative to the bone was a primary mode of failure for surgical constructs meant to stabilize vertebral bones.

22. By the mid-1990s, orthopedic surgeons and the implant industry had recognized that one of the most dangerous modes of failure involved bone screws backing out and/or pulling out of the bone.¹ The trend in the mid-1990s was to employ various mechanisms to minimize the risk that bone screws would back out from the bone. When screws backed out from bone, those screws would likely back out from the plate, and could thus cause damage to the surrounding tissue of patients. Back out of bone screws was an issue in all types of systems—*e.g.* fixed-

¹ Note that the terms “back-out” and “pull-out” are sometimes used interchangeably. Technically speaking though, “back-out” is when screws loosen or unthread from bone and “pull out” is when screws strip out of bone or literally pull-out of the bone without loosening. In other words, pull-out may be a form of back-out, but back-out is not necessarily pull-out. As this declaration speaks to inventions and embodiments designed to inhibit these phenomena, some of which involve the securing or fixing of the heads of screws to the plates, it is important to recognize that some of these designs prevent only the unthreading form of back-out, and not the pull-out form. In this declaration, unless specifically referring to pull-out to the exclusion of unthreading back-out, I will refer to both by the more generic term, “back-out.”

angle or variable-angle system, as well as constrained or unconstrained systems and bicortical or unicortical systems.

23. U.S. Patent No. RE43,008 (“the ’008 patent”) discloses and claims orthopedic implant assemblies for joining bones using bone screws and plates. The ’008 patent also discloses and claims stopping mechanisms aimed at preventing bone screws from backing out of a plate.

24. NuVasive, Inc. (“NuVasive”) has engaged me as an expert with respect to petitions for *Inter Partes* Review of the ’008 patent.

25. My experience and expertise inventing and prosecuting patents for Fastenetix and others of the companies that I co-founded are highly relevant to the ’008 patent.

26. During prosecution of my own patents in the 1990s, I became familiar with prior art from the 1980s and 1990s concerning plates and bone screws for fixation to the spine, as well as to other bony structures.

27. I also have significant knowledge about the state of the art prior to the filing date of the ’008 patent as it applies to orthopedic plate-and-screw implant assemblies for joining bones.

28. In the 1990s, different types of spine surgeries drove the marketplace for plate-and-screw implant assemblies. It was known by orthopedic surgeons that plates could be used for joining bones, and bone screws could be used to attach the

plates to bones. For example, surgeries that treated traumatic instability often used a constrained (or semi-constrained², (*i.e.*, rigid) attachment of screws to plates. Such constrained attachment did not allow for noticeable movement of the plate relative to the bone. Surgeries that treated degenerative instability often used an unconstrained (*i.e.*, non-rigid) attachment of screws to plates. Such unconstrained attachment permitted movements of the plate relative to the bone to allow for settling.

29. The differing needs and preferences of spine surgeons also drove the marketplace for plate-and-screw implant assemblies in the 1990s. Some surgeons, like Dr. Errico, who often cared for challenging patients with complicating factors, including anatomical abnormalities, preferred bone screws that they could insert at variable angles depending on the particular surgery they were performing and the particular physiology of the patient undergoing surgery. Other surgeons preferred bone screws inserted at fixed angles, thus making insertion simple and repeatable.

² In the context of the fixing of screws to plates, the term semi-constrained means that the screw is constrained in one or more degrees of motion relative to the plate, but unconstrained in other degrees of motion. For example, a screw that is blocked from moving longitudinally (*i.e.*, along its axis) relative to a plate, once inserted, could still have the ability to rotate and/or alter its angle relative to the plate.

Variable-angle and fixed-angle systems each had their benefits and drawbacks, and both systems had measures of clinical and commercial success.

30. In order to prevent unthreading back-out and inhibit pull-out, fixed-angle systems began to incorporate means for fixing the head of the screw to the plate. The initial attempts at achieving this goal often included multiple additional components that needed to be manipulated during surgery and often inside the patient after initial insertion of the construct. It was apparent that these designs required improvement.

31. By virtue of the variable insertion angles of the variable-angle screws relative to their corresponding plates, however, successful means for securing the screws to the plate across many potential relative angles had not been invented.

32. As discussed above, constrained, semi-constrained, and unconstrained fixation systems were used in the 1990s. Constrained and unconstrained systems each had surgeons who preferred the particular system and each type of system had some measure of success. At Fastenetix, I decided to focus mainly on developing improved implant assemblies that offered variable-angle insertion of bone screws and the ability to fix the screw to the plate, i.e., constrained or semi-constrained variable-angle assemblies. I did so with a two-part securing member consisting of a tapered coupling element attached to a spherical head of a screw. I also developed various locking mechanisms that locked the two-part securing member

to the plate, and thus minimized the risk of the securing member backing out. The locking mechanisms I employed were suitable for use with constrained or semi-constrained assemblies, or even modified to return to an unconstrained assembly, since they could be used to lock a securing member at a fixed position relative to the plate, which was useful for creating a semi-constrained assembly; alternatively, they could be used to lock a securing member within a bore of the plate while permitting rotational or angular motion of the screw (or other type of securing member) in the bore, which was useful for creating an unconstrained assembly that allowed for settling. Either type of locking makes the securing member and plate inseparable, even if some relative motion was permitted, which inhibited and/or prevented back-out.

33. In order to prevent unthreading back-out and inhibit pull-out, fixed-angle systems began to incorporate means for fixing the head of the screw to the plate. The initial attempts at achieving this goal often included multiple additional components that needed to be manipulated during surgery and often inside the patient after initial insertion of the construct. It was apparent that these designs required improvement. In one embodiment, I did so with a two-part securing member consisting of a tapered coupling element attached to a spherically headed screw. This securing member could be utilized with various locking mechanisms that locked the two-part securing member to the plate, in a constrained or semi-

constrained manner, and thus minimized the risk of the securing member backing out.

34. By virtue of the variable insertion angles of the variable-angle screws relative to their corresponding plates, however, successful means for securing the screws to the plate across many potential relative angles had not been invented previously.

35. As stated previously, some spine plate-and-screw implant assemblies commercialized in the mid-1990s provided some mechanism for minimizing the risk of post-operative bone-screw back-out, because it was well-known by the mid-1990s that post-operative back-out of bone screws could have catastrophic consequences for a patient. More specifically, such consequences could include damage to the tissue surrounding the implant, which could cause infection, septic shock, and even death.

36. As also stated previously, by the mid-1990s, there were several well-known mechanisms to minimize the risk of post-operative back-out of bone screws. Orthopedic surgeons routinely used stopping members to prevent bone screws from backing out of the bone. Examples included: threaded locking assemblies offset from bores; threaded locking assemblies centered in-bore on top of bone screws; in-bore snap-rings expanded by bone screws during insertion of bone screws before snapping into a locking position on top of the bone screws;

cam-locks; and several other known mechanisms designed to minimize the risk of post-operative back-out of bone screws.

37. At Fastenetix, as early as 1995, I developed different mechanisms for minimizing possible back-out of bone screws, including in-bore threaded caps and in-bore snap-rings. I described such mechanisms in an international patent publication discussed later in this declaration.

38. As a mechanical engineer, I realized that snap-rings were particularly effective for minimizing the risk of axial motion of a screw relative to a plate, thus inhibiting back-out of bone screws. Snap-rings did not suffer from possible cross-threading that was a recognized problem with any threaded locking mechanism, such as in-bore set screws. In addition, one could use snap-rings to minimize the possibility of back-out for different kinds of bone screws, including the two-part securing member used in Fastenetix designs, bone screws with integral heads where the screws were inserted at fixed angles, and bone screws with integral heads where the bone screws were inserted at variable angles. From my experience in designing and reducing to practice, and partnering with commercially successful companies who manufacture, and selling plates with snap-rings to minimize back-out of bone screws, adapting the snap-rings of various Fastenetix designs for use with different bone screws would have been, and was,

straightforward for designers and manufacturers of typical plate-and-screw spinal implant assemblies.

39. As early as 1995, I also discovered that snap-rings offered advantages to many surgeons, including Dr. Errico, who preferred implant assemblies that minimized “fiddle factor”—*e.g.* that reduced the number of surgical steps needed to attach a plate to bones, and also minimized the likelihood of bone screws backing out from the plate. Indeed, snap-rings had advantageous properties over set screw stopping members, including a reduction of “fiddle factor” and avoidance of cross-threading. Stopping mechanisms—such as in-bore set screws or off-bore set screws—used for preventing back-out of bone screws from plates were quite small. Surgeons had to be very careful not to drop and/or lose such small parts when trying to attach them to the bone plate. Lost parts not only increased the cost of procedures (*e.g.* \$50 per lost stopping mechanism), but more importantly, they increased risk because patients could suffer injury through loss of stopping-mechanism parts inside the patients when surgeons accidentally dropped stopping-mechanism parts during surgery. As a mechanical engineer, I viewed snap-rings as a good design choice for minimizing “fiddle factor” since snap-rings were either integral to the plate to begin with or were preassembled in the plate before surgery. Simply put, during surgery, surgeons could neither cross-thread snap-rings that were integral to plates nor drop such snap-rings inside patients.

II. ASSIGNMENT AND MATERIALS REVIEWED

40. I submit this declaration in support of a petition for *Inter Partes* Review of U.S. Patent No. RE43,008 (“the ’008 patent”).

41. I am not currently, and have not previously been, an employee of the Petitioner, NuVasive, Inc. (“NuVasive”), or any of its parents, affiliates or subsidiaries.

42. I am being compensated for my time at a rate of \$500 per hour. My compensation is in no way dependent upon the substance of the opinions I offer below, or upon the outcome of NuVasive’s petitions for *Inter Partes* Review, or the outcome of such *Inter Partes* Review, if a trial is initiated.

43. I have been asked to provide certain opinions relating to the patentability of the ’008 patent. Specifically, I have been asked to provide my opinion regarding (i) the state of the art to which the ’008 patent pertains, at the time of the priority date for the ’008 patent; (ii) the level of ordinary skill in the art to which the ’008 patent pertains at the time of the priority date for the ’008 patent; and (iii) the differences between claims 1-5, 10-19, 21, 29-32, 36-37, 44-50, 53-54, 59-63, 66, 68-73, 75-78, 80-87, 90-91, 101, and 103-104 of the ’008 patent and the prior art.

44. In forming my opinions, I have reviewed and relied upon the ’008 patent (EX1001) and its prosecution history (EX1004), as well as U.S. Pat. No.

6,261,291 (the '291 patent) (EX1003) from which the '008 patent is a Reissue, and the file history of the '291 patent (EX1016).

45. I have assumed that the priority date of the '008 patent is no earlier than July 8, 1999, which is the filing date of the '291 patent.

46. I have reviewed the following prior art to the '008 patent:

- a. U.S. Patent No. 6,228,085 to Theken et al. ("Theken") (EX1005), filed on July 14, 1998, and issued on May 8, 2001;
- b. International Publication No. WO 1996/032071 to Errico et al. ("Errico") (EX1006) filed on April 9, 1996, published on October 17, 1996, and claiming a priority date of April 13, 1995, on which I am an inventor and personally drafted the specification and claims;
- c. U.S. Patent No. 5,082,390 to Peter J. Balsells ("Balsells") (EX1007), filed on January 22, 1991, and issued on January 21, 1992;
- d. International Publication No. WO 1998/051226 to Farris et al. ("Farris") (EX1008) filed on May 12, 1998, published on November 19, 1998, and claiming a priority date of May 15, 1997.

47. Based on my experience, I am also familiar with the state of the art at the time that the '008 patent was filed and cite the references below to support the state of the art.

- a. "Techniques of Anterior Cervical Plating," by Baskin et al., (EX1017) published in Operative Techniques in Neurosurgery, vol. 1, No. 2, pp. 90-102, published on June 1998;
- b. U.S. Patent No. 5,876,402 to Errico et al. (EX1018), filed on March 29, 1996, and issued March 2, 1999, on which I am an inventor;
- c. U.S. Patent No. 5,411,348 to Peter J. Balsells ("Balsells-348") (EX1019), filed on October 26, 1993, and issued on May 2, 1995;
- d. U.S. Patent No. 5,904,683 to Pohndorf et al. (EX1020), filed on July 10, 1998, and issued on May 18, 1999;
- e. U.S. Patent No. 4,488,543 to Alain Tornier (EX1021), filed on January 19, 1983, and issued on December 18, 1984;

48. I am aware that DePuy Synthes Sales, Inc. filed IPR Nos. 2016-00329, 2016-00333, and 2016-00334 challenging claims of the '008 Patent based on U.S. Patent No. 5,876,402 in combination with other references but that institution of these IPRs was denied.

III. SUMMARY OF OPINIONS

49. Theken in view of Errico renders claims 1-5, 10-19, 21-22, 29-32, 36-37, 44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101, and 103-104 of the '008 Patent obvious under 35 U.S.C. Section 103. Theken in view of Errico and in

further view of Farris renders claims 3, 5, 11, 22, 30, 37, 62-63, and 87 of the '008 Patent obvious under 35 U.S.C. Section 103.

50. It is my opinion that as of July 8, 1999, a person of ordinary skill in the art (“POSA”) relevant to the '008 patent would typically have had: (1) an undergraduate or advanced degree in mechanical engineering, biomechanical engineering, biomedical engineering, or a related field of science, as well as three or more years of related experience in the field of orthopedic implants; or (2) would be a practicing orthopedic spinal surgeon with at least five years of experience, as well as some experience in the design of orthopedic implants.

51. From my review of the file history of the '008 Patent, the file history of the '291 and '008 patents, and the docket in the DePuy IPRs, neither the patent examiners nor the Board has considered the combination of Theken in view of Errico. Nor is the combination of Theken in view of Errico cumulative of any combination of prior art considered during examination or the DePuy IPRs. While DePuy did advance one of my patents, US5876402, as a primary reference in the DePuy IPR petitions, it did not advance the Errico '402 Patent as a secondary reference and did not argue to combine the Errico '402 Patent with Theken. Similarly, while patent examiners of the '008 Patent and the '291 patent considered at least one of my patents during examination, those patent examiners did not

advance any combination of a primary reference like Theken in combination with a secondary reference like Errico.

52. Similarly, from my review of the file history of the '008 Patent, the file history of the '291 patent, and the docket of the DePuy IPRs, neither the patent examiners nor the Board has considered the combinations of Theken in view of Errico in further view of Farris. Nor is the combination of Theken in view of Errico in further view of Farris cumulative of any combination of prior art considered during examination of either the '008 Patent or the '291 Patent, nor of any combination of references advanced by DePuy. Neither the patent examiners nor DePuy advanced any combination of a primary reference like Theken in combination with secondary references like Errico and Farris.

53. I understand that Acantha asserted the '008 patent against DePuy as early as 2015 but did not assert the '008 patent against NuVasive until 2019.

IV. LEVEL OF ORDINARY SKILL IN THE ART

54. As I mentioned in my Background and Qualifications, I am an engineer, having degrees in both aeronautical and astronautical engineering as well as mechanical engineering and materials science, and I am a registered patent attorney. I am an inventor on hundreds patents, a large proportion of which are in the field of orthopedic spinal surgery. I have founded multiple medical device companies since 1994, including several companies in the orthopedic implant field,

including companies that designed, manufactured, and sold bone screws and plates with mechanisms to minimize risk of screw back-out, to include mechanisms such as set screws, snap-rings and other stopping members to minimize the risk of screw back-out.

55. I understand that obviousness of a patent must be determined from the perspective of a “person of ordinary skill” (“POSA”) in the field of the patent at the time of the invention.

56. I understand that this hypothetical POSA is considered to have the normal skills and knowledge of a person in the technical field at issue. I understand that the technical field at issue is orthopedic implant devices, which includes plate-and-screw implants for attachment to bones.

57. I understand that this hypothetical POSA is presumed to possess ordinary creativity and to be aware of all prior art in his or her field of endeavor, as well as prior art that is relevant to any of the problems addressed by the claimed invention, which may include analogous prior art that is reasonably pertinent to the particular problem faced by the inventor even if not from the same field of endeavor. For example, it is my opinion that a hypothetical POSA who sought a solution to the problem of bone screw back-out would have consulted the general mechanical arts for mechanisms that locked cylindrical components, like screws, inside bores.

58. It is my opinion that as of July 8, 1999, a POSA relevant to the '008 patent would typically have had: (1) a undergraduate or advanced degree in mechanical engineering, biomechanical engineering, biomedical engineering, or a related field of science, as well as three or more years of related experience in the field of orthopedic implants; or (2) would be a practicing orthopedic surgeon with at least five years of experience, as well as some experience in the design of orthopedic implants.

59. As of July 8, 1999, a POSA with respect to orthopedic implant assemblies that join bone segments would have had knowledge of: bone plates (including vertebral bone plates); bone screws; mechanical design issues related to bone plates and screws (including constrained, semi-constrained, and unconstrained designs), anatomical issues related to bone plates and screws, including cervical and other vertebral bone plates; the potential for bone screw back-out; potential complications related to bone screw back-out; and mechanisms for minimizing the potential for bone screw back-out.

V. BACKGROUND ON THE STATE OF THE ART

60. At the time of the invention of the '008 patent on July 8, 1999, the use of plates and screws for joining bones together was well-known. Surgeons had used such plates and screws for screw-plate fixation of the cervical spine as early as 1964. *See generally*, EX1017, 97-99, Table 3, Fig. 7-10 (describing different

screw-plate systems available in 1998); EX1005, 1:14-17 (“Anterior treatment of thoraco-lumbar spinal instability has included the use of a conventional fixation system comprised of a generally planar plate and fasteners. ... The fasteners engage the appropriate vertebra to affix the plate thereto.”); EX1006, 2:27-3:5 (“A variety of systems have been disclosed in the art which achieve this immobilization by implanting artificial assemblies in or on the spinal column. ... The use of screw and plate assemblies for stabilization and immobilization via lateral or anterior entrance is common. Additionally, the use of plate assemblies in the posterior cervical spine is also common”); EX1008, 5:5-8 (“In one aspect of the invention, the fixation plate is provided with a plurality of holes through which bone screws extend for engagement into a number of vertebrae.”).

61. As of July 8, 1999, a POSA would have known there were different market opportunities for constrained, semi-constrained, and unconstrained plate-and-screw spinal implants, and also would have known that there were different market opportunities for fixed-angle insertion of bone screws and variable-angle insertion of bone screws. *See, e.g.* EX1017, Table 3 (demonstrating availability of fixed and variable screw trajectories), 97 (selection of a constrained, semi-constrained, or an unconstrained fixation construct is determined by the intrinsic instability of the pathologic condition being treated as well as the specific anatomy of the patient being treated. Patients with traumatic instability are likely better

served with a more rigid implant (constrained constructs), whereas patients with degenerative instability are more likely to maintain the integrity of a nonrigid design (semi-constrained or unconstrained constructs) that permits small amounts of settling over time. Historically, surgeons have had to choose their plating system, in part, based on a preference for placing screws through fixed (predetermined) or variable trajectory.”); EX1008, 3:33-35 (“It has been determined that semi-rigid fixation is preferable for the treatment of degenerative diseases of the spine.”), 4:7-9 (“...rigid screw fixation is believed to be preferable in the treatment of tumors or trauma to the spine, particularly in the cervical region.”); EX1006, 3:18-20 (“It has, therefore, been a goal of those in the art to provide screw plate assemblies which permit screws to be entered into the bone at angles other than 90 degrees.”) and 5:22-24 (“Surgeons ideally need to have freedom with respect to insertion angles so that the individual variations in fracture type, and bone anatomy may be accounted for in the fixation means.”).

62. As of July 8, 1999, a POSA would also have been well-aware that bone screw back-out after surgery was a well-documented problem. Accordingly, a POSA would have known as of July 8, 1999 that there was a desire to prevent bone screw back-out. *See, e.g.* EX1006, 3:8-10 (“...one of the primary concerns of physicians performing implantation surgeries, as well as of the patients in whom the implants are placed, is the risk of screw pull-out.”), 4:1-5 (“Because screw

pull-out represents one of the largest risks of implant failure, it has been an object of those in the art to produce a screw and plate design[] having a locking means which couples, not only the plate to the bone, but locks the screw to the plate. In such a design, it is intended that, even if the bone holding the screw fails, the screw will not separate from the plate”); EX1008, 2:34-3:1 (“The screws used to connect the plate to the vertebrae must not ... back out from the plate.”); EX1017, Table 3 and 98-99 (comparing different plate systems as of 1998 with different locking mechanisms for preventing screw back-out.)

63. As of July 8, 1999, a POSA would have known of different mechanisms for mechanically reducing the risk of screw back-out by locking the bone screws to the plate in orthopedic implants. It was well understood that each mode of potential relative motion between a screw and plate, including: (a) axial or longitudinal motion of the screw relative to the plate, in which the head and shaft of the screw either (i) unthread and back-out, or (ii) pull-out by virtue of the threads losing purchase (stripping the bone); (b) the screw rotating about its long axis, but not moving relative to the plate (i.e., the screw either losing purchase to the bone, but remaining fixed to the plate, in which case both the plate and the screw may separate away from the bone); and (c) the screw remaining fixed axially to the plate, but changing with respect to the angle it makes with the plate (sometimes referred to as “windshield-wiper”). Such well-known locking

means included in-bore snap-rings, in-bore set screws, locking screws offset relative to bores, locking cams over the top of bone screws, sliding mechanisms over the top of bone screws, and many others, each having the ability to either constrain or semi-constrain screws to their corresponding plates. *See, e.g.* EX1006, 6:1-2 (“Further, the present invention provides a simple and effective locking mechanism for locking the bone screw to the plate.”) and 23:12-14 (describing the snap-ring 180 as a retaining ring that can “lock the screw and coupling element within the tapered hole” of the plate 100c.); EX1005, 3:63-65 (“Set screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).”); EX1008, FIG. 20-23 and 23:33-25:26 (describing an “alternative” locking mechanism comprising a locking assembly 103 that includes a locking washer 120 and/or a locking screw 121, where the locking washer 120 that overlaps a portions of a bone screw head to prevent the bone screw from backing out); EX1017, 102, Fig. 16 (showing different types of locking mechanisms known as of 1998). It was known in the field that a locking washer (*e.g.*, 120) could be used to lock down a screw, that an alternate locking mechanism (*e.g.*, locking screw 121) could be used to lock down a screw, or that a combination of locking washers and other mechanisms could be used, optionally additively with other stopping mechanisms preventing screws from backing out of the bone.

64. As of July 8, 1999, a POSA would have known that locking assemblies like set screws, locking caps and screws coupled to disks, were popular choices for locking bone screws to plates, which was widely known to prevent back out. *See, e.g.* EX1020, 2:22-27 (“Concerns about screw loosening resulting in esophageal injury...led to the development of mechanisms for locking the head of the screw to the plate. Such locking mechanisms prevented the screw from backing out of the plate”); EX1006, FIG. 4b (showing a threaded coupling element 133 screwed into a plate) and 4: 1-5 (“it has been an object of those in the art to produce a screw and plate designs having a locking means which ... locks the screw to the plate. In such a design, it is intended that, even if the bone holding the screw fails, the screw will not separate from the plate”) and 23:9-11 (“Complete insertion of the coupling element 133 to the plate 100b, locks the coupling element and screw to the plate”); EX1008, 6:4-6 (“In a further aspect of the invention, a locking assembly is provided for locking the bone screws in the plate, thereby preventing screw back-out.”); EX1021, 2:35-43 (“As shown in FIG. 1, a threaded hole 8 is advantageously provided for receipt of a screw 9 which facilitates attachment of a disk 11. The disk...partially covers each of heads 3a of screws 3 to assure their being held in corresponding holes 6. This arrangement prevents, therefore, the backward movement of screws 3 out of holes 6 during the compression under load of the fracture.”).

65. As of July 8, 1999, a POSA also would have had general knowledge of biased mechanisms used in the general mechanical arts to mechanically lock cylindrical components (*e.g.*, a shaft) inside bores and prevent the cylindrical components from separating and backing out of the bores, including a canted-coil spring that (i) is embedded in a groove of plate-like components, (ii) elastically expands from an unexpanded configuration to an expanded configuration as a tapered section of the cylindrical component passes through the canted-coil spring, and (iii) returns to the unexpanded configuration above a flat anterior surface of the cylindrical component to prevent the cylindrical component from backing out. *See, e.g.* EX1019, FIG. 17-18, 6:1-68 (showing use of a canted-coil spring 290 that resides in a groove 293B of a bore 293A in a plate 284A, whereby the canted-coil spring 290 prevents back-out of an end portion 282B of a cylindrical member that was inserted into the bore 293A), 6:41-42 (Stating the “destruction of the spring 290 may be necessary in order to separate the member 282 from the plate 284”), FIG. 6B-C (Illustrating springs that have a smaller diameter (unexpanded) configuration and a larger diameter (expanded) configuration as an element passes through those springs); EX1007, FIG. 5a-c and 3:44-62 (Showing a locked relationship between a first member 12 and a second member 14 after (i) a ramped portion 68 of the second member 14 compresses a canted-coil spring 16 within a groove 24 of the first member 12 while the second member 14 moves into a hole of

the first member 12, and (ii) continued movement of the second member 14 into the first member 12 releases the coil 16 above the ramped portion 68 of the second member to create the locked relationship.).

66. As of July 8, 1999, a POSA would have known there was a desire to use mechanisms for stopping bone screw back out that were flush with or below the anterior surface of a bone plate so as to limit protrusions extending above the anterior surface of a bone plate and thus reduce risk of injuring surrounding anatomy of the patient. *See, e.g.* EX1006, 16:4-9 (describing FIG. 5 as showing “integral retaining rings formed in the upper portion of the holes”, and FIG. 6 showing a cross-sectional view of FIG. 5), FIG. 5 and 6 (showing a snap-ring 180 below anterior side of the plate 110 so as not to protrude above the anterior side of the plate 100); EX1018, 2:57-62 (“In addition to pull-out, however, it has been observed that if the screw plate design includes screw heads which protrude beyond the exterior surface of the plate, long term wearing of surrounding tissues may occur, leading to the development of abscesses and holes, which, once again, can have grave consequences.”); EX1008, 3:5-8 (plating systems “must minimize the intrusion into the patient and reduce the trauma to the surrounding soft tissue.”); EX1005, Fig. 2 (showing set screws 140 flush with plate 20 of the bone fixation system 10); EX1017, 99 (suggesting that “all locking screws [of the

Atlantis system] should be recessed to minimize the profile of the fixation construct”).

67. As of July 8, 1999, a POSA would have known there was a desire to use mechanisms for stopping bone screw back-out that could be attached to the plate during bone screw insertion. *See, e.g.* EX1006, 16:4-9 (describing FIG. 5 as showing “integral retaining rings formed in the upper portion of the holes”, and FIG. 6 showing a cross-sectional view of FIG. 5), FIG. 5 and 6 (showing a snapping ring 180 attached to the plate 110); EX1008, 24:21-23 (describing a locking screw 121 of a locking assembly 103 that is staked to the plate 101) and 21:35-22:3 (recognizing the benefit of fixing the locking assembly on the plate “so the surgeon need not fiddle with the locking assembly when the plate is engaged to a vertebra”); EX1017, 97 (“Systems that rely on unicortical screw purchase require a mechanism for securing the screw head to the plate. The trend in product development has been for this locking feature to be incorporated within the plate itself ... instead of as a separate component”).

68. As of July 8, 1999, a POSA would have known that fixed-angle plate-and-screw systems could be modified to provide variable-angle insertion of screws by modifying those plate-and-screw systems to accommodate spherical, or semi-spherical, screw heads. *See, e.g.* EX1005, 6:51-54 (“It will be appreciated that screw 100 may have other suitable geometries. For instance, the tapered head

could be replaced by a spherical head. The spherical head would allow variable screw angulation.”); and EX1008, 17:2-6 (“The variable angle screw 60 also includes a head 64....The head 64 also includes a spherical surface 67 disposed between the top surface 66 and the intermediate portion 62.”). A POSA would have known that accommodating a spherical or semi-spherical head could be achieved by using a curved/spherical recess in a posterior section of a bore. EX1008, 24:3-4 (“The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw.”), FIGS. 20-23.

69. As of July 8, 1999, a POSA would have known that an undeformed snap-ring was suitable for preventing a cylindrical component from passing through the snap-ring when a bottom surface of the snap-ring abuts top edges of the cylindrical component (*see, e.g.* EX1006, 24:4-10) and a POSA would have known that an undeformed canted-coil spring was suitable for preventing a cylindrical component from passing through the canted-coil spring when a bottom surface of the canted-coil spring abuts top edges of the cylindrical component (*see, e.g.* EX1019, FIG. 17-18, 6:1-68 (showing use of a canted-coil spring 290 that resides in a groove 293B of a bore 293A in a plate 284A, whereby the canted-coil spring 290 prevents back-out of an end portion 282B of a cylindrical member that was inserted into the bore 293A), 6:41-42 (Stating the “destruction of the spring 290 may be necessary in order to separate the member 282 from the plate 284”));

EX1007, FIG. 5a-c and 3:44-62 (Showing a locked relationship between a first member 12 and a second member 14 after movement of the second member 14 into the first member 12 releases the coil 16 above the ramped portion 68 of the second member to create the locked relationship).

70. As of July 8, 1999, a POSA would have known that a curved or linear tapered surface of a component that narrows towards one end of the component is suitable for expanding a snap-ring so long as the narrow end of the component has a diameter that is smaller than the inner diameter of the snap-ring, and the narrow end of the component is the first part of the component that passes through the snap-ring. *See, e.g.* EX1006, 23:22-24:4.

VI. PRIOR ART

71. The scope and content of the prior art as of July 8, 1999 would have broadly included all references related to orthopedic devices for attachment to bone.

72. The scope and content of the prior art as of July 8, 1999 also would have included all references in the mechanical arts related to stopping or “locking” mechanisms that prevent back-out of cylindrical members that are inserted into bores.

73. I understand that Theken (EX1005), Errico (EX1006), Balsells (EX1007), and Farris (EX1008) are prior art to the '008 patent. I am an inventor

on numerous patents related to orthopedic surgical devices, and I understand that some of these patents were considered during examination of the '008 patent, but that none of these patents were considered in combination with Theken (EX1005).

74. In my opinion, a POSA as of July 8, 1999 would have considered Theken, Errico and Farris to be within the same technical field as the subject matter set forth in the '008 patent, and further would have considered Balsells to be analogous prior art that is relevant to a problem addressed by the claims of the '008 patent (*e.g.* preventing back-out of cylindrical components, like screws, from bores). A POSA would have considered all of these references to be highly relevant prior art to the claims of the '008 patent. In addition to these references, a POSA also would have been aware of, informed by, and looked to many other relevant prior art references, including those listed in Section II above.

VII. LEGAL STANDARDS

75. I am informed and understand that a patentability analysis is performed from the viewpoint of a hypothetical POSA. I understand that POSA is a hypothetical person who is presumed to be aware of the universe of available prior art as of the time of the invention at issue.

76. I understand that a patent claim is unpatentable as obvious if the subject matter of the claim as a whole would have been obvious to a person of ordinary skill in the art as of the time of the invention at issue. I understand that the

following factors must be evaluated to determine whether the claimed subject matter is obvious: (1) the scope and content of the prior art; (2) the difference or differences, if any, between the scope of the claim of the patent under consideration and the scope of the prior art; (3) the level of ordinary skill in the art at the time the patent was filed; and (4) any secondary indicia of non-obviousness of record. I understand that obviousness may be shown by considering more than one item of prior art.

77. I understand that, for the purpose of an *inter partes* review, prior art that renders a claim obvious can include both patents and printed publications from anywhere in the world. I understand that some claims are written in dependent form, in which case they incorporate all of the limitations of the claim(s) from which they depend.

78. I understand that various rationales may support a conclusion of obviousness, including:

- a. Combining prior art elements according to known methods to yield predictable results;
- b. Simple substitution of one known element for another to obtain predictable results;
- c. Use of known technique to improve similar devices (methods, or products) in the same way;

- d. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- e. “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- f. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; or
- g. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

79. I understand a conclusion of obviousness is supported under the rationale of “combining prior art elements according to known methods to yield predictable results” when the following is provided: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately; (3) a finding that one of ordinary

skill in the art would have recognized that the results of the combination were predictable; and (4) whatever additional findings based on the factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

80. I understand a conclusion of obviousness is supported under the rationale of “Simple substitution of one known element for another to obtain predictable results” when the following is provided: (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components; (2) a finding that the substituted components and their functions were known in the art; (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

81. I understand a conclusion of obviousness is supported under the rationale of “Use of known technique to improve similar devices (methods, or products) in the same way” when the following is provided: (1) a finding that the prior art contained a “base” device (method, or product) upon which the claimed invention can be seen as an “improvement;” (2) a finding that the prior art

contained a "comparable" device (method, or product that is not the same as the base device) that has been improved in the same way as the claimed invention; (3) a finding that one of ordinary skill in the art could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

82. I understand a conclusion of obviousness is supported under the rationale of "Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results" when the following is provided: (1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement;" (2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product); (3) a finding that a POSA would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

83. I understand a conclusion of obviousness is supported under the rationale of “Obvious to try – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success” when the following is provided: (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem; (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem; (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

84. I understand a conclusion of obviousness is supported under the rationale of “Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art” when the following is provided: (1) a finding that the scope and content of the prior art, whether in the same field of endeavor as that of the applicant’s invention or a different field of endeavor, included a similar or analogous device (method, or product); (2) a finding that there were design incentives or market forces which

would have prompted adaptation of the known device (method, or product); (3) a finding that the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art; (4) a finding that one of ordinary skill in the art, in view of the identified design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art; and (5) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

85. I understand a conclusion of obviousness is supported under the rationale of “Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention” when the following is provided: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

86. I understand that, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

87. I understand that a combination that results in removal of *some* functionality of a primary reference does not necessarily obviate motivation to combine since a given course of action often has simultaneous advantages and disadvantages.

88. I understand that the disclosure of desirable embodiments does not necessarily negate a suggestion for modifying the prior art to arrive at the claimed invention.

89. I understand that, if a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references may not be sufficient to render the claims *prima facie* obvious.

90. I understand that, where there is a reason to modify or combine prior art to achieve the claimed invention, the claims may be rejected as *prima facie* obvious provided there is also a reasonable expectation of success.

91. I also understand that obviousness does not require absolute predictability, but at least some degree of predictability is required.

VIII. CLAIM CONSTRUCTION

92. I understand that in an *inter partes* review, claim terms are to be construed according to their ordinary and customary meaning to a POSA as of the priority date of the patent, consistent with the specification.

93. For purposes of my opinion, I have interpreted each claim term of the '008 patent according to its ordinary and customary meaning consistent with the specification when comparing the claims to the prior art. I understand that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

94. For the purposes of my opinion, unclaimed functionality or characteristics of embodiments shown in the specification or figures does not define a claim. For example, if figures illustrate or the detailed description discloses a particular type of angular insertion of bone screws (*e.g.* fixed or variable) but the particular type of angular insertion is not expressly claimed, the claims are not limited to that disclosed angular insertion. Also, if the figures illustrate or the detailed description discloses a particular type of attachment (*e.g.* constrained/rigid or unconstrained/non-rigid) but such particular attachment type is not expressly claimed, the claims are not limited to that type of attachment. I have reviewed a district court claim construction order from the DePuy litigation

(EX1014) and am of the opinion that my analysis of the claims in this declaration is consistent with those constructions.

95. Each of claims 1, 4, 10, 19, 21, 36, 37, 44, 59, and 101 and some claims dependent therefrom refer to anterior or posterior surfaces or positions. The term “posterior” as defined by the ’008 patent means “an inner portion of the assembly closer to the bone to which the assembly is attached” while the term “anterior” as defined by the ’008 patent means “an outer portion of the assembly further away from the bone.” EX1001, 1:44-48. It is my opinion that a POSA would have applied the terms “posterior” and “anterior” as defined by the specification.

96. Each of claims 2, 4, 17-19, 29, 47-50, 68-73, 80-82, and 203 refer to a collar or annular collar. The patent illustrates an example having a biased stopping member comprising an annular collar. EX1001, FIGS. 1-3, 4:16-44. Figures 2, 3, 3A, and 4A each display an annular collar (12) that is a discontinuous retaining ring, or snap-ring. Therefore, it is my opinion that a POSA would have understood that the claimed collar or annular collar includes such a discontinuous retaining ring or snap-ring.

97. Claims 17 and 68 each state the collar is formed “of an elastically deformable material” while claims 18 and 69 each state the collar can be formed of a “superelastic material.” The patent specification shows that deformable and

elastic materials include titanium, and that superelastic materials include nickel titanium alloys. EX1001, 5:65-67 (disclosing “the stopping member 12 is preferably elastically deformable, and formed of titanium, and superelastic or pseudoelastic materials such as NiTi alloys”). Therefore, it is my opinion that a POSA would have understood the claimed deformable and elastic material includes titanium, and the superelastic material includes nickel titanium alloys.

98. Claim 22 depends from claim 21 and recites “the step of longitudinally and angularly displacing the head of the securing element” after “the head of the securing element is positioned between the biased stopping member and the second opening in the stabilizing element.” EX1001, 9:64-10:3. The patent describes the angular displacement of the securing element occurs by tilting the head. *Id.* at 5:52-64 (“... the securing element is angularly displaceable within the transverse passageway posterior section **25** between the collar **12** and the second opening **17** in the stabilizing element, as illustrated in FIG. 6. The securing element can thus be tilted within the transverse passageway at an angle relative to the transverse passageway longitudinal axis ...”). FIG. 6 of the patent clearly illustrates the securing element body (23) entered the bone (15) at an angle. Furthermore, the text of neither one of claims 21-22 requires an act of tilting the head *after* the head is below the stopping member and positioned within the

patient's bone. EX1001, 9:24-10:3. Indeed, this would not be feasible if the securing member is already attached to bone.

IX. OBVIOUSNESS ANALYSIS

99. I separate my obviousness analysis below into two sections: (A) Theken in view of Errico renders claims 1-2, 4, 10, 12-19, 21, 29, 31-32, 36, 44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101, and 103-104 obvious; (B) Theken in view of Errico renders claims 3, 5, 11, 22, 30, and 37 obvious; and (C) Theken in view of Errico and in further view of Farris renders claims 3, 5, 11, 22, 30, 37, 62-63, and 87 obvious.

A. Theken in View of Errico Renders Claims 1-2, 4, 10, 12-19, 21, 29, 31-32, 36, 44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101, and 103-104 of the '008 patent Obvious

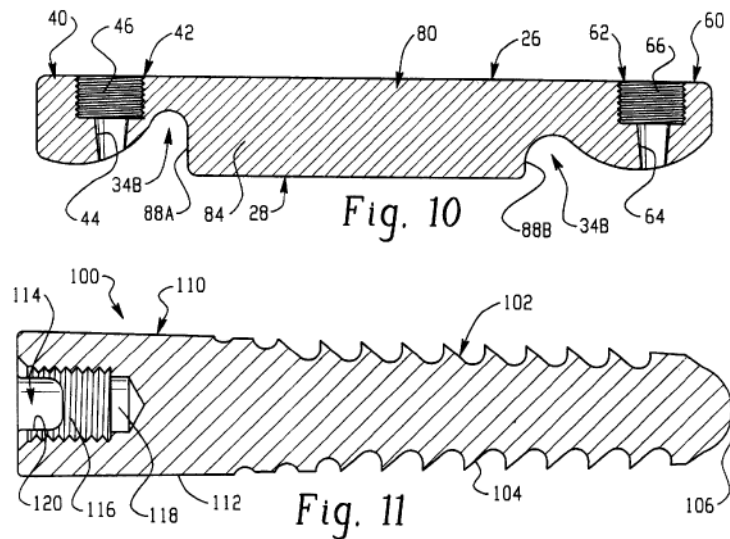
100. In my opinion, the combination of U.S. Patent No. 6,228,085 to Theken et al. ("Theken") (EX1005) with International Publication No. WO 1996/032071 to Errico et al. ("Errico") (EX1006) discloses all of the limitations described in claims 1-2, 4, 10, 12-19, 21, 29, 31-32, 36, 44-50, 53-54, 59-61, 66, 68-73, 75-78, 80-86, 90-91, 101, and 103-104 of the '008 patent. The combination of Theken in view of Errico renders those claims obvious under pre-AIA 35 U.S.C. 103(a).

101. Theken issued from US 09/114,996, the prosecution history of which I have reviewed. (EX1009). During prosecution, as-filed claims 12 and 13 were

found to be allowable if written in independent form, which the applicant did, resulting in issued claims 21 and 22, respectively. In my review of the prosecution history, I only observed amendments to the specification regarding minor typographical errors and the entry of figure descriptions. It is thus my opinion that a POSA would have been in possession of all of Theken's issued claims, especially claims 21 and 22. It is also my opinion that the as-filed application enabled a POSA to practice the issued claims, especially claims 21 and 22.

102. Theken discloses an orthopedic implant assembly as a bone fixation system 10. EX1005, FIGS. 1-14, 2:26-52, 3:54-65. The bone fixation system 10 includes a bone plate 20 (*i.e.*, a stabilizing/attachment element), bone screws 100 (*i.e.*, securing elements), and set screws 140 (*i.e.*, stopping members). *Id.* at 3:57-61. Theken also describes methods of attaching the bone fixation system 10 to bone. *Id.* at 8:34-9:65. The bone plate 20 (*i.e.*, a stabilizing/attachment element) in Theken includes a lateral side 26 (*i.e.*, anterior surface) with a first opening, and a medial side 28 (*i.e.*, a posterior surface) with a second opening. *Id.* at 4:7-8, FIGS. 5-6. The medial side 28 is in contact with the vertebrae. *Id.*, 5:59-66. The bone plate 20 includes “generally circular openings 62” (*i.e.*, bores), which are dimensioned to receive “[bone] screw 100 and set screw 140.” *Id.* at 4:36-39, FIGS. 1-2, 5-8, and 10. As shown in FIGS. 8 and 10 (reproduced below for reference), each “opening 62 has a tapered section 64 and a threaded section 66”

where the “[t]apered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28” and the “[t]hreaded section 66 includes threads that mate with the threads formed on set screw 140”. *Id.* at 4:36-49. It is thus clear that Theken describes a stabilizing element with an anterior surface, a posterior surface, and at least one bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a traverse passageway extending from the first opening to the second opening.



103. The bone screws 100 (*i.e.*, securing elements) in Theken each include an integral threaded portion 102 and head portion 110. *Id.* at 6:19-21, FIGS. 1-2, 11. The head portion 110 includes a tapered outer surface 112. *Id.* at 6:27, FIG. 11. The taper of the head portion 110 and the tapered section 64 of the bore match, which means that the head portion 110 has a maximum diameter greater than the

second opening at the bottom of the bore at the posterior surface. *Id.* at 4:21-26, 4:42-46, FIGS. 8 and 10. The head portion 110 is retained within the transverse passageway between the set screw 140 (*i.e.*, stopping member) and the second opening of the bore. *Id.* at FIG. 1 (showing an inserted, bottom-left bone screw 100 and dotted line to a set screw 140 that is to be inserted above the bone screw), and FIG. 2 (showing all bone screws 100 below inserted set screws 140).

Therefore Theken describes a securing element with an elongated body, a head at one end of the body and integral therewith having a maximum diameter greater than the second opening in the securing element. Theken also thus describes a securing element which is configured to be slidably disposed within the bore of the stabilizing element and which has an elongated body and an enlarged integral portion having a maximum transverse dimension.

104. The bone fixation system 10 described by Theken includes the elements of the implant assembly disclosed in claims 1, 21, and 36 of the patent at issue, the exception being the type of stopping member that prevents the bone screw from falling out by locking the bone screw to the plate. The set screw 140 (*i.e.*, stopping member) disclosed by Theken is in a threaded section 66 of the opening 62 (*i.e.*, bore) over the head portion 110 of the bone screw 100 such that an anterior surface of the head portion 110 is under (*i.e.*, is posterior to) a posterior

surface of the set screw 140. *Id.* at FIGS. 1-3, 6:60-66.³ Theken also describes driving the set screw 140 into the top of screw 100 prevents screw 100 from moving, preventing backing out movement. *Id.*, 9:22-24, 9:54-59.

105. Theken's bone fixation system 10 includes all elements of independent claims 1, 21, 36, 44, 59, and 101 in the '008 patent except for the type of stopping member to lock the bone screw to the plate and to prevent it from backing out. In particular, the set screw 140 of Theken does not elastically deform

³ Theken also includes embodiments that lock the bone screw 100 to the plate 20. Theken discusses different designs for locking the bone screw 100 to the plate 20. A first design locks the bone screw 100 to the plate 20 using "a press fit mechanism in which a [bone] screw [100] is driven into an undersized hole formed in the plate [20]" whereby "locking is provided by material deformation" of the bone screw 100 and/or the hole in the plate 20. *Id.* at 7:52-56. A second design locks the bone screw 100 to the plate 20 by driving the set screw 140 on top of the bone screw 100. *Id.* at 9:22:26 and 9:55-59. In each of these alternative designs, the set screw 140 is available to prevent the bone screw 100 from backing out of the plate 20 because the set screw 140 may be attached to the plate above the bone screw 100. However, the set screw 140 is not necessary to provide locking functionality when locking of the bone screw 100 to the plate 20 is desired.

between two configurations, or allow the securing element (bone screw 100) to pass through it. **However, Theken teaches that the “set screws 140 could be replaced by other suitable locking mechanisms.” EX1005, 7:33-35.** As discussed below, other suitable locking mechanisms were available before the time of the invention of the '008 patent on July 8, 1999. Theken clearly directs a POSA to utilize alternate suitable locking mechanisms. Use of biased stopping members to lock bone screws to plates and to prevent back-out of bone screws from plates was well-known to POSA's (for example, those knowledgeable of the mechanical arts) for many years before the invention. As described by Errico, screw pull-out represented “one of the largest risks of implant failure” and described “locking means” that “locks the screw to the plate” such that, “even if the bone holding the screw fails, the screw will not separate from the plate.” EX1006, 4:1-5.

106. Indeed, a POSA would have understood a biased stopping member in the form of a “snap-ring” was well-known in the art before July 1999. Errico describes one such locking mechanism: “a simple and effective locking mechanism for locking the bone screw to the plate[.]” EX1006, 6:1-2 (describing the snap-ring 180); *Id.* at 23:12-24:10 (describing “a retaining ring provided to further lock the screw and coupling element within the tapered hole” of the plate 100). Errico also discloses the “retaining ring expands as the corresponding coupling element is inserted into the hole, and snaps back into a retaining position

above the coupling element once the top of the element passes it into the hole” and therefore the retaining ring is a biased stopping member. EX1006, 8:13-17. This biased stopping member (*e.g.*, snap-ring 180) describes a reversibly expandable passageway with both a smaller diameter unexpanded configuration (*i.e.*, smaller than the maximum diameter of the head of the securing element) and a larger diameter expanded configuration. The biased stopping member is thus at least partially disposed within the bore of the stabilizing element, which has a posterior stopping surface, an expanded configuration within the bore allowing passage of the securing element into the posterior bore portion with the enlarged integral portion of the securing element disposed in the posterior bore portion posterior to the stopping member (*i.e.*, an expanded configuration) and an unexpanded configuration within the bore which has smaller transverse dimensions than the expanded configuration and smaller than the maximum transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion of the stabilizing element; and wherein the enlarged integral portion of the securing element is retained below the posterior surface of the stopping member.

107. Errico discloses an orthopedic implant assembly comprising a bone plate assembly. EX1006, FIG. 5-6, and 23:12-24:10. The bone plate assembly includes a plate 100c (*i.e.*, a stabilizing/attachment element), a screw 120 and

tapered coupling element 132 (*i.e.*, a non-integral securing element), and a snap-ring 180 (*i.e.*, a biased stopping member). *Id.* at FIGS. 5-6 and 23:25-26

(“Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown”). As shown in reproduced FIG. 6 of Errico (below), the plate 100c includes an anterior surface with a first opening, a posterior surface with a second opening:

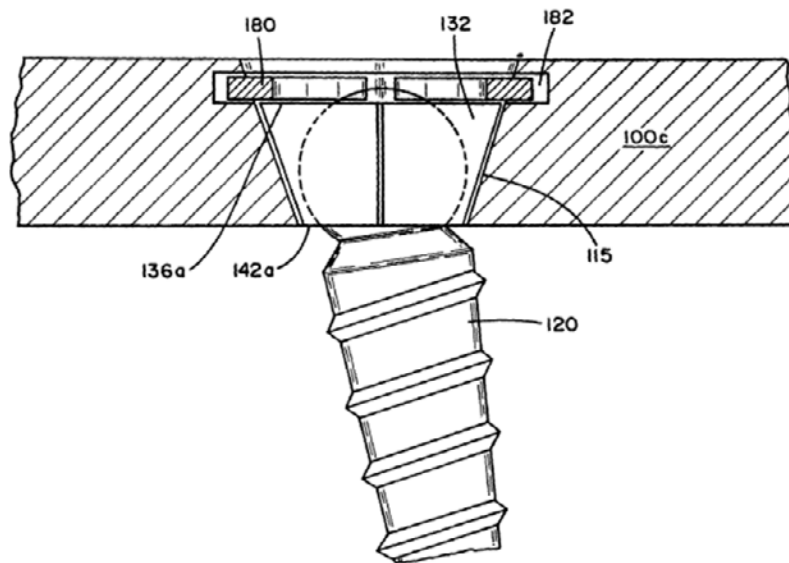


FIG.6

The plate 100c includes a tapered hole 110c (*i.e.*, bore with transverse passageway) that includes a tapered side wall 115 and a posterior section that receives the tapered coupling element 132 (*i.e.*, part of a non-integral securing element). *Id.* at FIGS. 5-6, 23:12-16, 24:4-5. The tapered coupling element 132, which has a flat upper (*i.e.*, anterior) surface 136a with a maximum diameter greater than the

second opening, is retained within a transverse passageway between the snap-ring 180 and the second opening. *Id.* at FIG. 6 (showing a diameter of the surface (a transverse dimension of the surface) 136a that is larger than the bottom opening of the tapered hole 110c), 24:4-5 (“... the coupling element 132 (or 133) is fully seated in the hole 110c” after insertion). The tapered side wall 115 further includes an anterior section with an annular recess 182 within which a snap-ring 180 (*i.e.*, biased stopping member) is positioned. *Id.* at FIGS. 5-6, 23:12-19. **The snap-ring 180 is a retaining ring to “lock the screw and coupling element within the tapered hole” of the plate 100c. *Id.* at 23:12-14 and FIGS. 5-6.**⁴ In addition to locking the coupling element and screw to the plate, Errico’s snap-ring 180 also prevents the coupling element from backing out of the plate. *Id.* at 24:7-10. During an implantation procedure as Errico describes, a surgeon inserts both the tapered

⁴ The locking mechanisms we developed at Fastenetix, including the snap-ring I included in the Errico disclosure, were suitable for use with constrained or unconstrained assemblies since they could be used to lock a securing member at a fixed position relative to the plate, which was useful for creating a constrained assembly, or could be used to lock a securing member within a bore of the plate, which was useful for creating an unconstrained assembly. Either type of locking makes the securing member and plate inseparable, which prevented back-out.

coupling element 132 and the screw 120 through the tapered hole 110c, and “the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from an unexpanded (first) configuration to an expanded (second) configuration. *Id.* at 23:27-24:4. As Errico further explains, “[o]nce the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the unexpanded configuration. *Id.* at 24:4-7. The undeformed unexpanded configuration of Errico’s snap-ring 180 prevents the tapered “coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” *Id.* at 24:7-10. Errico’s snap-ring 180 will open (*i.e.*, deform into an expanded (second) configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. *Id.* at 24:9-10 (indicating a taper can push open the snap-ring).

108. Theken described that his “set screws 140 could be replaced by other suitable locking mechanisms”. EX1005, 7:33-35. The snap-ring 180 in Errico shows that a POSA would have known a retaining ring (*e.g.*, a snap-ring) is a suitable locking mechanism as envisioned by Theken, and therefore that Errico describes the snap-ring is “a simple and effective locking mechanism for locking

the bone screw to the plate” that “lock[s] the screw and coupling element within the tapered hole” of the plate 100c. EX1005, 6:1-2 and 23:12-14.

109. In my opinion, it would have been obvious to a POSA by the priority date of the '008 patent to combine the teachings of Theken and Errico, and use Errico's snap-ring and an in-bore annular recess to lock Theken's tapered bone screw 100 to Theken's bone plate 20 and to prevent Theken's tapered bone screw 100 from backing out. In one embodiment of the combination of Theken and Errico, Theken is modified to include Errico's annular recess 182 and snap-ring 180 in place of Theken's threaded section 66 and set screw 140. One embodiment of the combination of Theken and Errico is a fixed-angle bone screw and plate assembly with a snap-ring and annular recess, which I discuss below.

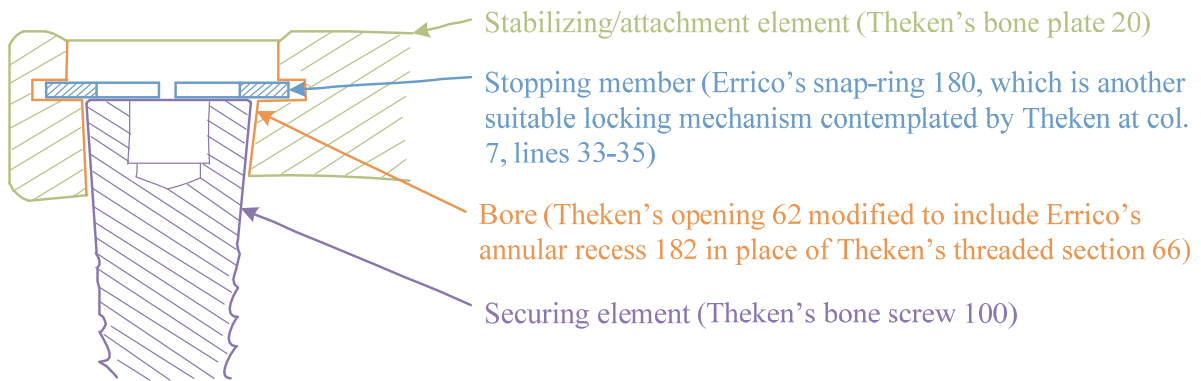
110. A POSA would be have combined Theken and Errico to yield predictable and desirable results. It was known before the priority date of the '008 patent that the retention ring (*e.g.*, the snap-ring) and annular recess is a simple and inexpensive way to prevent screw back-out in Theken's assembly, and that such retention ring and annular device was suitable for an orthopedic assembly. For example, a POSA would have been motivated to—and would have understood how to—adjust the respective dimensions of Theken's tapered screw head portion 110 and Errico's snap-ring 180 to ensure Theken's tapered screw head portion 110 expanded Errico's snap-ring 180 and was retained by Errico's snap-ring 180 during

use. Such adjustments include: (i) sizing the inner undeformed diameter of the snap-ring to be larger than the smallest diameter of Theken's head portion 110 and also smaller than the diameter at the top of Theken's head portion 110, and also sizing the inner deformed diameter of the snap-ring to be larger than the diameter at the top of Theken's head portion 110; (ii) varying the degree of taper for Theken's head portion 110 and Theken's opening 62 such that the smallest diameter of Theken's head portion 110 is smaller and the diameter at the top of Theken's head portion 110 is larger than the inner undeformed diameter of the snap-ring, and also such that the diameter at the top of Theken's head portion 110 is smaller than the inner deformed diameter of the snap-ring (*i.e.*, Errico's snap-ring is reversibly expanded by a tapered shape, permitting the tapered shape to move posteriorly to the snap-ring, retaining the tapered element to lock the screw to the plate and to prevent it from separating from the plate); (iii) using a generally flat top surface for Theken's head portion 110 similar to Errico's coupling element 132; and (iv) partially disposing the snap-ring in an annular recess in the bore, such as annular recess 192 from Errico being employed in Theken's bore.

111. Below, for reference, I illustrate two obvious implementations for the combination of Theken and Errico.

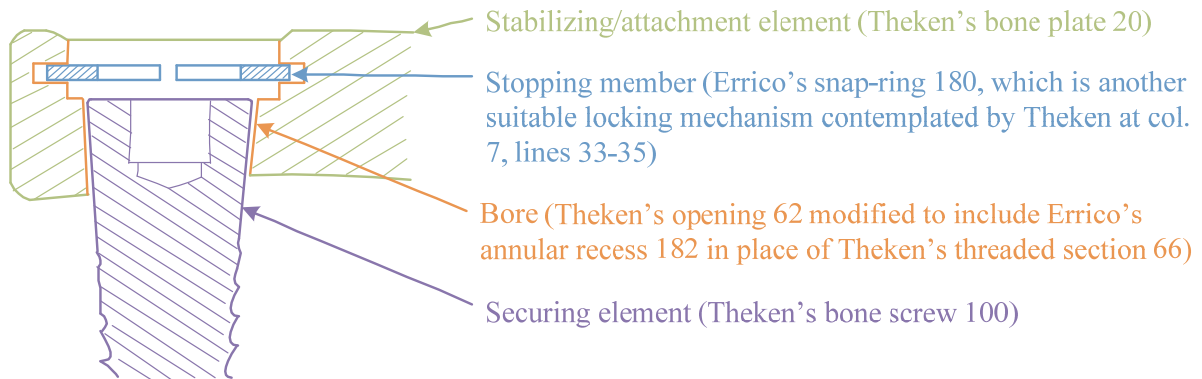
112. In a first implementation of the combination (shown below), the annular recess 182 is positioned at the bottom of the threaded section 66. A POSA

would be motivated to include the annular recess 182 at the bottom location so as to create a constrained system that is desirable for some surgeries I mentioned in paragraphs 19, 28, 32, and 61 above, where the posterior surface of the snap-ring 180 abuts the top of an inserted bone screw 100 so as to prevent noticeable movement.

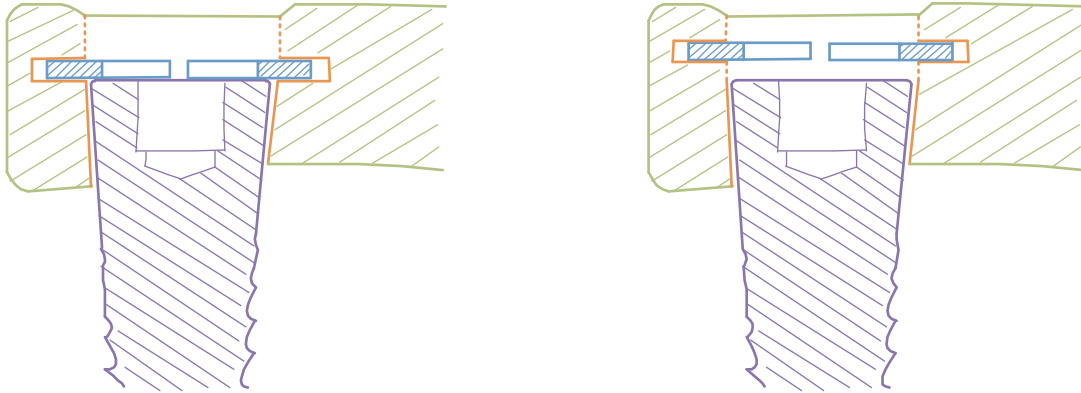


113. In a second implementation of the combination (shown below), the annular recess 182 is located in the middle of the threaded section 66. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for other surgeries I mentioned in paragraphs 19, 28, 32, and 61 above, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for some settling after surgery. In the second implementation, the head portion 110 of the bone screw 100 is longitudinally displaceable within a transverse passageway between the posterior surface of the

snap-ring 180 and the second opening in the posterior surface of the plate 20, which permits the settling after surgery, and also advantageously allows for different depths of bone screw insertion 100 during surgery.



114. Each of the above implementations can have the uniform contour of Errico's tapered wall 115 so the wall of the opening 62 is uninterrupted across the anterior portion of the opening 62 (*i.e.*, the modified threaded section 66) and the posterior portion of the opening 62 (*i.e.*, the tapered section 64). A POSA would have been motivated to include the uniform contour for various reasons, including, *e.g.* greater plate strength achieved by inwardly moving the walls of the modified threaded section 66, easier manufacture of the plate, narrower pathway in the modified threaded section that guides the bone screw 100 into the tapered section 64, and retention of the snap-ring using the retention design disclosed by Errico.



115. A POSA would have reasonably expected success in combining Theken and Errico, which would provide predictable results for the following reasons:

- a. Theken's bore (opening 62) and Errico's bore (hole 110c) both have tapered profiles for receiving tapered shapes;
- b. Theken's screw head 110 and Errico's coupling element 132 both have tapered shapes, and are both inserted into tapered bores;
- c. Errico's snap-ring 180 is expanded by a tapered shape (EX1006, 24:9-10), and would be deformed by Theken's tapered screw head 110 because Theken's screw head 110 and Errico's coupling element 132 are both tapered and have a similar insertion pathway into respective bores (Theken's opening 62 and Errico's hole 110c);
- d. Errico's snap-ring 180 is designed specifically for the purpose of retaining a tapered component with a flat anterior surface to lock the screw to the plate and to prevent it from separating from the plate (hole 110c).

Errico's snap-ring 180 would similarly retain Theken's tapered screw head 110 with flat anterior surface to lock the screw to the plate and to prevent it from backing out of a bore (opening 62);

e. The stopping members of Theken (set screw 140) and Errico (snap-ring 180) are both inside a bore;

f. Errico's snap-ring 180 locks a bone screw to a plate, and would similarly lock Theken's bone screw 100 to the plate 20;

g. Errico shows how a bore (hole 110c) can include an annular recess 182. Errico also exemplifies how an annular recess could similarly be included in place of the threaded section 66 of Theken's bore (opening 62).

116. Multiple rationales support the combination of Theken and Errico.

More particularly, there are several reasons supporting the use of Errico's snap-ring 180 within Errico's in-bore annular recess 182 in place of Theken's set screw 140 within the threaded section 66 of the Theken bore (*e.g.* opening 62). Below, I identify some of the reasons and rationales supporting the combination of Theken in view of Errico:

a. *Teaching, suggestion, or motivation in the prior art to combine prior art reference teachings to arrive at the claimed invention:* The Theken, Errico and '008 patent systems are in the same field of endeavor. Some of the many motivations for using Errico's snap-ring 180 within an in-bore annular

recess (instead of using Theken's set screw and corresponding threaded section of Theken's bore) include without limitation: (i) avoiding possible cross-threading surgeons often encountered when placing set screws in threaded-bores of plates; (ii) avoiding what surgeons called "fiddle-factor" by eliminating the need to place a small, slippery set screw in the threaded-bore of a plate with gloved-hands during a time-sensitive surgical procedure (in other words, integration of the snap-ring in the plate obviated the need for a separate, small, and unwieldy piece of hardware in the form of a set-screw); (iii) reducing the number procedural steps necessary to fully insert a bone screw during time-sensitive surgical procedures by eliminating the step of placing a small, slippery set screw into the threaded-bore of a plate; (iv) eliminating the risk of a surgeon dropping a small, slippery set screw while the surgeon tries to place the set screw in a threaded-bore of a plate with the surgeon's relatively insensitive gloved-hand; (v) reducing the risk of and liability associated with losing surgical hardware (namely set screws) in the "surgical field" (*i.e.* inside patients) during surgery; and/or (vi) minimizing protrusions above the anterior surface of the plate because such protrusion can damage surrounding tissue, causing post-surgical complications and further expose surgeons to liability. I provide in the preceding paragraph 115

reasons why there was a reasonable expectation of success when using Errico's snap-ring in an annular recess.

b. *“Obvious to try” with a reasonable expectation of success:* Both Theken and Errico provided stopping members that locked bone screws to plates and that prevented bone screws from separating from plates in the event the bone screws backed out. Solutions to lock bone screws to plates in the event of back-out included, without limitation, Theken's in-bore set screw above a bone screw, Errico's in-bore snap-ring above a bone screw, among other in-bore solutions known in the art, and also deformable screw heads of Theken and Errico. Theken contemplates using alternative stopping members: “set screws 140 could be replaced by other suitable locking mechanisms.” EX1005, 7:33-35. The snap-ring 180 in Errico “provides a simple and effective locking mechanism for locking the bone screw to the plate” that “lock[s] the screw and coupling element within the tapered hole” of the plate 100c. EX1006, 6:1-2 and 23:12-14. Using Errico's snap-ring with Theken's tapered screw head would have had a reasonable expectation of success because Errico successfully used the snap-ring with a tapered coupling element inserted in the same way a surgeon would insert Theken's tapered screw through the snap-ring and into a bore. I provide in paragraph 115 above reasons why a POSA would have had a

reasonable expectation of success when trying the Errico snap-ring as a predictable solution from a finite number of identified, predictable solutions.

c. *Substitution of one known element for another to obtain predictable results:* Errico's snap-ring was a known stopping member that had the functions of the '008 patent's stopping member. A *POSA* easily would have substituted the Errico snap-ring for Theken's set screw to yield predictable results because Errico showed the snap-ring works with a tapered shape and Theken's bone screw head comprises a compatible tapered shape. I provide in paragraph 115 above reasons why a *POSA* would have obtained predictable results when using the Errico snap-ring in an annular recess in place of Theken's set screw in a threaded section.

d. *Use of known technique to improve similar devices in the same way:* Theken was a "base" device using an in-bore set screw to lock an integral securing element to a plate, which prevented the integral securing element from separating from the plate. Using an in-bore biased stopping member that is capable of locking an integral securing element (*e.g.* integral bone screw) to a plate, preventing separation of the securing element from the plate, where known. Errico was a "comparable" device that was incorporable with Theken in the same way as the '008 patent—*i.e.* using an in-bore biased stopping member that prevents back-out of a securing element (*e.g.* non-

integral coupling element and bone screw) from a plate. A POSA would have applied the known “improvement” technique (*e.g.* the snap-ring of Errico) in the same way to the “base” device (*e.g.* Theken’s bone fixation system) with results predictable to a POSA in terms of locking a bone screw to a plate so as to prevent separation of the bone screw from the plate. I provide in paragraph 115 above reasons why a POSA would have obtained predictable results when using the Errico snap-ring in an annular recess in place of Theken’s set screw in a threaded section.

e. *Applying a known technique to a known device ready for improvement to yield predictable results:* Theken was a “base” device using an in-bore set screw to lock an integral securing element to a plate, which prevented the integral securing element from separating from the plate. Using an in-bore biased stopping member that is capable of locking an integral securing element (*e.g.* integral bone screw) to a plate prevented separation of the securing element from the plate. A POSA would have understood such integral placement could optionally include locking into position the screws at set angles. Errico’s snap-ring was a known technique capable of locking a securing element to a plate to prevent separation of the securing element from the plate. Errico was applicable to Theken’s “base” device because Errico’s snap-ring could be used with tapered shapes (*e.g.* the tapered screw

head of Theken) that are inserted into tapered bores (*e.g.* the tapered section of Theken's bore). I provide in preceding paragraph 115 above reasons why a POSA would have obtained predictable results when using the Errico snap-ring in an annular recess in place of Theken's set screw in a threaded section.

f. *Combining prior art elements to yield predictable results:* Each element claimed is the combination of Theken and Errico. A POSA could have combined the elements as claimed by known methods (*e.g.*, use of Errico's annular recess 182 to hold Errico's snap-ring 180 to hold the bone screw in Theken's plate). Errico's snap-ring 180 performs the same function as it does in Errico (*i.e.* to lock a bone screw to a plate), Theken's bone screw performs the same functions as it does in Theken (*i.e.* is placed through Theken's plate and attaches to bone), and Theken's plate performs the same functions as it does in Theken (*i.e.* to connect two vertebrae). I provide in paragraph 115 above reasons why a POSA would have recognized that the results of the combination were predictable.

117. Accordingly, for the reasons stated above, it is my opinion that at the time of the invention of the '008 patent, a POSA would have combined Theken's orthopedic implant assembly (bone fixation system 10) with Errico's snap-ring and in-bore annular recess.

118. Combining Theken and Errico in the manner described above does not render Theken's bone fixation system unsatisfactory for its intended purpose or change its principle operation. The intended purpose and principle operation of Theken's bone fixation system is plainly described as providing an "internal bone fixation system for the treatment of bone anomalies". EX1005, 1:4-7, Abstract. Theken contemplates different embodiments for achieving the principle operation and intended purpose of treating bone anomalies, including an embodiment that locks the bone screw 100 to the plate 20 by material deformation of the bone screw 100 and/or the hole in the plate 20 (*Id.* at 7:53-56), and an embodiment that locks the bone screw 100 to the plate 20 with the set screw 140. (*Id.* at 9:22:26 and 9:55-59). Moreover, Theken expressly teaches that the "set screws 140 could be replaced by other suitable locking mechanisms" (EX1005, 7:33-35) and achieve the same results. Using Errico's snap-ring in Theken's bone fixation system supports Theken's principle operation and intended purpose of treating bone anomalies while also providing numerous advantages as set forth above in paragraph 116 above.

1. Claim 1 of the '008 patent is Obvious over Theken in view of Errico

119. It is my opinion that the combination of Theken and Errico renders claim 1 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 1) that follows.

120. With respect to the preamble to claim 1, Theken is directed to an orthopedic attachment assembly comprising a bone fixation system 10. EX1005, 4:7-55, 5:59-66, 3:54-65, FIGS. 1-9 and 10.

121. With respect to claim element 1(a), Theken discloses an orthopedic implant assembly comprising the stabilizing element (*e.g.* bone plate 20) having an anterior surface (*e.g.* lateral side 26), a posterior surface (*e.g.* medial side 28), and at least one bore (*e.g.* circular openings 62), the bore having a first opening (*e.g.* at top of a threaded section 66) in the anterior surface, a second opening (*e.g.* at bottom of a tapered section 64) in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening. *Id.* at 4:7-55, 5:59-66, FIGS. 1-8 and 10.

122. With respect to claim element 1(b), Theken discloses a stopping member (*e.g.* set screws 140). *Id.* at 3:63-65, 6:60-66, 9:22-24, 9:54-59, FIGS. 1-3. Theken provides for use of other types of stopping members. *Id.* at 7:33-35 (“It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.”).

123. With respect to claim element 1(c), Theken discloses a securing element (*e.g.* bone screw 100) having an elongated body (*e.g.* threaded portion 102), and a head (*e.g.* tapered head portion 110) at one end of the body and integral therewith, the head (*e.g.* tapered head portion 110) having a maximum diameter

greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element. *Id.* at 4:21-26, 4:42-46, 6:19-31, FIGS. 1-2, 8-11 (the head portion 110 has a taper that matches the taper of the tapered section 64 of the plate, such that the top of the head portion 110 has a maximum diameter that is greater than the second opening at the bottom of the tapered section 64 of the plate 20).

124. With respect to claim element 1(b) and claim element 1(c), Errico discloses a biased stopping member (*e.g.* snap-ring 180) defining at least in part a reversibly expandable passageway having a smaller diameter unexpanded configuration and a larger diameter expanded configuration. EX1006, 4:1-4, 6:1-2, 8:13-17, 23:25-24, FIGS. 5-6. Errico also discloses a head (*e.g.* tapered coupling element 132) having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member (*e.g.* snap-ring 180) so that the head (coupling element 132) is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element. *Id.* at 6:1-2, 23:12-24:10, FIGS. 5-6.

125. As I explain above in paragraph 115, Theken's tapered head portion 110 would function in the same way as Errico's tapered coupling element 132 with

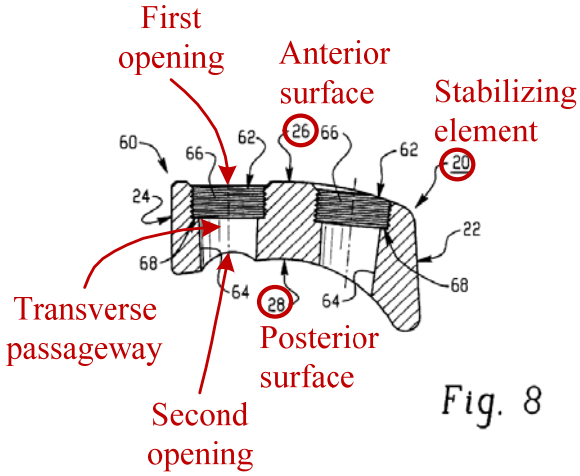
a flat upper surface in terms of inserting into a tapered bore, expanding a snap-ring in the bore, and being retained by the snap-ring.

126. It is my opinion that it would have been obvious for a POSA to use Errico's snap-ring and in-bore annular recess to perform the function of preventing back-out of the screw in Theken's apparatus. As I explain above in paragraphs 115 and 116, it would have been obvious for a POSA to configure the Theken apparatus with the snap-ring and annular recess of Errico based on various rationales (discussed above), and there would be a reasonable expectation of success along with predictable results whereby the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring, being retained by the snap-ring, and having relative sizes compared to sizes of the snap-ring and portions of a bore. As I also explain above in paragraph 118, configuring the Theken apparatus with the snap-ring and annular recess of Errico would not render the Theken apparatus unsatisfactory for its intended purpose or change its principle operation.

127. Therefore, it is my opinion that the combination of Theken and Errico discloses all of the limitations of claim 1 of the '008 patent, and thus claim 1 would have been obvious to a POSA in view of the combination of Theken and Errico.

TABLE 1

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
<p>1. An orthopedic implant assembly, comprising</p>	<p><i>Theken (EX1005)</i>: "... FIG. 1 shows an exploded view of a bone fixation system 10 Fixation system 10 is generally comprised of a bone plate 20, a plurality of bone screws 100, and a plurality of set screws 140." <i>Id.</i> at 3:54-65, FIGS. 1-14.</p> Id. at 4:35-48. See also <i>Id.</i> at FIG. 8."
<p>a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;</p>	<p><i>Theken (EX1005)</i>: "... plate 20 has ... a lateral side 26, a medial side 28" <i>Id.</i> at 4:7-8. Plate 20 "includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10)." <i>Id.</i> at 4:35-48. See also <i>Id.</i> at FIG. 8.</p>

	 <p>Fig. 8</p>
<p>b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and</p>	<p><i>Theken (EX1005)</i>: Non-biased “[s]et screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).” <i>Id.</i> at 4:63-65, FIGS. 1-2. “It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.” <i>Id.</i> at 7:33-35.</p> <p><i>Errico (EX1006)</i>: “Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown.” <i>Id.</i> at 23:25-26. The snap-ring 180 is a biased stopping member that “provides a simple and effective locking mechanism for locking the bone screw to the plate”. <i>Id.</i> at 6:1-2. The snap-ring 180 is suitable to lock a non-integral securing element/member comprising a screw and coupling element within the tapered hole of the plate 100c. <i>Id.</i> at 23:12-14. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller diameter</p>

	<p>(unexpanded) configuration to a larger diameter (expanded) configuration. <i>Id.</i> at 23:27-24:4. As further explained by Errico, “[o]nce the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. <i>Id.</i> at 24:4-7. Errico’s snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10. <i>See also Id.</i> at FIGS. 5-6.</p>
<p>c) a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.</p>	<p><i>Theken (EX1005)</i>: “Screws 100 will now be described in detail with reference to FIGS. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from the lower end of head portion 110 to rounded tip 106.” <i>Id.</i> at 6:20-22, FIG. 11. “Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in FIG. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in tapered sections 44 and 64 of plate 20.” <i>Id.</i> at 6:27-31. Because the head portion 110 has a taper than matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a maximum diameter that is greater than the second opening at the bottom of the tapered section 64 of the plate 20.</p>

Errico (EX1006): Errico's coupling element 132 has a "tapered exterior surface" that "causes the snap-ring 180 to expand". *Id.* at 24:3. The tapered coupling element 132 has a maximum diameter greater than the undeformed smaller diameter configuration of the snap-ring 180. *Id.* at FIG. 6, 24:1-10.

Smaller
diameter
configuration

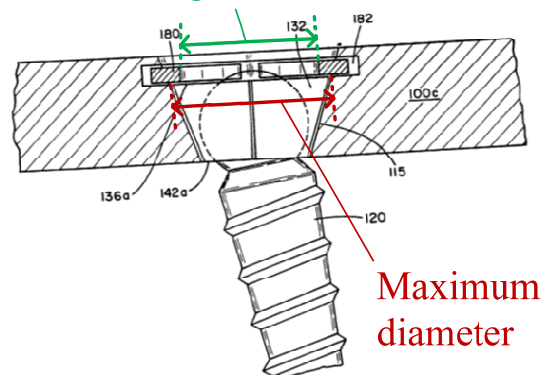


FIG. 6

"In its [the snap-ring] undeflected state it prevents the coupling element 132 ... from backing out of the plate 100c" *Id.* at 24:7-8.

Theken (EX1005): Since the head portion 110 of Theken has a tapered outer surface 112, it has a maximum diameter at the top portion of the head portion 110. *Id.* at FIG. 11, 6:20-31. When implementing the snap-ring 180 of Errico for use with the tapered bone screw 100 of Theken, the maximum diameter of the bone screw 100 of Theken will be greater than the smaller diameter configuration of the snap-ring 180 by proper sizing of the snap-ring 180. The degree of taper in the tapered

	<p>outer surface 112 can also be adjusted as desired to ensure the maximum diameter at the top of Theken's head portion 110 is greater than the smaller diameter configuration of Errico's snap-ring 180, and to ensure the smaller diameter configuration of Errico's snap-ring 180 is greater than the diameter of the tapered head portion 110 adjacent to the threaded portion 102, such that Theken's tapered outer surface 112 expands Errico's snap-ring 180, and Theken's head portion 110 is retained within the transverse passageway between Errico's snap-ring 180 and the second opening of Theken's plate 20.</p>
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2. Each of Claims 2, 4, 10, 12, 13, 14, 15, 16, 17, 18, 19, 29, 31, and 32 of the '008 patent is Obvious over Theken in view of Errico

128. It is my opinion that the combination of Theken and Errico renders each of claims 2, 4, 10, 12, 13, 14, 15, 16, 17, 18, 19, 29, 31, and 32 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 2) that follows.

129. Claim 2 depends from claim 1, which is discussed in paragraphs 119 through 127. The rationale for combining Theken and Errico with respect to claim 1 also applies to claim 2. With respect to the limitations in claim 2, as shown in Table 2 below, the combination of Theken and Errico comprises a biased stopping member (*e.g.* snap-ring 180) comprising a collar defining a passageway, enlargeable from an unexpanded inner diameter to an expanded inner diameter,

wherein the head of the securing element has a maximum diameter greater than the unexpanded inner diameter of the collar and less than the expanded inner diameter of the collar. *See, e.g.* EX1006, FIGS. 5-6, 8:13-17, 23:12-24:10.

130. Claim 4 depends from claim 2 which is discussed in paragraph 129. The rationale for combining Theken and Errico with respect to claim 2 also applies to claim 4. With respect to the limitations in claim 4, as shown in Table 2 below, the combination of Theken and Errico comprises a bore that has a groove (*e.g.* annular recess 182) in an anterior portion of the transverse passageway having a diameter and a height, and wherein the collar (*e.g.* snap-ring 180) is a reversibly expandable annular collar seated in the groove, the collar having an expanded outer diameter, and an unexpanded outer diameter which is less than the diameter of the groove and greater than a diameter of the transverse passageway. *See, e.g.* EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6.

131. Claim 10 depends from claim 1, which is discussed in paragraphs 119 through 127. The rationale for combining Theken and Errico with respect to claim 1 also applies to claim 10. With respect to the limitations in claim 10, as shown in Table 2 below, the combination of Theken and Errico comprises a head of the securing element that is longitudinally displaceable within the transverse passageway between a posterior surface of the biased stopping member and the second opening in the posterior surface of the stabilizing element. In one obvious

implementation of the combination illustrated in paragraph 113, the annular recess 182 is placed at the middle of Theken's threaded section 66, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for an unconstrained system that allows for settling after certain surgeries. In this implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20).

132. Claim 12 depends from claim 1, which is discussed in paragraphs 119 through 127. The rationale for combining Theken and Errico with respect to claim 1 also applies to claim 12. With respect to the limitations in claim 12, as shown in Table 2 below, the combination of Theken and Errico comprises a stabilizing element (*e.g.* plate 20) that includes at least two bores (*e.g.* openings 42 and 62). *See, e.g.* EX1005, 3:62, 4:4-7, 4:16-18, 4:35-38, FIGS. 1-3, 5-8, 10.

133. Claim 13 depends from claim 1, which is discussed in paragraphs 119 through 127. The rationale for combining Theken and Errico with respect to claim 1 also applies to claim 13. With respect to the limitations in claim 13, as shown in Table 2 below, the combination of Theken and Errico comprises a stabilizing

element (*e.g.* plate 20) that is configured to conform to and extend between at least two bone segments (*e.g.* vertebral bodies V_1 and V_2). *See, e.g.* EX1005, 3:65-66, 5:34-36, 5:59-64, FIGS. 3-4.

134. Claim 14 depends from claim 13, which is discussed in paragraph 133. The rationale for combining Theken and Errico with respect to claim 13 also applies to claim 14. With respect to the limitations in claim 14, as shown in Table 2 below, the combination of Theken and Errico comprises a stabilizing element (*e.g.* plate 20) that has a curved surface (*e.g.* surface at notches 34A, 34B). *See, e.g.* EX1005, 5:34-36, 5:59-6:7, FIG. 4.

135. Claim 15 depends from claim 1, which is discussed in paragraphs 119 through 127. The rationale for combining Theken and Errico with respect to claim 1 also applies to claim 15. With respect to the limitations in claim 15, as shown in Table 2 below, the combination of Theken and Errico comprises a stabilizing element (*e.g.* plate 20) that is selected from the group consisting of rods and plates. *See, e.g.* EX1005, 3:59-61, FIGS. 1-10.

136. Claim 16 depends from claim 1, which is discussed in paragraphs 119 through 127. The rationale for combining Theken and Errico with respect to claim 1 also applies to claim 16. With respect to the limitations in claim 16, as shown in Table 2 below, the combination of Theken and Errico comprises a securing

element (*e.g.* bone screws 100) that is selected from the group consisting of screws and nails. *See, e.g.* EX1005, 3:59-60, 6:19-34, FIGS. 1-2 and 11.

137. Claim 17 depends from claim 2, which is discussed in paragraph 129. The rationale for combining Theken and Errico with respect to claim 2 also applies to claim 17.

138. With respect to the limitations in claim 17, as shown in Table 2 below, the combination of Theken and Errico comprises a collar (*e.g.* snap-ring 180) that is formed of an elastically deformable material. The snap-ring 180 is formed of an elastically deformable material, as shown by its range of motion from inward deformation to outward deformation. *See, e.g.* EX1006, 8:14-17 (“each retaining ring expands as the corresponding coupling element is inserted into the hole, and snaps back into a retaining position about the coupling element once the top of the element passes it into the hole.”); 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state”).

139. Each of Theken and Errico also disclose forming an orthopedic assembly from titanium. EX1005, 7:37-41 (screws and set screws), EX1006,

17:20-18:2 (plate). Titanium was a known elastically deformable and biocompatible material at the critical date. As the remaining parts of the assembly were also contemplated to be made of titanium, it would have been obvious to a POSA to likewise form the collar from titanium to be support the range of motion described in Errico using a biocompatible material that would hold up during long-term contact against the remaining titanium components of the assembly.

140. Claim 18 depends from claim 2, which is discussed in paragraph 129. The rationale for combining Theken and Errico with respect to claim 2 also applies to claim 18.

141. With respect to the limitations in claim 18, as shown in Table 2 below, the combination of Theken and Errico comprises a collar (*e.g.* snap-ring 180) that is formed of a material selected from the group consisting of titanium and superelastic material. The snap-ring 180 is formed of an elastic material, evidenced by its supported range of motion from inward deformation to outward deformation. EX1006, 8:14-17 (“each retaining ring expands as the corresponding coupling element is inserted into the hole, and snaps back into a retaining position about the coupling element once the top of the element passes it into the hole.”); 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-

ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”).

142. As discussed above in paragraph 137, each of Theken and Errico also disclose forming an orthopedic assembly from titanium, and it therefore would have been obvious to use a collar that was also formed of titanium, a known elastically deformable material. EX1005, 7:37-41 (screws and set screws), EX1006, 17:20-18:2 (plate). Using particular types of elastic material, such as superelastic materials, is a simple design choice. Superelastic nickel-titanium (NiTi, Nitinol) alloys were well-known in the field for clinical use in orthopedic appliances. As described in EX1010, superelastic Nitinol alloys have properties that were known to have properties that “could be very useful in surgical applications” and “have good potential for clinical use.” EX1010, 481-88. It was known such materials could be “very useful in orthopedic surgery.” EX1011, 451-57. In my opinion, it would have been obvious to a POSA to form the snap-ring from a superelastic nickel-titanium alloy because of its biocompatibility, elasticity, and shape memory characteristics.

143. Claim 19 depends from claim 2, which is discussed in paragraph 129. The rationale for combining Theken and Errico with respect to claim 2 also applies to claim 19. With respect to the limitations in claim 19, as shown in Table 2 below, the combination of Theken and Errico comprises a collar (*e.g.* snap-ring 180) that

has a posterior surface perpendicular to a longitudinal axis of the transverse passageway. *See, e.g.* EX1006, FIG. 6 (the snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the transverse passageway between the top and bottom of Errico's plate 100c and, when combined with Theken, the lateral side 26 and the medial side 28 of Theken's plate 20.).

144. Claim 29 depends from claim 4, which is discussed in paragraph 130. The rationale for combining Theken and Errico with respect to claim 4 also applies to claim 29. With respect to the limitations in claim 29, as shown in Table 2 below, the combination of Theken and Errico comprises a collar (*e.g.* snap-ring 180) that has a height less than the height of the groove (*e.g.* annular recess 182). *See, e.g.* EX1006, FIG. 6.

145. Claim 31 depends from claim 10, which is discussed in paragraph 131. The rationale for combining Theken and Errico with respect to claim 10 also applies to claim 31. With respect to the limitations in claim 31, as shown in Table 2 below, the combination of Theken and Errico comprises a stabilizing element (*e.g.* plate 20) that is selected from the group consisting of rods and plates. *See, e.g.* EX1005, 3:59-61, FIGS. 1-10.

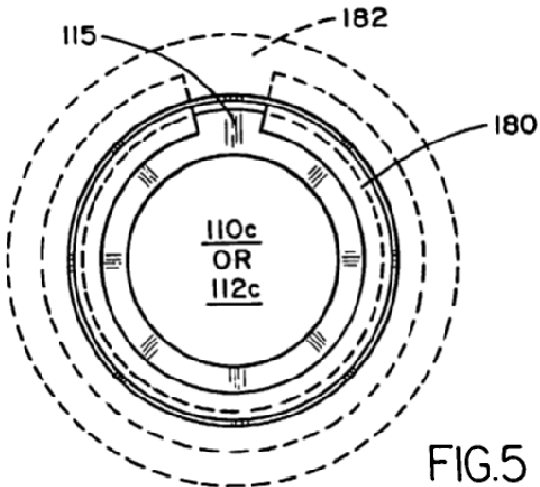
146. Claim 32 depends from claim 10, which is discussed in paragraph 131. The rationale for combining Theken and Errico with respect to claim 10 also applies to claim 32. With respect to the limitations in claim 32, as shown in Table

2 below, the combination of Theken and Errico comprises a securing element (*e.g.* bone screw 100) that is selected from the group consisting of screws and nails.

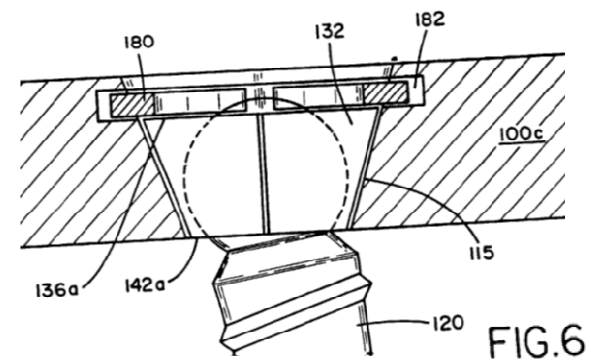
See, e.g. EX1005, 3:59-60, 6:19-34, FIGS. 1-2 and 11.

TABLE 2

‘008 Patent Claim	Theken (EX1005) and Errico (EX1006)
<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><i>Errico (EX1006)</i>: “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180” that forms a collar. <i>Id.</i> at 23:18-19. <i>See also Id.</i> at FIG. 5 (selected portion shown below), which illustrates a collar shape for snap-ring 180. The snap-ring 180 operates by enlarging from an unexpanded inner diameter to an expanded inner diameter as a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded inner diameter after the tapered coupling element 132 passes through the snap-ring 180. <i>Id.</i> at 23:27-24:10 (“... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182. Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c”), and FIG. 6. A maximum diameter of the tapered coupling element 132 is greater than the unexpanded inner diameter of the snap-ring 180 so as to expand it, and is less than the expanded inner diameter</p>

	<p>so as to pass through the expanded snap-ring 180.</p> 
<p>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 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.</p>	<p><i>Errico (EX1006)</i>: "... the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole" <i>Id.</i> at 23:16-17. The snap-ring 180 is retained in the annular recess 182 when in an unexpanded state and an expanded state, so its unexpanded outer diameter must be less than the diameter of the groove, and it must have an expanded outer diameter. <i>Id.</i> at 23:18-19 ("Within this annular recess 182 is provided a discontinuous '7/8ths' snap-ring 180."), 24:3-4 ("... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182."). The unexpanded outer diameter is greater than a diameter of the transverse passageway. <i>Id.</i> at 23:19-21 ("The undeflected outer diameter of the snap-ring is greater than the diameter of the hole 110c or 112c (so that it will remain in the recess)"). <i>See also Id.</i> at FIGS. 5-6 (selected portions shown below),</p>

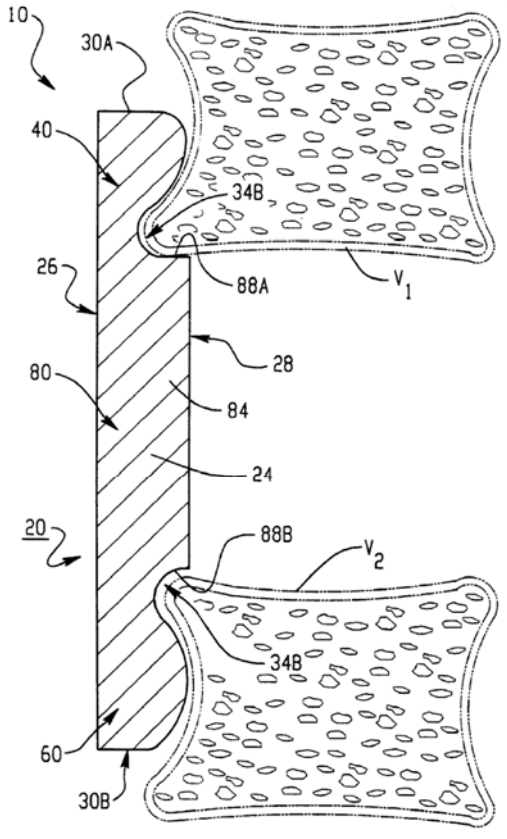
10. The assembly of claim 1 wherein the head of the securing element is longitudinally displaceable within the transverse passageway between a



The combination of Theken and Errico uses Errico's snap-ring 180 with Errico's in-hole annular recess 182 in Theken's threaded section 66.

<p>posterior surface of the biased stopping member and the second opening in the posterior surface of the stabilizing element.</p>	<p>In a first implementation of the combination, the annular recess 182 is placed at the bottom of the threaded section 66. A POSA would be motivated to include the annular recess 182 at the bottom location so as to create a constrained system that is desirable for some surgeries, where the posterior surface of the snap-ring 180 abuts the top of an inserted bone screw 100 so as to prevent noticeable movement.</p> <p>In a second implementation of the combination, the annular recess 182 is placed at the middle of Theken's threaded section 66. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for other surgeries, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for settling after surgery. In the second implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20).</p>
<p>12. The assembly of claim 1 wherein the stabilizing element includes at least two bores.</p>	<p><i>Theken (EX1005)</i>: There are at least two "holes formed in plate 20." <i>Id.</i> at 3:62. "Top portion 40 [of the plate 20] includes a pair of generally circular</p>

	<p>openings 42, which are dimensioned to receive fastener means, namely, bone screw 100 and set screw 140.” <i>Id.</i> at 4:16-18. “Bottom portion 60 [of the plate 20] includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140.” <i>Id.</i> at 4:35-38.</p>
<p>13. The assembly of claim 1 wherein the stabilizing element is configured to conform to and extend between at least two bone segments.</p>	<p><i>Theken (EX1005)</i>: “FIGS. 3 and 4 illustrate fixation system 10 as attached to vertebral bodies V₁ and V₂.” <i>Id.</i> at 3:65-66. “Referring now with particular reference to FIGS. 3 and 4, the gaps or notches 34A, 34B are dimensioned to receive a portion of a vertebral body.” <i>Id.</i> at 5:34-36. “It should be appreciated that medial side 28 has an outer surface that is anatomically contoured to match the profile of aspects common to vertebral bodies. ... The surface of medial side 28 is contoured to fit the vertebrae. Accordingly, the anterior portion of the medial side surface is relatively curved.” <i>Id.</i> at 5:59-64. <i>See also Id.</i> at FIG. 4 (showing conforming and extending aspects of the plate 20).</p>

	 <p style="text-align: center;"><i>Fig. 4</i></p>
<p>14. The assembly of claim 13 wherein the stabilizing element has a curved surface.</p>	<p><i>Theken (EX1005)</i>: “Referring now with particular reference to FIGS. 3 and 4, the gaps or notches 34A, 34B are dimensioned to receive a portion of a vertebral body.” <i>Id.</i> at 5:34-36. <i>See also Id.</i> at FIG. 4, showing curved surface of the notches 34A and 34B.</p>
<p>15. The assembly of claim 1 wherein the stabilizing element is selected from the group consisting of rods and plates.</p>	<p><i>Theken (EX1005)</i>: “Fixation system 10 is generally comprised of a bone plate 20” <i>Id.</i> at 3:59-60. <i>See also Id.</i> at FIGS. 1-2 (showing the plate 20).</p>
<p>16. The assembly of claim 1 wherein the securing element is selected from the group consisting of screws and nails.</p>	<p><i>Theken (EX1005)</i>: “Fixation system 10 is generally comprised of ... a plurality of bone screws 100” <i>Id.</i> at 3:59-60. <i>See also Id.</i> at FIGS. 1-2 and 11 (showing the bone screws 100).</p>

<p>17. The assembly of claim 2 wherein the collar is formed of an elastically deformable material.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 inherently is formed of an elastically deformable material to support its range of motion from inward deformation to outward deformation. <i>Id.</i> at 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”).</p>
<p>18. The assembly of claim 2 wherein the collar is formed of a material selected from the group consisting of titanium and superelastic material.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 inherently is formed of an elastic material to support its range of motion from inward deformation to outward deformation. <i>Id.</i> at 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”). Using particular types of elastic material, such as superelastic materials, is a simple design choice.</p>
<p>19. The assembly of claim 2 wherein the collar has a posterior surface perpendicular to a longitudinal axis of the transverse passageway.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the transverse passageway between the top and bottom of Errico’s plate 100c and, when combined with Theken, the lateral side 26 and the medial side 28 of</p>

	Theken's plate 20. <i>See, e.g. Id.</i> at FIG. 6.
29. The assembly of claim 4 wherein the collar has a height less than the height of the groove.	<i>Errico (EX1006)</i> : The height of snap-ring 180 is less than the height of the snap-ring 180, which is necessary for fitting the snap-ring 180 into the annular recess 182. <i>See, e.g. Id.</i> at FIG. 6.
31. The assembly of claim 10 wherein the stabilizing element is selected from the group consisting of rods and plates.	<i>Theken (EX1005)</i> : "Fixation system 10 is generally comprised of a bone plate 20" <i>Id.</i> at 3:59-60. <i>See also Id.</i> at FIGS. 1-2 (showing the plate 20).
32. The assembly of claim 10 wherein the securing element is selected from the group consisting of screws and nails.	<i>Theken (EX1005)</i> : "Fixation system 10 is generally comprised of ... a plurality of bone screws 100" <i>Id.</i> at 3:59-60. <i>See also Id.</i> at FIGS. 1-2 and 11 (showing the bone screws 100).

3. Claim 21 of the '008 patent is Obvious over Theken in view of Errico

147. It is my opinion that the combination of Theken and Errico renders claim 21 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 3) that follows.

148. With respect to the preamble to claim 21, Theken is directed to a method of attaching an orthopedic implant assembly to a bone of a patient. EX1005, 8:34-9:65 ("Installation of fixation system 10 will now be described ...").

149. With respect to claim element 21(a), Theken discloses positioning a stabilizing element (*e.g.* plate 20) against a surface of the patient's bone, the stabilizing element having an anterior surface (*e.g.* lateral side 26), a posterior surface (*e.g.* medial side 128), and at least one bore (*e.g.* opening 62), the bore

having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening. *Id.* at 8:33-38, 4:7-55, 5:59-66, FIGS. 1-10, in particular FIGS. 3-4.

150. With respect to claim element 21(a), Theken discloses a stopping member (*e.g.* set screw 140) within the bore. *Id.* at 3:63-65, 6:60-66, 7:33-35, 9:22-24, 9:54-59, FIGS. 1-3. As discussed above in paragraph 124, it would have been obvious to use a biased stopping member (*e.g.*, Errico's snap-ring) that defines a reversibly expandable passageway both smaller (unexpanded) and larger (expanded) diameter configurations.

151. With respect to claim element 21(b), Theken discloses providing a securing element (*e.g.* bone screw 100) having an elongated body (*e.g.* threaded portion 102), and a head (*e.g.* tapered head portion 110) at one end of the body and integral therewith, the head having a maximum diameter greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the stopping member (*e.g.*, set screw 140) and the second opening in the stabilizing element. EX1005, 4:21-26, 4:42-46, 6:19-31, FIG. 11. Because the head portion 110 has a taper that matches the taper of a tapered section 64 of the plate 20, the top of the head portion 110 has a maximum diameter that is

greater than the second opening at the bottom of the tapered section 64 of the plate 20.

152. With respect to claim element 21(c), Theken discloses positioning the body of the securing element (*e.g.* bone screw 100) in the transverse passageway (*e.g.* through opening 62) and posteriorly advancing the head of the securing element from the anterior surface to the posterior surface of the stabilizing element. *Id.* at 4:35-38, 8:34-37, 8:56-9:1.

153. With respect to claim element 21(d), Theken discloses attaching the stabilizing element (*e.g.* plate 20) to the bone by advancing the head (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) posteriorly of the stopping member (*e.g.* set screw 140, inserted later), to position the head (*e.g.* tapered head portion 110) within a posterior section (*e.g.* tapered section 64) of the transverse passageway (*e.g.* opening 62) between the stopping member (*e.g.* set screw 140) and the second opening in the stabilizing element (*e.g.* plate 20), and to position the body of the securing element (*e.g.* bone screw 100) within the patient's bone, so that the securing element (*e.g.* bone screw 100) is attached to the bone and is retained within the posterior section (*e.g.* tapered section 64) of the transverse passageway of the stabilizing element (*e.g.* plate 20). *Id.* at 4:35-38, 8:56-9:1.

154. With respect to claim element 21(a)-(d), Errico discloses a biased stopping member (*e.g.* snap-ring 180) within a bore (*e.g.* hole 110c) and defining at

least in part a reversibly expandable passageway having a smaller (unexpanded) diameter configuration and a larger (expanded) diameter configuration. EX1006, 6:1-2, 23:12-14, 23:25-24:10, FIGS. 5-6.

155. With respect to claim element 21(b), Errico discloses a maximum diameter (*e.g.* diameter of top 136a) of a head (*e.g.* tapered coupling element 132) of a securing element (*e.g.* coupling element 132 attached to bone screw 120) being greater than the smaller diameter configuration of the passageway defined by the biased stopping member so that the head (*e.g.* tapered coupling element 132) is retained within a transverse passageway between the biased stopping member (*e.g.* snap-ring 180) and a second opening in a stabilizing element (*e.g.* plate 100c). *Id.* at 8:13-17, 24:1-10, FIG. 6. Since the head portion 110 of Theken has a tapered outer surface 112, it has a maximum diameter at the top portion of the head portion 110. *Id.* at FIG. 11, 6:20-31. When implementing the snap-ring 180 of Errico for use with the tapered bone screw 100 of Theken, the maximum diameter of the tapered head portion 110 of Theken's bone screw 100 will be greater than the smaller unexpanded diameter configuration of the snap-ring 180 by proper sizing of the snap-ring 180 or adjusting the degree of taper in the tapered outer surface 112 of the head portion 110.

156. With respect to claim element 21(c), Errico discloses posteriorly advancing a head (*e.g.* tapered coupling element 132) of a securing element (*e.g.*

coupling element 132 attached to bone screw 120) within the passageway defined by the biased stopping member (*e.g.* snap-ring 180) and thereby displacing the biased stopping member (*e.g.* snap-ring 180) to form the larger expanded diameter configuration passageway defined thereby. *Id.* at 8:13-17, 23:27-24:7.

157. With respect to claim element 21(d), Errico discloses attaching a stabilizing element (*e.g.* plate 100c) to a bone by advancing the head (*e.g.* tapered coupling element 132) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) posteriorly of the biased stopping member (*e.g.* snap-ring 180) so that the passageway defined thereby returns to the smaller diameter configuration. *Id.* at 8:13-17, 24:4-10, FIG. 6. As a result, the head (*e.g.* tapered coupling element 132) is positioned within a posterior section of the transverse passageway (*e.g.* hole 110c) between the biased stopping member (*e.g.* snap-ring 180) and the second opening in the stabilizing element (*e.g.* plate 100c), the securing element positioned within a patient's bone and retained within the posterior section of the transverse passageway of the stabilizing element. *Id.* at 23:9-24:10, FIG. 6.

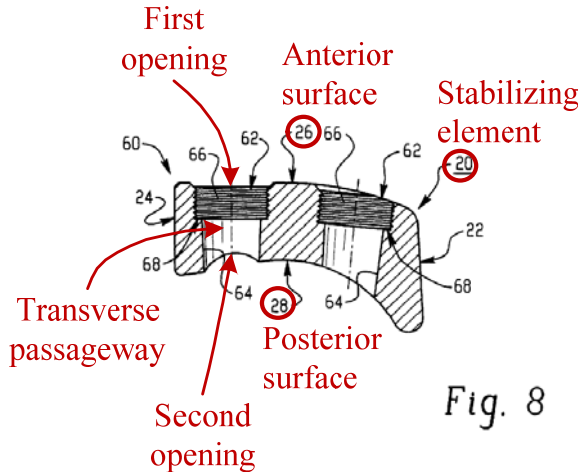
158. As I explain above in paragraph 115 above, Theken's tapered head portion 110 would function in the same way as Errico's tapered coupling element 132 with a flat upper surface in terms of inserting into a bore, expanding a snap-ring in the bore, and being retained by the snap-ring.

159. It is my opinion that it would have been obvious for a POSA to use Errico's snap-ring and in-bore annular recess to perform the function of preventing back-out of the screw in Theken's apparatus by locking the screw to the plate. As I explain above in paragraphs 115 and 116, it would have been obvious for a POSA to configure the Theken apparatus with the snap-ring and annular recess of Errico based on various rationales (discussed above), and there would be a reasonable expectation of success along with predictable results whereby the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring, being retained by the snap-ring, and having relative sizes compared to sizes of the snap-ring and portions of a bore. As I also explain above in paragraph 118, configuring the Theken apparatus with the snap-ring and annular recess of Errico would not render the Theken apparatus unsatisfactory for its intended purpose or change its principle operation.

160. Therefore, it is my opinion that the combination of Theken and Errico discloses all of the limitations of claim 21 of the '008 patent, and thus claim 21 would have been obvious to a POSA in view of the combination of Theken and Errico.

TABLE 3

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
21. A method of attaching an orthopedic implant assembly to a bone of a patient, comprising	<i>Theken (EX1005)</i> : "Installation of fixation system 10 will now be

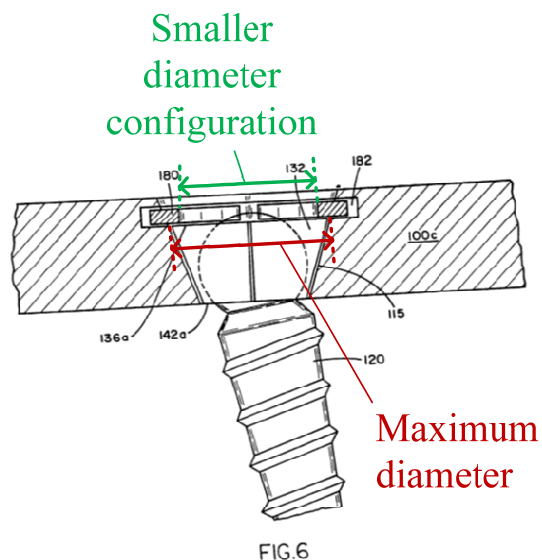
	described with particular reference to FIGS. 1-4.” <i>Id.</i> at 8:34-9:65.
a) positioning a stabilizing element against a surface of the patient's bone, the stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, 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;	<p><i>Theken (EX1005)</i>: “... plate 20 will fit into the narrow waist of the adjacent vertebral bodies.” <i>Id.</i> at 8:37-38. “plate 20 has...a lateral side 26, a medial side 28” <i>Id.</i> at 4:7-8. Plate 20 “includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10).” <i>Id.</i> at 4:35-48. <i>See also Id.</i> at FIG. 8.</p>  <p><i>Fig. 8</i></p> <p><i>Theken (EX1005)</i>: Non-biased “[s]et screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).” <i>Id.</i> at 4:63-65, FIGS. 1-2. “It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.” <i>Id.</i> at 7:33-35.</p>

	<p><i>Errico (EX1006)</i>: “Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown.” <i>Id.</i> at 23:25-26. The snap-ring 180 is a biased stopping member that “provides a simple and effective locking mechanism for locking the bone screw to the plate”. <i>Id.</i> at 6:1-2. The snap-ring 180 is suitable to lock a non-integral securing element/member comprising a screw and coupling element within the tapered hole of the plate 100c. <i>Id.</i> at 23:12-14. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller diameter (unexpanded) configuration to a larger diameter (expanded) configuration. <i>Id.</i> at 23:27-24:4. As further explained by Errico, “[o]nce the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. <i>Id.</i> at 24:4-7. Errico’s snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10. <i>See also Id.</i> at FIGS. 5-6.</p>
b) 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	<p><i>Theken (EX1005)</i>: “Screws 100 will now be described in detail with reference to FIGS. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from the lower end of head portion 110 to</p>

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;

rounded tip 106.” *Id.* at 6:20-22, FIG. 11. “Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in FIG. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in tapered sections 44 and 64 of plate 20.” *Id.* at 6:27-31. Because the head portion 110 has a taper than matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a maximum diameter that is greater than the second opening at the bottom of the tapered section 64 of the plate 20.

Errico (EX1006): Errico’s coupling element 132 has a “tapered exterior surface” that “causes the snap-ring 180 to expand”. *Id.* at 24:3. The tapered coupling element 132 has a maximum diameter greater than the undeformed smaller diameter configuration of the snap-ring 180. *Id.* at FIG. 6, 24:1-10.



	<p>“In its [the snap-ring] undeflected state it prevents the coupling element 132... from backing out of the plate 100c.” <i>Id.</i> at 24:7-8.</p> <p><i>Theken (EX1005)</i>: Since the head portion 110 of Theken has a tapered outer surface 112, it has a maximum diameter at the top portion of the head portion 110. <i>Id.</i> at FIG. 11, 6:20-31. When implementing the snap-ring 180 of Errico for use with the tapered bone screw 100 of Theken, the maximum diameter of the bone screw 100 of Theken will be greater than the smaller diameter configuration of the snap-ring 180 by proper sizing of the snap-ring 180. The degree of taper in the tapered outer surface 112 can also be adjusted as desired to ensure the maximum diameter at the top of Theken’s head portion 110 is greater than the smaller diameter configuration of Errico’s snap-ring 180, and to ensure the smaller diameter configuration of Errico’s snap-ring 180 is greater than the diameter of the tapered head portion 110 adjacent to the threaded portion 102, such that Theken’s tapered outer surface 112 expands Errico’s snap-ring 180, and Theken’s head portion 110 is retained within the transverse passageway between Errico’s snap-ring 180 and the second opening of Theken’s plate 20.</p>
c) 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	<p><i>Theken (EX1005)</i>: “Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100....” <i>Id.</i> at 4:35-38. “Screw 100 is then driven into the bone.” <i>Id.</i> at 8:59-</p>

<p>displacing the biased stopping member to form the larger diameter configuration passageway defined thereby; and</p>	<p>60. “It should be appreciated that the driving tapered head 112 of screw 100 into mating tapered section 44, 64 of plate 20, forces proper alignment between screw 100 and plate 20” <i>Id.</i> at 8:65-9:1.</p> <p><i>Errico (EX1006):</i> “During the implantation procedure, the screw 120 and the coupling element 132 (or 133) are inserted through the hole. Once the bottom 142a (or 142b) of the coupling element 132 (or 133), respectively, seats in the top of the hole 110c or 112c, and begins to travel into it, the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.” <i>Id.</i> at 23:27-24:4.</p>
<p>d) 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><i>Theken (EX1005):</i> “Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100” <i>Id.</i> at 4:35-38. “Screw 100 is then driven into the bone.” <i>Id.</i> at 8:59-60. “It should be appreciated that the driving tapered head 112 of screw 100 into mating tapered section 44, 64 of plate 20, forces proper alignment between screw 100 and plate 20” <i>Id.</i> at 8:65-9:1.</p> <p><i>Errico (EX1006):</i> “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from</p>

	backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” <i>Id.</i> at 24:4-10. <i>See also Id.</i> at FIG. 6 (showing placement of coupling element 132 within a posterior section of the transverse passageway.
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4. *Claim 36 of the '008 patent is Obvious over Theken in view of Errico*

161. It is my opinion that the combination of Theken and Errico renders claim 36 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 4) that follows.

162. With respect to the preamble to claim 36, it is identical to the preamble of claim 21. Theken is directed to a method of attaching an orthopedic implant assembly to a bone of a patient. EX1005, 8:34-9:65 (“Installation of fixation system 10 will now be described...”).

163. With respect to claim element 36(a), Theken discloses providing a securing member (*e.g.* bone screw 100) with an elongated body (*e.g.* threaded portion 102) and an enlarged integral portion (*e.g.* tapered head portion 110) having a maximum transverse dimension. *Id.* at 4:21-26, 4:42-46, 6:19-31, FIGS. 1-2, 8-11. Theken further discloses an attachment member (*e.g.* plate 20) which has an anterior surface (*e.g.* lateral side 26) and a posterior surface (*e.g.* medial side 28) and which has at least one bore (opening 62) extending through the

attachment member from the anterior surface to the posterior surface and is configured to receive the securing member (*e.g.* bone screw 100), the bore having an anterior bore portion (*e.g.* section 66 of the opening 62), and a posterior bore portion (*e.g.* tapered section 64 of the opening 62) with at least one transverse dimension smaller than a transverse dimension of the anterior bore portion and smaller than the maximum transverse dimension of the enlarged integral portion of the securing member. *Id.* at 4:7-65, 5:59-66, FIGS. 1-8, 10. Because the head portion 110 has a taper that matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a maximum transverse dimension that is greater than a posterior portion dimension at the bottom of the tapered section 64 of the plate 20. Theken also discloses a stopping member (*e.g.* set screw 140) which has a posterior surface to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member. EX1005, 3:63-65, 6:60-66, 7:33-35, 9:22-24, 9:54-59, FIGS. 1-3. Theken indicates that “set screws 140 could be replaced by other suitable locking mechanisms.” *Id.* at 7:33-35.

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

165. With respect to claim element 36(c), Theken discloses attaching the securing member (*e.g.* plate 20) to the patient's bone by advancing the securing member (*e.g.* bone screw 100) within the bore (*e.g.* opening 62) of the attachment member (*e.g.* plate 20) until the enlarged integral portion (*e.g.* tapered head portion 110) of the securing member (*e.g.* bone screw 100) passes a location for stopping member (*e.g.* section 66 of the opening 62) and is disposed in the posterior bore portion (*e.g.* tapered section 64 of the opening 62), wherein a stopping member (*e.g.* set screw 140) retains the enlarged integral portion (*e.g.* tapered head portion 110) within the posterior bore portion (*e.g.* tapered section 64) below a posterior surface of the stopping member (*e.g.* set screw 140). *Id.* at 4:33-38, 8:56-9:1, FIGS. 1-2.

166. With respect to claim element 36(a), Errico discloses a suitable stopping member (*e.g.* snap-ring 180) which has a first configuration (*e.g.* expanded configuration) which allows passage of an enlarged integral portion (*e.g.* tapered coupling element 132) of the securing member (*e.g.* coupling element 132 attached to bone screw 120) and has a second configuration (*e.g.* unexpanded configuration) that reduces a transverse dimension of a bore (*e.g.* hole 110c) that is smaller than a maximum transverse dimension (*e.g.* top surface 136) of the enlarged integral portion (*e.g.* tapered coupling element 132) in order to retain the enlarged integral portion (*e.g.* tapered coupling element 132) within a posterior

bore portion of an attachment member (*e.g.* plate 20), wherein the stopping member has an anterior surface and a posterior surface. EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-24:10, FIGS. 5-6.

167. With respect to claim element 36(c), Errico discloses attaching the securing member (*e.g.* plate 100c) to the patient's bone by advancing the securing member (*e.g.* coupling element 132 attached to bone screw 120) within the bore (*e.g.* hole 110c) of the attachment member (*e.g.* plate 100c) until the enlarged portion (*e.g.* tapered coupling element 132) of the securing member (*e.g.* coupling element 132 attached to bone screw 120) passes the stopping member (*e.g.* snap-ring 180) thereby displacing the stopping member (*e.g.* snap-ring 180) to the first configuration (*e.g.* expanded configuration) and is disposed in the posterior bore portion, the stopping member (*e.g.* snap-ring 180) then returning to the second configuration (*e.g.* undeformed/unexpanded configuration) to retain the enlarged portion (*e.g.* tapered coupling element 132) of the securing member within the posterior bore portion below the posterior surface of the stopping member (*e.g.* snap-ring 180).

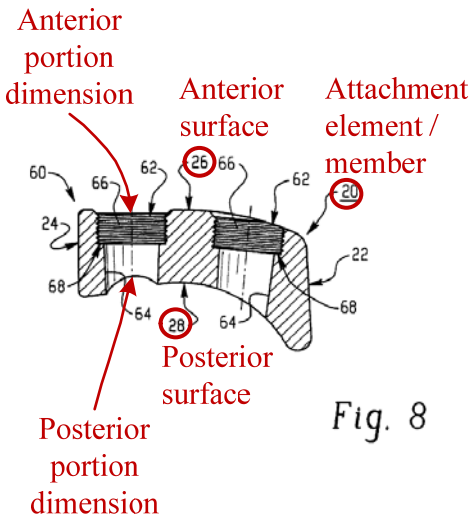
168. As I explain above in paragraph 115, Theken's tapered head portion 110 would function in the same way as Errico's tapered coupling element 132 with a flat upper surface in terms of inserting into a bore, expanding a snap-ring in the bore, and being retained by the snap-ring.

169. It is my opinion that it would have been obvious for a POSA to use Errico's snap-ring and in-bore annular recess to perform the function of preventing back-out of the screw in Theken's apparatus by locking the screw to the plate. As I explain above in paragraphs 115 and 116, it would have been obvious for a POSA to configure the Theken apparatus with the snap-ring and annular recess of Errico based on various rationales (discussed above), and there would be a reasonable expectation of success along with predictable results whereby the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring , being retained by the snap-ring, and having relative sizes compared to sizes of the snap-ring and portions of a bore. As I also explain above in paragraph 118, configuring the Theken apparatus with the snap-ring and annular recess of Errico would not render the Theken apparatus unsatisfactory for its intended purpose or change its principle operation.

170. Therefore, it is my opinion that the combination of Theken and Errico discloses all of the limitations of claim 36 of the '008 patent, and thus claim 36 would have been obvious to a POSA in view of the combination of Theken and Errico.

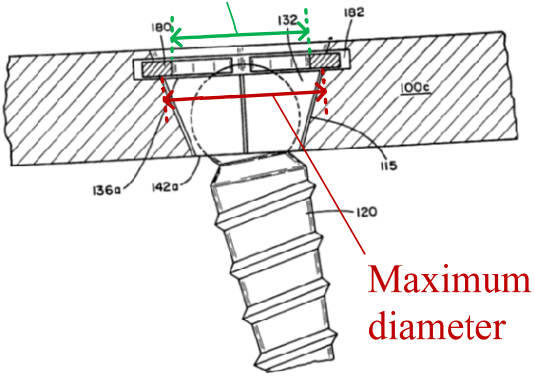
TABLE 4

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
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<p>36. A method of attaching an orthopedic implant assembly to a bone of a patient, comprising</p>	<p><i>Theken (EX1005)</i>: “Installation of fixation system 10 will now be described with particular reference to FIGS. 1-4.” <i>Id.</i> at 8:34-9:65.</p>
<p>a) providing a securing member with an elongated body and an enlarged integral portion having a maximum transverse dimension, 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 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>Attachment member:</u> <i>Theken (EX1005)</i>: “... plate 20 has ... a lateral side 26, a medial side 28” <i>Id.</i> at 4:7-8. Plate 20 “includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10).” <i>Id.</i> at 4:35-48. <i>See also Id.</i> at FIGS. 1-2 showing the slidable disposition of screws 100. <i>See also</i> FIG. 8.</p>  <p><u>Securing member:</u> <i>Theken (EX1005)</i>: “Screws 100 will now be described in detail with reference to FIGS. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from</p>

	<p>the lower end of head portion 110 to rounded tip 106.” <i>Id.</i> at 6:20-22, FIG. 11. “Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in FIG. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in tapered sections 44 and 64 of plate 20.” <i>Id.</i> at 6:27-31. Because the head portion 110 has a taper than matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a maximum transverse dimension that is greater than a posterior portion dimension at the bottom of the tapered section 64 of the plate 20.</p> <p><u>Stopping member:</u> <i>Theken (EX1005):</i> Non-biased “[s]et screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).” <i>Id.</i> at 4:63-65, FIGS. 1-2. “It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.” <i>Id.</i> at 7:33-35.</p> <p><i>Errico (EX1006):</i> “Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown.” <i>Id.</i> at 23:25-26. The snap-ring 180 is a biased stopping member that “provides a simple and effective locking mechanism for locking the bone screw to the plate”. <i>Id.</i> at 6:1-2. The snap-ring 180 is suitable to lock a non-integral securing</p>
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element/member comprising a screw and coupling element within the tapered hole of the plate 100c. *Id.* at 23:12-14. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller unexpanded ‘second’ diameter configuration to a larger expanded ‘first’ diameter configuration that allows passage of a tapered head of a securing member. *Id.* at 23:27-24:4. As further explained by Errico, “[o]nce the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller ‘second’ diameter configuration that reduces a transverse dimension of the bore, and 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. *Id.* at 24:4-7. “In its [the snap-ring] undeflected state it prevents the coupling element 132... from backing out of the plate 100c....” *Id.* at 24:7-8. Errico’s snap-ring 180 will open (*i.e.* deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. *Id.* at 24:9-10. *See also* FIGS. 5-6, which show the anterior and posterior surfaces of the snap-ring 180, demonstrate the different dimensions of a head of a securing member (coupling element

	<p>132) and an undeformed configuration of the stopping member (snap-ring 18), and also illustrate how the snap-ring 180 carries out the claimed features of the stopping member.</p> <p>Smaller diameter configuration</p>  <p>FIG. 6</p>
<p>b) positioning the attachment member with at least part of the posterior surface thereof against a surface of the patient's bone; and</p>	<p><i>Theken (EX1005)</i>: “FIGS. 3 and 4 illustrate fixation system 10 as attached to vertebral bodies V_1 and V_2.” <i>Id.</i> at 3:65-66. “Referring now with particular reference to FIGS. 3 and 4, the gaps or notches 34A, 34B are dimensioned to receive a portion of a vertebral body.” <i>Id.</i> at 5:34-36. “... plate 20 will fit into the narrow waist of the adjacent vertebral bodies.” <i>Id.</i> at 8:37-38. <i>See also Id.</i> at FIG. 4 (showing conforming and extending aspects of the plate 20, where notches 34A, 34B of the posterior surface—<i>i.e.</i> medial side 28—are against a surface of a patient’s bone).</p>

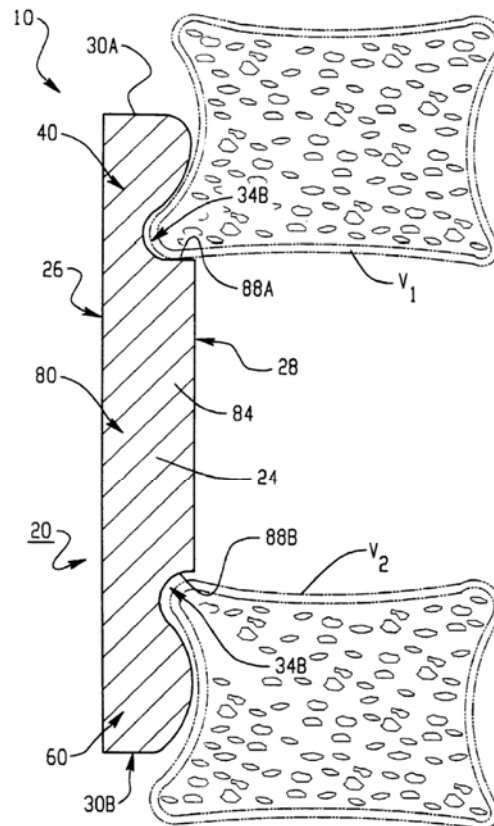


Fig. 4

c) 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

Theken (EX1005): "Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100" *Id.* at 4:35-38. "Screw 100 is then driven into the bone." *Id.* at 8:59-60. "It should be appreciated that the driving tapered head 112 of screw 100 into mating tapered section 44, 64 of plate 20, forces proper alignment between screw 100 and plate 20" *Id.* at 8:65-9:1.

Errico (EX1006): "... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to

portion below the posterior surface of the stopping member.	expand in the recess 182”. <i>Id.</i> at 23:27-24:4 “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” <i>Id.</i> at 24:4-10. <i>See also Id.</i> at FIG. 6 (showing placement of coupling element 132 within a posterior section of the bore.
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5. *Claim 44 of the '008 patent is Obvious over Theken in view of Errico*

171. It is my opinion that the combination of Theken and Errico renders claim 44 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 5) that follows.

172. With respect to the preamble to claim 44, Theken is directed to an orthopedic implant assembly. EX1005, 3:54-65, FIGS. 1-14.

173. With respect to claim element 44(a), Theken discloses a stabilizing element (*e.g.* plate 20) having an anterior surface (*e.g.* lateral side 26), a posterior surface (*e.g.* medial side 128), and at least one bore (*e.g.* opening 62) extending through the stabilizing element (*e.g.* plate 20) from the anterior surface to the posterior surface and the bore (*e.g.* opening 62) having an anterior bore portion

(*e.g.* section 66) with a transverse dimension and a posterior bore portion (*e.g.* tapered section 64) which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion (*e.g.* section 66). *Id.* at 4:7-55,5:59-66, FIGS. 1-8 and 10.

174. With respect to claim element 44(b), Theken discloses a securing element (*e.g.* bone screw 100) which is configured to be slidably disposed within the bore (*e.g.* opening 62) of the stabilizing element (*e.g.* plate 20) and which has an elongated body (*e.g.* threaded portion 102) and an enlarged integral portion (*e.g.* tapered head portion 110) with a maximum transverse dimension. EX1005, 4:21-46, 6:19-31, FIGS. 1-2 (showing the slidable disposition of screw 100), FIG. 11 (showing features of screw 100). Because the head portion 110 has a taper that matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a maximum transverse dimension that is greater than the posterior portion dimension at the bottom of the tapered section 64 of the plate 20.

175. With respect to claim element 44(c), Theken discloses a stopping member (*e.g.* set screw 140) to facilitate retention of the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) within the posterior bore portion (*e.g.* tapered section 64) of the stabilizing element (*e.g.* plate 20), wherein the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) is retained below the posterior

surface of the stopping member (set screw 140). EX1005, 3:63-65, 4:63-65, 6:60-66, 7:33-35, 9:22-24, 9:54-59, FIGS. 1-3.

176. With respect to claim element 44(c), Errico discloses a stopping member (*e.g.* snap-ring 180) which is at least partially disposed within a bore (*e.g.* hole 110c) of a stabilizing element (*e.g.* plate 100c), which has a posterior stopping surface, a first configuration (*e.g.*, an expanded configuration) within the bore (*e.g.* hole 110c) allowing passage of a securing element (*e.g.* coupling element 132 attached to bone screw 120) into the posterior bore portion with an enlarged integral portion (*e.g.* tapered coupling element 132) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) disposed in a posterior bore portion posterior to the stopping member (*e.g.* snap-ring 180) and a second configuration (*e.g.*, an unexpanded configuration) within the bore (*e.g.* hole 110c) which has smaller transverse dimensions than the first configuration and smaller than the maximum transverse dimension of the enlarged integral portion (*e.g.* tapered coupling element 132) to facilitate retention of the enlarged integral portion (*e.g.* tapered coupling element 132) within the posterior bore portion of the stabilizing element (*e.g.* plate 100c), wherein the enlarged integral portion (*e.g.* tapered coupling element 132) is retained below the posterior surface of the stopping member (*e.g.* snap-ring 180). EX1006, 4:1-5, 6:1-2, 8:13-17, 23:12-24:10, FIGS 5-6.

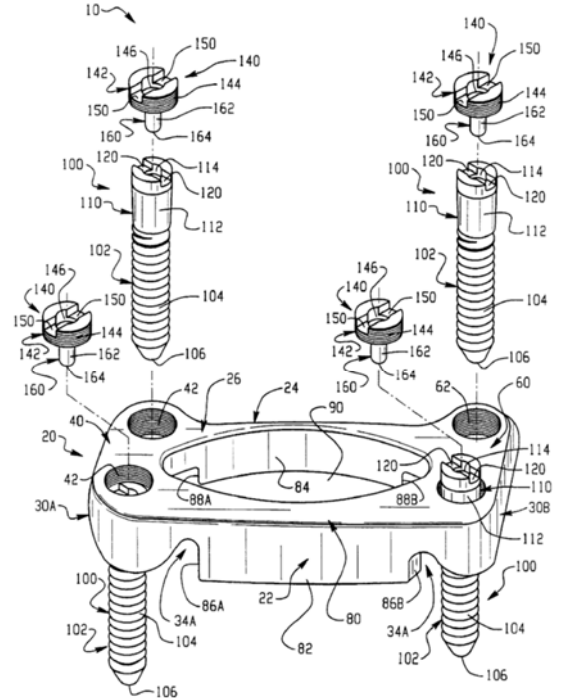
177. As I explain above in paragraph 115, Theken's tapered head portion 110 would function in the same way as Errico's tapered coupling element 132 with a flat upper surface in terms of inserting into a bore, expanding a snap-ring in the bore, and being retained by the snap-ring.

178. It is my opinion that it would have been obvious for a POSA to use Errico's snap-ring and in-bore annular recess to perform the function of preventing back-out of the screw in Theken's apparatus by locking the screw to the plate. As I explain above in paragraphs 115 and 116, it would have been obvious for a POSA to configure the Theken apparatus with the snap-ring and annular recess of Errico based on various rationales (discussed above), and there would be a reasonable expectation of success along with predictable results whereby the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring, being retained by the snap-ring, and having relative sizes compared to sizes of the snap-ring and portions of a bore. As I also explain above in paragraph 118, configuring the Theken apparatus with the snap-ring and annular recess of Errico would not render the Theken apparatus unsatisfactory for its intended purpose or change its principle operation.

179. Therefore, it is my opinion that the combination of Theken and Errico discloses all of the limitations of claim 44 of the '008 patent, and thus claim 44

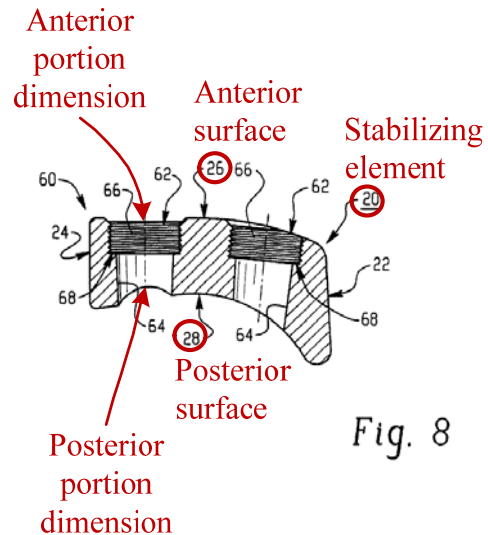
would have been obvious to a POSA in view of the combination of Theken and Errico.

TABLE 5

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
44. An orthopedic implant assembly, comprising:	<p><i>Theken (EX1005)</i>: "... FIG. 1 shows an exploded view of a bone fixation system 10 Fixation system 10 is generally comprised of a bone plate 20, a plurality of bone screws 100, and a plurality of set screws 140." <i>Id.</i> at 3:54-65, FIGS. 1-14.</p>  <p style="text-align: center;"><i>Fig. 1</i></p>
a. a stabilizing element having an anterior surface, a posterior surface, and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface and the bore having an anterior bore portion with a transverse dimension and a posterior bore portion which has a	<p><i>Theken (EX1005)</i>: "... plate 20 has ... a lateral side 26, a medial side 28" <i>Id.</i> at 4:7-8. Plate 20 "includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded</p>

posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion;

section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10).” *Id.* at 4:35-48. *See also Id.* at FIG. 8.



b. a securing element which is configured to be slidably disposed within the bore of the stabilizing element and which has an elongated body and an enlarged integral portion with a maximum transverse dimension; and

Theken (EX1005): “Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 ...” *Id.* at 4:35-38. *See also Id.* at FIGS. 1-2 showing the slidable disposition of screws 100. “Screws 100 will now be described in detail with reference to FIGS. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from the lower end of head portion 110 to rounded tip 106.” *Id.* at 6:20-22, FIG. 11. “Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in FIG. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in tapered sections 44 and 64 of plate 20.”

	<p><i>Id.</i> at 6:27-31. Because the head portion 110 has a taper that matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a maximum transverse dimension that is greater than the posterior portion dimension at the bottom of the tapered section 64 of the plate 20.</p>
<p>c. a stopping member which is at least partially disposed within the bore of the stabilizing element, which has a posterior stopping surface, a first configuration within the bore allowing passage of the securing element into the posterior bore portion with the enlarged integral portion of the securing element disposed in the posterior bore portion posterior to the stopping member and a second configuration within the bore which has smaller transverse dimensions than the first configuration and smaller than the maximum transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion of the stabilizing element; and wherein the enlarged integral portion of the securing element is retained below the posterior surface of the stopping member.</p>	<p><i>Theken (EX1005)</i>: Non-biased “[s]et screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).” <i>Id.</i> at 4:63-65, FIGS. 1-2. “It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.” <i>Id.</i> at 7:33-35.</p> <p><i>Errico (EX1006)</i>: “More specifically with respect to Figure 5, which is a top view of the hole and retaining ring of this variation, the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole (the hole may be either smooth as in Figure 1a or threaded as in Figure 1b). Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180.” <i>Id.</i> at 23:14-19, FIG. 5. “Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown.” <i>Id.</i> at 23:25-26, FIG. 6 (showing posterior stopping surface). The snap-ring 180 is a biased stopping member that “provides a simple and effective locking mechanism for locking the bone screw to the plate”. <i>Id.</i> at 6:1-2. The snap-ring 180 is suitable to lock a non-integral securing element/member comprising a</p>

	<p>screw and coupling element within the tapered hole of the plate 100c. <i>Id.</i> at 23:12-14. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller diameter (unexpanded) configuration to a larger diameter (expanded) configuration. <i>Id.</i> at 23:27-24:4. “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. <i>Id.</i> at 24:4-7. “In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” <i>Id.</i> at 24:7-10. Errico’s snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10.</p>
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6. *Each of Claims 45, 46, 47, 48, 49, 50, 53, and 54 of the '008 patent is Obvious over Theken in view of Errico*

180. It is my opinion that the combination of Theken and Errico renders each of claims 45, 46, 47, 48, and 54 of the '008 patent obvious by disclosing each and

every element of the claim, as shown below and in the claim chart (Table 6) that follows.

181. Claim 45 depends from claim 44, which is discussed in paragraphs 171 through 179. The rationale for combining Theken and Errico with respect to claim 44 also applies to claim 45. With respect to the limitations in claim 45, as shown in Table 6 below, the combination of Theken and Errico comprises a stopping member (*e.g.* snap-ring 180) that is configured to prevent the back-out of the securing element through the bore of the stabilizing element. *See, e.g.* EX1006, 8:13-17, 23:12-24:10. Theken's tapered head portion 110 is inserted into a bore in the same manner as Errico's tapered coupling element 132, and would be prevented from backing out in the same manner as Errico's tapered coupling element 132.

182. Claim 46 depends from claim 44, which is discussed in paragraphs 171 through 179. The rationale for combining Theken and Errico with respect to claim 44 also applies to claim 46. With respect to the limitations in claim 46, as shown in Table 6 below, the combination of Theken and Errico comprises a stopping member (*e.g.* snap-ring 180) that is biased to the second configuration (*i.e.*, unexpanded configuration). *See, e.g.* EX1006, 8:13-17, 23:12-24:10.

183. Claim 47 depends from claim 46, which is discussed in paragraph 182. The rationale for combining Theken and Errico with respect to claim 46 also applies to claim 47. With respect to the limitations in claim 47, as shown in Table 6 below,

the combination of Theken and Errico comprises a stopping member (*e.g.* snap-ring 180) that comprises a biased collar having a passageway therethrough. *See, e.g.* EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6.

184. Claim 48 depends from claim 47, which is discussed in paragraph 183. The rationale for combining Theken and Errico with respect to claim 47 also applies to claim 48. With respect to the limitations in claim 48, as shown in Table 6 below, the combination of Theken and Errico comprises the bore that has a groove (*e.g.* annular recess 182) in an anterior portion thereof configured to receive the biased collar (*e.g.* snap-ring 180), and wherein the biased collar (*e.g.* snap-ring 180) is configured to be reversibly expandable when seated in the groove (*e.g.* annular recess 182). *See, e.g.* EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6. Errico shows an annular recess 182 that is positioned in an anterior section of Errico's hole 110c. EX1006, at FIG. 6. In the combination, the annular recess 182 is similarly positioned in the anterior portion (*e.g.* section 66) of Theken's bore (*e.g.* opening 62).

185. Claim 54 depends from claim 44, which is discussed in paragraphs 171 through 179. The rationale for combining Theken and Errico with respect to claim 44 also applies to claim 54. With respect to the limitations in claim 54, as shown in Table 6 below, the combination of Theken and Errico comprises an enlarged integral portion of a securing element that is configured to be longitudinally displaceable within the posterior bore portion of the bore of the stabilizing element. In one

implementation of the combination illustrated in paragraph 113, the annular recess 182 is placed at the middle of Theken's threaded section 66, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for an unconstrained system that allows for settling after certain surgeries. In this implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20).

TABLE 6

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
45. The assembly of claim 44 wherein the stopping member is configured to prevent the back-out of the securing element through the bore of the stabilizing element.	<i>Errico (EX1006)</i> : "In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open)." <i>Id.</i> at 24:7-10. Theken's tapered head portion 110 is inserted into a bore in the same manner as Errico's tapered coupling element 132, and would be prevented from backing out in the same manner as Errico's tapered coupling element 132.
46. The assembly of claim 44 wherein the stopping member is biased to the second configuration.	<i>Errico (EX1006)</i> : "... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to

	<p>expand in the recess 182” from a smaller diameter (i.e., unexpanded) configuration to a larger diameter (i.e., expanded) configuration. <i>Id.</i> at 23:27-24:4. “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. <i>Id.</i> at 24:4-7.</p>
<p>47. The assembly of claim 46 wherein the stopping member comprises a biased collar having a passageway therethrough.</p>	<p><i>Errico (EX1006)</i>: “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180” that forms a collar. <i>Id.</i> at 23:18-19. <i>See also Id.</i> at FIG. 5 (selected portion shown below), which illustrates a collar shape for snap-ring 180. The snap-ring 180 operates by enlarging from an unexpanded inner diameter to an expanded inner diameter as a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded inner diameter after the tapered coupling element 132 passes through the snap-ring 180. <i>Id.</i> at 23:27-24:10, FIG. 6.</p> <div data-bbox="844 1323 1380 1806"> </div> <p style="text-align: right;">FIG.5</p>

48. The assembly of claim 47 wherein the bore has a groove in an anterior portion thereof configured to receive the biased collar, and wherein the biased collar is configured to be reversibly expandable when seated in the groove.

Errico (EX1006): "... the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole Within this annular recess 182 is provided a discontinuous '7/8ths' snap-ring 180." *Id.* at 23:16-19, FIGS. 5-6. "The snap-ring 180 is deflected inward for positioning in the recess 182." *Id.* at 23:26-27. "... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182." *Id.* at 24:3-4.

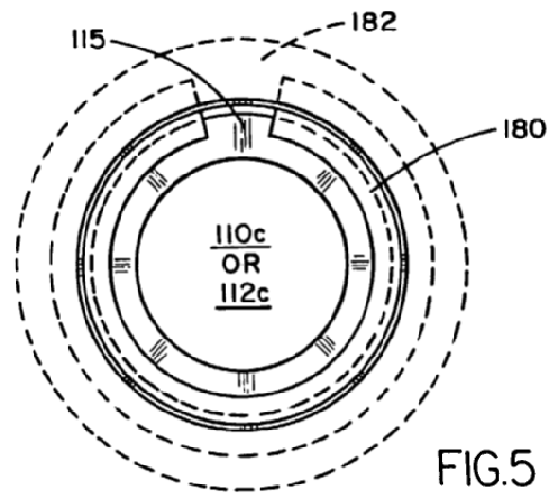


FIG.5

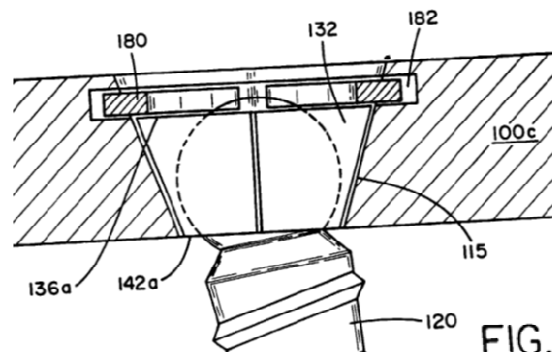


FIG.6

The combination of Theken and Errico uses Errico's in-hole annular recess 182 and snap-ring 180. Therefore, the resultant modification of Theken has the

	<p>same characteristics as Errico's annular recess 182 and snap-ring 180 in terms of positioning of the annular recess 182 in an anterior portion of a bore and in terms of the expansion of the snap-ring 180.</p>
<p>54. The assembly of claim 44 wherein the enlarged integral portion of the securing element is configured to be longitudinally displaceable within the posterior bore portion of the bore of the stabilizing element.</p>	<p>The combination of Theken and Errico uses Errico's snap-ring 180 with Errico's in-hole annular recess 182 in Theken's threaded section 66.</p> <p>In a first implementation of the combination, the annular recess 182 is placed at the bottom of the threaded section 66. A POSA would be motivated to include the annular recess 182 at the bottom location so as to create a constrained system that is desirable for some surgeries, where the posterior surface of the snap-ring 180 abuts the top of an inserted bone screw 100 so as to prevent noticeable movement.</p> <p>In a second implementation of the combination, the annular recess 182 is placed at the middle of Theken's threaded section 66. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for other surgeries, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for settling after surgery. In the second implementation, the head of the securing element (head portion 110 of</p>

	the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20).
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7. Each of claims 49, 50, and 53 of the '008 patent are Obvious over Theken in view of Errico

186. It is my opinion that the combination of Theken and Errico renders each of claims 49-50 and 53 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 7) that follows.

187. Claim 49 depends from claim 48, which is discussed in paragraph 184. The rationale for combining Theken and Errico with respect to claim 48 also applies to claim 49. Claim 53 depends from claim 44, which is discussed in paragraphs 171-179. The rationale for combining Theken and Errico with respect to claim 44 also applies to claim 53. With respect to the limitations in claims 49 and 53, as shown in Table 4 below, the combination of Theken and Errico comprises an enlarged integral portion of the securing element, and said enlarged integral portion has a curved posterior surface. The curved posterior surface is configured to expand the collar as the enlarged integral portion is displaced posteriorly through the collar passageway. With respect to the limitations of claim 49, as shown in Table 4 below, the combination of Theken and Errico comprises a

curved posterior surface configured to expand the collar as the enlarged integral portion is displaced posteriorly through the collar passageway. EX1006, 18:14-19:2, 19:13-20, FIGS. 2, 6 (integral spherical head portion 122 of screw 120); EX1005, 6:51-56. Claim 53 depends from claim 44

188. Claim 50 depends from claim 49, which is discussed in paragraph 187. The rationale for combining Theken and Errico with respect to claim 49 also applies to claim 50. Errico discloses that the minimum transverse dimension of the posterior surface of an enlarged portion (*e.g.* coupling element 132) of the securing element should be smaller than the transverse dimension of the passageway of the unexpanded collar, which configures it to expand the collar by contacting the collar at an anterior surface of the collar and deflecting the collar away from the longitudinal axis of the collar passageway as the enlarged portion is displaced posteriorly through the collar passageway. EX1006, 8:13-17, 23:12-24:10 & FIGS 5-6.

TABLE 7

‘008 Patent Claim	Theken (EX1005) and Errico (EX1006)
49. The assembly of claim 48 wherein the curved posterior surface of the enlarged integral portion of the securing element is configured to expand the collar as the enlarged integral portion of the securing element is displaced posteriorly through the collar passageway.	<i>Errico (EX1006):</i>

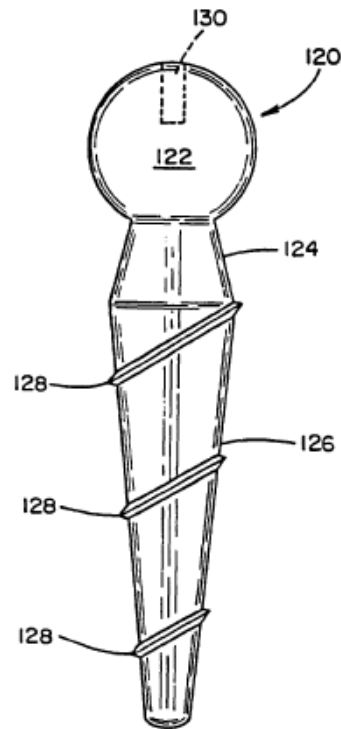


FIG. 2

FIG. 2 (*see also*: FIG. 6, below) illustrating the curved posterior surface of the enlarged integral portion of the securing element (*i.e.*, head portion 122 of screw 120). *Id.* at 24:7-10. Errico's spherical head expands the collar (*e.g.*, snap ring 180 of FIG. 6) as said enlarged integral portion is displaced posteriorly through the passageway.

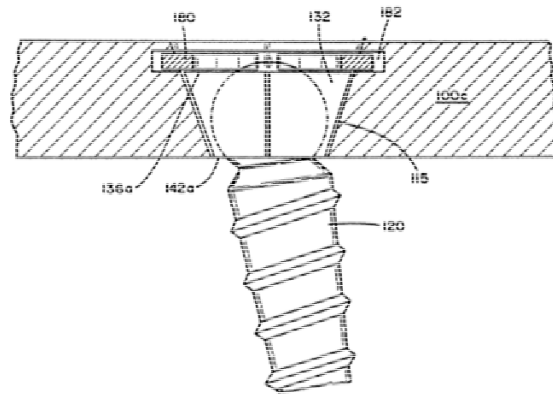


FIG. 6

FIG. 6.

Theken (EX1005): "...the tapered head could be replaced by a spherical bead. The spherical bead would allow variable screw angulation." *Id.* at 6:51-56.

50. The assembly of claim 49 wherein the curved posterior surface of the enlarged integral portion of the securing element has a minimum transverse dimension smaller than a transverse dimension of the passageway of the unexpanded collar, and which is configured to contact an anterior surface of the collar and deflect the collar away from a longitudinal axis of the collar passageway as the enlarged integral portion of the securing element is displaced posteriorly through the collar passageway.

Errico (EX1006):

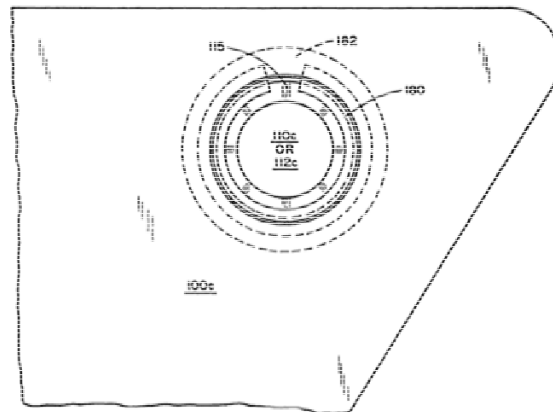
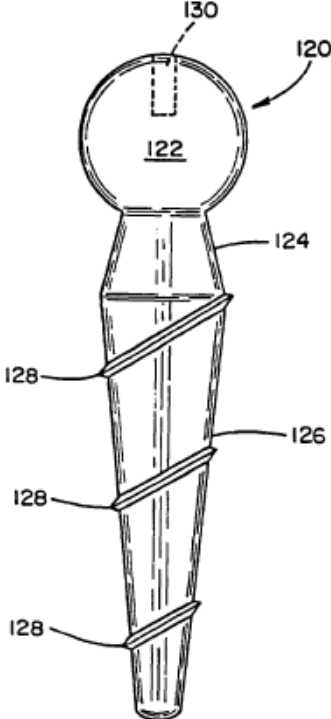


FIG. 5

FIG. 5 (*see also*: FIG. 6, above) illustrating the minimum transverse dimension of the posterior surface of an enlarged portion (*e.g.* coupling element 132) of the securing element should be smaller than the transverse dimension of the passageway of the unexpanded collar, which configures it to expand the collar by contacting the collar at an anterior surface of the collar and

	deflecting the collar away from the longitudinal axis of the collar passageway as the enlarged portion is displaced posteriorly through the collar passageway.
53. The assembly of claim 44 wherein the enlarged integral portion of the securing element has a curved posterior surface.	<p><i>Errico (EX1006):</i></p>  <p>FIG. 2</p> <p>FIG. 2 (see also: FIG. 6, above) illustrating the enlarged integral portion (head 122) of the securing element (screw 120) has a curved posterior surface.</p>

8. *Claim 59 of the '008 patent is Obvious over Theken in view of Errico*

189. It is my opinion that the combination of Theken and Errico renders claim 59 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 8) that follows.

190. With respect to the preamble to claim 59, Theken is directed to an orthopedic attachment assembly. EX1005, 3:54-65, 8:34-9:65, FIGS. 1-14.

191. With respect to claim element 59(a), Theken discloses an elongated securing element (*e.g.* bone screw 100) having an enlarged integral portion (*e.g.* tapered head portion 110) with a length, an anterior surface (*e.g.* top), a posterior surface (*e.g.* tapered outer surface 112) and a transverse dimension. EX1005, 6:20-31, FIG. 11.

192. With respect to claim element 59(b), Theken discloses an attachment element (*e.g.* plate 20) that has an anterior surface (*e.g.* lateral side 26) a posterior surface (*e.g.* medial side 128), and at least one bore (*e.g.* opening 62) extending from the anterior surface (*e.g.* lateral side 26) to the posterior surface (*e.g.* medial side 128) that is configured to receive the securing element (*e.g.* bone screw 100), and that includes an anterior bore portion (*e.g.* section 66 of the opening 62) and a posterior bore portion (*e.g.* tapered section 64 of the opening 62) that has a transverse dimension that is smaller than the transverse dimension of the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) to facilitate retention of the enlarged integral portion (*e.g.* tapered head portion 110) within the posterior bore portion (*e.g.* tapered section 64). EX1005, 4:7-8, 4:35-48, FIGS. 1-2 and 8. Because the head portion 110 has a taper than matches the taper of the tapered section 64 of the plate, the top of the head portion

110 has a maximum transverse dimension that is greater than a posterior portion dimension at the bottom of the tapered section 64 of the plate 20.

193. With respect to claim element 59(c), Theken discloses a stopping member (*e.g.* set screw 140) which has a posterior stopping surface that is configured to engage with the anterior surface (*e.g.* top) of the enlarged integral portion (*e.g.* head portion 110) of the securing member (*e.g.* bone screw 100). EX1005, 4:63-65, FIGS. 1-2. Theken indicates that “set screws 140 could be replaced by other suitable locking mechanisms.” *Id.* at 7:33-35.

194. With respect to claim element 59(c), Errico discloses a biased stopping member (*e.g.* snap-ring 180) which has a posterior stopping surface, a first configuration (*e.g.* undeformed/unexpanded configuration) which extends within a bore (*e.g.* hole 110c) of an attachment member (*e.g.* plate 100c) that is elastically deformed to a second configuration (*e.g.* expanded configuration) as an enlarged portion (*e.g.* tapered coupling element 132) of a securing member (*e.g.* coupling element 132 attached to bone screw 120) passes into a posterior bore portion of the bore (*e.g.* hole 110c), the biased stopping member (*e.g.* snap-ring 180) returning to the first configuration (*e.g.* undeformed/unexpanded configuration) upon passage of the enlarged portion (*e.g.* tapered coupling element 132) into the posterior bore portion, the posterior stopping surface of the biased stopping member (*e.g.* snap-ring 180) configured to engage with an anterior

surface (*e.g.* top surface 136) of the enlarged portion (*e.g.* tapered coupling element 132) facilitating retention of the enlarged portion (*e.g.* tapered coupling element 132) within the posterior bore portion of the attachment member (*e.g.* plate 100c). EX1006, 6:1-2, 8:13-17, 23:12-24:10, FIGS. 5-6.

195. As I explain above in paragraph 115, Theken's tapered head portion 110 would function in the same way as Errico's tapered coupling element 132 with a flat upper surface in terms of inserting into a bore, expanding a snap-ring in the bore, and being retained by the snap-ring.

196. It is my opinion that it would have been obvious for a POSA to use Errico's snap-ring and in-bore annular recess to perform the function of preventing back-out of the screw in Theken's apparatus by locking the screw to the plate. As I explain above in paragraphs 115 and 116, it would have been obvious for a POSA to configure the Theken apparatus with the snap-ring and annular recess of Errico based on various rationales (discussed above), and there would be a reasonable expectation of success along with predictable results whereby the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring, being retained by the snap-ring, and having relative sizes compared to sizes of the snap-ring and portions of a bore. As I also explain above in paragraph 118, configuring the Theken apparatus with the

snap-ring and annular recess of Errico would not render the Theken apparatus unsatisfactory for its intended purpose or change its principle operation.

197. Therefore, it is my opinion that the combination of Theken and Errico discloses all of the limitations of claim 59 of the '008 patent, and thus claim 59 would have been obvious to a POSA in view of the combination of Theken and Errico.

TABLE 8

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
59. An orthopedic attachment assembly, comprising:	<i>Theken (EX1005)</i> : "... FIG. 1 shows an exploded view of a bone fixation system 10 Fixation system 10 is generally comprised of a bone plate 20, a plurality of bone screws 100, and a plurality of set screws 140." <i>Id.</i> at 3:54-65. <i>See also</i> FIGS. 1-14.

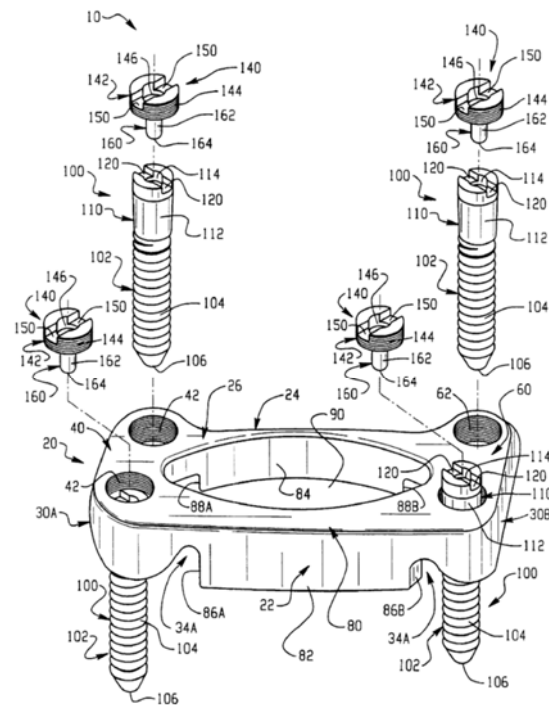
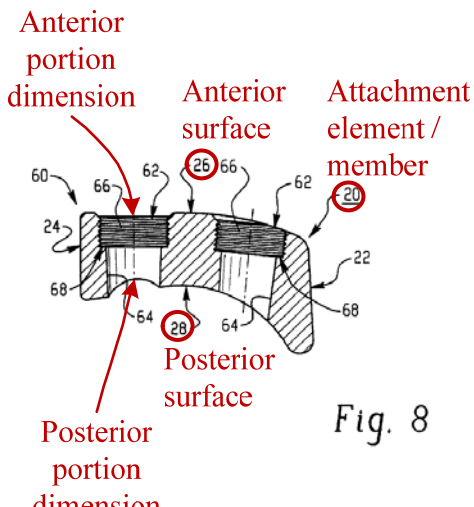


Fig. 1

a. an elongated securing element having an enlarged integral portion with a length, an anterior surface, a posterior surface and a transverse dimension;

Theken (EX1005): “Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 ...” *Id.* at 4:35-38. *See also Id.* at FIGS. 1-2 showing the slidable disposition of screws 100. “Screws 100 will now be described in detail with reference to FIGS. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from the lower end of head portion 110 to rounded tip 106.” *Id.* at 6:20-22, FIG. 11. “Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in FIG. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in

	<p>tapered sections 44 and 64 of plate 20.” <i>Id.</i> at 6:27-31. Because the head portion 110 has a taper than matches the taper of the tapered section 64 of the plate, the top of the head portion 110 has a transverse dimension that is greater than the posterior portion dimension at the bottom of the tapered section 64 of the plate 20.</p>
<p>b. an attachment element which has an anterior surface and a posterior surface and which has at least one bore extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element, the bore having an anterior bore portion, and a posterior bore portion, the posterior bore portion having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing element to facilitate retention of the enlarged integral portion of the securing member within the posterior bore portion; and</p>	<p><i>Theken (EX1005)</i>: “... plate 20 has ... a lateral side 26, a medial side 28” <i>Id.</i> at 4:7-8. Plate 20 “includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10).” <i>Id.</i> at 4:35-48. <i>See also</i> FIG. 8.</p>  <p style="text-align: right;">Fig. 8</p>
<p>c. a biased stopping member which has a posterior stopping surface, a first configuration which extends within the bore that is elastically deformed to a second configuration as the enlarged</p>	<p><i>Theken (EX1005)</i>: Non-biased “[s]et screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).” <i>Id.</i> at 4:63-65, FIGS. 1-2. “It will be appreciated that in an</p>

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

alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.” *Id.* at 7:33-35.

Errico (EX1006): “More specifically with respect to Figure 5, which is a top view of the hole and retaining ring of this variation, the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole (the hole may be either smooth as in Figure 1a or threaded as in Figure 1b). Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180.” *Id.* at 23:14-19, FIG. 5. “Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown.” *Id.* at 23:25-26, FIG. 6 (showing posterior stopping surface). The snap-ring 180 is a biased stopping member that “provides a simple and effective locking mechanism for locking the bone screw to the plate”. *Id.* at 6:1-2. The snap-ring 180 is suitable to lock a non-integral securing element/member comprising a screw and coupling element within the tapered hole of the plate 100c. *Id.* at 23:12-14. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller (*i.e.*, unexpanded) diameter configuration to a larger (*i.e.*, expanded) diameter configuration. *Id.* at 23:27-24:4. “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or

	133) and snaps back to its undeflected state” of the smaller diameter configuration. <i>Id.</i> at 24:4-7. “In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” <i>Id.</i> at 24:7-10. Errico’s snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10.
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9. *Each of Claims 60, 61, 66, 68, 69, 70, 71, 72, 73, 75, 76, 77, 78, 80, 81, 82, 83, 84, 85, 86, 90, and 91 of the '008 patent is Obvious over Theken in view of Errico*

198. It is my opinion that the combination of Theken and Errico renders each of claims 60, 61, 66, 68, 69, 70, 71, 72, 73, 75, 76, 77, 78, 80, 81, 82, 83, 84, 85, 86, 90, and 91 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 9) that follows.

199. Claim 60 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 60. With respect to the limitations in claim 60, as shown in Table 9 below, the combination of Theken and Errico comprises a first configuration (*e.g.* undeformed/unexpanded configuration) of the stopping member

(*e.g.* snap-ring 180) that has inner transverse dimensions that are smaller than transverse dimensions of the enlarged integral portion of the securing member to facilitate retention of the enlarged integral portion of the securing member within the posterior bore portion and a second configuration (*e.g.* expanded configuration) of the stopping member that has inner transverse dimensions that are greater than transverse dimensions of the enlarged integral portion of the securing member to allow passage of the enlarged integral portion of the securing member into the posterior bore portion. *See, e.g.* EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6. The snap-ring 180 operates by enlarging from an unexpanded inner diameter to an expanded inner diameter as a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded inner diameter after the tapered coupling element 132 passes through the snap-ring 180. Theken's tapered head portion 110 is inserted into a bore in the same manner as Errico's tapered coupling element 132, and would pass through the snap-ring 180 in the same manner as Errico's tapered coupling element 132.

200. Claim 61 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 61. With respect to the limitations in claim 61, as shown in Table 9 below, the combination of Theken and Errico comprises a securing element (*e.g.* bone screw 100) having an enlarged integral portion (*e.g.*

tapered head portion 110) is slidably disposed within the bore (*e.g.* opening 62). *See, e.g.* EX1005, 4:35-48, 8:65-9:1, FIGS. 1-2 (showing the slidable disposition of screws 100).

201. Claim 66 depends from claim 61, which is discussed in paragraph 200. The rationale for combining Theken and Errico with respect to claim 61 also applies to claim 66. With respect to the limitations in claim 66, as shown in Table 9 below, the combination of Theken and Errico comprises a securing member (*e.g.* bone screw 100) that is selected from the group consisting of screws and nails. *See, e.g.* EX1005, 3:59-60, 6:19-34, FIGS. 1-2 and 11.

202. Claim 71 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 71. With respect to the limitations in claim 71, as shown in Table 9 below, the combination of Theken and Errico comprises a biased stopping member (*e.g.* snap-ring 180) that is a collar having at least in part a passageway enlargeable from a first inner dimension (*e.g.* undeformed dimension) to a second inner dimension (*e.g.* expanded dimension) by the passage of the enlarged integral portion of the securing member therethrough. *See, e.g.* EX1006, FIGS. 5-6, 8:13-17, 23:12-24: 10.

203. Claim 68 depends from claim 71, which is discussed in paragraph 202. The rationale for combining Theken and Errico with respect to claim 71 also

applies to claim 68. With respect to the limitations in claim 68, as shown in Table 9 below, the combination of Theken and Errico comprises a collar (*e.g.* snap-ring 180) that is formed of an elastically deformable material. The snap-ring 180 is formed of an elastically deformable material as shown by its range of motion from inward deformation to outward deformation. *See, e.g.* EX1006, 8:13-17 (“each retaining ring expands as the corresponding coupling element is inserted into the hole, and snaps back into a retaining position about the coupling element once the top of the element passes it into the hole.”), 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”). Both Theken and Errico teach making the orthopedic assembly from titanium. EX1005, 7:37-41 (screws and set screws); EX1006, 17:20-18:2 (plate). As discussed above in paragraph 137, a POSA would have had good reason to employ a collar that is formed of titanium, an elastically deformable material.

204. Claim 69 depends from claim 71, which is discussed in paragraph 202. The rationale for combining Theken and Errico with respect to claim 71 also applies to claim 69. With respect to the limitations in claim 69, as shown in Table

9 below, the combination of Theken and Errico comprises a collar that is formed of a material selected from the group consisting of titanium and superelastic material. The snap-ring 180 is formed of an elastic material to support its range of motion from inward deformation to outward deformation. EX1006, 8:13-17 (“each retaining ring expands as the corresponding coupling element is inserted into the hole, and snaps back into a retaining position about the coupling element once the top of the element passes it into the hole.”), 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”). Both Theken and Errico teach making the orthopedic assembly from titanium. EX1005, 7:37-41 (screws and set screws); EX1006, 17:20-18:2 (plate). As discussed above in paragraph 138, a POSA would have had good reason to employ a collar that is formed of a material selected from the group consisting of titanium and superelastic material.

205. Claim 70 depends from claim 71, which is discussed in paragraph 202. The rationale for combining Theken and Errico with respect to claim 71 also applies to claim 70. With respect to the limitations in claim 70, as shown in Table 9 below, the combination of Theken and Errico comprises a collar (*e.g.* snap-ring

180) that has a posterior surface perpendicular to a longitudinal axis of the bore extending through the attachment member. *See, e.g.* EX1006, FIG. 6 (snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the bore extending through Errico's plate 100c and, when combined with Theken, the lateral side 26 and the medial side 28 of Theken's plate 20).

206. Claim 72 depends from claim 71, which is discussed in paragraph 202. The rationale for combining Theken and Errico with respect to claim 71 also applies to claim 72. With respect to the limitations in claim 72, as shown in Table 9 below, the combination of Theken and Errico comprises a bore that has a groove (*e.g.* annular recess 182) which receives the collar (*e.g.* snap-ring 180). *See, e.g.* EX1006, 8:13-17, 23:12-24:10, FIGS. 5-6. Errico shows an annular recess 182 that is positioned in an anterior section of Errico's hole 110c. *Id.* at FIG. 6. In the combination, the annular recess 182 is similarly positioned in the anterior portion (*e.g.* section 66) of Theken's bore (*e.g.* opening 62).

207. Claim 73 depends from claim 71, which is discussed in paragraph 202. The rationale for combining Theken and Errico with respect to claim 71 also applies to claim 73. With respect to the limitations in claim 73, as shown in Table 9 below, the combination of Theken and Errico comprises an enlarged integral portion having a curved posterior surface as recited by claim 73. Theken and Errico each disclose an enlarged integral portion of the securing element having a

curved posterior surface. EX1006, 18:14-19:2, 19:13-20, FIGS. 2, 6; EX1005, 6:51-56. Errico also discloses the posterior surface of an enlarged portion of a securing element (*e.g.* coupling element 132) configured to expand the collar by contacting the collar at an anterior surface of the collar and expanding the collar away from the longitudinal axis of the collar passageway as the enlarged portion is displaced posteriorly through the collar passageway. EX1006, 8:13-17, 23:12-24:10 & FIGS 5-6.

208. Claim 75 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 75. With respect to the limitations in claim 75, as shown in Table 9 below, the combination of Theken and Errico comprises an attachment member (*e.g.* plate 20) that includes at least two bores (*e.g.* openings 42 and 62). *See, e.g.* EX1005, 3:62, 4:4-7, 4:16-18, 4:35-38, & FIGS. 1-3, 5-8, 10.

209. Claim 76 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 76. With respect to the limitations in claim 76, as shown in Table 9 below, the combination of Theken and Errico comprises an attachment member (*e.g.* plate 20) that is configured to conform to and extend between at least two bone segments (*e.g.* vertebral bodies V_1 and V_2). *See, e.g.* EX1005, 3:65-66, 5:34-36, 5:59-64, FIGS. 3-4.

210. Claim 77 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 77. With respect to the limitations in claim 77, as shown in Table 9 below, the combination of Theken and Errico comprises a posterior surface (*e.g.* medial side 28) of the attachment member (*e.g.* plate 20) that is at least in part a concave surface. *See, e.g.* EX1005, 5:34-36, 5:59-6:7, FIGS. 1-4, 10 (showing concave posterior surface formed by the notches 34A and 34B).

211. Claim 78 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 78. With respect to the limitations in claim 78, as shown in Table 9 below, the combination of Theken and Errico comprises an attachment member is selected from the group consisting of rods and plates. *See, e.g.* EX1005, 3:59-60, FIGS. 1-10.

212. Claim 80 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 80. With respect to the limitations in claim 80, as shown in Table 9 below, the combination of Theken and Errico includes a stopping element (*e.g.* snap-ring 180) that comprises a biased collar. *See, e.g.* EX1006, 8:13-17, 23:18-19, FIGS. 5-6.

213. Claim 81 depends from claim 80, which is discussed in paragraph 212. The rationale for combining Theken and Errico with respect to claim 80 also applies to claim 81. With respect to the limitations in claim 81, as shown in Table 9 below, the combination of Theken and Errico comprises a biased collar (*e.g.* snap-ring 180) that is elastically deformable to the second (*i.e.*, expanded) configuration. *See, e.g.* EX1006, 8:13-17, 23:27-24:10, FIGS. 5-6.

214. Claim 82 depends from claim 81, which is discussed in paragraph 213. The rationale for combining Theken and Errico with respect to claim 81 also applies to claim 82. With respect to the limitations in claim 82, as shown in Table 9 below, the combination of Theken and Errico comprises a biased collar (*e.g.* snap-ring 180) that extends at least partially within the bore of the stabilizing element. *See, e.g.* EX1006, 23:16-19, FIGS. 5-6.

215. Claim 83 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 83. With respect to the limitations in claim 83, as shown in Table 9 below, the combination of Theken and Errico comprises a stopping member (*e.g.* snap-ring 180) that is a biased stopping member which reduces a transverse configuration of the anterior bore portion to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member. *See, e.g.* EX1006, 24:4-10 (“In its undeflected state it

prevents the coupling element 132 (or 133) from backing out of the plate 100c”), FIG. 6.

216. Claim 84 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 84. With respect to the limitations in claim 84, as shown in Table 9 below, the combination of Theken and Errico comprises a biased stopping member (*e.g.* snap-ring 180) that resiliently returns (*e.g.* snaps) to the first configuration (*e.g.* undeformed/unexpanded state) after passage of the enlarged portion of the securing member. *See, e.g.* EX1006, 23:27-24:10 (“Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”), FIG. 6.

217. Claim 85 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 85. With respect to the limitations in claim 85, as shown in Table 9 below, the combination of Theken and Errico comprises a posterior bore portion that has a length sufficiently greater than the length of the enlarged integral portion of the securing element so that the enlarged integral portion of the securing element is longitudinally displaceable within the posterior bore portion when retained therein. In one implementation of the combination

illustrated in paragraph 113, the annular recess 182 is placed at the middle of Theken's threaded section 66, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for an unconstrained system that allows for settling after certain surgeries. Placement of the annular recess 182 in this manner creates a posterior bore portion under the snap-ring 180 that has a length sufficiently greater than the length of the head of Theken's bone screw (*i.e.* enlarged integral portion of the securing element), which makes the head longitudinally displaceable within a transverse passageway between the posterior surface of the snap-ring 180 (*i.e.* stopping member) and the second opening of the plate (*i.e.* the stabilizing element).

218. Claim 86 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 86. With respect to the limitations in claim 86, as shown in Table 9 below, the combination of Theken and Errico comprises an elongated securing element (*e.g.* bone screw 100) that has an enlarged integral portion (*e.g.* head portion 110) with a length, a posterior surface (*e.g.* tapered surface 112) and a transverse dimension and a shaft (*e.g.* threaded portion 102) extending from the enlarged integral portion configured to be secured within bone. *See, e.g.* EX1005, FIG. 11, 6:19-34. The combination of Theken and Errico also

comprises an attachment element (*e.g.* plate 20) has an anterior surface (*e.g.* later side 26) and a posterior surface (*e.g.* medial side 28) and has at least one bore (*e.g.* opening 62) extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element (*e.g.* bone screw 100), the bore having an anterior bore portion (*e.g.* section 66), a posterior bore portion (*e.g.* section 64) having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing element to retain the enlarged integral portion of the securing element within the posterior bore portion. EX1005, 4:7-8, 4:35-48, FIG. 8, FIGS. 1-2 (showing claimed retention). The combination of Theken and Errico also comprises a stopping member that defines in part a passageway in the posterior bore portion, where the posterior bore portion (*e.g.* section under Errico's snap-ring 180) is longer than the length of the enlarged integral portion (*e.g.* head portion 110) of the securing element (*e.g.* bone screw 100) to allow longitudinal displacement of the enlarged integral portion of the securing element within the posterior bore portion. In one implementation of the combination illustrated in paragraph 113, the annular recess 182 is placed at the middle of the threaded section 66, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for an unconstrained system that allows

for settling after certain surgeries. In this implementation, the head of the securing element (*i.e.* Theken's head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (*i.e.* Errico's snap-ring 180) and the second opening in the posterior surface of the stabilizing element (*i.e.* Theken's plate 20).

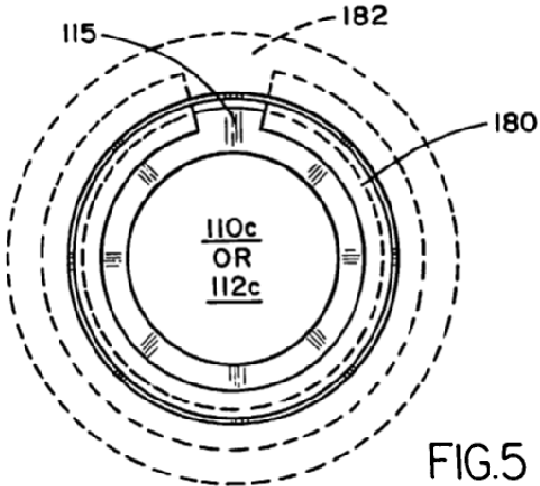
219. Claim 90 depends from claim 86, which is discussed in paragraph 218. The rationale for combining Theken and Errico with respect to claim 86 also applies to claim 90. With respect to the limitations in claim 90, as shown in Table 9 below, the combination of Theken and Errico comprises a second (*i.e.*, expanded) configuration of the stopping member that has a transverse dimension that is larger than the transverse dimension of the stopping member in the first (*i.e.*, unexpanded) configuration. *See, e.g.* EX1006, 8:13-17, 23:27-24:10, FIGS. 5-6.

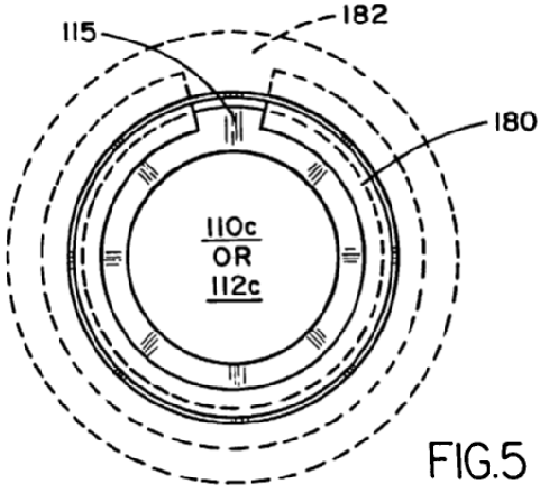
220. Claim 91 depends from claim 59, which is discussed in paragraphs 189 through 197. The rationale for combining Theken and Errico with respect to claim 59 also applies to claim 91. With respect to the limitations in claim 91, as shown in Table 9 below, the combination of Theken and Errico comprises a posterior stopping surface of the stopping member (*e.g.* snap-ring 180) that is perpendicular to the longitudinal axis of a bore. *See, e.g.* EX1006, FIG. 6.

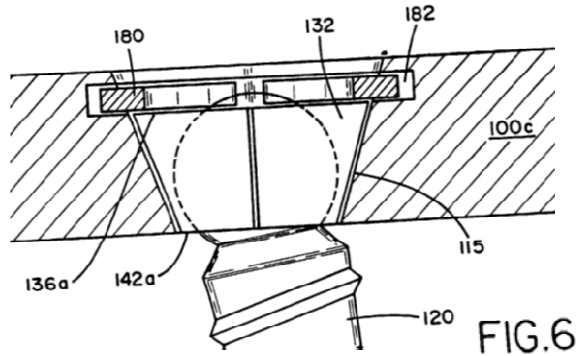
TABLE 9

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
<p>60. The attachment assembly of claim 59 wherein the first configuration of the stopping member has inner transverse dimensions that are smaller than transverse dimensions of the enlarged integral portion of the securing member to facilitate retention of the enlarged integral portion of the securing member within the posterior bore portion and the second configuration of the stopping member has inner transverse dimensions that are greater than transverse dimensions of the enlarged integral portion of the securing member to allow passage of the enlarged integral portion of the securing member into the posterior bore portion.</p>	<p><i>Errico (EX1006)</i>: "... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182" from a smaller diameter configuration to a larger diameter configuration. <i>Id.</i> at 23:27-24:4. As further explained by Errico, "[o]nce the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state" of the smaller diameter configuration. <i>Id.</i> at 24:4-7. Errico's snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10. <i>See also</i> FIGS. 5-6.</p>
<p>61. The attachment assembly of claim 59 wherein the securing element having an enlarged integral portion is slidably disposed within the bore.</p>	<p>Plate 20 "includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 ..." <i>Id.</i> at 4:35-48. <i>See also Id.</i> at FIGS. 1-2 showing the slidable disposition of screws 100. <i>See also</i> FIG. 8. "It should be appreciated that the driving tapered head 112 of screw 100 into mating tapered section 44, 64 of plate 20, forces proper alignment between screw 100 and plate 20" <i>Id.</i> at 8:65-9:1</p>
<p>66. The attachment assembly of claim 61 wherein the securing member is selected from the group consisting of screws and nails.</p>	<p><i>Theken (EX1005)</i>: "Fixation system 10 is generally comprised of ... a plurality of bone screws 100 ..." <i>Id.</i> at 3:59-60. <i>See also Id.</i> at FIGS. 1-2 and 11 (showing the bone screws 100).</p>

<p>71. The attachment assembly of claim 59 wherein the biased stopping member is a collar having at least in part a passageway enlargeable from a first inner dimension to a second inner dimension by the passage of the enlarged integral portion of the securing member therethrough.</p>	<p><i>Errico (EX1006)</i>: “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180” that forms a collar. <i>Id.</i> at 23:18-19. <i>See also Id.</i> at FIG. 5 (selected portion shown below), which illustrates a collar shape for snap-ring 180. The snap-ring 180 operates by enlarging from an unexpanded inner diameter to an expanded inner diameter as a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded inner diameter after the tapered coupling element 132 passes through the snap-ring 180. <i>Id.</i> at 23:27-24:10 (“... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182. Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c”), and FIG. 6. A maximum diameter of the tapered coupling element 132 is greater than the unexpanded inner diameter of the snap-ring 180 so as to expand it, and is less than the expanded inner diameter so as to pass through the expanded snap-ring 180.</p>
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	 <p style="text-align: right;">FIG.5</p>
<p>68. The attachment assembly of claim 71 wherein the collar is formed of an elastically deformable material.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 inherently is formed of an elastically deformable material to support its range of motion from inward deformation to outward deformation. <i>Id.</i> at 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”).</p>
<p>69. The attachment assembly of claim 71 wherein the collar is formed of a material selected from the group consisting of titanium and superelastic material.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 inherently is formed of a superelastic material to support its range of motion from inward deformation to outward deformation. <i>Id.</i> at 23:26-27 (“The snap-ring 180 is deflected inward for positioning in the recess 182.”); 24:3-4 (“the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.”); and 24:5-7 (“the snap-</p>

	ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state.”)
70. he attachment assembly of claim 71 wherein the collar has a posterior surface perpendicular to a longitudinal axis of the bore extending through the attachment member.	<i>Errico (EX1006)</i> : The snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the transverse passageway between the top and bottom of Errico’s plate 100c and, when combined with Theken, the plate 20. <i>See, e.g. Id.</i> at FIG. 6.
72. The attachment assembly of claim 71 wherein the bore has a groove which receives the collar.	<p><i>Errico (EX1006)</i>: “... the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180.” <i>Id.</i> at 23:16-19, FIGS. 5-6. “The snap-ring 180 is deflected inward for positioning in the recess 182.” <i>Id.</i> at 23:26-27. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182.” <i>Id.</i> at 24:3-4.</p>  <p style="text-align: right;">FIG.5</p>



The combination of Theken and Errico uses Errico's in-hole annular recess 182 and snap-ring 180. Therefore, the resultant modification of Theken has the same characteristics as Errico's annular recess 182 and snap-ring 180 in terms of positioning of the annular recess 182 in an anterior portion of a bore and in terms of the expansion of the snap-ring 180.

73. The attachment assembly of claim 71 wherein the enlarged integral portion of the securing member has a curved posterior surface which is configured to contact an anterior surface of the collar and expand the collar as the enlarged integral portion of the securing member is displaced posteriorly through the collar passageway.

Errico (EX1006):

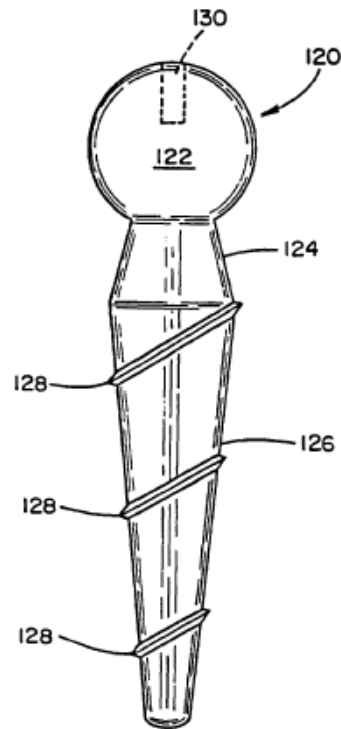
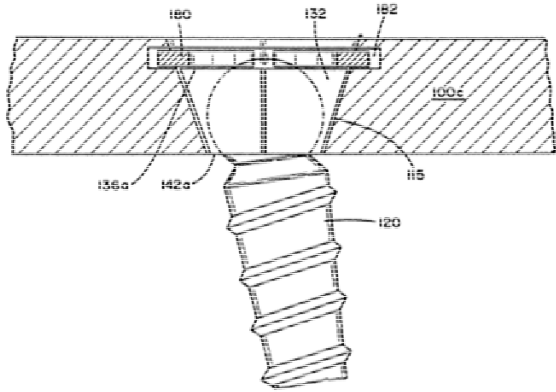
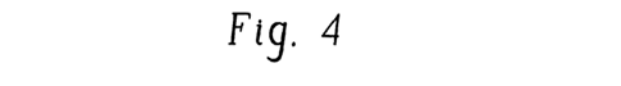


FIG. 2

FIG. 2 (*see also*: FIG. 6, below) illustrating the curved posterior surface of the enlarged integral portion of the securing element (*i.e.*, head portion 122 of screw 120). *Id.* at 24:7-10. Errico's spherical head expands the collar (*e.g.*, snap ring 180 of FIG. 6) as said enlarged integral portion is displaced posteriorly through the passageway.

	 <p data-bbox="1089 646 1149 674">FIG. 6</p> <p data-bbox="821 695 1421 940"> FIG. 6. <i>Theken (EX1005):</i> “...the tapered head could be replaced by a spherical bead. The spherical bead would allow variable screw angulation.” <i>Id.</i> at 6:51-56. </p>
<p data-bbox="201 953 797 1073">75. The attachment assembly of claim 59 wherein the attachment member includes at least two bores.</p>	<p data-bbox="821 953 1421 1497"> <i>Theken (EX1005):</i> There are at least two “holes formed in plate 20.” <i>Id.</i> at 3:62. “Top portion 40 [of the plate 20] includes a pair of generally circular openings 42, which are dimensioned to receive fastener means, namely, bone screw 100 and set screw 140.” <i>Id.</i> at 4:16-18. “Bottom portion 60 [of the plate 20] includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140.” <i>Id.</i> at 4:35-38. </p>
<p data-bbox="201 1509 797 1675">76. The attachment assembly of claim 59 wherein the attachment member is configured to conform to and extend between at least two bone segments.</p>	<p data-bbox="821 1509 1421 1833"> <i>Theken (EX1005):</i> “FIGS. 3 and 4 illustrate fixation system 10 as attached to vertebral bodies V₁ and V₂.” <i>Id.</i> at 3:65-66. “Referring now with particular reference to FIGS. 3 and 4, the gaps or notches 34A, 34B are dimensioned to receive a portion of a vertebral body.” <i>Id.</i> at 5:34-36. <i>See also Id.</i> at FIG. 4 </p>



Then (EX1005): See *Id.* at FIG. 4, showing concave posterior surface formed by the notches 34A and 34B.

Then (EX1005): See *Id.* at FIG. 4, showing concave posterior surface formed by the notches 34A and 34B.

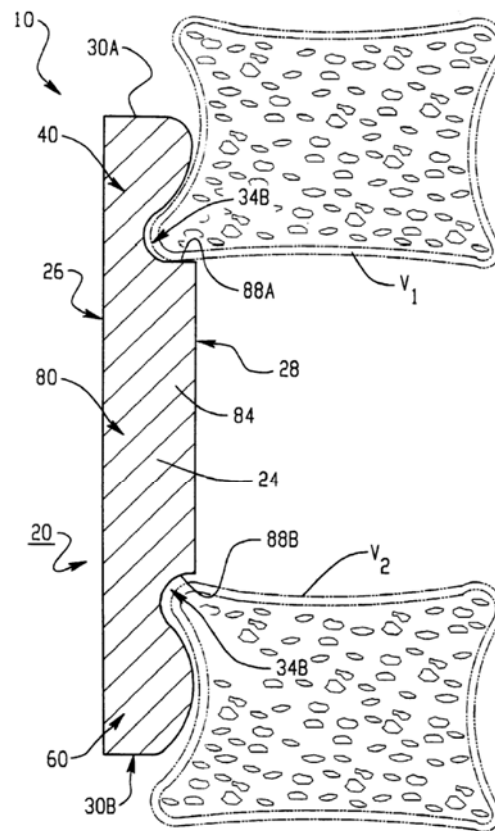


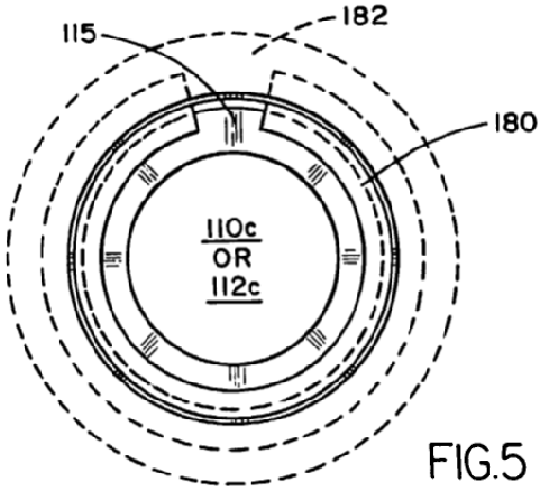
Fig. 4

78. The attachment assembly of claim 59 wherein the attachment member is selected from the group consisting of rods and plates.

Theken (EX1005): “Fixation system 10 is generally comprised of a bone plate 20” *Id.* at 3:59-60. *See also Id.* at FIGS. 1-2 (showing the plate 20).

80. The assembly of claim 59 wherein the stopping element comprises a biased collar.

Errico (EX1006): “Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180” that forms a collar. *Id.* at 23:18-19. *See also Id.* at FIG. 5 (selected portion shown below), which illustrates a collar shape for snap-ring 180.

	 <p style="text-align: right;">FIG.5</p>
<p>81. The assembly of claim 80 wherein the biased collar is elastically deformable to the second configuration.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 operates by deformably enlarging from an unexpanded configuration to an expanded configuration as a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded configuration after the tapered coupling element 132 passes through the snap-ring 180. <i>Id.</i> at 23:27-24:10 (“... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182. Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c”), and FIGS. 5-6.</p>
<p>82. The assembly of claim 81 wherein the biased collar extends at least partially within the bore of the stabilizing element.</p>	<p><i>Errico (EX1006)</i>: “... the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole Within this annular recess 182 is provided a discontinuous ‘7/8ths’</p>

snap-ring 180.” *Id.* at 23:16-19. *See also Id.* at FIGS. 5-6 (showing placement of snap-ring 180 within a bore of a plate).

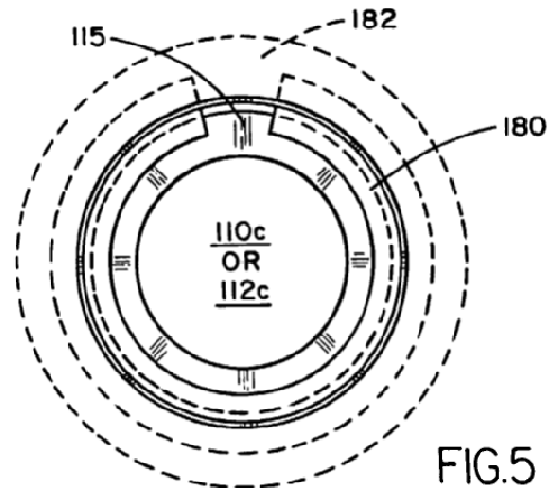


FIG.5

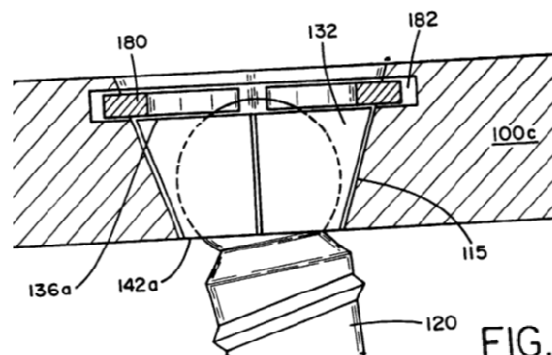


FIG.6

83. The attachment assembly of claim 59, wherein the stopping member is a biased stopping member which reduces a transverse configuration of the anterior bore portion to retain the enlarged integral portion of the securing member within the posterior bore portion of the attachment member.

Errico (EX1006): “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. *Id.* at 24:4-7. “In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring

	open).” <i>Id.</i> at 24:7-10. <i>See also Id.</i> at FIG. 6.
84. The attachment assembly of clam 59 wherein the biased stopping member resiliently returns to the first configuration after passage of the enlarged integral portion of the securing member.	<i>Errico (EX1006)</i> : “the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182. Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state. In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c”. <i>Id.</i> at 23:27-24:10, FIG. 6.
85. The orthopedic attachment assembly of claim 59 wherein the posterior bore portion has a length sufficiently greater than the length of the enlarged integral portion of the securing element so that the enlarged integral portion of the securing element is longitudinally displaceable within the posterior bore portion when retained therein.	The combination of Theken and Errico uses Errico’s snap-ring 180 with Errico’s in-hole annular recess 182 and somewhere in Theken’s threaded section 66. In one implementation of the combination, the annular recess 182 is placed at the middle of the threaded section 66. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for other surgeries, where the inserted bone screw 100 can be driven down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for settling after surgery. In the second implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member

	(snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20).
86. The orthopedic attachment assembly of claim 59 wherein, a. the elongated securing element has an enlarged integral portion with a length, a posterior surface and a transverse dimension and a shaft extending from the enlarged integral portion configured to be secured within bone; b. the attachment element has an anterior surface and a posterior surface and has at least one bore extending through the attachment element from the anterior surface to the posterior surface and is configured to receive the securing element, the bore having an anterior bore portion, a posterior bore portion having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing element to retain the enlarged integral portion of the securing element within the posterior bore portion; and c. the stopping member defines in part a passageway in the posterior bore portion, said posterior bore portion being longer than the length of the enlarged integral portion of the securing element to allow longitudinal displacement of the enlarged integral portion of the securing element within the posterior bore portion.	<p><i>Theken (EX1005)</i>: Bone screw 100 includes an integral head portion 110 that has a tapered surface 112 and a transverse dimension, and bone screw 100 includes a threaded portion 102 extending from the head portion 110 that is configured to be secured within bone. <i>Id.</i> at FIG. 11, 6:19-34. “... plate 20 has ... a lateral side 26, a medial side 28 ...” <i>Id.</i> at 4:7-8. Plate 20 “includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10).” <i>Id.</i> at 4:35-48. <i>See also Id.</i> at FIG. 8. <i>See also Id.</i> at FIGS. 1-2 (showing retention of head portion 110 of bone screw 100 in tapered section 64 of opening 62)..</p> <p>The combination of Theken and Errico uses Errico’s snap-ring 180 with Errico’s in-hole annular recess 182 and somewhere in Theken’s threaded section 66. In a second implementation of the combination, the annular recess 182 is placed at the middle of the threaded section 66. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for other surgeries, where the inserted bone screw 100 can be driven</p>

	<p>down into the tapered section 64 of the opening 62 so as to create a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100, which would allow for settling after surgery. In the second implementation, the head of the securing element (head portion 110 of the bone screw 100) is longitudinally displaceable within a transverse passageway between the posterior surface of the biased stopping member (snap-ring 180) and the second opening in the posterior surface of the stabilizing element (plate 20).</p>
<p>90. The orthopedic attachment assembly of claim 86 wherein the second configuration of the stopping member has a transverse dimension that is larger than the transverse dimension of the stopping member in the first configuration.</p>	<p><i>Errico (EX1006)</i>: “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller diameter configuration to a larger diameter configuration. <i>Id.</i> at 23:27-24:4. As further explained by Errico, “[o]nce the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. <i>Id.</i> at 24:4-7. Errico’s snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10. <i>See also</i> FIGS. 5-6.</p>
<p>91. The assembly of claim 59 wherein the posterior stopping surface of the stopping member is perpendicular to the longitudinal axis of the bore.</p>	<p><i>Errico (EX1006)</i>: The snap-ring 180 has a posterior surface that is perpendicular to a longitudinal axis of the transverse passageway between the top and bottom of Errico’s plate 100c</p>

	and, when combined with Theken, the lateral side 26 and the medial side 28 of Theken's plate 20. <i>See, e.g. Id.</i> at FIG. 6.
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10.Claim 101 of the '008 patent is Obvious over Theken in view of Errico

221. It is my opinion that the combination of Theken and Errico renders claim 101 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 10) that follows.

222. With respect to the preamble to claim 101, Theken is directed to an orthopedic implant assembly. EX1005, 3:54-65, FIGS. 1-14.

223. With respect to claim element 101(a), Theken discloses a stabilizing element (*e.g.* plate 20) having an anterior surface (*e.g.* lateral side 26), a posterior surface (*e.g.* medial side 128), and at least one bore (*e.g.* opening 62) extending through the stabilizing element (*e.g.* plate 20) from the anterior surface to the posterior surface with an anterior bore portion (*e.g.* section 66) which has a transverse dimension, a posterior bore portion (*e.g.* tapered section 64) which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion. *Id.* at 4:7-8, 4:35-48, FIG. 8.

224. With respect to claim element 101(b), Theken discloses a securing element (*e.g.* bone screw 100) having an elongated body (*e.g.* threaded portion 102) and an enlarged integral portion (*e.g.* tapered head portion 110) having an anterior surface (*e.g.* top). *Id.* at 6:20-31, FIG. 11.

225. With respect to claim element 101(c), Theken discloses a stopping member (*e.g.* set screw 140) which has a posterior stopping surface (*e.g.* bottom) positioned to engage the anterior surface (*e.g.* top) of the securing element (*e.g.* bone screw 100) and prevent the securing element (*e.g.* bone screw 100) from backing out of the posterior bore portion (*e.g.* tapered section 64) and to facilitate retention of the enlarged integral portion (*e.g.* tapered head portion 110) of the securing element (*e.g.* bone screw 100) within the posterior bore portion (*e.g.* tapered section 64). *Id.* at 4:63-65, 7:33-35, FIGS. 1-2.

226. With respect to claim element 101(c), Errico discloses a biased stopping member (*e.g.* snap-ring 180) which has a posterior stopping surface, which has a first (*i.e.*, unexpanded) configuration within an anterior bore portion that has a first transverse dimension and is elastically deformable to a second (*i.e.*, expanded) configuration within the anterior bore portion that has a second transverse dimension larger than the first transverse dimension that allows an enlarged portion (*e.g.* tapered coupling element 132) of a securing element (*e.g.* coupling element 132 attached to bone screw 120) to pass into a posterior bore portion (*e.g.*, tapered section 64). EX1005, 4:63-65, 7:33-35, FIGS. 1-2. Errico discloses a biased stopping member (*e.g.* snap-ring 180), the biased stopping member (*e.g.* snap-ring 180) returning to the first (*i.e.*, unexpanded) configuration so that the posterior surface of the stopping member (*e.g.* snap-ring 180) is

positioned to engage an anterior surface (*e.g.* upper surface 136a) of the enlarged portion (*e.g.* coupling element 312) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) and to prevent the securing element (*e.g.* coupling element 132 attached to bone screw 120) from backing out of the posterior bore portion and to facilitate retention of the enlarged portion (*e.g.* coupling element 312) of the securing element (*e.g.* coupling element 132 attached to bone screw 120) within the posterior bore portion. EX1006, 6:1-2, 23:12-19, 23:25-24:10.

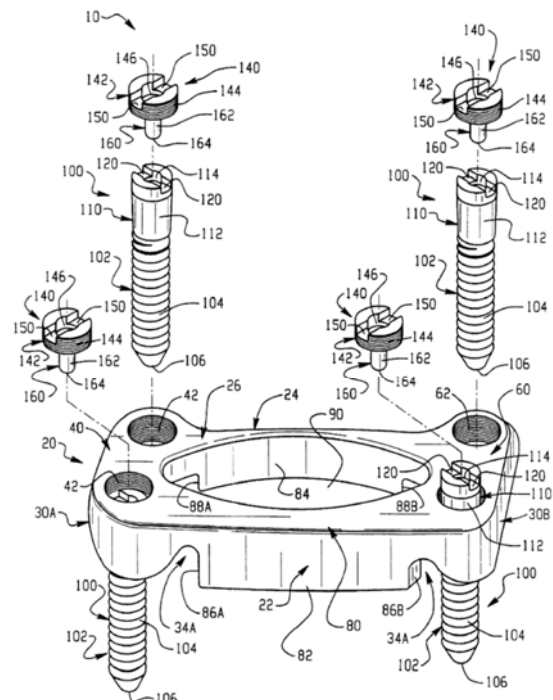
227. As I explain above in paragraph 115, Theken's tapered head portion 110 would function in the same way as Errico's tapered coupling element 132 with a flat upper surface in terms of inserting into a bore, expanding a snap-ring in the bore, and being retained by the snap-ring.

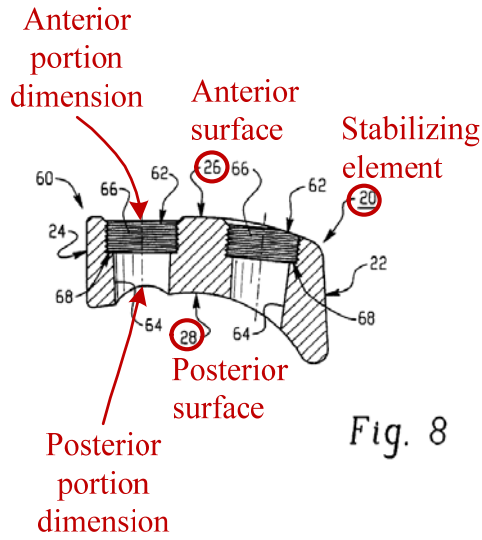
228. It is my opinion that it would have been obvious for a POSA to use Errico's snap-ring and in-bore annular recess to perform the function of preventing back-out of the screw in Theken's apparatus by locking the screw to the plate. As I explain above in paragraphs 115 and 116, it would have been obvious for a POSA to configure the Theken apparatus with the snap-ring and annular recess of Errico based on various rationales, and there would be a reasonable expectation of success along with predictable results whereby the tapered screw head of Theken would function in the same way as the tapered coupling element of Errico in terms of expanding the snap-ring in terms of expanding the snap-ring, being retained by the

snap-ring, and having relative sizes compared to sizes of the snap-ring and portions of a bore. As I also explain above in paragraph 118, configuring the Theken apparatus with the snap-ring and annular recess of Errico would not render the Theken apparatus unsatisfactory for its intended purpose or change its principle operation.

229. Therefore, it is my opinion that the combination of Theken and Errico discloses all of the limitations of claim 101 of the '008 patent, and thus claim 101 would have been obvious to a POSA in view of the combination of Theken and Errico.

TABLE 10

<p>‘008 Patent Claim</p>	<p>Theken (EX1005) and Errico (EX1006)</p>
<p>101. An orthopedic implant assembly, comprising:</p>	<p><i>Theken (EX1005):</i> “... FIG. 1 shows an exploded view of a bone fixation system 10 Fixation system 10 is generally comprised of a bone plate 20, a plurality of bone screws 100, and a plurality of set screws 140.” <i>Id.</i> at 3:54-65, FIGS. 1-14.</p>  <p style="text-align: center;"><i>Fig. 1</i></p>
<p>a. a stabilizing element having an anterior surface, a posterior surface, and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface with an anterior bore portion which has a transverse dimension, a posterior bore portion which has a posterior opening with a transverse dimension smaller than the transverse dimension of the anterior bore portion;</p>	<p><i>Theken (EX1005):</i> “... plate 20 has ... a lateral side 26, a medial side 28” <i>Id.</i> at 4:7-8. Plate 20 “includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. ... Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating</p>

	<p>at medial side 28 (FIGS. 8 and 10).” <i>Id.</i> at 4:35-48. <i>See also Id.</i> at FIG. 8.</p>  <p style="text-align: right;">Fig. 8</p>
<p>b. a securing element having an elongated body and an enlarged integral portion having an anterior surface; and</p>	<p><i>Theken (EX1005)</i>: “Screws 100 will now be described in detail with reference to FIGS. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from the lower end of head portion 110 to rounded tip 106.” <i>Id.</i> at 6:20-22, FIG. 11. “Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in FIG. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in tapered sections 44 and 64 of plate 20.” <i>Id.</i> at 6:27-31.</p>
<p>c. a biased stopping member which has a posterior stopping surface, which has a first configuration within the anterior bore portion that has a first transverse dimension and is elastically deformable to a second configuration within the anterior bore portion that has a second</p>	<p><i>Theken (EX1005)</i>: Non-biased “[s]et screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2).” <i>Id.</i> at 4:63-65, FIGS. 1-2. “It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be</p>

transverse dimension larger than the first transverse dimension that allows the enlarged integral portion of the securing element to pass into the posterior bore portion posterior to the biased stopping member, the biased stopping member returning to the first configuration so that the posterior surface of the stopping member is positioned to engage the anterior surface of the securing element and prevents the securing element from backing out of the posterior bore portion and to facilitate retention of the enlarged integral portion of the securing element within the posterior bore portion.

replaced by other suitable locking mechanisms.” *Id.* at 7:33-35.

Errico (EX1006): “More specifically with respect to Figure 5, which is a top view of the hole and retaining ring of this variation, the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole (the hole may be either smooth as in Figure 1a or threaded as in Figure 1b). Within this annular recess 182 is provided a discontinuous ‘7/8ths’ snap-ring 180.” *Id.* at 23:14-19, FIG. 5. “Referring now also to Figure 6, the assembled screw 120, coupling element 132, snap-ring 180 and plate 100c are shown.” *Id.* at 23:25-26, FIG. 6 (showing posterior stopping surface). The snap-ring 180 is a biased stopping member that “provides a simple and effective locking mechanism for locking the bone screw to the plate”. *Id.* at 6:1-2. The snap-ring 180 is suitable to lock a non-integral securing element/member comprising a screw and coupling element within the tapered hole of the plate 100c. *Id.* at 23:12-14. “... the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand in the recess 182” from a smaller diameter configuration to a larger diameter configuration. *Id.* at 23:27-24:4. “Once the coupling element 132 (or 133) is fully seated in the hole 110c, the snap-ring 180 is freed from the outward radial pressure of the coupling element 132 (or 133) and snaps back to its undeflected state” of the smaller diameter configuration. *Id.* at 24:4-7.

	<p>“In its undeflected state it prevents the coupling element 132 (or 133) from backing out of the plate 100c inasmuch as the flat upper surface 136a (or 136b) of the coupling element is incapable of deflecting the ring outward (it has no taper to push the snap-ring open).” <i>Id.</i> at 24:7-10. Errico’s snap-ring 180 will open (<i>i.e.</i> deform into the larger diameter configuration) when a tapered shape pushes on the snap-ring 180 during insertion of the tapered shape. <i>Id.</i> at 24:9-10.</p>
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11. Each of Claims 103 and 104 of the '008 patent is Obvious over Theken in view of Errico

230. It is my opinion that the combination of Theken and Errico renders each of claims 103 and 104 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 11) that follows.

231. Claim 103 depends from claim 101, which is discussed in paragraphs 221 through 229. The rationale for combining Theken and Errico with respect to claim 101 also applies to claim 103. With respect to the limitations in claim 103, as shown in Table 11 below, the combination of Theken and Errico comprises a biased stopping member (*e.g.* snap-ring 180) that comprises a collar. *See, e.g.* EX1006, 23:18-19, FIG. 5.

232. Claim 104 depends from claim 103, which is discussed in paragraph 231. The rationale for combining Theken and Errico with respect to claim 103 also applies to claim 104. With respect to the limitations in claim 104, as shown in Table 11 below, the combination of Theken and Errico comprises a biased collar (*e.g.* snap-ring 180) that is disposed in part within a recess of a stabilizing element. *See, e.g.* EX1006, 23:16-19, 23:26-27, 24:3-4, FIGS. 5-6. Errico shows an annular recess 182 that is positioned in an anterior section of Errico's hole 110c. *Id.* at FIG. 6. In the combination, the annular recess 182 is similarly positioned in the anterior portion (*e.g.* section 66) of Theken's bore (*e.g.* opening 62).

TABLE 11

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
103. The assembly of claim 101 wherein the biased stopping member comprises a collar.	<i>Errico (EX1006)</i> : "Within this annular recess 182 is provided a discontinuous '7/8ths' snap-ring 180" that forms a collar. <i>Id.</i> at 23:18-19. <i>See also Id.</i> at FIG. 5 (selected portion shown below), which illustrates a collar shape for snap-ring 180. The snap-ring 180 operates by enlarging from an unexpanded inner diameter to an expanded inner diameter as a tapered coupling element 132 travels into the snap-ring 180, and then returning to the unexpanded inner diameter after the tapered coupling element 132 passes through the snap-ring 180. <i>Id.</i> at 23:27-24:10, FIG. 6.

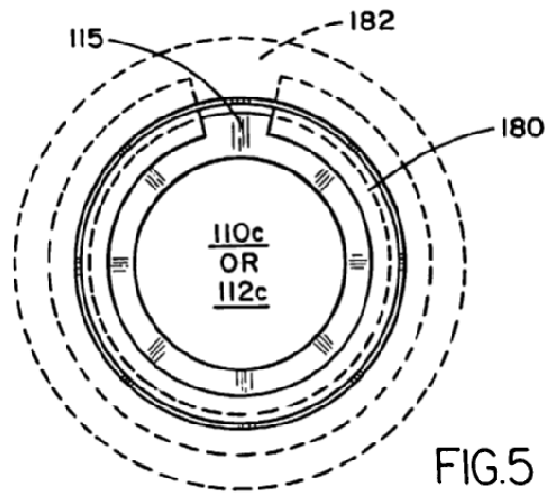


FIG.5

104. The assembly of claim 103 wherein the biased collar is disposed in part within a recess of the stabilizing element.

Errico (EX1006): "... the tapered hole 110c or 112c includes an annular recess formed 182 in the side wall 115 of the hole Within this annular recess 182 is provided a discontinuous '7/8ths' snap-ring 180." *Id.* at 23:16-19, FIGS. 5-6. "The snap-ring 180 is deflected inward for positioning in the recess 182." *Id.* at 23:26-27. "the tapered exterior surface of the coupling element 132 (or 133) causes the snap-ring 180 to expand into the recess 182." *Id.* at 24:3-4.

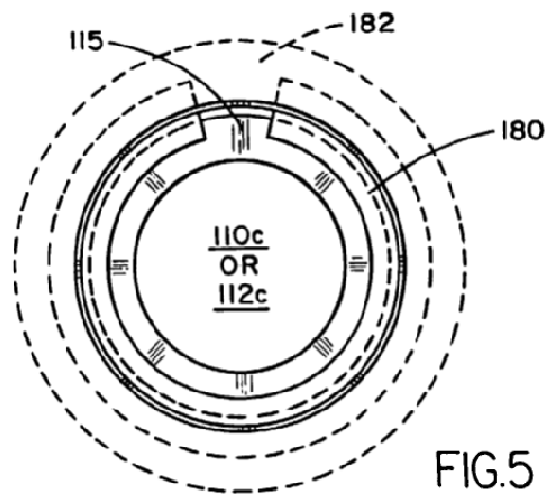
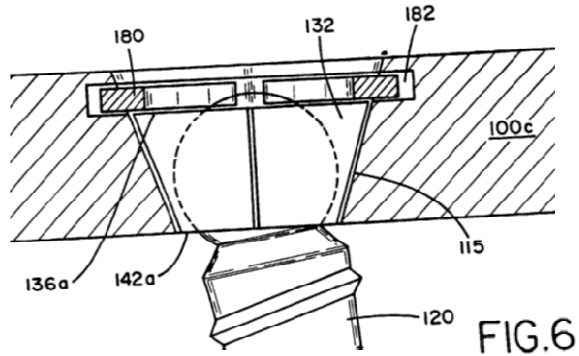


FIG.5



The combination of Theken and Errico uses Errico's in-hole annular recess 182 and snap-ring 180. Therefore, the resultant modification of Theken has the same characteristics as Errico's annular recess 182 and snap-ring 180 in terms of positioning of the annular recess 182 in an anterior portion of a bore and in terms of the expansion of the snap-ring 180.

B. Theken in View of Errico Renders Claims 3, 5, 11, 22, 30, and 37 of the '008 patent Obvious

233. In my opinion, the combination of U.S. Patent No. 6,228,085 to Theken et al. ("Theken") (EX1005) with International Publication No. WO 1996/032071 to Errico et al. ("Errico") (EX1006) discloses all of the limitations described in claims 3, 5, 11, 22, 30, and 37 of the '008 patent. The combination of Theken in view of Errico renders those claims obvious under pre-AIA 35 U.S.C. Section 103(a).

234. Each of claims 11, 22, 30, and 37 includes limitations of claims rendered obvious by the Theken and Errico combination discussed above in sub-

section A, which applies equally here. Each of the claims also include, or depend from claims that include, limitations related to a variable-angle bone screw, such as: (i) inserting a bone screw into bone at an angle relative to an axis of a bore; and (ii) using a curved surface in a posterior section of a bore that can accommodate a spherical head of a variable-angle bone screw.

235. Theken's plate can be used with bone screws that "may have other suitable geometries" such as "a spherical head" that "would allow variable screw angulation." EX1005, 6:51-56 (describing "It will be appreciated that screw 100 may have other suitable geometries. For instance, the tapered head could be replaced by a spherical head. The spherical head would allow variable screw angulation."); 7:57-60. Theken thus provides for using bone screws with spherical heads to provide variable-angle insertion of screws into bones (*i.e.*, variable-angle bone screws). As of July 8, 1999, variable-angle screws with spherical heads were available for insertion at an angle relative to an axis of a bore, including bores with a curved surface in a posterior section of the bore.

236. An example embodiment of the combination of Theken and Errico is a variable-angle bone screw and plate assembly with a snap-ring and annular recess where respective dimensions of Theken's variable-angle screw head and Errico's snap-ring 180 are sized to ensure the variable-angle screw head expanded Errico's snap-ring 180 and was retained by Errico's snap-ring 180 after being

inserted—*e.g.* by sizing the inner undeformed diameter of Errico’s snap-ring 180 to be larger than the smallest diameter of the variable-angle bone screw head, by sizing the posterior surface area of the snap-ring 180 so it abuts a top-most surface of the variable-angle bone screw when the bone screw is inserted at the greatest angle possible, and also sizing the inner deformed diameter of Errico’s snap-ring 180 to be larger than the widest diameter of the variable-angle bone screw head when inserted at any angle.

237. Errico describes benefits associated with using variable-angle bone screws. For example, Errico describes that “Surgeons ideally need to have freedom with respect to insertion angles so that the individual variations in fracture type, and bone anatomy may be accounted for in the fixation means.” EX1006, 5:22-24. See also: EX1006, 3:6-20 (“It has, therefore, been a goal of those in the art to provide screw plate assemblies which permit screws to be entered into the bone at angles other than 90 degrees.”), 6:15-27 (variable-angle screws with semi-spherical head, and locking said screw at a desired angle), 11:11-12:2 (head of the screw is retained during insertion to permit angular movement), 14:3-15:20 (means of fastening the plate to bone include variable-angle screws), FIGS. 4A-4B, 6, 9-10, 13.

238. Therefore a POSA would have had good reason to use the variable-angle bone screw of Errico in Theken’s plate assembly having a snap-ring and

annular recess for the same reasons discussed above in Section IX.A. It is thus my opinion that the combination of Errico and Theken renders each of claims 3, 5, 11, 22, 30, and 37 obvious.

1. Each of Claims 3 and 5 of the '008 patent is Obvious over Theken in view of Errico

239. It is my opinion that the combination of Theken and Errico renders each of claims 3 and 5 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 12) that follows.

240. Claims 3 and 5 each require that the head of the securing element has a curved posterior surface having a minimum outer diameter smaller than the unexpanded inner diameter of the collar. Claim 3 depends from claim 2, which in turn depends from claim 1 while claim 5 depends from claim 4, which in turn depends from claim 1, each of which are discussed above. The rationale for combining Theken and Errico with respect to claims 1, 2, and 4 also applies to claims 3 and 5.

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

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

TABLE 12

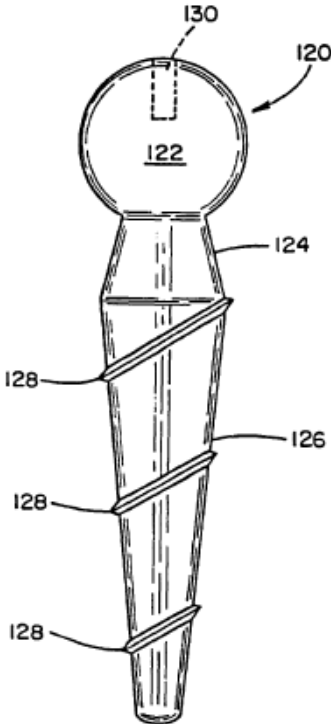
'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
<p>3. The assembly of claim 2 wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof.</p>	<p><i>Errico (EX1006):</i></p>  <p>FIG. 2</p>

FIG. 2 (*see also*: FIG. 6, below) illustrating head of the securing element has a curved posterior surface. *Id.* at 24:7-10. Errico's spherical head has an outer diameter smaller than the unexpanded inner diameter of the collar (*e.g.*, snap ring 180 of FIG. 6) and is configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof.

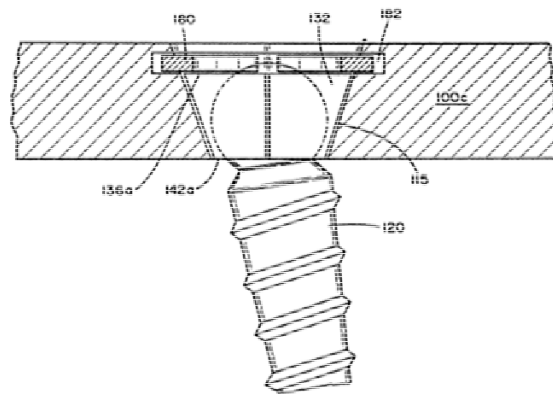


FIG.6

FIG. 6.

Theken (EX1005): "...the tapered head could be replaced by a spherical bead. The spherical bead would allow variable screw angulation." *Id.* at 6:51-56.

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.

Errico (EX1006):

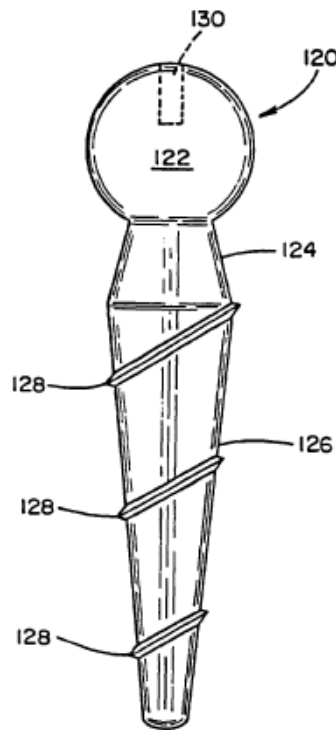


FIG. 2

FIG. 2 (*see also*: FIG. 6, below) illustrating head of the securing element has a curved posterior surface. *Id.* at 24:7-10. Errico's spherical head has an outer diameter smaller than the unexpanded inner diameter of the collar (*e.g.*, snap ring 180 of FIG. 6) which is configured to contact the collar anterior surface and expand the collar as the head is displaced posteriorly through the collar passageway.

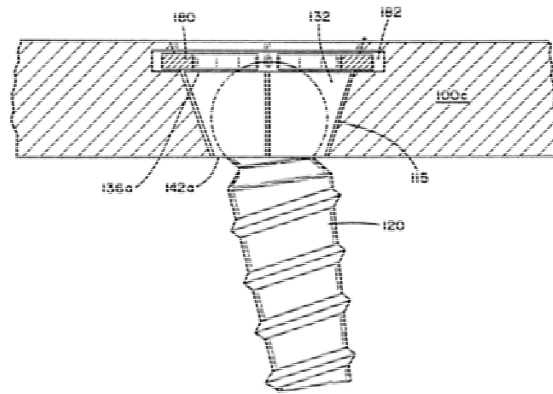


FIG. 6

FIG. 6.

Theken (EX1005): “...the tapered head could be replaced by a spherical bead. The spherical bead would allow variable screw angulation.” *Id.* at 6:51-56.

2. *Each of Claims 11, 22, 30, and 37 of the '008 patent is Obvious over Theken in view of Errico*

242. It is my opinion that the combination of *Theken* and *Errico* renders each of claims 11, 22, 30, and 37 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 13) that follows.

243. As discussed above at paragraph 236, *Theken* discloses that its integral screws 100 can be variable-angle bone screws (EX1005, 6:51-56, 7:57-60) and *Errico* teaches certain benefits of variable-angle bone screws. EX1006, Abstract, 3:6-20, 5:22-25, 6:15-27, 11:11-12:2, 14:3-15:20, FIGS. 4A-B, 6, 9-10, 13. A POSA would have understood *Theken*'s instruction that “the tapered head

could be replaced with a spherical head,” that “the spherical head would allow variable screw angulation,” and that “a screw with a flat or oval head which could be captured” by the set screw (*i.e.*, stopping member) to be a suggestion that variable screw angulation could be used in Theken’s assembly. EX1005, 6:51-56.

244. Claim 37 depends from claim 36, which is discussed in paragraphs 161 through 170. The rationale for combining Theken and Errico with respect to claim 36 also applies to claim 37. A POSA would have understood Theken and Errico’s disclosure of “variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion,” teach “the securing member is angularly displaceable within the posterior bore portion so that the bone screw may be secured with the patient’s bone at an angle relative to the longitudinal axis of the bore,” as required by claim 37.

245. Claim 11 depends from claim 10, which is discussed in paragraph 131. The rationale for combining Theken and Errico with respect to claim 10 also applies to claim 11. A POSA would have understood Theken and Errico’s disclosure of “variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion,” teach that “the securing element may be angularly displaced within the transverse passageway and the second opening in the stabilizing element,” as required by claim 11. Theken discloses that body of the securing element (e.g., bone screw 100) has a diameter

smaller than the second opening in the stabilizing element (e.g., plate 20). EX1005, 6:19-31, 8:33-38, 8:56-60, FIGS. 1-4, 10-11.

246. Claim 30 depends from claim 10, which is discussed in paragraph 131. The rationale for combining Theken and Errico with respect to claim 10 also applies to claim 30. A POSA would have understood Theken and Errico's disclosure of "variable screw angulation" at "angles other than 90 degrees" and "relative to the bottom opening of the socket portion," teach that "the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element," as required by claim 30. Theken also discloses that the body of the securing element (e.g., bone screw 100) has a transverse dimension smaller than the second opening of the stabilizing element (e.g., plate 20), including along the length of the threaded portion 102 and at the rounded tip 106, such that a securing element (e.g., bone screw 100) extends from the second opening to be screwed into the vertebral body. EX1005, 6:19-31, 8:33-38, 8:56-60, FIGS. 1-4, 10-11.

247. Claim 22 depends from claim 21, which is discussed in paragraphs 147 through 160. The rationale for combining Theken and Errico with respect to claim 21 also applies to claim 22. A POSA would have understood Theken and Errico's disclosure of "variable screw angulation" at "angles other than 90 degrees" and "relative to the bottom opening of the socket portion," teach a step of

angularly displacing the head of the securing element within the transverse passageway so that the body of the securing element is positioned at an angle within the patient's bone relative to the surface of the bone, as required by claim 22. Angularly displacing the head of the securing element (e.g., bone screw 100) within the transverse passageway, such that the body of the securing element is positioned at an angle within the patient's bone relative to the surface of the bone, is obvious by Theken and Errico for the same reasons discussed above for claims 11, 30, and 37. Theken and Errico disclose longitudinally displacing the head of the securing element (e.g., bone screw 100) in order to secure the securing member within the patient's bone. EX1005, 8:56; EX1006, 5:3-4. In the context of an unconstrained assembly, it would have been obvious to have longitudinal and angular displacement occur after the head of the securing element (e.g., bone screw 100) is positioned between the biased stopping member (e.g., snap-ring 180) and the second opening in the stabilizing element (e.g., plate 20).

248. In an example unconstrained assembly, Theken's annular recess 182 is placed in the middle of threaded section 66, so positioned that there is a space between the posterior surface of the snap-ring 180 and the top of the bone screw 100. A person of ordinary skill in the art would have understood that this unconstrained assembly was useful for allowing settling after a surgery, and for different depths of bone screw insertion during surgery. In such an assembly, the

head of the securing element is longitudinally displaceable within a transverse passageway between the biased stopping member and the second opening in the stabilizing element. When combined with the variable-angle bone screws suggested by Theken, the head of the securing element (e.g., bone screw 100) would be longitudinally and angularly displaced within the transverse passageway after the heads is positioned between the biased stopping member (e.g., snap-ring 180) and the second opening so that the body of the securing element is positioned at an angle within the patient's bone relative to the surface of the bone, as required by claim 22.

249. Therefore, in view of the cited teachings discussed above in paragraphs 242 through 248, it is my opinion that the combination of Theken and Errico discloses all of the limitations for each of claims 11, 22, 30, and 37 of the '008 patent, and thus each of those claims would have been obvious to a POSA in view of the combination of Theken and Errico.

TABLE 13

'008 Patent Claim	Theken (EX1005) and Errico (EX1006)
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.	<i>Errico (EX1006):</i>

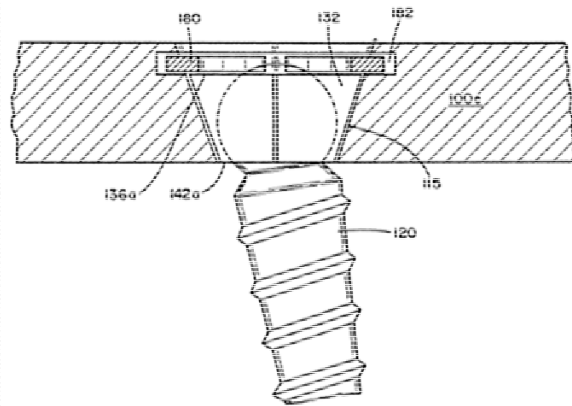


FIG.6

FIG. 6 (*Id.*) illustrating the body of the securing element (screw 120) having a diameter smaller than the opening in the stabilizing element (e.g., at 142a), and the securing element (screw 120) may be angularly displaced within the transverse passageway and the second opening of the stabilizing element. *See also: id.*, 3:6-20, 5:22-25, 6:15-27, 11:11-12:2, 14:3-15:20 (benefits of variable-angle bone screws).

Theken (EX1005): 6:19-31, 8:33-38, 8:56-60 (“variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion,” angular displacement within the transverse passageway and the second opening in the stabilizing element.” The body of the securing element (e.g., bone screw 100) has a diameter smaller than the second opening in the stabilizing element (e.g., plate 20)). *See also: id.*, FIGS. 1-4, 10-11.

22. The method of claim 21 including, after the head of the securing element is positioned between the biased stopping

Theken (EX1005) 6:19-31, 8:33-38, 8:56-60 (“variable screw angulation” at “angles other than 90 degrees” and

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 patient's bone relative to the surface of the bone.

“relative to the bottom opening of the socket portion,” teach angularly displacing the head of the securing element (e.g., screw bone 100) within the transverse passageway so that the body of the securing element is positioned at an angle within the patient’s bone relative to the surface of the bone). *See also: Errico (EX1006) 5:3-4.*

In the context of an unconstrained assembly, it would have been obvious to have longitudinal and angular displacement occur after the head of the securing element (e.g., bone screw 100) is positioned between the biased stopping member (e.g., snap-ring 180) and the second opening in the stabilizing element (e.g., plate 20) (above).

30. 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.

Errico (EX1006):

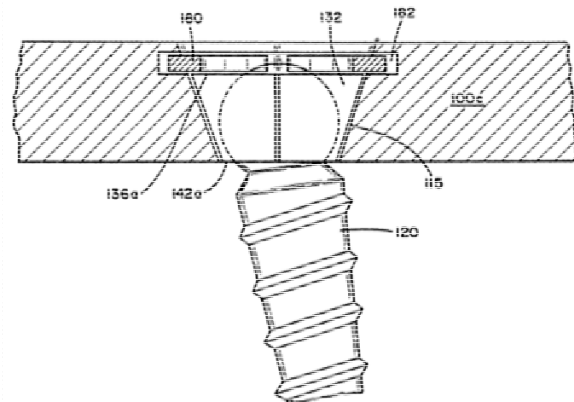
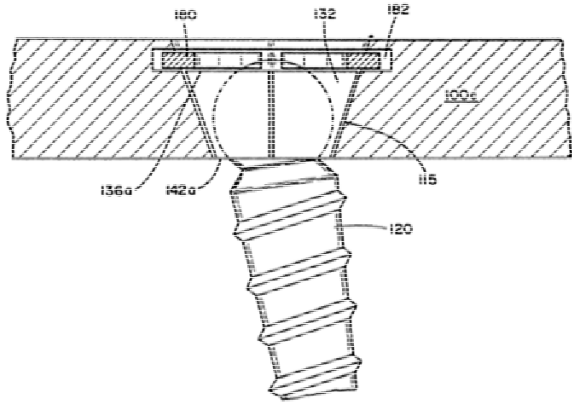


FIG. 6

FIG. 6 (*Id.*) illustrating the body of the securing element (screw 120) having a transverse dimension smaller than the second opening of the stabilizing element (e.g., at 142a), and the securing element (screw 120) may be angularly displaced within a posterior portion of

	<p>the bore of the stabilizing element. <i>See also: id.</i>, 3:6-20, 5:22-25, 6:15-27, 11:11-12:2, 14:3-15:20 (benefits of variable-angle bone screws).</p> <p><i>Theken (EX1005)</i> 6:19-31, 8:33-38, 8:56-60 (“variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion,” teach the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element.). <i>See also: id.</i>, 6:19-31, 8:33-38, 8:56-60, FIGS. 1-4, 10-11 (bone screw 100) has a transverse dimension smaller than the second opening of the stabilizing element (e.g., plate 20), including along the length of the threaded portion 102 and at the rounded tip 106, such that a securing element (e.g., bone screw 100) extends from the second opening to be screwed into the vertebral body.).</p>
<p>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.</p>	<p><i>Errico (EX1006)</i>:</p>  <p>FIG. 6 (<i>Id.</i>) illustrating the securing member (screw 120) is angularly displaceable within the posterior bore portion so that the securing member may be secured within the patient's</p>

	<p>bone at an angle relative to a longitudinal axis of the bore.</p> <p><i>Theken (EX1005)</i> 6:19-31, 8:33-38, 8:56-60 (“variable screw angulation” at “angles other than 90 degrees” and “relative to the bottom opening of the socket portion,” suggests 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 the longitudinal axis of the bore.</p>
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C. Theken in View of Errico and in further view of Farris Renders Claims 3, 5, 11, 22, 30, 37, 62-63, and 87 of the '008 patent Obvious

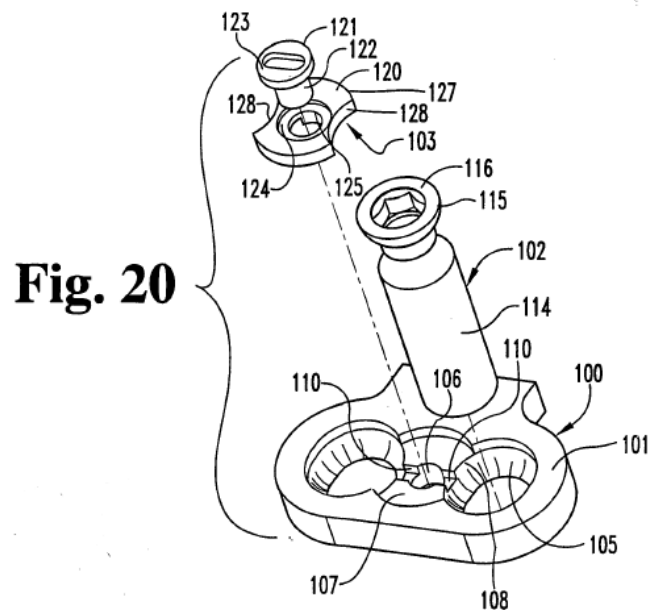
250. In my opinion, the combination of U.S. Patent No. 6,228,085 to Theken et al. (“Theken”) (EX1005) with International Publication No. WO 1996/032071 to Errico et al. (“Errico”) (EX1006) and further with International Publication No. WO 1998/051226 to Farris et al. (“Farris”) (EX1008) discloses all of the limitations described in claims 3, 5, 11, 22, 30, 37, 62-63, and 87 of the '008 patent, and renders these claims obvious under pre-AIA 35 U.S.C. 103(a).

251. As described above in Section IX(B), each of claims 11, 22, 30, 37 depend from claims 10, 21, or 36 and are rendered obvious by the Theken and Errico combination discussed above in sub-sections A-B, which applies equally here. Claims 62, 63, and 8 also depend from claims (e.g., 59, 61, or 86) that are rendered obvious by the combination discussed above in sub-section A, which

applies equally here. Each of the claims also include, or depend from claims that include, limitations related to the following concepts: (i) inserting a bone screw into bone at an angle relative to an axis of a bore; or (ii) using a curved surface in a posterior section of a bore that can accommodate a spherical head of a variable-angle bone screw.

252. Theken's plate can be used with bone screws that "may have other suitable geometries" such as "a spherical head" that "would allow variable screw angulation." EX1005, 6:51-54. As of July 8, 1999, variable-angle screws with spherical heads were available for insertion at an angle relative to an axis of a bore, including bores with a curved surface in a posterior section of the bore. One such bone screw and curved surface is described in Farris. Farris discloses an orthopedic implant assembly comprising a plate assembly 100 that is from the same field as Theken and Errico. EX1008, FIG. 20-23, and 23:33-25:26. The plate assembly 100 includes a plate 101 (*i.e.*, a stabilizing/attachment element), one-piece bone screws 102 (*i.e.*, integral securing elements), and a locking assembly 103 (*i.e.*, a stopping member) to "lock the bone screw within the plate". *Id.* at 23:35-24:3, FIGS. 20-23. The plate 101 includes a spherical recess 105 in a posterior section of a bore to receive a spherical head of the bone screw. *Id.* at 24:3-4. The bone screw can be similar to other variable-angle bone screws described in Farris. *Id.* at 24:6-8. Farris describes spinal plating systems having

different “degrees of fixation of a bone screw” which are “more advantageous for treating certain pathologies.” EX1008, 3:17-26. Farris shows assemblies used bone screws in rigid fashions (e.g., for treatment of tumors or trauma to the spine) or in a semi-rigid fashion (e.g., for grafts and treatment of degenerative diseases of the spine). EX1008, 3:27-4:25. Farris’s spherical screw head is used with a curved/spherical recess in a posterior section of a bore. EX1008, 24:3-4, FIGS. 20-23. Farris Figure 20 is reproduced below for reference.



253. Farris discloses fixed and variable angle screws, each having a threaded shank for screwing into the vertebra, a spherical head to seat within a spherical recess in the bore, and an intermediate portion that resides in the screw hole when the screw is fixed to the plate. EX1008, 5:8-22. The intermediate portion of the fixed angle screw “has an outer diameter sized for a close fit” within

the adjacent screw hole so that the screw “is prevented from rotating or pivoting within the screw hole” whereas the intermediate portion of the variable angle bone screw “has an outer diameter that is significantly smaller” than the diameter of the adjacent screw hole so that “the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” EX1008, 5:22-6:3, 15:17-16:1, 16:24-17:26, 18:33-20:11, 21:8-22, 22:29-23:26, FIGS 18-19. Farris teaches this variable angle screw permits angulation of 20 degrees from the axis of the recess and the bore. *Id.*, 23:9-11. Farris discloses a locking assembly may be used to prevent screw back-out, including a washer seated above the head of the bone screw to lock the screw head in position, the washer residing within a recess in the plate and optionally keyed into notches in the plate. EX1008, 6:4-31; *see also id.*, 20:12-21:7, 21:23-22:3.

254. Theken considers using bone screws with spherical heads to provide variable-angle insertion of screws into bones: “It will be appreciated that screw 100 may have other suitable geometries. For instance, the tapered head could be replaced by a spherical head. The spherical head would allow variable screw angulation.” EX1005, 6:51-54. Farris provides a variable-angle bone screw that uses a spherical head. EX1008, 24:3-8 (the bone screw 102 with a spherical head 115 can be similar to like components described elsewhere in Farris, such as the variable-angle screw 60), 17:2-6 (“The variable angle screw 60 also includes a

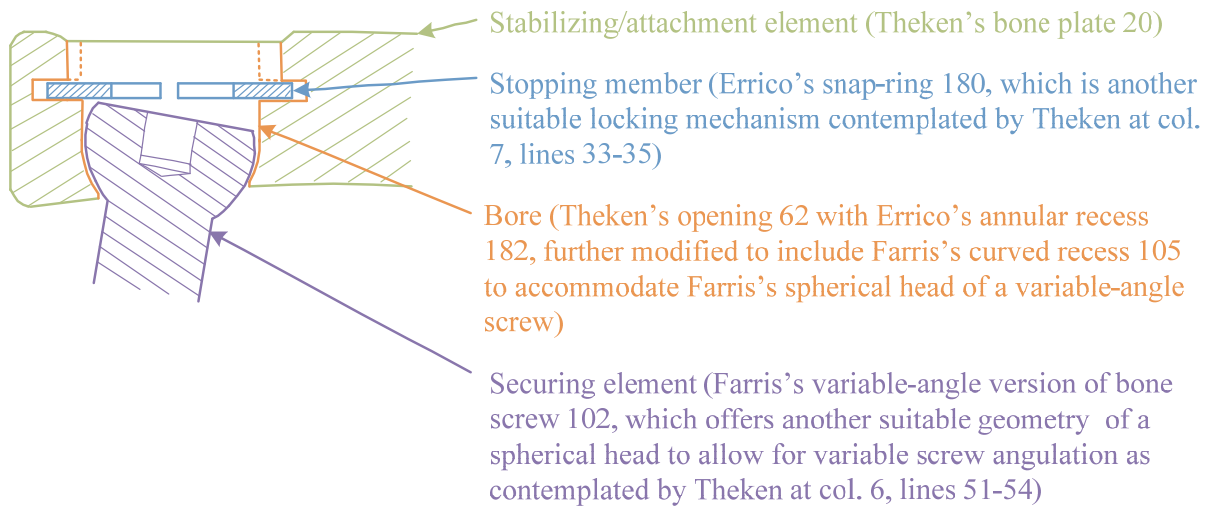
head 64 The head 64 also includes a spherical surface 67 disposed between the top surface 66 and the intermediate portion 62.”). Farris’s spherical screw head is used with a curved/spherical recess in a posterior section of a bore. *Id.* at 24:3-4 (“The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw.”), FIGS. 20-23. An intermediate portion of Farris’s bone screw is sized to be smaller than a hole of the spherical recess to allow for a range of insertion angles. *Id.* at 5:28-6:3 (The “relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.”).

255. In my opinion, it would have been obvious to a POSA at the time of the invention of the ’008 patent to combine the teachings of Theken, Errico, and Farris by using a variable-angle bone screw with a spherical head and spherical recess in a posterior section of a bore, as disclosed in Farris, with Theken’s plate and Errico’s snap-ring. Indeed, Farris provides an example of a bone screw contemplated by Theken for providing variable angle insertion of the bone screw—e.g., a bone screw that has spherical geometries to allow for angular displacement—and can therefore be used in Theken’s plate system. A POSA would have recognized the curved posterior bore section of Farris is compatible for use in a posterior bore section of the bore in Theken with the spherical screw head.

A POSA also would have recognized Farris's variable-angle bone screw spherical screw head is suitable for use with Errico's snap-ring 180. A POSA would have been motivated to and would have understood how to adjust the respective dimensions of Farris's screw head and Errico's snap-ring 180 to ensure Farris's spherical screw head expanded Errico's snap-ring 180 and was retained by Errico's snap-ring 180 after being inserted at an angle—*e.g.* by sizing the inner undeformed diameter of Errico's snap-ring 180 to be larger than the smallest diameter of Farris's spherical head, by sizing the posterior surface area of the snap-ring and could still be angularly displaced within a posterior section of the bone, and also sizing the inner deformed diameter of Errico's snap-ring 180 to be larger than the widest diameter of Farris's spherical head when inserted at any angle. The resulting combination of Theken, Errico and Farris would provide a bone fixation system that offers variable-angle insertion of bone screws that are locked to a plate by a snap-ring.

256. One implementation showing a bone fixation system of the combination of Theken, Errico and Farris is shown below. The dotted lines indicate adjustments that can be made to have a uniform contour from the anterior portion of the bore to the posterior portion of the bore, which would provide greater plate strength, easier manufacture, and optimal retention of the snap-ring

using the retention design disclosed by Errico.



By nature of the relative positions of the posterior surface of the snap-ring and the top-most part of the bone screw head for different angles of insertion, longitudinal movement of the bone screw head within the posterior section of the bore is available, which advantageously provides for unconstrained uses of the bone fixation system taught by Farris as advantageous for treating, e.g., degenerative disease. However, material deformation of the bone screw head and/or bore (e.g., as described by Theken (*e.g.* EX1005, 7:53-56)) would offer the option for a constrained use of the bone fixation system which Farris taught was useful for treating traumatic injury. EX1008, 3:17-4:25.

257. A POSA would have had a reasonable expectation of success in combining Theken, Errico and Farris and thereby obtaining predictable results for the following reasons: (i) the stopping members of Theken (set screw 140) and Errico (snap-ring 180) are both inside a bore; (ii) Errico shows how a bore (hole

110c) can include an annular recess 182; (iii) Errico also exemplifies how an annular recess could similarly be included in place of the threaded section 66 of Theken's bore (opening 62); (iv) Theken considers using a spherical head of a bone screw to provide variable-angle insertion of the bone screw, and Farris describes a variable-angle bone screw with a spherical head; (v) Errico's snap-ring 180 is deformed by a tapered coupling element 132, and a POSA would expect Errico's snap-ring 180 to be similarly deformed by the curved taper of Farris's screw head 115 because Farris's screw head 115 and Errico's coupling element 132 are both contoured from a minimum diameter to a maximum diameter; and (vi) the posterior surface area of Errico's snap-ring 180 is sizable to abut any top-most part of Farris's bone screw when the bone screw is inserted at the greatest angle possible (as shown by the illustration in preceding paragraph 256).

258. Multiple rationales support the combination of Theken, Errico and Farris. More particularly, there are several reasons supporting (i) the use of Errico's snap-ring 180 within Errico's in-bore annular recess 182 in place of Theken's set screw 140 within the threaded section 66 of the Theken bore (*e.g.* opening 62), and (ii) the use of Farris's variable-angle screw and curved recess in place of Theken's bone screw and straight-tapered posterior bore section. Included below are some of the reasons and rationales supporting the combination of Theken in view of Errico and in further view of Farris:

a. *Teaching, suggestion, or motivation to combine prior art reference teachings to arrive at the claimed invention:* This rationale with respect to Theken and Errico is described above in paragraph 116. The Theken, Errico, Farris and the '008 patent systems are in the same field of endeavor. Farris discloses an orthopedic implant assembly comprising a plate assembly 100 (stabilizing/attachment element), bone screws (integral securing element/member) to attach the plate to the bone, and locking assemblies (non-biased stopping members) to lock the bones screws to the plate and to prevent back out. Reasons why there was a reasonable expectation of success when using Errico's snap-ring in an annular recess and when using Farris's variable-angle bone screw and spherical recess of a posterior bore section in place of Theken's bone screw and posterior bore section, are provided above in the preceding paragraph 257. One motivation for using Farris's variable-angle bone screw and Farris's curved posterior bore section instead of using Theken's bone screw and straight-tapered posterior bore section is provided by Theken as follows: "The spherical head would allow variable screw angulation." EX1005, 6:51-54.

b. *"Obvious to try" with a reasonable expectation of success:* POSAs were very familiar with different types of bone screws that provided different types of angular insertion capabilities (e.g., fixed and/or variable

angles). Theken described a fixed-angle bone screw 100, but also recognized spherical heads of other bone screws allowed for variable-angle insertion of bone screws. Farris provided a variable-angle bone screw with a spherical head that sat in a posterior bore portion with a curved recess, which would have been obvious to try in Theken's plate given Theken's contemplation of bone screws with spherical heads for providing angular insertion of bone screws, and Farris's bone screw being one of a finite number of predictable bone screw solutions. Reasons why there was a reasonable expectation of success when using Farris's variable-angle bone screw and spherical recess of a posterior bore section in place of Theken's bone screw and posterior bore section are provided above in the preceding paragraph 257.

Additionally, POSAs were very familiar with different types of mechanisms for mechanically reducing the risk of screw back-out by locking the bone screws to the plate in orthopedic implants. (Paragraph 63, above). All of Theken, Errico and Farris provided stopping members that locked bone screws to plates and that prevented bone screws from separating from plates in the event the bone screws backed out. (Paragraphs 103, 107, and 235, above). Errico's snap-ring would have been obvious to try in Theken's plate and with Farris's curved-head bone screw as one of a finite number of predictable solutions that lock bone screws to plates and prevent back out.

Reasons why there was a reasonable expectation of success when using Errico's snap-ring in an annular recess are provided above in the preceding paragraph 257.

c. *Simple substitution of one known element for another to obtain predictable results:* The Theken, Errico, Farris and the '008 patent systems are all in the same field of endeavor. Errico's snap-ring was a known biased stopping member, and Farris's variable-angle bone screw and curved recess in a posterior section of a bore were known in the art. A POSA easily would have substituted (i) the Errico snap-ring for Theken's set screw and (ii) the Farris variable-angle bone screw and curved recess for Theken's bone screw and tapered bore section to yield predictable results because Errico showed the snap-ring works with a tapered shape and Farris's curved bone screw head comprises a compatible curved tapered shape. Reasons why a POSA would have obtained predictable results when using Errico's snap-ring in an annular recess when using Farris's variable-angle bone screw and spherical recess of a posterior bore section in place of Theken's bone screw and posterior bore section, are provided above in the preceding paragraph 257.

d. *Use of known technique to improve similar devices in the same way:* Theken was a "base" device using an in-bore set screw to lock an integral securing element to a plate, which prevented the integral securing element

from separating from the plate. Farris was a "comparable" device that was compatible with Theken in the same way as the '008 patent—*i.e.* providing variable-angle insertion of a bone screw through a plate. A POSA would have applied the known “improvement” technique (*e.g.* the variable-angle bone screw of Farris) in the same way to the “base” device to yield predictable results to a POSA in terms of providing variable-angle bone screw insertion, including variable-angle bone screw insertion through a snap-ring stopping member. Reasons why predictable results would have been obtained are provided above in the preceding paragraph 257.

e. *Applying a known technique to a known device ready for improvement to yield predictable results:* Theken was a “base” device using an in-bore set screw to lock an integral securing element to a plate, which prevented the integral securing element from separating from the plate. Farris’s variable-angle bone screw with a spherical head was a known technique for providing different angles of inserting a bone screw within a spherical recess of a bore. Farris was applicable to Theken’s “base” device because Theken specified its plate could be used with bone screws that have spherical heads for the purpose of providing variable bone screw angulation. For the reasons stated in the preceding paragraph 257, a POSA would have recognized that applying the known technique of a snap-ring together with a curved-taper

screw-head would have yielded predictable results and an improved system—*e.g.* a system offering different angles of inserting bone screws while locking those bone screws to the plate and preventing back out.

f. *Combining prior art elements to yield predictable results:* Each element claimed is in the combination of Theken, Errico and Farris. A POSA could have combined the elements as claimed by known methods (*e.g.*, use of Errico's annular recess 182 to hold Errico's snap-ring 180 to hold the bone screw in Theken's plate, use of Farris's variable-angle bone screw with spherical head and Farris's spherical recess in a posterior section of a bore. In the combination, Farris's bone screw and recess perform the same functions as they do in Farris (*i.e.* to provide variable angulation of bone screw insertion), Errico's snap-ring 180 performs the same function as it does in Errico (*i.e.* to lock a bone screw to a plate), and Theken's plate performs the same functions as it does in Theken (*i.e.* to connect two vertebrae by receiving a bone screw that attaches to bone of the vertebrae). Reasons why predictable results would have been obtained are provided above in the preceding paragraph 257.

259. Accordingly, for the reasons stated above, it is my opinion that at the time of the invention of the '008 patent, a POSA would have modified Theken's orthopedic implant assembly (bone fixation system 10) with (i) Errico's snap-ring

and in-bore annular recess, and also (ii) Farris's variable-angle bone screw and curved recess in a posterior section of a bore.

260. Combining Theken, Errico, and Farris in the manner described above does not render Theken's bone fixation system unsatisfactory for its intended purpose or change its principle operation. The intended purpose and principle operation of Theken's bone fixation system is plainly described as providing an "internal bone fixation system for the treatment of bone anomalies". EX1005, 1:4-7 and the first sentence of the Abstract. Theken contemplates different embodiments for achieving the principle operation and intended purpose of treating bone anomalies, including an embodiment where "set screws 140 could be replaced by other suitable locking mechanisms", and an embodiment that uses bone screws with spherical heads to allow variable screw angulation. EX1005, 6:51-54 and 7:33-35. Using Errico's snap-ring and Farris's variable-angle bone screws in Theken's bone fixation system supports Theken's principle operation and intended purpose of treating bone anomalies.

1. Each of Claims 3 and 5 of the '008 patent is Obvious over Theken in view of Errico and in further view of Farris

261. It is my opinion that the combination of Theken, Errico and Farris renders each of claims 3 and 5 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 14) that follows. It is my opinion, for each of claims 3 and 5, that it would have been

obvious for a POSA to use Farris's variable-angle bone screw with spherical head and spherical recess in a posterior section of a bore to perform the function of providing variable bone screw angulation in Theken's system.

262. Claim 3 depends from claim 2, which is discussed above in section IX.A.2. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 251 to 260 applies to claim 3. With respect to the limitations in claim 3, as shown in Table 14 below, the combination of Theken, Errico and Farris comprises a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a head having a curved posterior surface (bone screw 102 and spherical recess 105 are matched so bone screw 102 receives spherical head 115), and the head has a minimum outer diameter smaller than the unexpanded inner diameter of the collar (*e.g.* diameter of an intermediate portion of the head is smaller than a second opening having a locking washer 120) and is configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface (*see, e.g.*, collared openings at EX1008, FIGS. 21-23). *See, also:* EX1008, 24:3-6, FIG. 5, 20, 24:6-8, 17:2-6, 5:28-6:3. A POSA would have understood how to adjust the respective dimensions of Farris's screw head and Errico's snap-ring 180 to ensure Farris's spherical screw head expanded Errico's snap-ring 180 and was retained by Errico's snap-ring 180 after being inserted.

263. Claim 5 depends from claim 4, which is discussed above in section IX.A.2. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 251 to 260 applies to claim 5. With respect to the limitations in claim 5, as shown in Table 14 below, the combination of Theken, Errico and Farris comprises a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a head having a curved posterior surface (bone screw 102 and spherical recess 105 are matched so bone screw 102 receives spherical head 115), and the head has a minimum outer diameter smaller than the unexpanded inner diameter of the collar (*e.g.* diameter of an intermediate portion of the head is smaller than a second opening having a locking washer 120), and is configured to contact the collar anterior surface and expand the collar as the head is displaced posteriorly through the collar passageway. EX1008, 24:3-6, FIG. 5, 20, 24:6-8, 17:2-6, 5:28-6:3. A POSA would have understood how to adjust the respective dimensions of Farris’s screw head and Errico’s snap-ring 180 to ensure Farris’s spherical screw head expanded Errico’s snap-ring 180 and was retained by Errico’s snap-ring 180 after being inserted.

TABLE 14

‘008 Patent Claim	Theken (EX1005) and Errico (EX1006) and Farris (EX1008)
3. The assembly of claim 2 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	<i>Farris (EX1008):</i> “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.”

<p>collar, configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof.</p>	<p><i>Id.</i> at 24:3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.</p>
<p>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.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24:3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the</p>

	bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.
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2. Each of Claims 11, 22, 30, 37, 62-63, and 87 of the '008 patent is Obvious over Theken in view of Errico and in further view of Farris

264. It is my opinion that the combination of Theken, Errico and Farris renders each of claims 11, 22, 30, 37, 62-63, and 87 of the '008 patent obvious by disclosing each and every element of the claim, as shown below and in the claim chart (Table 15) that follows. It is my opinion, for each of claims 11, 22, 30, 37, 62-63, 85, 87, 88 and 89, that it would have been obvious for a POSA to use Farris's variable-angle bone screw with spherical head and spherical recess in a posterior section of a bore to perform the function of providing variable bone screw angulation in Theken's system. As I explain above in paragraphs 257 and 258, it would have been obvious for a POSA to configure the Theken system with the variable-angle bone screw and spherical recess of Farris based on various rationales, and there would be a reasonable expectation of success along with predictable results. As I also explain above in paragraph 260, configuring the Theken system with the variable-angle bone screw and spherical recess of Farris would not render the Theken system unsatisfactory for its intended purpose or change its principle operation. Therefore, in view of the cited teachings discussed below in paragraphs 265 through 271, it is my opinion that the combination of

Theken, Errico and Farris discloses all of the limitations for each of individual claims 11, 22, 30, 37, 62-63, and 87 of the '008 patent, and thus each of those claims would have been obvious to a POSA in view of the combination of Theken, Errico, and Farris.

265. Claim 11 depends from claim 10, which is discussed in paragraph 131. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 11. With respect to the limitations in claim 11, as shown in Table 15 below, the combination of Theken, Errico and Farris comprises a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a body that has a diameter (*e.g.* diameter of an intermediate portion) smaller than a second opening in a stabilizing element (*see e.g.* opening at bottom of recess 105 in Farris's plate 101), and that may be angularly displaced within a transverse passageway and a second opening in a stabilizing element. *See, e.g.* EX1008, 24:3-6, FIG. 20-23, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (The "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.").

266. Claim 22 depends from claim 21, which is discussed in paragraphs 147 through 160. The rationales for combining Farris with the combination of

Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 22.

With respect to the limitations in claim 22, as shown in Table 15 below, the combination of Theken, Errico and Farris comprises a step, after a head of a securing element (*e.g.* spherical head of a bone screw 102 having similar features from other disclosed bone screws) is positioned between a biased stopping member and a second opening (*see e.g.* opening at bottom of recess 105) in a stabilizing element, of longitudinally and angularly displacing the head of the securing element within the transverse passageway, so that the body of the securing element is positioned at an angle within the patient's bone relative to the surface of the bone. *See, e.g.* EX1008, 24:3-6, FIG. 20-23, 24:6-8, 5:28-6:3 (the “relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.”) As stated before with respect to claim 10, Errico’s annular recess 182 is placed at the middle of Theken’s bore section 66 to allow for longitudinal displacement of a bone screw between the stopping member and the posterior hole of the bore. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for certain surgeries. This approach using a semi-rigid system can also be used for Farris’s bone screw so as to provide longitudinally displacement of a bone screw between Errico’s snap-ring 180 and

the posterior hole of Farris's spherical recess, which would advantageously allow for settling as desired for certain surgeries.

267. Claim 30 depends from claim 10, which is discussed in paragraph 131. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 30. With respect to the limitations in claim 30, as shown in Table 15 below, the combination of Theken, Errico and Farris comprises a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a body that has a transverse dimension (*e.g.* diameter of an intermediate portion) smaller than the second opening of the stabilizing element (*see e.g.* opening at bottom of recess 105 in Farris's plate 101), and wherein the securing element may be angularly displaced within a posterior portion of the bore of the stabilizing element. *See, e.g.* EX1008, 24:3-6, FIG. 20-23, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (the "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.").

268. Claim 37 depends from claim 36, which is discussed in paragraphs 161 through 170. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 37. With respect to the limitations in claim 37, as shown in Table 15 below, the

combination of Theken, Errico and Farris comprises a securing member (*e.g.* bone screw 102 having similar features from other disclosed bone screws) that is angularly displaceable within a posterior bore portion (*see e.g.* opening at bottom of recess 105 in Farris's plate 101) so that the securing member may be secured within the patient's bone at an angle relative to a longitudinal axis of the bore. *See, e.g.* EX1008, 24:3-6, FIG. 20-23, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (the "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.").

269. Claim 62 depends from claim 61, which is discussed in paragraph 200. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 62. With respect to the limitations in claim 62, as shown in Table 15 below, the combination of Theken, Errico and Farris comprises a securing member (*e.g.* bone screw 102 having similar features from other disclosed bone screws) with a portion posterior to an enlarged integral portion that has transverse dimensions (*e.g.* diameter of an intermediate portion below spherical head of bone screw) sufficiently smaller than the transverse dimensions of the posterior bore portion (*see e.g.* opening at bottom of recess 105 in Farris's plate 101) so the securing member may be angularly displaced within the bore. *See, e.g.* EX1008, 24:3-8, FIGS. 20-23, 24:6-8, FIG. 5,

17:2-6, 5:28-6:3 (the “relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.”)

270. Claim 63 depends from claim 62, which is discussed in paragraph 269. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 63. With respect to the limitations in claim 63, as shown in Table 15 below, the combination of Theken, Errico and Farris comprises a posterior surface of an enlarged integral portion of a securing member (*e.g.* spherical surface of spherical head of variable-angle bone screw) that is configured at least in part to conform to a posterior surface of a posterior bore portion (*e.g.* spherical recess) to facilitate angulation of the securing member within the posterior bore portion. *See, e.g.* EX1008, FIGS. 20-23, 24:3-8 (“... a spherical recess 105 to receive the spherical head 115 of the bone screw.”), 24:6-8, 17:2-6, 5:28-6:3 (the “relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.”). The curved surfaces facilitate tilting the bone screw at angles.

271. Claim 87 depends from claim 86, which is discussed in paragraph 218. The rationales for combining Farris with the combination of Theken and Errico discussed in paragraphs 257-258 and 264 applies to claim 87. With respect to the limitations in claim 87, as shown in Table 15 below, the combination of Theken, Errico and Farris comprises a securing element (*e.g.* bone screw 102 having similar features from other disclosed bone screws) that has a portion posterior to the enlarged integral portion that has a transverse dimension (*e.g.* diameter of an intermediate portion) smaller than a transverse dimension of an opening in the posterior bore portion (*see e.g.* opening at bottom of recess 105 in Farris's plate 101) to provide angular displacement of the securing element within the posterior bore portion. *See, e.g.* EX1008, 24:3-6, FIG. 20-23, 24:6-8, FIG. 5, 17:2-6, 5:28-6:3 (the "relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.")

TABLE 15

'008 Patent Claim	Theken (EX1005) and Errico (EX1006) and Farris (EX1008)
<p>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.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24: 3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.</p>
<p>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 patient's bone relative to the surface of the bone.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24: 3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate</p>

	<p>portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.</p> <p>As stated before with respect to claim 10, Errico’s annular recess 182 is placed at the middle of Theken’s bore section 66. A POSA would be motivated to include the annular recess 182 at the middle location so as to create an unconstrained system that is desirable for other surgeries. This approach can also be used for Farris’s bone screw so as to provide longitudinally displacement under Errico’s snap-ring 180 that would allow for settling after surgery.</p>
<p>30. 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.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24: 3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly</p>

	<p>smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.</p>
<p>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.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24:3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.</p>
<p>62. The attachment assembly of claim 61 wherein a portion of the securing member posterior to the enlarged integral portion has transverse dimensions sufficiently smaller than the transverse dimensions of the posterior bore portion so the securing member</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24: 3-6, FIGS. 20-23. “It is understood that the bone screw 102 and</p>

<p>may be angularly displaced within the bore.</p>	<p>spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.</p>
<p>63. The attachment assembly of claim 62 wherein the posterior surface of the enlarged integral portion of the securing member is configured at least in part to conform to the posterior surface of the posterior bore portion to facilitate angulation of the securing member within the posterior bore portion.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. ... It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:3-8, FIGS. 20-23. <i>Farris</i>’s bone screw includes a spherical head 64 with a spherical surface 67. <i>Id.</i> at FIG. 5, 17:2-6. The curved mating surfaces permit tilting at angles.</p>
<p>87. The orthopedic attachment assembly of claim 86 wherein the securing element has a portion posterior to the enlarged integral portion that has a transverse dimension smaller than a transverse dimension of an opening in the posterior bore portion to provide angular displacement of the securing element within the posterior bore portion.</p>	<p><i>Farris (EX1008)</i>: “The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess.” <i>Id.</i> at 24: 3-6, FIGS. 20-23. “It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.” <i>Id.</i> at 24:6-8. “The variable angle bone screw includes an intermediate portion</p>

	that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.” 5:28-6:3.
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X. CONCLUDING STATEMENTS

272. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

273. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: **March 13, 2020**

By: 

Joseph P. Errico.

XI. APPENDIX - EXHIBITS

Exhibit No.	Exhibit Name
1001	U.S. Patent No. RE43,008
1002	Declaration of Joseph P. Errico
1003	U.S. Patent No. 6,261,291
1004	File History for U.S. Patent No. RE43,008
1005	U.S. Patent No. 6,228,085 to Theken <i>et al.</i>
1006	International Publication No. WO 1996/032071 to Errico <i>et al.</i>
1007	U.S. Patent No. 5,082,390 to Balsells
1008	International Publication No. WO 1998/051226 to Farris <i>et al.</i>
1009	File History for U.S. Patent No. 6,228,085
1010	Ryhanen, J. <i>et al.</i> , <i>In vivo biocompatibility evaluation of nickel-titanium shape memory metal alloy: muscle and perineural tissue responses and capsule membrane thickness</i> , 41 J. Biomed. Mater. Res. 481-88 (Sep. 1998).
1011	Ryhanen, J. <i>et al.</i> , <i>Biocompatibility of nickel-titanium shape memory metal and its corrosion behavior in human cell cultures</i> , 35 J. Biomed. Mater. Res. 451-57 (Jun. 1997).
1012	<i>Reserved</i>
1013	<i>Reserved</i>
1014	Claim Construction Order from <i>Acantha LLC v. DePuy Synthes Sales, Inc.</i> , Eastern District of Wisconsin Case No. 15-c-1257-WCG.
1015	Curriculum Vitae for Joseph P. Errico.
1016	File History for U.S. Patent No. 6,261,291

1017	Baskin et al., <i>Techniques of Anterior Cervical Plating, 1 Operative Techniques in Neurosurgery</i> , 90-102 (June 1998).
1018	U.S. Patent No. 5,876,402 to Errico et al.
1019	U.S. Patent No. 5,411,348 to Peter J. Balsells
1020	U.S. Patent No. 5,904,683 to Pohndorf et al.
1021	U.S. Patent No. 4,488,543 to Alain Tornier