IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number	:	7,128,744
Issued	:	October 31, 2006
Application Number	:	10/665,505
Filing date	:	September 22, 2004
Title	:	BONE PLATING SYSTEM
Docket No.	:	47063.000073
Customer No.	:	**21967**

Attn: Mail Stop "*Inter Partes* Reexamination"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Request for *Inter Partes* Reexamination of U.S. Patent No. 7,128,744

Sir:

Reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.903-927 is hereby requested for claims 1-55 of U.S. Patent No. 7,128,744 ("the '744 Patent") (Exhibit A), entitled "Bone Plating System," which is assigned to Synthes USA, LLC ("Synthes") (Reel/Frame 011364/0057 and 022299/0001).

This request is being made by third party requester Smith & Nephew, Inc., which is also the real party in interest (37 C.F.R. § 1.915(b)(8)).

This request is further to the *Ex Parte* Reexamination Control No. 90/009,377 filed January 8, 2009 and granted February 13, 2009 ("*Ex Parte* Request for Reexamination"). Requestor respectfully requests that this request be merged with the prior *Ex Parte* proceeding in accordance with 37 C.F.R. § 1.989(b).

The Director is hereby authorized to charge the fee as set forth in 37 C.F.R. § 1.20(c)(2), to Deposit Account No. 50-0206. It is believed that no other fees are required for consideration

of this *Inter Partes* reexamination request. However, should any additional fees be necessary, the Commissioner is authorized to charge such fees to Deposit Account No. 50-0206.

A copy of the patent to be reexamined, in double column format and printed on only one side of the page, is enclosed as Exhibit A to this request. A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on the attached Form PTO/SB/08.

The '744 Patent is currently the subject of the following copending litigation styled: *Synthes (U.S.A.) v. Smith & Nephew, Inc.* (E.D. Pa. Case No. 03-0084).

It is certified that the estoppel provisions of 37 CFR § 1.907 do not prohibit this reexamination. 37 CFR 1.915(b)(7).

A copy of this request and all papers and references filed in support thereof was served by first class mail on May 5, 2009, as provided in 37 CFR 1.33(c), on the patent owner of record by its representative:

Brian M. Poissant, Esquire
Jones Day
222 East 41st Street
New York, NY 10017

Please direct all communications for the third party requestor to the address associated with Customer No. **21967**.

A statement identifying each substantial new question of patentability based on the references being relied upon, an identification of every claim for which reexamination is requested, and a detailed explanation of the pertinence and manner of applying each cited reference to every claim for which reexamination is requested, are included in the request below.

Table of Contents

I. THE '744 PATENT AND RELATED LITIGATION

A. Subject Matter of the '744 Patent

The '744 patent claims include system claims directed to bone plating systems. All claims of the '744 patent require:

- a head portion having a width greater than the width of the shaft portion and with only bone anchor holes having a threaded portion;
- a shaft portion having a width, either a central longitudinal axis or a longitudinal axis, and bone anchor holes; and
- the lower surface of the shaft portion having a plurality of arched cut-outs extending transverse to the longitudinal axis.

The '744 patent includes three independent claims — claims 1, 24, and 53. Claim 1 is representative:

> A bone plating system for improving the stability of a bone fracture in a long bone comprising:
> a bone plate having:
> an upper surface;
> a lower surface;
> a shaft portion having a width and a central longitudinal axis,
> the shaft portion configured and dimensioned to extend along at least a portion of a diaphysis of the bone and
> the lower surface of the shaft portion having a plurality of arched cut-outs extending transverse to the longitudinal axis; and
> a head portion that flares outward from the shaft portion so as to have a width that is greater than the width of the shaft portion,
> the head portion curving upward from the shaft portion and having at least three bone anchor holes,
> the bone anchor holes being conically tapered from the upper surface to the lower surface,
> the at least three bone anchor holes having at least a portion that has a thread to engage a thread on a head of a bone anchor,
> wherein the head portion has only bone anchor holes having the threaded portion,
> the shaft portion having a plurality of holes having at least a portion that has a thread to contact the thread on the head of a bone anchor.

B. The Prosecution Of The '744 Patent

The '744 patent was filed as a United States patent application on September 22, 2003. The application originally recited forty-six claims, but on August 20, 2004, Synthes filed a preliminary amendment canceling original claims 1-46, and adding new claims 47-100. Claim 47 (as filed and reproduced below), is exemplary:

> 47. A bone plating system for improving the stability of a bone fracture in a long bone comprising:
>
> a bone plate having:
>
> an upper surface;
>
> a lower surface;
>
> a shaft portion having a width, the shaft portion configured and dimensioned to extend along at least a portion of a diaphysis of the bone; and
>
> a head portion that flares outward from the shaft portion so as to have a width that is greater than the width of the shaft portion, the head portion curving upward from the shaft portion and having at least three bone anchor holes, the bone anchor holes being conically tapered from the upper surface to the lower surface, the at least three bone anchor holes having at least a portion that has a thread to engage a thread on a head of a bone anchor,
>
> wherein the head portion has only bone anchor holes having the threaded portion, the shaft portion having a plurality of holes having at least a portion that has a thread to contact the thread on the head of a bone anchor.

Claim 47 (as filed).

On January 26, 2006, the United States Patent and Trademark Office ("USPTO") issued a comprehensive, thirteen-page Office Action (the "Office Action") rejecting all of the application's claims except for claims 60-61 and 88-89. Claims 60, 61, 88 and 89 depended from claims 47, 59, 73, and 87, respectively, and further limited these claims to a "lower surface of the shaft portion [that] has a plurality of arched cut-outs extending transverse to the longitudinal axis of the shaft portion." Synthes amended all of its independent claims to include

the "arched cut-out" limitation after the patent examiner indicated that doing so would place the claims in condition for allowance. Following this amendment, the claims issued, all including the "arched cut-outs" limitation.

II. PRIOR ART AND PRINTED PUBLICATIONS UPON WHICH THE REEXAMINATION REQUEST IS BASED

Each of the references relied upon by the Requestor qualifies as prior art to the '744 patent. The '744 patent was filed on September 22, 2003 as a continuation of U.S. Application No. 09/660,287, now U.S. Patent No. 6,623,486. The '744 patent also claims priority to a provisional patent application (No. 60/153,239) that was filed on September 13, 1999. A reference qualifies as prior art under 35 U.S.C. § 102(b) if it was "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

Requestor relies on the following references:

- Summary of Safety and Effectiveness Information [510(k) Summary], K982222, July 29, 1998 ("K982222 Summary")
- Manual of Internal Fixation, Techniques Recommended by the AO-ASIF Group, pp. 200-51, Springer-Verlag, 1991 ("Manual Of Internal Fixation")
- Koval, K., *et al.*, "Distal Femoral Fixation: A Biomechanical Comparison of the Standard Condylar Buttress Plate, a Locked Buttress Plate, and the 95-Degree Blade Plate," J. of Orthopaedic Trauma, vol. 11(7), pp. 521-524, Lippencott-Raven Publishers, October 1997 ("Koval Article")
- Vattolo, M., Thesis, "The Effect of Grooves in Osteosynthesis Plates on the Restructuring of the Corticalis," Laboratory for Experimental Surgery, Swiss Research Institute, 1986 (original in German, translation to English attached with certification) ("Vattolo")
- Perren et al., "The Limited Contact Dynamic Compression Plate (LC-DCP)," Arch. Orthopaedic & Trauma Surg., Vol. 109, pp. 304-310, 1990 ("Perren Article")
- U.S. Patent No. 5,053,036 to Perren, *et al.* ("Perren '036")

- U.S. Patent No. 5,002,544 to Klaue, *et al.* ("Klaue")
- Surgical Instruments Catalog, pp. 392-97, Collin & Co., 1935 (original in French, translation to English attached with certification) ("Collin Catalog")
- Zimmer Advertisement, J. of Orthopaedic Trauma, Vol. 12, No. 5, June/July 1998 ("Zimmer Ad")
- Synthes 1997 Catalog, published by Synthes, March 1997 ("Synthes 1997 Catalog")
- Haas, N.P., *et al.*, "LISS – Less Invasive Stabilization System – A New Internal Fixator for Distal Femur Fractures," OP J., vol. 13(3), pp. 340-344, Georg Thieme Verlag, December 1997 (original in German, translation to English attached with certification) ("Haas Article")
- The Locking Reconstruction Plate Technique Guide, published by Synthes, 1997 ("Locking Plate Reconstruction Technique Guide")

Requestor also relies upon the following references which were of record during the prosecution of the '744 patent:

- U.S. Patent No. 5,190,544 to Chapman *et al.* ("Chapman")
- U.S. Patent No. 5,601.553 to Trebing *et al.* ("Trebing")
- U.S. Patent No. 5,954.722 to Bono ("Bono")
- DE 43 43 117 to Wolter ("Wolter '117")

The following includes a discussion of the prior art status of the references described in this request and a detailed explanation of the pertinence and manner of applying the cited prior art.

III. STATEMENT OF NEW QUESTIONS OF PATENTABILITY ("SNQs")

A. The K982222 Summary

1. The K982222 Summary Is Prior Art

Synthes, the patent holder, is a manufacturer of bone plates, which are classified as medical devices and are regulated by the Food and Drug Administration ("FDA"). As such,

bone plate manufacturers typically are required to submit a Premarket Notification Application to the FDA under section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360, requesting permission to market a bone plate. This type of filing is known as a "510(k) filing," and such filings include a "Summary of Safety and Effectiveness Information" that describes the product. On June 23, 1998, Synthes submitted a 510(k) filing for a bone plate system that Synthes called the "DFP System." This filing received a unique identifier — "K982222" — from the FDA. The FDA published the K982222 "Summary of Safety and Effectiveness Information" on its website no later than August 26, 1998.

The K982222 Summary is prior art under 35 U.S.C. § 102(b) because it is a printed publication that was available to the public more than one year before the earliest filing date of the '744 patent. To determine the date the K982222 Summary was published, Requestor submitted a Freedom of Information Act ("FOIA") asking the FDA to indicate the date on which the K982222 Summary was available to the public. In response, the FDA certified that "510(K) Number K982222 was uploaded to the FDA's FTP web server on August 26,1998, making 510(k) Number K982222 accessible to the public through the FDA website as of that date." *See* Exhibit B. Therefore, the K982222 Summary qualifies as a publicly available printed publication that is prior art to the '744 patent.

The K982222 Summary is not of record in the prosecution history of the '744 patent application.

2. Substantial New Questions of Patentability Stemming From The K982222 Summary

The K982222 Summary raises a substantial new question of patentability not addressed in the original prosecution or the *Ex Parte* Reexamination.

The K982222 Summary discloses a bone plate with several key features not disclosed in

any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, the K982222 Summary discloses a bone plate system with the following key features:

- **A condylar buttress plate with a head portion and a shaft portion** ("The plate is available with an anatomically curved head"); ("The DFP shaft features dynamic compression unit (DCU) screw holes")
- **Fully-threaded locking plate holes in the head** ("four of the six holes are threaded")
- **A plate with a limited contact profile** ("The DFP shaft features … a limited-contact profile")
- **A combination of some plate holes that are fully threaded and others that are unthreaded** ("The DFP shaft features dynamic compression unit (DCU) screw holes and a limited-contact profile")
- **Holes in the plate head that are between 5mm and 7mm in diameter** ("the two posterior holes are non-threaded and will accept 6.5 mm cancelleous screws")

All of these features are recited in the claims and are relevant to patentability:

- **A condylar buttress plate with a head portion and a shaft portion** (Claims 1-52 include the following limitation: "a shaft portion having a width and a central longitudinal axis … and a head portion that flares outward from the shaft portion"; claims 53-55 include the limitation "a shaft portion having a width and a longitudinal axis … and a head portion having a width that is greater than the width of the shaft portion")
- **Fully-threaded locking plate holes in the head** (Claims 1-23 include the following limitation: "bone anchor holes having at least a portion that has a thread to engage a thread on a head of a bone anchor, wherein the head portion has only bone anchor holes having the threaded portion"; claims 24-55 include the limitation "the head portion having a plurality of conically tapered holes having at least a portion that has a thread to contact a bone anchor.")
- **A plate with a limited contact profile** (All claims include the following limitation: "the lower surface of the shaft portion having a plurality of arched cut-outs")
- **A combination of some plate holes that are fully threaded and others that are unthreaded** (Claim 54: "wherein the bone plate includes at least one non-threaded screw hole")
- **Holes in the plate that are between 5mm and 7mm in diameter** (Claims 22 and 49: "the holes have a diameter between approximately 5 mm and approximately 7 mm")

A substantial new question of patentability exists with respect to the K98222 Summary because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, the K982222 Summary is not cumulative to the art of record and a reasonable examiner would find the K982222 Summary important in deciding whether the claims are patentable.

In the original prosecution, the Examiner relied upon Chapman and Bono as prior art. While Chapman disclosed a bone plate with a head and a shaft, it lacked threaded holes, and the Examiner had to rely on the Bono reference for a disclosure of threaded holes. Bono, however, discloses a spine bone plate and lacks a head and a shaft. Further, Bono discloses threaded inserts rather than threaded holes. Clearly, the K982222 Summary provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog only shows unthreaded holes while the Haas Article only shows all threaded screw holes. In contrast to these two references, the K9822222 Summary discloses both threaded and unthreaded holes in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference disclosed a condylar buttress plate with a shaft and head that had threaded holes and a limited contact profile, as disclosed in the K982222 Summary. All of these features are recited in the claims, and clearly the K982222 Summary provides additional teachings in a single reference. The K98222 Summary, therefore, presents a different and

distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

B. The Koval Article

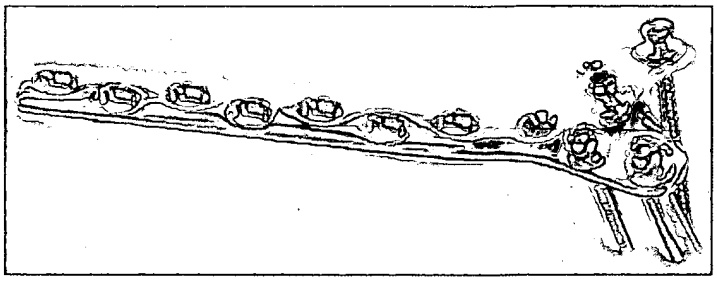
1. The Koval Article Is Prior Art

The Koval Article describes a hybrid bone plating system that has a head portion to match the metaphysis of a bone and a shaft portion to match the diaphysis of a bone and uses first and second fasteners in a combination of first and second holes for fracture fixation of the distal femur. *See, e.g.*, Koval Article at 521, 'Objectives' and 'Design,' ¶ 1, Fig. 1. The Koval Article was published in a widely distributed medical journal — The Journal of Orthopaedic Trauma — in October 1997. Accordingly, the Koval Article qualifies as a publicly available printed publication that is prior art to the '744 patent. The Koval Article is not of record in the prosecution history of the '744 patent.

2. Substantial New Questions of Patentability Stemming From The Koval Article

The Koval Article discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, the Koval Article discloses a bone plate system with the following key features:

- **A condylar buttress plate with a head portion and a shaft portion** (The Koval Article discloses "a modified lateral condylar buttress plate made by welding four tapped nuts … into the screw holes of the distal plate flange in the identical pattern used for the standard buttress plate … to create a locked screw system"; Fig. 1)



- **Fully-threaded locking plate holes** (Four of the six holes are converted to threaded holes by the inclusion of welded-in threaded nuts; the Koval Article further discloses that the holes in the bone plate may be threaded (*i.e.*, tapped) *without* the use of a nut.)
- **A combination of some plate holes that are fully threaded and others that are unthreaded** (the shaft of the Koval plate were unmodified, unthreaded screw holes)

All of these features are recited in the claims and are relevant to patentability:

- **A condylar buttress plate with a head portion and a shaft portion** (Claims 1-52 include the following limitation: "a shaft portion having a width and a central longitudinal axis ... and a head portion that flares outward from the shaft portion"; claims 53-55 include the limitation "a shaft portion having a width and a longitudinal axis ... and a head portion having a width that is greater than the width of the shaft portion")
- **Fully-threaded locking plate holes** (Claims 1-23 include the following limitation: "bone anchor holes having at least a portion that has a thread to engage a thread on a head of a bone anchor, wherein the head portion has only bone anchor holes having the threaded portion"; claims 24-55 include the limitation "the head portion having a plurality of conically tapered holes having at least a portion that has a thread to contact a bone anchor.")
- **A combination of some plate holes that are fully threaded and others that are unthreaded** (Claim 54: "wherein the bone plate includes at least one non-threaded screw hole")

A substantial new question of patentability exists with respect to the Koval Article because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, the Koval Article is not cumulative to the art of record and a reasonable examiner would find the Koval Article important in deciding whether the claims are patentable.

In the original prosecution, the Examiner relied upon Chapman and Bono as prior art. While Chapman disclosed a bone plate with a head and a shaft, it lacked threaded holes, and the Examiner had to rely on the Bono reference for a disclosure of threaded holes. Bono, however, discloses a spine bone plate and lacks a head and a shaft. Further, Bono discloses threaded inserts rather than threaded holes. Clearly, the Koval Article provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog only shows unthreaded holes while the Haas Article only shows all threaded screw holes. In contrast to these two references, the Koval Article discloses both threaded and unthreaded holes in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference disclosed a condylar buttress plate with a shaft and head that had threaded holes, as disclosed in the Koval Article. All of these features are recited in the claims, and clearly the Koval Article provides additional teachings in a single reference. The Koval Article, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

C. The Manual Of Internal Fixation

1. The Manual Of Internal Fixation Is Prior Art

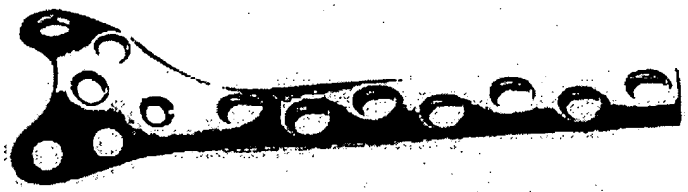
Requestor relies on the Third Edition (1991, 3rd Printing 1995) of the Manual of Internal Fixation. The Manual of Internal Fixation describes surgical techniques recommended by the AO/ASIF Group, an association founded to study and promote the use of internal fracture fixation. The Manual of Internal Fixation is not of record in the prosecution history of the '744

patent.

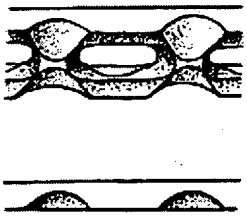
2. Substantial New Questions of Patentability Stemming From The Manual Of Internal Fixation

The Manual of Internal Fixation discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, the Manual of Internal Fixation discloses bone plate systems with the following key features:

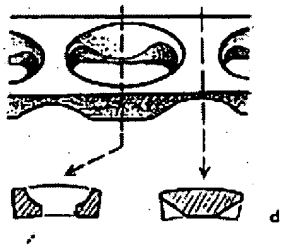
- **A condylar buttress plate with a head portion and a shaft portion** (*See* p. 271, Fig. 3.25)



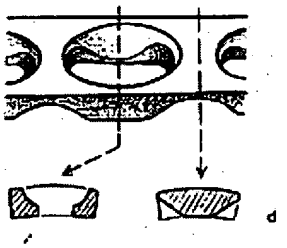
- **A plate with arched cut-outs on its lower surface** (*See* p. 241-43 (The DCP has a "structured undersurface"; "The different undercuts greatly reduce the contact area between the plate and bone."); Fig. 3.40Ac. Even though this is a straight bone plate, like the shaft portion of the claimed plate, the arched cut-outs would be located over the diaphysis of a bone)



- **A trapezoid cross section** (*See* p. 241-43 ("The trapezoid cross section of the plate with the smaller surface in contact with the bone has resulted in the formation of lower and broader ridges of bone along the length of the plate than those previously observed with the plates rectangular cross section."); Fig. 3.40Ad)



- **A plate with a curved lower surface** (*See* p. 243, Fig. 3.40Ad)



All of these features are recited in the claims and are relevant to patentability:

- **A condylar buttress plate with a head portion and a shaft portion** (Claims 1-52 include the following limitation: "a shaft portion having a width and a central longitudinal axis … and a head portion that flares outward from the shaft portion"; claims 53-55 include the limitation "a shaft portion having a width and a longitudinal axis … and a head portion having a width that is greater than the width of the shaft portion")
- **A plate with arched cut-outs on its lower surface** (All claims include the following limitation: "the lower surface of the shaft portion having a plurality of arched cut-outs")
- **A trapezoid cross section** (Claims 12, 39, : "wherein the shaft portion of the bone plate has a trapezoidal shaped cross section in regions between the plate holes for minimizing contact between the bone and the lower surface")
- **A plate with a curved lower surface** (Claims 13, 40: "wherein the lower surface of the shaft portion of the bone plate is curved along a direction transverse to the longitudinal axis of the shaft portion")

A substantial new question of patentability exists with respect to the Manual of Internal Fixation because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, the Manual of Internal Fixation is not cumulative to the art of record and a reasonable examiner would find the Manual of Internal Fixation important in deciding whether the claims are patentable.

In the original prosecution, the examiner relied on Chapman, Bono, and Berger as prior art. The combination of Chapman and Bono did not disclose a bone plate having a trapezoidal-shaped cross section, and the examiner cited Berger to supply the missing trapezoidal-shaped cross section. Berger, however, is an angled forked bone plate that lacks cut-outs on its lower surface. Clearly, the Manual of Internal Fixation provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog shows a plate having a plurality of arched cut-outs, but does not state that the plate has a shaft having a trapezoidal-shaped cross section, or a shaft that is curved along a direction transverse to the longitudinal axis of the shaft. The Manual of Internal Fixation, however, expressly discloses all of these elements in the same reference, albeit in different embodiments. Combining these embodiments does not require a leap of inventiveness and one of ordinary skill in the art would be able to combine the two embodiments.[1] Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference expressly disclosed these elements. All of these features are recited in the claims, and clearly the Manual of Internal Fixation provides additional teachings in a single reference. The Manual of Internal Fixation, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

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[1] *See Boston Scientific SciMed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

D. The Vattolo Dissertation

1. Vattolo Is Prior Art

Requestor relies on a 1986 Dissertation by Mauro Vattolo, entitled "The Effect Of Grooves In Osteosynthesis Plates On The Restructuring Of The Corticalis." The original dissertation was written in German, but Requestor has obtained and is supplying a certified English-language translation of this dissertation.

Vattolo is a printed publication.[2] Since January 1987, Vattolo has been indexed in "*Das Schweizer Buch*," the national bibliography of Switzerland (the "Swiss Library Index") published by the Swiss National Library. The Swiss Library Index is published as booklets twenty-four times annually. Vattolo is indexed in the January 1, 1987 version of the Swiss Library Index. The documents in the Swiss Library Index are indexed in a mixed register of authors, titles and keywords, and Vattolo can be found in the Swiss Library Index by keyword.

Requestor submits relevant pages from the January 1, 1987 version of the Swiss Library

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[2] Whether or not a reference is a "printed publication" turns on its public accessibility. *SRI Int'l, Inc. v. Internet Sec. Sys.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (*en banc*); *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986) "A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006). Courts have consistently held that a reference is publicly available when there exists "some type of systematic index or catalogue of the materials in question." *Id.* (finding Canadian patent application publicly available, in part, because it was indexed and distinguishing *In re Cronyn*, 890 F.2d 1158, 1159 (Fed. Cir. 1989) because there was no meaningful index in that case); *In re Hall*, 781 F.2d 897, 898-99 (Fed. Cir. 1986) (finding thesis "publicly available," and affirming final rejection of patent claims where thesis was shown to be indexed in a single library approximately two months prior to critical date); *Amex, LLC v. Mopex, Inc.*, 250 F.Supp. 2d 323, 330 (S.D.N.Y. 2003). "The decision whether a particular reference is a printed publication 'must be approached on a case-by-case basis.'" *SRI*, 511 F.3d 1194-95 (citing *In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989)).

Index that lists Vattolo. *See* Exhibit C.[3] The Swiss Library Index was available in the United States at the Library of Congress in Washington, D.C. as early as June 11, 1987. The January 1, 1987 version contains a June 11, 1987 date-stamp of the Library of Congress. Requestor is also submitting a declaration from a librarian at the Swiss National Library, Simone Bleuler, (the "Bleuler Declaration"). *See* Exhibit D. The Bleuler Declaration contains additional evidence that Vattolo was in fact indexed in the Swiss Library Index and available to the public at least by that time.

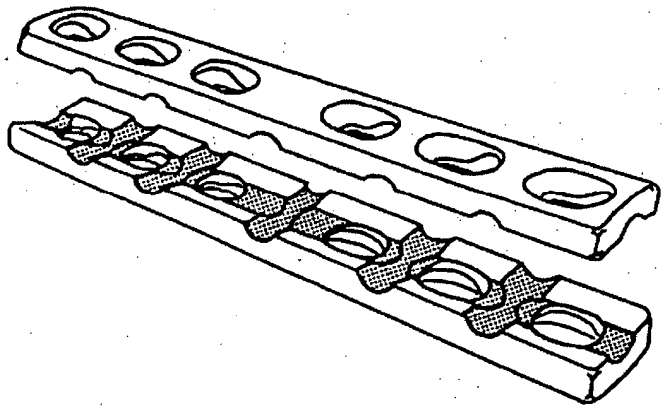
Vattolo is not of record in the prosecution history of the '744 patent.

2. Substantial New Questions of Patentability Stemming From Vattolo

Vattolo discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, Vattolo discloses a bone plate system with the following key features:

- **A plate with arched cut-outs on its lower surface** (The Vattolo Plate was a modification of a standard AO dynamic compression plate having transverse grooves between the screw holes and adding a single longitudinal groove extending lengthwise along the plate; *see* Fig. 2 (reproduced below). Even though this is a straight bone plate, like the shaft portion of the claimed plate, the arched cut-outs would be located over the diaphysis of a bone)

[3] Requestor has included, at the end of Exhibit C, a certified copy of an English language translation of the Introduction page of *Das Schweizer Buch.*



- **A trapezoidal-shaped cross section** (*See* Fig. 2)
- **A plate with a curved lower surface** (*See* Fig. 2)

All of these features are recited in the claims and are relevant to patentability:

- **A plate with arched cut-outs on its lower surface** (All claims include the following limitation: "the lower surface of the shaft portion having a plurality of arched cut-outs")
- **A trapezoidal-shaped cross section** (Claim 12, 39: "wherein the shaft portion of the bone plate has a trapezoidal shaped cross section in regions between the plate holes for minimizing contact between the bone and the lower surface")
- **A plate with a curved lower surface** (Claim 13, 40: "wherein the lower surface of the shaft portion of the bone plate is curved along a direction transverse to the longitudinal axis of the shaft portion")

A substantial new question of patentability exists with respect to Vattolo because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, Vattolo is not cumulative to the art of record and a reasonable examiner would find Vattolo important in deciding whether the claims are patentable.

In the original prosecution, the examiner relied on Chapman, Bono, and Berger as prior art. The combination of Chapman and Bono did not disclose a bone plate having a trapezoidal-shaped cross section, and the examiner cited Berger to supply the missing trapezoidal-shaped cross section. Berger, however, is an angled forked bone plate that lacks cut-outs on its lower surface. Clearly, Vattolo provides additional teachings in a single reference and therefore

presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog shows a plate having a plurality of arched cut-outs, but does not state that the plate has a shaft having a trapezoidal-shaped cross section, or a shaft that is curved along a direction transverse to the longitudinal axis of the shaft. Vattolo, however, expressly discloses all of these elements in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference expressly disclosed these elements. All of these features are recited in the claims, and clearly Vattolo provides additional teachings in a single reference. Vattolo, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

E. The Perren Article

1. The Perren Article Is Prior Art

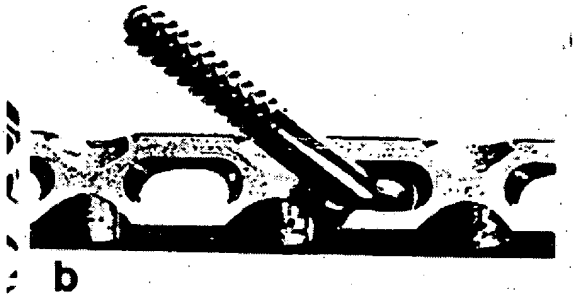
The Article "The Limited Contact Dynamic Compression Plate (LC-DCP)" by S. M. Perren *et al.* describes a limited contact dynamic compression plate "to realize the new concept of biological internal fixation." *See, e.g.*, Perren, Summary. The Perren Article was published in a publicly distributed medical journal — Archives of Orthopaedic and Trauma Surgery — in 1990. Accordingly, the Perren Article qualifies as a publicly available printed publication that is prior art to the '744 patent. The Perren Article is not of record in the prosecution history of the '744 patent.

2. Substantial New Questions of Patentability Stemming From The Perren Article

The Perren Article discloses a bone plate with several key features not disclosed in any

single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, the Perren Article discloses bone plate systems with the following key features:

- **A plate with arched cut-outs on its lower surface** (*See* Perren Article at 306. The Perren Article discloses a bone plate having a "structured undersurface" consisting of "grooves within the undersurface of the plate" that significantly improve the blood supply of plated bone segments; Fig. 3b)



- **A trapezoidal cross section** (Perren Article at 307-08, the "side faces are slightly inclined to form a trapezoidal cross section interrupted by undercuts which form arcs. At these locations the cross-section has two strongly inclined sides. Seen from below the clearances for the plate holes and the above-mentioned undercuts result in an important reduction of the contact surface")

All of these features are recited in the claims and are relevant to patentability:

- **A plate with arched cut-outs on its lower surface** (All claims include the following limitation: "the lower surface of the shaft portion having a plurality of arched cut-outs")
- **A trapezoidal cross section** (Claim 12, 39: "wherein the shaft portion of the bone plate has a trapezoidal shaped cross section in regions between the plate holes for minimizing contact between the bone and the lower surface")

A substantial new question of patentability exists with respect to the Perren Article because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, the Perren Article is not cumulative to the art of record and a reasonable examiner would find the Perren Article important in deciding whether the claims are patentable.

In the original prosecution, the examiner relied on Chapman, Bono, and Berger as prior art. The combination of Chapman and Bono did not disclose a bone plate having a trapezoidal-shaped cross section, and the examiner cited Berger to supply the missing trapezoidal-shaped cross section. Berger, however, is an angled forked bone plate that lacks cut-outs on its lower surface. Clearly, the Perren Article provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog shows a plate having a plurality of arched cut-outs, but does not state that the plate has with a shaft having a trapezoidal-shaped cross section. The Perren Article expressly discloses both of these elements in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference expressly disclosed these elements. All of these features are recited in the claims, and clearly the Perren Article provides additional teachings in a single reference. The Perren Article, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

F. Perren '036

1. The Perren '036 Patent Is Prior Art

The application for U.S. Patent No. 5,053,036 to Perren *et al.* was filed on March 8, 1990. It is therefore prior art under 35 U.S.C. § 102(b). Although Perren '036 is not of record in the prosecution history of the '744 patent, a U.S. Patent No. 5,151,103, a division of Perren '036, is identified as a reference cited on the face of the '744 patent. Neither Perren '036 nor U.S. Patent No. 5,151,103 were applied during the examination of the '744 patent.

2. Substantial New Questions of Patentability Stemming From The Perren Article

Perren '036 discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, Perren '036 discloses bone plate systems with the following key features:

- **A plate with arched cut-outs on its lower surface** (Perren '036 discloses "[a] bone plate for use in osteosynthesis having a plurality of contact elements extending from its lower surface so that the contact between the plate and bone is reduced to the minimum contact needed." Perren '036, Abstract. This structure "results in reduced damage to bone, particularly damage to the intramedullary vascular system." Perren '036, Col. 1, lines 52-54; Fig. 4)

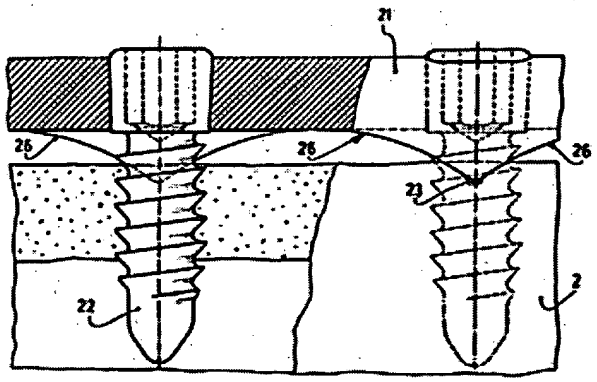


FIG. 4

- **A plate with a curved lower surface** (*See* Fig. 3)

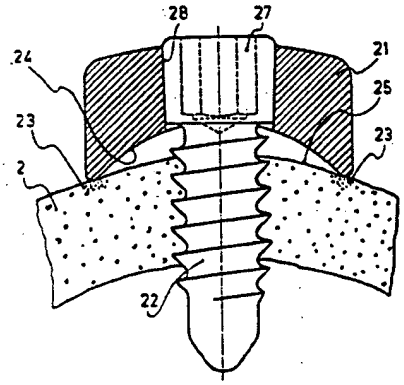


FIG. 3

All of these features are recited in the claims and are relevant to patentability:

- **A plate with arched cut-outs on its lower surface** (All claims include the following limitation: "the lower surface of the shaft portion having a plurality of arched cut-outs")
- **A plate with a curved lower surface** (Claim 13, 40: "wherein the lower surface of the shaft portion of the bone plate is curved along a direction transverse to the longitudinal axis of the shaft portion")

A substantial new question of patentability exists with respect to Perren '036 because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, Perren '036 is not cumulative to the art of record and a reasonable examiner would find Perren '036 important in deciding whether the claims are patentable.

In the original prosecution, the examiner relied on Chapman and Bono as prior art. While Chapman disclosed a bone plate, it lacked a shaft portion having a lower surface that is curved along a direction transverse to the longitudinal axis of the shaft portion, and the Examiner had to rely on the Bono reference for a disclosure of such a lower surface. Bono, however, discloses a spine bone plate and lacks a head and a shaft. Clearly, Perren '036 provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog shows a plate having a plurality of arched cut-outs, but does not state that the plate has a shaft that is curved along a direction transverse to the longitudinal axis of the shaft. Perren '036 expressly discloses both of these elements in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference expressly disclosed these elements. All of these

features are recited in the claims, and clearly Perren '036 provides additional teachings in a single reference. Perren '036, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

G. Klaue

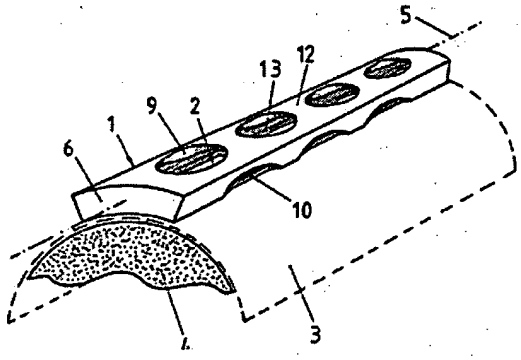
1. Klaue Is Prior Art

The application for U.S. Patent No. 5,002,544 to Klaue *et al.* was filed on July 26, 1990. It is therefore prior art under 35 U.S.C. § 102(b). Klaue is of record in the prosecution history of the '744 patent, however Klaue was not applied for the features cited herein.

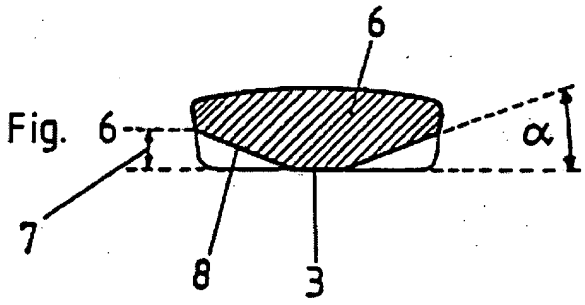
2. Substantial New Questions of Patentability Stemming From Klaue

Klaue discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, Klaue discloses a bone plate system with the following key features:

- **A plate with arched cut-outs on its lower surface** (Klaue discloses "[a]n osteosynthetic pressure plate having several holes for bone screws positioned along it longitudinal axis and having an underside with curved recesses." Klaue, Abstract; Fig. 1. This configuration "causes minimal bone contact, which in turn promotes vascularization and bone growth." *Id.* Col. 3, lines 46-48)



- **A trapezoidal-shaped cross section** (Klaue further discloses that "[t]he cross section 6 shown in Figure 6 taken between screw holes has an approximately trapezoidal shape." Col. 3, lines 1-2; Fig. 6)



- **A plate with a curved lower surface** (Klaue discloses that "[t]he plate may be curved, as shown, and the side walls of the plate are preferably included inwardly toward the bone." Col. 3, lines 13-15; Fig. 8.)

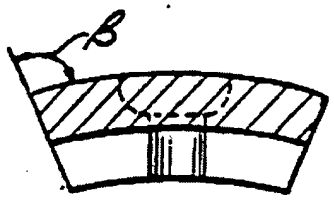


FIG.8

All of these features are recited in the claims and are relevant to patentability:

- **A plate with arched cut-outs on its lower surface** (All claims include the following limitation: "the lower surface of the shaft portion having a plurality of arched cut-outs")
- **A trapezoidal-shaped cross section** (Claim 12, 39: "wherein the shaft portion of the bone plate has a trapezoidal shaped cross section in regions between the plate holes for minimizing contact between the bone and the lower surface")
- **A plate with a curved lower surface** (Claims 13, 40: "wherein the lower surface of the shaft portion of the bone plate is curved along a direction transverse to the longitudinal axis of the shaft portion")

A substantial new question of patentability exists with respect to Klaue because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, Klaue is not cumulative to the art of record and a reasonable examiner would find Klaue important in deciding whether the claims are patentable.

In the original prosecution, the examiner relied on Chapman, Bono, and Berger as prior

art. The combination of Chapman and Bono did not disclose a bone plate having a trapezoidal-shaped cross section, and the examiner cited Berger to supply the missing trapezoidal-shaped cross section. Berger, however, is an angled forked bone plate that lacks cut-outs on its lower surface. Clearly, Klaue provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog shows a plate having a plurality of arched cut-outs, but does not state that the plate has a shaft having a trapezoidal-shaped cross section, or a shaft that is curved along a direction transverse to the longitudinal axis of the shaft. Klaue, however, discloses all of these elements in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference expressly disclosed these elements. All of these features are recited in the claims, and, clearly Klaue provides additional teachings in a single reference. Klaue, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

H. Collin Catalog

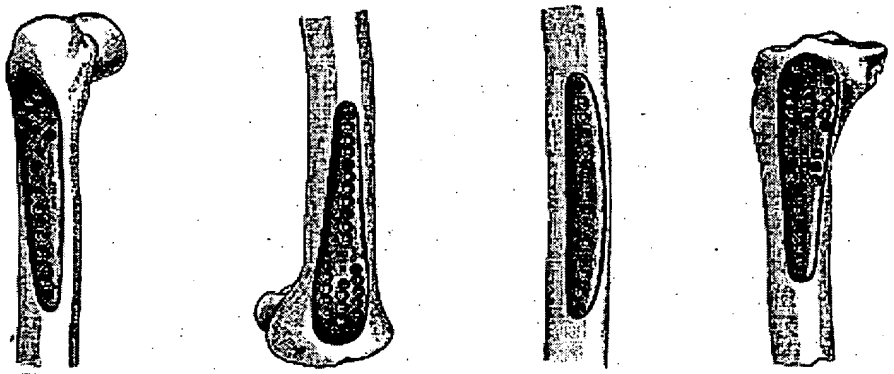
1. The Collin Catalog Is Prior Art

The Catalog "Instruments de Chirurgie" (translation: "Surgical Instruments") by Collin, shown below, was published in 1935 in France. The Collin Catalog was published in French, so a certified translation of the applicable pages is provided with this request. The Collin Catalog is not of record in the prosecution history of the '744 patent application.

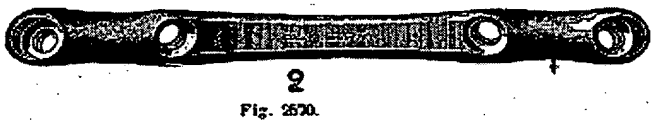
2. Substantial New Questions of Patentability Stemming From The Collin Catalog

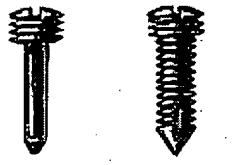
The Collin Catalog discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, the Collin Catalog discloses a bone plate system with the following key features:

- **A bone plate with a head portion and a shaft portion** (The Collin catalog also disclose bone plates that are shaped to confirm to a metaphysis and a diaphysis of a bone. *See, e.g.* Figs. 2553-2556)



- **Fully-threaded locking plate holes** (The Collin catalog discloses bone plates having all threaded plate holes, and interchangeable pins and screws having threaded heads that fit in these threaded holes. *See, e.g.*, Figs. 2570-2572)





- **Unthreaded plate holes** (The Collin catalog discloses bone plates having all unthreaded plate holes and screws for use with these holes. *See, e.g.*, Figs. 2559, 2561)

Fig. 2561.

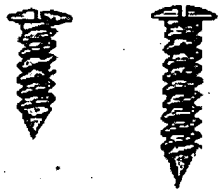


Fig. 2559.

All of these features are recited in the claims and are relevant to patentability:

- **A bone plate with a head portion and a shaft portion** (Claims 1-52 include the following limitation: "a shaft portion having a width and a central longitudinal axis … and a head portion that flares outward from the shaft portion"; claims 53-55 include the limitation "a shaft portion having a width and a longitudinal axis … and a head portion having a width that is greater than the width of the shaft portion")
- **Fully-threaded locking plate holes** (Claims 1-23 include the following limitation: "bone anchor holes having at least a portion that has a thread to engage a thread on a head of a bone anchor, wherein the head portion has only bone anchor holes having the threaded portion"; claims 24-55 include the limitation "the head portion having a plurality of conically tapered holes having at least a portion that has a thread to contact a bone anchor.")
- **Unthreaded plate holes** (Claim 54: "wherein the bone plate includes at least one non-threaded screw hole")

A substantial new question of patentability exists with respect to the Collin Catalog because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, the Collin Catalog is not cumulative to the art of record and a reasonable examiner would find the Collin Catalog important in deciding whether the claims are patentable.

In the original prosecution the Examiner relied upon Chapman and Bono as prior art. While Chapman disclosed a bone plate with a head and a shaft, it lacked threaded holes, and the Examiner had to rely on the Bono reference for a disclosure of threaded holes. Bono, however,

discloses a spine bone plate and lacks a head and a shaft. Further, Bono discloses threaded inserts rather than threaded holes. Clearly, the Collin Catalog provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The LC-DCP plate in the Synthes 1997 Catalog only shows unthreaded holes while the Haas Article only shows all threaded screw holes. In contrast to these two references, the Collin Catalog discloses both threaded and unthreaded holes in different plates. Combining these two embodiments does not require a leap of inventiveness and one of ordinary skill in the art would be able to combine the two embodiments.[4] Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference disclosed a plate with a shaft and head that had threaded holes as disclosed in the Collin Catalog. All of these features are recited in the claims, and clearly the Collin Catalog provides additional teachings in a single reference. The Collin Catalog, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

[4] *See Boston Scientific*, 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

I. The Zimmer Ad

1. The Zimmer Ad Is Prior Art

The Journal of Orthopaedic Trauma, Vol. 12, No. 5, June/July, 1998 included an advertisement from Zimmer describing and illustrating its Periarticular Plating System.[5] The Journal of Orthopaedic Trauma is a widely distributed medical journal. Accordingly, the Zimmer Ad qualifies as a publicly available printed publication that is prior art to the '744 patent. The Zimmer Ad is not of record in the prosecution history of the '744 patent application.

2. Substantial New Questions of Patentability Stemming From The Zimmer Ad

The Zimmer Ad discloses a bone plate with several key features not disclosed in any single prior art reference that was of record in the original prosecution or the *Ex Parte* Request for Reexamination. Specifically, the Zimmer Ad discloses a bone plate system with the following key features:

- **An plate with a head portion and a shaft portion** (The plate shown the Zimmer Ad has a head portion and a shaft portion. The plate is described as "precontoured" to "provide excellent fit to bone geometry"

[5] The advertisement is located in the front of Journal, prior to the start of the articles.

- **A head portion including suture holes** (The Zimmer Ad discloses a bone plate having three suture holes in its head)

All of these features are recited in the claims and are relevant to patentability:

- **A plate with a head portion and a shaft portion** (Claims 1-52 include the following limitation: "a shaft portion having a width and a central longitudinal axis … and a head portion that flares outward from the shaft portion"; claims 53-55 include the limitation "a shaft portion having a width and a longitudinal axis … and a head portion having a width that is greater than the width of the shaft portion")
- **A head portion including suture holes** (Claims 15, 42: "wherein the at least one provisional fixation hole is an unthreaded suture hole"; claim 16, 43: "wherein the suture hole is located in the head portion."; claim 55: "wherein the bone plate includes at least one non-threaded suture hole")

A substantial new question of patentability exists with respect to the Zimmer Ad because no other prior art reference of record in the original prosecution of the '744 patent or relied upon by the Requestor in the *Ex Parte* Request for Reexamination of the '744 patent included all of these key features in a single reference. Accordingly, the Zimmer Ad is not cumulative to the art of record and a reasonable examiner would find the Zimmer Ad important in deciding whether the claims are patentable.

In the original prosecution, the examiner relied on Chapman as prior art. Chapman did

not state that the plate included suture holes; rather, the examiner found this element obvious because "any of the holes are capable of functioning as a provisional fixation hole; likewise that hole is capable of accepting a suture for the provisional fixation." Clearly, the Zimmer Ad provides additional teachings in a single reference and therefore presents a SNQ over patentability issues addressed in the original prosecution.

In the *Ex Parte* Request for Reexamination, the Requestor relied primarily on the Synthes 1997 Catalog (disclosing the LC-DCP plate) and the Haas Article to demonstrate substantial new questions of patentability. The Haas Article discloses a plate having head portion and a shaft portion, and states that the plate may be used with "temporary Kirschner wires." *See* Haas Article at p. 341. The Haas Article does not state that it includes unthreaded suture holes. The Zimmer Ad, however, discloses all of these elements in the same plate. Further, in contrast to the prior art relied on in the *Ex Parte* Request for Reexamination, no single reference expressly disclosed these elements. All of these features are recited in the claims, and clearly the Zimmer Ad provides additional teachings in a single reference. The Zimmer Ad, therefore, presents a different and distinct SNQ over the SNQs found in the Order granting *Ex Parte* Request for Reexamination of the '744 Patent.

IV. DETAILED EXPLANATION OF THE PERTINENCY AND MANNER OF APPLYING THE CITED PRIOR ART

The following section identifies specific proposed grounds of rejection applying the prior art references listed above and on the attached PTO-1449 (SB/08) to the claims for which *inter partes* reexamination is requested. The details regarding each proposed rejection are set forth in the accompanying claim charts attached as Exhibits E-Z.

A. The Law of Obviousness

A patent claim is invalid as obvious if the claimed subject matter would have been obvious to a person of ordinary skill in the art at the time of the invention. 35 U.S.C. § 103(a). ***The question of obviousness is a question of law*** with factual underpinnings. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004); MPEP § 2141(II) ("Obviousness is a question of law based on underlying factual inquiries."). "Those factual underpinnings include the scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the art." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). The obviousness of the claimed subject matter is determined against these factors, which are often referred to as the *Graham* factors. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Obviousness is evaluated on a "claim by claim" basis. *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1372 (Fed. Cir. 2006). Secondary factors of non-obviousness, such as commercial success, a long felt but unsolved need, and failure of others, may be considered in determining whether the claimed subject matter is obvious if they are relevant. *Id.* at 17-18. Such secondary considerations, however, cannot be used to overcome a strong showing of obviousness under the *Graham* factors. *See, e.g., Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Pfizer, Inc. v. Apotex*, 480 F.3d 1348, 1372 (Fed. Cir. 2007).

Prior to the Supreme Court's recent landmark decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-16 (2007), a patent that combined elements from two or more prior art references was obvious only if there was some explicit *teaching, suggestion or motivation* ("TSM") to combine the references. Under the TSM test for obviousness, it was difficult to invalidate combination patents as being obvious because it was often impossible to find an express teaching, suggestion, or motivation to combine the known prior art elements. The

Supreme Court's *KSR* decision did away with the rigid application of the TSM test and instead adopted an "expansive and flexible approach" to the obviousness analysis that was grounded in "common sense." *Id.* at 415-16, 421.

The Supreme Court observed that there was an "overemphasis on the importance of published articles and the explicit content of issued patents." *Id.* at 419. The Court emphasized the ability of persons of ordinary skill in the art to use their skill and common sense to reach predictable solutions:

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

Id. at 421.

Further, while a "patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art," "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416, 418. In this context, the law presumes that the hypothetical person of ordinary skill in the art is presumed to be aware of ***all*** of the prior art. *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997).

According to *KSR* and the MPEP, "[w]hen considering obviousness of a combination of known elements, ***the operative question is thus 'whether the improvement is more than the predictable use of prior art elements according to their established functions.***'" MPEP § 2141(I) (emphasis added). "If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *KSR*, 550 U.S. at 417. A "person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421. Accordingly, "Office personnel

may also take into account 'the inferences and creative steps that a person of ordinary skill in the art would employ.'" MPEP § 2141(II) (citing *KSR*). Finally, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR*, 550 U.S. at 417.

The MPEP sets forth the standard for determining obviousness. Once the *Graham* factors are resolved, a determination is made as to whether the claimed invention would have been obvious in light of not just the prior art, but also the understanding of one of ordinary skill in the art. MPEP § 2141(III). "In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. ***Factors other than the disclosures of the cited prior art may provide a basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap.***" *Id.* (emphasis added). "The Court in *KSR* identified a number of rationales to support a conclusion of obviousness," including the following:

> (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;
>
> . . .
>
> (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.

MPEP § 2141(III).

B. Proposed Claim Rejections Under 35 U.S.C. § 103(a)

1. Overview Of Motivation to Combine Prior Art References

A strong motivation existed to combine the references relied upon by Requestor into the combinations set forth herein which form the bases for the proposed rejections. The motivation to combine these references is evidenced by several factors.

First, all of the prior art references relied upon by Requestor are in the same specific art area — namely, metal bone plates. Indeed, many of the references relied upon by Requestor disclose one specific type of bone plate — shaped periarticular plates having distinct head portions and shaft portions. These shaped bone plates may be used to treat fractures in, for example, the femur or the tibia, including fractures in the condyle of those bones.

Second, while the prior art references relied upon by Requestor all disclose a common set of features, characteristics and functions, the various prior art references each disclose additional, and in some cases, unique features. A person of ordinary skill in the art would be motivated to combine such references to obtain the advantages of certain features disclosed in one prior art reference with the similar bone plate disclosed in another prior art reference. For example, some of the shaped bone plate prior art references include a limited contact feature like arched cuts-outs (*e.g.*, the Limited Contact, Dynamic Compression Plate , or "LC-DCP," disclosed in the Synthes Catalog). Other shaped bone plate references disclose locking features, like threaded holes and locking screws (*e.g.*, the K982222 Summary and the Koval Article). Still other shaped bone plate references disclose provisional fixation holes (*e.g.*, suture holes) in the plate (*e.g.*, the Zimmer Ad).

An example of a combination of shaped bone plate references is that of the K982222 Summary and the LC-DCP plate from the Synthes Catalog. The motivation to combine the

references is found in the references themselves. Although the K982222 Summary discloses a shaped bone plate with a shaft having a "limited-contacted profile," the K982222 Summary does not describe the specific structure used to implement this limited-contact profile. Upon reading the K982222 Summary, one of ordinary skill in the art would be motivated to seek out similar types of shaped bone plates with shafts having limited-contact profiles. One such plate is described in the Snythes Catalog — the LC-DCP. Thus, one of ordinary skill in the art, based on the prior art references, would be motivated to combine the disclosure of arched cut outs from Synthes' catalog's LC-DCP plate with the plate described in the K982222 Summary.

Requestor also relies on references disclosing what may appear to be a different type of bone plate — a straight bone plate. Even though these plates are straight, they generally correspond to the shaft portions of the shaped bone plates.[6] The straight plates are generally positioned over the same part of the bone — the diaphysis — that the shaft portion of the shaped bone plates are positioned, and can even be thought of as shaped bone plates without head portions. Based on these similarities, one of ordinary skill in the art would be motivated to look to these straight plates, and their low-contact features, and implement those features in the straight shaft portions of the shaped bone plates.

An example combination of a shaped bone plate and a straight plate is that of the K982222 Summary and the Perren Article. As noted above, the K982222 Summary discloses a shaped bone plate with a shaft having a "limited-contact profile." One of ordinary skill in the art seeking to implement this limited-contact profile in the straight shaft portion of a shaped bone plate would also look at straight bone plates with limited contact profiles. The Perren Article

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[6] Note that the claims of the '744 patent only claim the low contact features (*i.e.,* arched cut-outs and a trapezoidal shaped cross section) in the *shaft* of the bone plate.

discloses a such a straight bone plate having a "structured undersurface" consisting of "grooves within the undersurface of the plate" that significantly improve the blood supply of plated bone segments; Fig. 3b). These grooves are formed as arch cut-outs. Thus, one of ordinary skill in the art would be motivated to combine the Perren Article's arched cut-outs with the limited contact profile shaft disclosed in the K982222 Summary, given the predictable use of such arched cut-outs in the prior art Perren Article.

Evidence of the a motivation to combine these references is further shown by the fact that the specific features disclosed in the various references can be easily and predictably applied to the plates shown in other references. For example, like the K982222 Summary, the Zimmer Ad illustrates a shaped bone plate. The Zimmer Ad plate, however, has the additional disclosure of provisional fixation holes, specifically unthreaded suture holes, in the head of the plate. There are known advantages to having suture holes present in bone plates to enable surgeons to use sutures (when patient circumstances dictated such use) to assist in securing the plate to the bone. Give the known advantages of suture holes and the very close similarities between the Zimmer Ad and the K982222 Summary shaped bone plates, one of ordinary skill in the art would be motivated to combine the Zimmer Ad with the K98222 Summary, resulting in a shaped bone plate having all of the features disclosed in the K982222 Summary with the additional feature of suture holes. Further, the suture holes disclosed in the Zimmer Ad, when combined with the bone plate described in the K98222 Summary, will perform in a predictable and similar manner to those in the Zimmer Ad plate. Given the predictable use of such features, the known advantages of such features, and the similarities of the plates shown in the various references, a person of ordinary skill in the art would have been motivated to combine the various references relied upon by Requestor into the combinations set forth herein.

These, and other specific examples of motivations to modify or combine the known prior art, can be found below and in the appended claim charts.

2. Rejections Based On the K982222 Summary In View Of The Synthes Catalog and the Haas Article

The attached K982222 Summary in view of the Synthes Catalog[7] And Haas § 103 Claim Chart (Exhibit E) is incorporated by reference herein.

(i) Claims 1-11, 14, 17-26, 29-38, 41, 44-50, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Synthes Catalog and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art be motivated to combine the condylar buttress plate with a shaft having a limited-contact profile disclosed in the K982222 Summary with the arched cut-outs in the shaft portion of the condylar buttress plate shown in the Synthes Catalog. Indeed, the condylar buttress plate is identified as a "predicate device" for the system described in the K982222 Summary. Upon reading the K982222 Summary, one of ordinary skill in the art would be motivated to seek out similar types of shaped bone plates having limited-contact profiles, including the LC-DCP condylar buttress plate. The inclusion of arched cut-outs would achieve the known benefit and predictable solution of minimizing disruption in blood flow in the bone.

One of ordinary skill in the art would be motivated to further modify this combination to include the conically-tapered and threaded holes disclosed in the Haas Article. Like the K982222 Summary and the Synthes Catalog, the Haas Article discloses a shaped bone plate having a head portion and a shaft portion. One would be motivated to include all conically-

[7] Note that the Synthes Catalog was discussed in detail in *Ex Parte* Reexamination Control No. 90/009,377.

tapered, threaded holes in order to provide a flush fit between the screw and the screw holes, and the use of threaded, conically tapered holes would provide an angularly stable screw/plate connection both in the head portion and in the shaft portion.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 12 and 39 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Synthes Catalog and the Haas Article and in further view of Klaue

Klaue discloses a straight bone plate having limited contact features. Because it is a straight bone plate, like the shaft portion of a shaped bone plate, it is generally applied to the diaphysis of a bone. Thus, one of ordinary skill in the art seeking to implement the K982222 Summary's shaft having a "limited-contact profile" would refer to straight bone plates having limited contact features, such as Klaue's trapezoidal shaped cross section. Klaue discloses that such a structure "minim[izes] bone contact, which in turn promotes vascularization and bone growth." Klaue, Col. 3, lines 46-48. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the K982222 Summary, the Synthes Catalog, and the Haas Article to achieve the known and predictable benefits of promoting vascularization and bone growth.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 13 and 40 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Synthes Catalog and the Haas Article and in further view of Chapman

Chapman, like the K982222 Summary and the Synthes Catalog, describes a condylar buttress plate having a head portion and a shaft portion. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to other shaped bone plates, such as that disclosed in Chapman, to include a shaft portion having a lower surface that is curved along a direction transverse to the longitudinal axis of the shaft portion to provide a better fit to

the femoral shaft. *See* Chapman, col. 15, lines 57-59. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the K982222 Summary, the Synthes Catalog, and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Synthes Catalog and the Haas Article and in further view of the Zimmer Ad

Like the K982222 Summary, the Synthes Catalog, and the Haas Article, the Zimmer Ad describes a bone plate having a head portion and a shaft portion, and with similar application to the bone. Based on this, one of ordinary skill in the art would be motivated to modify the combination of the K982222 Summary, the Synthes Catalog, and the Haas Article with the known provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad to achieve the predictable solution of enabling the plate to be used with sutures.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 27, 28, 51, and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Synthes Catalog and the Haas Article and in further view of Bono

Bono discloses a bone plate having screw holes with a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate. One seeking to achieve flexibility in the bone plate by providing screw holes in a "desirable orientation" for surgery would be motivated to refer to Bono, another bone plate, and implement the known, predicable solutions disclosed therein.

Detailed grounds for rejection are provided in the attached claim chart.

3. Rejections Based On the K982222 Summary In View Of The Manual of Internal Fixation and the Haas Article

The attached K982222 Summary in view of the Manual of Internal Fixation And the Haas Article § 103 Claim Chart (Exhibit F) is incorporated by reference herein.

(i) Claims 1-14, 17-27, 29-41, 44-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the condylar buttress plate with a shaft having a limited-contact profile disclosed in the K982222 Summary with the arched cut-outs in the plate shown in the Manual of Internal Fixation. Indeed, although the Manual of Internal Fixation discloses a straight bone plate having limited contact features, as discussed above, the straight plates correspond to the shaft portion of the shaped bone plates. Thus, one seeking to implement the K982222 Summary's plate with a shaft portion having a "limited-contact profile" would refer to a straight plate having arched cut-outs like the LC-DCP plate disclosed in the Manual of Internal Fixation. By the inclusion of arched cut-outs, one of ordinary skill in the art would achieve the known, predictable solution of minimizing disruption in blood flow in the bone.

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the conically-tapered and threaded holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Haas Article and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Haas Article and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes with a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

4. Rejections Based On the K982222 Summary In View Of The Manual of Internal Fixation and The Locking Reconstruction Plate Guide

The attached K982222 Summary in view of the Manual of Internal Fixation and The Locking Reconstruction Plate Guide § 103 Claim Chart (Exhibit G) is incorporated by reference herein.

(i) Claims 1-13, 17-27, 29-40, 44-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and in further view of the Locking Reconstruction Plate Guide

As described above, one of ordinary skill in the art would be motivated to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile with the Manual of Internal Fixation plate having arched cut-outs. One of ordinary skill in the art would be further motivated to modify this combination with the conically-tapered and threaded holes disclosed in the Locking Reconstruction Plate Guide. The Locking Reconstruction Plate Guide describes a bone plate having threaded, conically tapered holes. One seeking to reduce

the profile of the screw and plate combination would refer to other bone plates using threaded holes and threaded screws, like the Locking Reconstruction Plate Guide.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 14-16, 41-43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Locking Reconstruction Plate Guide and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Locking Reconstruction Plate Guide and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

5. Rejections Based On the K982222 Summary In View Of The Manual of Internal Fixation and The Collin Catalog

The attached K982222 Summary in view of the Manual of Internal Fixation and The Collin Catalog § 103 Claim Chart (Exhibit H) is incorporated by reference herein.

Detailed grounds for rejection are provided in the attached claim chart.

(i) Claims 1-13, 18-27, 29-40, 45-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and in further view of the Collin Catalog

As described above, one of ordinary skill in the art would be motivated to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile with the Manual of Internal Fixation plate having arched cut-outs. One of ordinary skill in the art would be further motivated to modify this combination with the conically-tapered and threaded holes disclosed in the Collin Catalog. The Collin Catalog describes bone plates, including shaped bone plates having head portions and shaft portions, and straight bone plates having it conically-tapered and threaded holes.[8] Because of this, one would be motivated to incorporate these threaded, conically tapered holes with locked screws to achieve the known, predictable solution of using threaded, conically tapered holes with locked screws to reduce the profile of the screw/plate combination and to achieve an angularly stable screw/plate connection both in the head portion and in the shaft portion of the shaped bone plate.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 14-16, 41-43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Collin Catalog and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Collin Catalog and in further view of the Haas Article

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[8] *See Boston Scientific SciMed,* 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

In addition to disclosing conically-tapered, threaded holes, the Haas Article discloses that these holes have multiple lead threads. As discussed above, one of ordinary skill in the art would be motivated to further modify this combination with the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Manual of Internal Fixation and the Collin Catalog and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

6. Rejections Based On the K982222 Summary In View Of The Perren Article And The Zimmer Ad

The attached K982222 Summary in view of the Perren Article And The Zimmer § 103 Claim Chart (Exhibit I) is incorporated by reference herein.

(i) Claims 1-27, 29-51, and 53-55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Perren Article and in further view of the Haas Article and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile with the arched cut-outs in the plate shown in the Perren Article. The Perren Article discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in the Perren Article achieves a limited-contact profile by providing a "structured

undersurface" consisting of "grooves within the undersurface of the plate." Perren Article at 306. The Perren Article plate further has "side faces [that] are slightly inclined to form a trapezoidal cross section interrupted by undercuts which form arcs." *Id.* Implementing these arched cut-outs in the shaft portion of the K982222 Summary's bone plate would achieve the known, predictable solution of "significantly improv[ing] the blood supply of plated bone segments." *Id.*

Further, as discussed above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes disclosed in the Haas Article and the provisional fixation holes, *i.e.*, unthreaded suture holes, of the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of the Perren Article, the Haas Article, and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

7. Rejections Based On the K982222 Summary In View Of Klaue And Further In View Of the Haas Article And The Zimmer Ad

The attached K982222 Summary in view of Klaue, the Haas Article, and The Zimmer Ad § 103 Claim Chart (Exhibit J) is incorporated by reference herein.

(i) Claims 1-27, 29-51, and 53-55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of Klaue and in further view of the Haas Article and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile

with the arched cut-outs in the plate shown in Klaue. Klaue discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in the Klaue achieves a limited-contact profile by providing arched cut-outs in the lower surface of the bone plate. Including arched cut-outs in the shaft portion of the K982222 Summary's condylar buttress plate would achieve the known, predictable solution of "minimiz[ing] bone contact, which in turn promotes vascularization and bone growth." Klaue, Col. 3, lines 46-48.

Further, as discussed above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes disclosed in the Haas Article and the provisional fixation holes, *i.e.*, unthreaded suture holes, of the Zimmer Ad as described above.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of Klaue, the Haas Article, and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

8. Rejections Based On the K982222 Summary In View Of Vattolo And Further In View Of the Haas Article And The Zimmer Ad

The attached K982222 Summary in view of Vattolo, the Haas Article, and The Zimmer Ad § 103 Claim Chart (Exhibit K) is incorporated by reference herein.

(i) Claims 1-27, 29-51, and 53-55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of Vattolo and in further view of the Haas Article and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile with the arched cut-outs in the plate shown in Vattolo. Vattolo discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in Vattolo achieves a limited-contact profile by providing a plate that is concave transversly to the longitudinal axis of the plate, has a longitudinal groove extending lengthwise along the plate, and includes arched cut-outs extending transverse to the longitudinal axis. Vattolo found that the "grooves in the plate underside, by decreasing the contact area and protecting the periosteum" provided the predictable solution of "decreas[ing] the size of the temporarily porotic restructuring area." Vattolo Dissertation at 42. Implementing these arched cut-outs in the shaft portion of the K982222 Summary's bone plate would achieve the known, predictable solutions identified in Vattolo.

Further, as described above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes disclosed in the Haas Article and the provisional fixation holes, *i.e.*, unthreaded suture holes, of the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of Vattolo, the Haas Article, and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

9. Rejections Based On the K982222 Summary In View Of Perren '036 And Further In View Of the Haas Article And The Zimmer Ad

The attached K982222 Summary in view of Perren '036, the Haas Article, and The Zimmer Ad § 103 Claim Chart (Exhibit L) is incorporated by reference herein.

(i) Claims 1-27, 29-51, and 53-55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of Perren 036 and in further view of the Haas Article and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile with the arched cut-outs in the plate shown in Perren '036. Perren '036 discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in Perren '036 achieves a limited-contact profile by providing a plate that is has "a plurality of contact elements extending from its lower surface so that the contact between the plate and bone is reduced to the minimum contact needed." Perren '036, Abstract. By this structure, Perren '036 discloses arched cut-outs on the lower surface of the bone plate. According to Perren '036, this structure provides the predictable result of "reduced damage to bone, particularly damage to the intramedullary vascular system." Perren '036, Col. 1, lines 52-54. Implementing these arched cut-outs in the shaft portion of the K982222 Summary's bone plate would achieve the known, predictable solutions identified in Perren '036.

Further, as described above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes disclosed in the Haas Article and the provisional fixation holes, *i.e.*, unthreaded suture holes, of the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the K982222 Summary in view of Perren 036, the Haas Article, and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

10. Rejections Based On the Koval Article In View Of The Synthes Catalog and the Haas Article

The attached Koval In View Of The Synthes Catalog and the Haas Article § 103 Claim Chart (Exhibit M) is incorporated by reference herein.

(i) Claims 1-11, 14, 17-27, 29-38, 41, 44-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Synthes Catalog and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the modified condylar buttress plate disclosed in the Koval Article with the with the arched cut-outs in the shaft portion of the condylar buttress plate shown in the Synthes Catalog. Specifically, both the Koval Article and the Synthes Catalog describe the same type of bone plate, the condylar buttress plate, that is used for to treat the same sort of fractures, namely periarticular fractures. One of ordinary skill in the art seeking to modify the plate shown in the Koval Article to reduce contact between the bone plate and the bone would look to the features of other shaped bone plates, such as those disclosed in the Synthes Catalog, and would be

motivated to implement those features to achieve the known and predictable benefits of promoting vascularization and bone growth.

One of ordinary skill in the art would be motivated to further modify this combination to include the conically-tapered and threaded holes disclosed in the Haas Article. Like the Koval Article and the Synthes Catalog, the Haas Article discloses a shaped bone plate having a head portion and a shaft portion. One would be motivated to include all conically-tapered, threaded holes in order to provide a flush fit between the screw and the screw holes, and the use of threaded, conically tapered holes would provide an angularly stable screw/plate connection both in the head portion and in the shaft portion.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 12 and 39 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Synthes Catalog and the Haas Article and in further view of Klaue

Klaue discloses a straight bone plate having limited contact features. Because it is a straight bone plate, like the shaft portion of a shaped bone plate, it is generally applied to the diaphysis of a bone. Thus, one of ordinary skill in the art seeking to reduce contact between the Koval Article's bone plate and the bone would refer to straight bone plates having limited contact features, such as Klaue's trapezoidal shaped cross section. Klaue discloses that such a structure "minim[izes] bone contact, which in turn promotes vascularization and bone growth." Klaue, Col. 3, lines 46-48. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Koval Article, Synthes Catalog, and the Haas Article to achieve the known and predictable benefits of promoting vascularization and bone growth.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 13 and 40 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Synthes Catalog and the Haas Article and in further view of Chapman

Chapman, like the Koval Article and the Synthes Catalog, describes a shaped bone plate having a head portion and a shaft portion. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to other shaped bone plates, such as that disclosed in Chapman, and would be motivated to modify the plate in the Koval Article to have a lower surface that is curved along a direction transverse to the longitudinal axis of the shaft portion. *See* Chapman, col. 15, lines 57-59. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Koval Article, the Synthes Catalog, and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Synthes Catalog and the Haas Article and in further view of the Zimmer Ad

Like the Koval Article, the Synthes Catalog, and Haas, the Zimmer Ad describes a bone plate having a head portion and a shaft portion, and with similar application to the bone. Based on this, one of ordinary skill in the art would be motivated to modify the combination of the Koval Article, the Synthes Catalog, and the Haas Article with the known unthreaded suture holes disclosed in the Zimmer Ad to achieve the predictable solution of enabling the plate to be used with sutures.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Synthes Catalog and the Haas Article and in further view of Bono

Bono discloses a bone plate having screw holes with a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate. One seeking to achieve flexibility in the bone plate by providing screw holes in a "desirable orientation" for

surgery would be motivated to refer to Bono, another bone plate, and implement the known, predicable solutions disclosed therein.

Detailed grounds for rejection are provided in the attached claim chart.

11. Rejections Based On the Koval Article In View Of The Manual of Internal Fixation and the Haas Article

The attached Koval In View Of The Manual of Internal Fixation and Haas § 103 Claim Chart (Exhibit N) is incorporated by reference herein.

(i) Claims 1-14, 17-27, 29-41, 44-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the modified condylar buttress plate disclosed in the Koval Article with the with the arched cut-outs in the plate shown in the shown in the Manual of Internal Fixation. Indeed, although the Manual of Internal Fixation discloses a straight bone plate having limited contact features, as discussed above, the straight plates correspond to the shaft portion of the shaped bone plates. Thus, one seeking to implement the reduce the contact between the Koval Article's bone plate and the bone would refer to a straight plate having arched cut-outs like the LC-DCP plate disclosed in the Manual of Internal Fixation. By the inclusion of arched cut-outs, one of ordinary skill in the art would achieve the known, predictable solution of minimizing disruption in blood flow in the bone.

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the conically-tapered and threaded holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Haas Article and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Haas Article and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

12. Rejections Based On the Koval Article In View Of The Manual of Internal Fixation and the Locking Reconstruction Plate Guide

The attached Koval In View Of The Manual of Internal Fixation and the Locking Reconstruction Plate Guide § 103 Claim Chart (Exhibit O) is incorporated by reference herein.

(i) Claims 1-13, 17-27, 29-40, 44-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and in further view of the Locking Reconstruction Plate Guide

As described above, one of ordinary skill in the art would be motivated to combine the Koval Article's modified condylar buttress plate with the Manual of Internal Fixation plate having arched cut-outs. One of ordinary skill in the art would be further motivated to modify this combination with the conically-tapered and threaded holes disclosed in the Locking Reconstruction Plate Guide. The Locking Reconstruction Plate Guide describes a bone plate having threaded, conically tapered holes. One seeking to reduce the profile of the screw and

plate combination would refer to other bone plates using threaded holes and threaded screws, like the Locking Reconstruction Plate Guide.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 14-16, 41-43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Locking Reconstruction Plate Guide and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Locking Reconstruction Plate Guide and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

13. Rejections Based On the Koval Article In View Of The Manual of Internal Fixation and the Collin Catalog

The attached Koval In View Of The Manual of Internal Fixation and the Collin Catalog § 103 Claim Chart (Exhibit P) is incorporated by reference herein.

(i) Claims 1-13, 18-27, 29-40, 45-51, 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and in further view of the Collin Catalog

As described above, one of ordinary skill in the art would be motivated to combine the Koval Article's modified condylar buttress plate with the Manual of Internal Fixation plate

having arched cut-outs. One of ordinary skill in the art would be further motivated to modify this combination with the conically-tapered and threaded holes disclosed in the Collin Catalog. The Collin Catalog describes bone plates, including shaped bone plates having head portions and shaft portions, and straight bone plates having it conically-tapered and threaded holes.[9] Because of this, one would be motivated to incorporate these threaded, conically tapered holes with locked screws to achieve the known, predictable solution of using threaded, conically tapered holes with locked screws to reduce the profile of the screw/plate combination and to achieve an angularly stable screw/plate connection both in the head portion and in the shaft portion.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 14-16, 41-43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Collin Catalog and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Collin Catalog and in further view of Wolter '117

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination of the Koval Article, the Manual of Internal Fixation, and the Collin Article with the bone plate holes disclosed in Wolter '117. Wolter '117 discloses a bone plate

[9] *See Boston Scientific SciMed,* 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

having conically tapered, threaded holes having multiple lead threads, and corresponding locking screws. One seeking to improve the construction of the locking screw/plate interface refer to other bone plates having threaded holes and locking screws, and would be motivated to implement their known features.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Manual of Internal Fixation and the Collin Catalog and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

14. Rejections Based On the Koval Article In View Of The Perren Article and the Haas Article

The attached Koval In View Of The Perren Article and Haas § 103 Claim Chart (Exhibit Q) is incorporated by reference herein.

(i) Claims 1-14, 17, 19-27, 29-41, 44, 46-51, 53, and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Perren Article and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the modified condylar buttress plate disclosed in the Koval Article with the bone plates having arched cut-outs shown in the Perren Article. The Perren Article discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in the

Perren Article achieves a limited-contact profile by providing a "structured undersurface" consisting of "grooves within the undersurface of the plate." Perren Article at 306. The Perren Article plate further has "side faces [that] are slightly inclined to form a trapezoidal cross section interrupted by undercuts which form arcs." *Id.* Thus, one seeking to implement the reduce the contact between the Koval Article's bone plate and the bone would refer to a straight plate having arched cut-outs like the LC-DCP plate disclosed in the Perren Article. Implementing these arched cut-outs in the shaft portion of the Koval Article's bone plate would achieve the known, predictable solution of "significantly improv[ing] the blood supply of plated bone segments." *Id.*

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the conically-tapered and threaded holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Perren Article and the Haas Article and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 18 and 45 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Perren Article and the Haas Article and in further view of the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the Koval Article's condylar buttress plate so it can be used on other periarticular fractures, such as those on the tibia. The Koval Article discloses a shaped bone plate having a head portion and a

shaft portion that is for treatment of fractures in the femur. One seeking to treat fractures in the tibia, another long bone, would be motivated to look to other shaped bone plates for use with the tibia. The Synthes Catalog discloses, on the same page as the LC-DCP condylar buttress plate, a shaped tibia buttress plate having a head and shaft portion that is used to treat fractures in the tibia. Further, the tibia buttress plate includes arched cut-outs on the lower surface of its shaft portion.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of the Perren Article and the Haas Article and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

15. Rejections Based On the Koval Article In View Of Klaue and the Haas Article

The attached Koval In View Of Klaue and the Haas Article § 103 Claim Chart (Exhibit R) is incorporated by reference herein.

(i) Claims 1-14, 17, 19-27, 29-41, 44, 46-51, 53, and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Klaue and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the modified condylar buttress plate disclosed in the Koval Article with the bone plates having arched cut-outs shown in Klaue. Klaue discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to reduce contact between the bone plate described in the Koval Article and the bone would be motivated to refer

to straight bone plates having low contact features. The plate described in the Klaue achieves a limited-contact profile by providing arched cut-outs in the lower surface of the bone plate. Including arched cut-outs in the shaft portion of the Koval Article's condylar buttress plate would achieve the known, predictable solution of "minimiz[ing] bone contact, which in turn promotes vascularization and bone growth." Klaue, Col. 3, lines 46-48.

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the conically-tapered and threaded holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Klaue and the Haas Article and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 18 and 45 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Klaue and the Haas Article and in further view of the Synthes Catalog

As described above, one of ordinary skill in the art would be motivated to further modify this combination so that the plate can be used to treat fractures in the tibia, as described in the Synthes Catalog.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Klaue and the Haas Article and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

16. Rejections Based On the Koval Article In View Of Vattolo and the Haas Article

The attached Koval In View Of Vattolo and the Haas Article § 103 Claim Chart (Exhibit S) is incorporated by reference herein.

(i) Claims 1-11, 13, 14, 17-27, 29-38, 40, 41, 44, 46-51, 53, and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Vattolo and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the modified condylar buttress plate disclosed in the Koval Article with the bone plates having arched cut-outs shown in Vattolo. Vattolo discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in Vattolo achieves a limited-contact profile by providing a plate that is concave transversly to the longitudinal axis of the plate, has a longitudinal groove extending lengthwise along the plate, and includes arched cut-outs extending transverse to the longitudinal axis. Vattolo found that the "grooves in the plate underside, by decreasing the contact area and protecting the periosteum" provided the predictable solution of "decreas[ing] the size of the temporarily porotic restructuring area." Vattolo Dissertation at 42. One of ordinary skill in the art seeking to reduce contact between the bone plate described in the Koval Article and the bone would be motivated to refer to straight bone plates having low contact features.

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 12 and 39 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Vattolo and the Haas Article and in further view of Klaue

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the trapezoidal shaped cross section disclosed in Klaue.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Vattolo and the Haas Article and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Vattolo and the Haas Article and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

17. Rejections Based On the Koval Article In View Of Perren '036 and the Haas Article

The attached Koval In View Of Perren '036 and Haas § 103 Claim Chart (Exhibit T) is incorporated by reference herein.

(i) Claims 1-11, 13, 14, 17, 19-27, 29-38, 40, 41, 44, 46-51, 53, and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Perren 036 and in further view of the Haas Article

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the modified condylar buttress plate disclosed in the Koval Article with the bone plates having arched cut-outs shown Perren '036. Perren '036 discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in Perren '036 achieves a limited-contact profile by providing a plate that is has "a plurality of contact elements extending from its lower surface so that the contact between the plate and bone is reduced to the minimum contact needed." Perren '036, Abstract. By this structure, Perren '036 discloses arched cut-outs on the lower surface of the bone plate. According to Perren '036, this structure provides the predictable result of "reduced damage to bone, particularly damage to the intramedullary vascular system." Perren '036, Col. 1, lines 52-54. Implementing these arched cut-outs in the shaft portion of the Koval Article's bone plate would achieve the known, predictable solutions identified in Perren '036.

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 12 and 39 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Perren 036 and the Haas Article and in further view of Klaue

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the trapezoidal shaped cross section disclosed in Klaue.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 15, 16, 42, 43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Perren 036 and the Haas Article and in further view of the Zimmer Ad

The Zimmer Ad describes a shaped bone plate having a head portion and a shaft portion, and with similar application to the bone as the Koval condylar buttress plate. Based on this, one of ordinary skill in the art would be motivated to modify the Collin Catalog with the known unthreaded suture holes disclosed in the Zimmer Ad to achieve the predictable solution of enabling the plate to be used with sutures.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 18 and 45 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Perren 036 and the Haas Article and in further view of the Synthes Catalog

As described above, one of ordinary skill in the art would be motivated to further modify this combination so that the shaped plate can be used to treat fractures in the tibia, as described in the Synthes Catalog.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Koval Article in view of Perren 036 and the Haas Article and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

18. Rejections Based On the Collin Catalog In View Of The Synthes Catalog

The attached Collin Catalog In View Of The Synthes Catalog § 103 Claim Chart (Exhibit U) is incorporated by reference herein.

(i) Claims 1-4, 6-11, 18-32, 34-38, and 45-54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the shaped bone plate having a head portion and a shaft portion disclose in the Collin Catalog with the arched cut-outs in the shaft portion of the shaped bone plate shown in the Synthes Catalog. Specifically, both the Collin Catalog and the Synthes Catalog describe the same type of bone plate, shaped bone plates, that are used for to treat the same sort of fractures, namely periarticular fractures. One of ordinary skill in the art seeking to modify the plate shown in the Collin Catalog to reduce contact between the bone plate and the bone would look to the features of other shaped bone plates, such as those disclosed in the Synthes Catalog, and would be motivated to implement those features to achieve the known and predictable benefits of promoting vascularization and bone growth.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 33 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Synthes Catalog and in further view of Trebing

Trebing discloses a bone plate having different diameters holes in its head portion. One of ordinary skill in the art seeking to provide flexibility in the types and sizes of screws that can be used in the head portion of the bone plate of the Collin Catalog would be motivated to look to other bone plates, such as Trebing, and implement their known features.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 12, 13, 39, and 40 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Synthes Catalog and in further view of Klaue

Klaue discloses a straight bone plate having limited contact features. Because it is a straight bone plate, like the shaft portion of a shaped bone plate, it is generally applied to the diaphysis of a bone. Thus, one of ordinary skill in the art seeking to reduce contact between the Collin Catalog's shaped bone plate and the bone would refer to straight bone plates having limited contact features, such as Klaue's trapezoidal shaped cross section. Klaue discloses that such a structure "minim[izes] bone contact, which in turn promotes vascularization and bone growth." Klaue, Col. 3, lines 46-48. Further, one seeking to improve the fit between the bone plate disclosed in the Collin Catalog would be motivated to modify the shaft portion of the bone plate to include a curved lower surface.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 14-16, 41-43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Synthes Catalog and in further view of the Zimmer Ad

Like the Collin Catalog and the Synthes Catalog, the Zimmer Ad describes a shaped bone plate having a head portion and a shaft portion, and with similar application to the bone. Based on this, one of ordinary skill in the art would be motivated to modify the combination of the Collin Catalog and the Synthes Catalog with the known unthreaded suture holes disclosed in the Zimmer Ad to achieve the predictable solution of enabling the shaped plate to be used with sutures.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Synthes Catalog and in further view of the Haas Article

The Haas Article discloses a shaped bone plate having a head portion and a shaft portion. The Haas Article further discloses that all of the holes in the plate are conically-tapered, threaded, multiple lead holes. One of ordinary skill in the art seeking to provide an angularly stable screw/plate connection both in the head portion and in the shaft portion would refer to other shaped bone plates having a head and a shaft portion, and threaded holes, such as the plate described by the Haas Article, and would be motivated to implement their known features.

Detailed grounds for rejection are provided in the attached claim chart.

19. Rejections Based On the Collin Catalog In View Of The Manual of Internal Fixation

The attached Collin Catalog In View Of The Manual of Internal Fixation § 103 Claim Chart (Exhibit V) is incorporated by reference herein.

(i) Claims 1-13, 18-40, and 45-54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Manual of Internal Fixation

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the bone plate having a head portion and a shaft portion disclose in the Collin Catalog with the arched cut-outs in shown in the Manual of Internal Fixation. Indeed, although the Manual of Internal Fixation discloses a straight bone plate having limited contact features, as discussed above, the straight plates correspond to the shaft portion of the bone plate disclosed in the Collin Catalog. Thus, one seeking to implement the reduce the contact between the Collin Catalog's bone plate and the bone would refer to a straight plate having arched cut-outs like the LC-DCP plate disclosed in the Manual of Internal Fixation. By the inclusion of arched cut-outs, one of ordinary skill in the art would achieve the known, predictable solution of minimizing disruption in blood flow in the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 14-16, 41-43, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Manual of Internal Fixation and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Manual of Internal Fixation and in further view of the Haas Article

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered and threaded holes having multiple lead threads disclosed in the Haas Article as described above.

Detailed grounds for rejection are provided in the attached claim chart.

20. Rejections Based On the Collin Catalog In View Of The Perren Article

The attached Collin Catalog In View Of The Perren Article § 103 Claim Chart (Exhibit W) is incorporated by reference herein.

(i) Claims 1-4, 6-16, 18-27, 29-32, 34-43, 45-51, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Perren Article and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the shaped bone plate having a head portion and a shaft portion disclose in the Collin Catalog with the arched cut-outs shown in the Perren Article. The Perren Article discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in

the Perren Article achieves a limited-contact profile by providing a "structured undersurface" consisting of "grooves within the undersurface of the plate." Perren Article at 306. The Perren Article plate further has "side faces [that] are slightly inclined to form a trapezoidal cross section interrupted by undercuts which form arcs." *Id.* Thus, one seeking to implement the reduce the contact between the Collin Catalog's bone plate and the bone would refer to a straight plate having arched cut-outs like the LC-DCP plate disclosed in the Perren Article. Implementing these arched cut-outs in the shaft portion of the Collin Catalog's bone plate would achieve the known, predictable solution of "significantly improv[ing] the blood supply of plated bone segments." *Id.*

The Zimmer Ad further discloses a shaped bone plate having a head portion flaring outward from the shaft with a width greater than the width of the shaft and curving upward from the shaft portion. As described above, one of ordinary skill in the art would be motivated to implement features from the Zimmer Ad bone plate as also has a head portion and a shaft portion. Thus, it would be obvious to modify the Collin Catalog with this head portion given the advantages of using such a head portion to allow the bone plate to properly fit the bone — an "[a]natomically [p]recontoured" bone plate. *See* Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 33 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Perren Article and the Zimmer Ad and in further view of the Manual of Internal Fixation

The Manual of Internal Fixation discloses bone plates having holes with different diameters in the head portion. As discussed above, one of ordinary skill in the art would be motivated to implement features from the plates described in the Manual of Internal Fixation to achieve the known benefits of such features, in this case, providing flexibility in the types and sizes of screws that can be used in the head portion of the bone plate.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Perren Article and the Zimmer Ad and in further view of the Haas Article

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the conically-tapered, threaded, multiple lead holes disclosed in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Perren Article and the Zimmer Ad and in further view of Bono

Bono discloses holes in the head that have an angle between approximately 0° and approximately 15°. One seeking to achieve flexibility in the bone plate by providing screw holes in a "desirable orientation" for surgery would be motivated to refer to Bono, another bone plate, and implement the known, predicable solutions disclosed therein.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Perren Article

In addition to describing bone plates having all threaded holes, the Collin Catalog discloses bone plates having unthreaded holes.[10] As described above, one of ordinary skill in the art would be motivated to combine the bone plates of the Collin Catalog with the disclosure of the structured undersurface and bone plates of the Perren Article, and further include a non-threaded screw hole.

Detailed grounds for rejection are provided in the attached claim chart.

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[10] *See Boston Scientific SciMed,* 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

21. Rejections Based On the Collin Catalog In View Of Klaue And The Zimmer Ad

The attached Collin Catalog In View Of Klaue And The Zimmer Ad § 103 Claim Chart (Exhibit X) is incorporated by reference herein.

(i) Claims 1-4, 6-16, 18-27, 29-32, and 34-43, 45-51, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Klaue and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the shaped bone plate having a head portion and a shaft portion disclose in the Collin Catalog with the arched cut-outs shown in Klaue. Klaue discloses a straight bone plate having limited contact features. Because it is a straight bone plate, like the shaft portion of a shaped bone plate, it is generally applied to the diaphysis of a bone. Thus, one of ordinary skill in the art seeking to reduce contact between the shaft of the Collin Catalog's shaped bone plate and the bone would refer to straight bone plates having limited contact features, such as Klaue's trapezoidal shaped cross section. Klaue discloses that such a structure "minim[izes] bone contact, which in turn promotes vascularization and bone growth." Klaue, Col. 3, lines 46-48. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the Collin Catalog to achieve the known and predictable benefits of promoting vascularization and bone growth.

The Zimmer Ad further describes that the head portion of its shaped bone plate curves upward from the shaft portion. As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad. In addition, one would be motivated to include the curved head potion described in the Zimmer Ad top provide a better fit to the condyle portion of the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 33 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Klaue and the Zimmer Ad and in further view of the Manual of Internal Fixation

As described above, one of ordinary skill in the art would be motivated to further modify this combination with screw holes having different diameters described in the Manual of Internal Fixation.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Klaue and the Zimmer Ad and in further view of the Haas Article

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the multiple lead screw holes described in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Klaue and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Klaue

In addition to describing bone plates having all threaded holes, the Collin Catalog discloses shaped bone plates having unthreaded holes.[11] As described above, one of ordinary

[11] *See Boston Scientific SciMed,* 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

skill in the art would be motivated to combine the bone plates of the Collin Catalog with the disclosure of the arched cut-outs of Klaue, and further include a non-threaded screw hole.

Detailed grounds for rejection are provided in the attached claim chart.

22. Rejections Based On the Collin Catalog In View Of Vattolo And The Zimmer Ad

The attached Collin Catalog In View Of Vattolo And The Zimmer Ad § 103 Claim Chart (Exhibit Y) is incorporated by reference herein.

(i) Claims 1-4, 6-11, 13-16, 18-27, 29-32, 34-38, 40-43, 45-51, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Vattolo and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the shaped bone plate having a head portion and a shaft portion disclose in the Collin Catalog with the arched cut-outs shown in Vattolo. Vattolo discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in Vattolo achieves a limited-contact profile by providing a plate that is concave transversly to the longitudinal axis of the plate, has a longitudinal groove extending lengthwise along the plate, and includes arched cut-outs extending transverse to the longitudinal axis. Vattolo found that the "grooves in the plate underside, by decreasing the contact area and protecting the periosteum" provided the predictable solution of "decreas[ing] the size of the temporarily porotic restructuring area." Vattolo Dissertation at 42. One of ordinary skill in the art seeking to reduce contact between the shaft of the shaped bone plate described in the Collin Catalog and the bone would be motivated to refer to straight bone plates having low contact features.

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the curved head portion disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 33 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Vattolo and the Zimmer Ad and in further view of the Manual of Internal Fixation

As described above, one of ordinary skill in the art would be motivated to further modify this combination with screw holes having different diameters described in the Manual of Internal Fixation.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 12 and 39 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Vattolo and the Zimmer Ad and in further view of Klaue

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the trapezoidal shaped cross section disclosed by Klaue.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Vattolo and the Zimmer Ad and in further view of the Haas Article

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the multiple lead screw holes described in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Vattolo and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Vattolo

In addition to describing bone plates having all threaded holes, the Collin Catalog discloses shaped bone plates having unthreaded holes.[12] As described above, one of ordinary skill in the art would be motivated to combine the bone plates of the Collin Catalog with the disclosure of the arched cut-outs of Vattolo, and further include a non-threaded screw hole.

Detailed grounds for rejection are provided in the attached claim chart.

23. Rejections Based On the Collin Catalog In View Of Perren '036 And The Zimmer Ad

The attached Collin Catalog In View Of Perren '036 And The Zimmer Ad § 103 Claim Chart (Exhibit Z) is incorporated by reference herein.

(i) Claims 1-4, 6-11, 13-16, 18-27, 29-32, 34-38, 40-43, 45-51, and 55 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Perren 036 and the Zimmer Ad

As set forth in the chart, one of ordinary skill in the art would find it obvious to combine the shaped bone plate having a head portion and a shaft portion disclose in the Collin Catalog with the arched cut-outs shown in Perren '036. Perren '036 discloses a straight bone plate having low contact features and, as discussed above, one of ordinary skill in the art seeking to implement a limited contact profile in the shaft portion of a shaped bone plate would be motivated to refer to straight bone plates having low contact features. The plate described in Perren '036 achieves a limited-contact profile by providing a plate that is has "a plurality of contact elements extending from its lower surface so that the contact between the plate and bone

[12] *See Boston Scientific SciMed,* 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

is reduced to the minimum contact needed." Perren '036, Abstract. By this structure, Perren '036 discloses arched cut-outs on the lower surface of the bone plate. According to Perren '036, this structure provides the predictable result of "reduced damage to bone, particularly damage to the intramedullary vascular system." Perren '036, Col. 1, lines 52-54. Implementing these arched cut-outs in the shaft portion of the Collin Catalog's bone plate would achieve the known, predictable solutions identified in Perren '036.

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the curved head portion disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 33 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Perren 036 and the Zimmer Ad and in further view of the Manual of Internal Fixation

As described above, one of ordinary skill in the art would be motivated to further modify this combination with screw holes having different diameters described in the Manual of Internal Fixation.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 12 and 39 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of the Perren 036 and the Zimmer Ad and in further view of Klaue

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the trapezoidal shaped cross section disclosed by Klaue.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 17 and 44 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Perren 036 and the Zimmer Ad and in further view of the Haas Article

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the multiple lead screw holes described in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 28 and 52 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Perren 036 and the Zimmer Ad and in further view of Bono

As described above, one of ordinary skill in the art would be motivated to further modify this combination with the screw holes having a non-perpendicular angular orientation with respect to the plane defined by the upper surface of the plate disclosed in Bono.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 53 and 54 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Collin Catalog in view of Perren 036

In addition to describing bone plates having all threaded holes, the Collin Catalog discloses shaped bone plates having unthreaded holes.[13] As described above, one of ordinary skill in the art would be motivated to combine the bone plates of the Collin Catalog with the disclosure of the arched cut-outs of Vattolo, and further include a non-threaded screw hole.

Detailed grounds for rejection are provided in the attached claim chart.

[13] *See Boston Scientific SciMed,* 554 F.3d at 991 ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

V. CONCLUSION

For the reasons set forth above, Requesters respectfully request reexamination and rejection of claims 1-55 of the '744 Patent.

Respectfully submitted,

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