PTO/SB/57 (08-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also referred to as FORM PTO-1465)

REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

Address to:
Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attorney Docket No.: 47063.000067

Date: January 8, 2009

1. ☑ This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 6,623,486 issued September 23, 2003. The request is made by:

   ☐ patent owner. ☑ third party requester.

2. ☑ The name and address of the person requesting reexamination is:

   Smith & Nephew, Inc.

   1450 Brooks Road

   Memphis, TN 38116

3. ☐ a. A check in the amount of $_____ is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(1);

   ☑ b. The Director is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(1) to Deposit Account No. 50-0206 ; or

   ☐ c. Payment by credit card. Form PTO-2038 is attached.

4. ☑ Any refund should be made by ☐ check or ☑ credit to Deposit Account No. 50-0206. 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.

5. ☑ A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4)

6. ☐ CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
   ☐ Landscape Table on CD

7. ☐ Nucleotide and/or Amino Acid Sequence Submission
   If applicable, items a. – c. are required.

   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:

      i. ☐ CD-ROM (2 copies) or CD-R (2 copies); **or**
      ii. ☐ paper

   c. ☐ Statements verifying identity of above copies

8. ☑ A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.

9. ☑ Reexamination of claim(s) 1-18 is requested.

10. ☑ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO/SB/08, PTO-1449, or equivalent.

11. ☑ An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

12. ☑ The attached detailed request includes at least the following items:

a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.510(b)(1)
b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2)

13. ☐ A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e)

14. ☑ a. It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c).
The name and address of the party served and the date of service are:

Brian Poissant, Jones Day

222 East 41st Street

New York, NY 10017-6702

Date of Service: January 8, 2009; or

☐ b. A duplicate copy is enclosed since service on patent owner was not possible.

15. Correspondence Address: Direct all communication about the reexamination to:

☑ The address associated with Customer Number: 21967

OR

☐ Firm or Individual Name

Address

City	State	Zip
Country		
Telephone	Email	

16. ☑ The patent is currently the subject of the following concurrent proceeding(s):

☐ a. Copending reissue Application No. _____
☐ b. Copending reexamination Control No. _____
☐ c. Copending Interference No. _____
☑ d. Copending litigation styled:

Synthes (USA) vs. Smith & Nephew, Inc.

Case No.: 03-0084, E.D.P.A.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Authorized Signature	January 8, 2009 Date
Robert A. King Typed/Printed Name	42,738 Registration No.

☐ For Patent Owner Requester
☑ For Third Party Requester

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number	:	6,623,486
Issued	:	September 23, 2003
Application Number	:	09/660,287
Filing date	:	September 12, 2000
Title	:	BONE PLATING SYSTEM
Docket No.	:	47063.000067
Customer No.	:	**21967**

MAIL STOP EX PARTE REEXAM
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Request for *Ex Parte* Reexamination of U.S. Patent No. 6,623,486

Sir:

Smith & Nephew, Inc. ("Smith & Nephew" or "Requestor") respectfully requests *ex parte* reexamination of claims 1-18 of U.S. Patent No. 6,623,486[1] (the "'486 patent") pursuant to 35 U.S.C. §§ 302-307 and 37 C.F.R. § 1.510 as these claims are unpatentable under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 103(a). As discussed in detail below, the relied-upon prior art documents were not considered by the United States Patent & Trademark Office (the "Patent Office") during the original prosecution of the '486 patent. This new prior art, therefore, raises a substantial new question of patentability as to at least one of claims 1-18 of the '486 patent. Requestor relies on the following prior art in this request for reexamination:

[1] The '486 patent is assigned to Synthes (U.S.A.) ("Synthes") and is currently being asserted in the following pending litigation: *Synthes (U.S.A.) v. Smith & Nephew, Inc.* (E.D. Pa. Case No. 03-0084).

- The Titanium Distal Radius Plate Technique Guide, published by Synthes, 1997 (the "DRP Guide");
- 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 (the "Koval Article"); and
- 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 (the "Haas Article") (original in German, translation to English attached with certification).

The above-listed references are relied upon to establish substantial new questions of patentability regarding the '486 patent. Requestor also relies on additional art of record in combination with the above:

- Features admitted in the '486 patent to be in the prior art;
- U.S. Patent No. 5,129,901 to Decoste (the "Decoste prior art patent"); and
- U.S. Patent No. 5,002,544 to Klaue et al. (the "Klaue prior art patent").

Although these references were of record during prosecution, they are presented in combination with the above prior art not of record and therefore presented in a new light not considered during prosecution.

A. INTRODUCTION

The '486 patent claims include system claims directed to bone plating systems, as well as method claims that relate to a method for fracture fixation of a bone using a bone plate and a first and second fastener. The system claims (claims 1-9 and 14-18, with claims 1, 14, and 16-18

independent) of the '486 patent each require a set of common elements for the bone plate:

- plates of specific shapes that have a head portion to match the metaphysis of a bone and a shaft portion to match the diaphysis of a bone;
- a combination of threaded, "first" holes and unthreaded, "second" holes;[2]
- first screws used in the first holes, the first screws having threads on the shaft and also threads on the head of the screw, such that the threads on the head of the screw mate with the threads of the first holes; and
- second screws with threads on the shaft to be used in second holes.

In addition to these common elements, various system claims include additional limitations, such as:

- the head portion of the plate having only first plate holes (claim 1)
- the head portion of the plate flares outward from the shaft (claim 14)
- the shaft portion of the plate having both first and second plate holes (claim 17)

Claim 1 of the '486 patent is representative:

> A bone plating system for fixation of bone comprising:
> a bone plate having: an upper surface; a bone-contacting surface;
> at least one first hole passing through the upper and bone-contacting surfaces and having a thread;
> and at least one second hole passing through the upper and bone-contacting surfaces;
> a first screw having a shaft with a thread for engaging bone and a head with a thread configured and dimensioned to mate with the thread of the first hole;
> and a second screw having a shaft with a thread for engaging bone and a head,
> wherein the first and second screws remain seated in their respective holes for substantially as long as the bone plate is implanted,
> wherein the bone plate includes a plurality of first and second holes, and a corresponding plurality of first and second screws are provided, and
> wherein the bone plate includes a head portion configured and

[2] In this Request, Smith & Nephew applies the following claim construction adopted by the district court for "second holes": "a hole that is not threaded (i.e., does not have any threads)". While the claim constructions adopted by the district court are not binding on the Patent Office, a copy of the Court's claim construction order from the *Synthes v. Smith & Nephew* case is attached at Exhibit D.

dimensioned to conform to a metaphysis of a bone and a shaft portion configured and dimensioned to conform to a diaphysis of a bone and the head portion has only first plate holes.

The method claims (claims 10-13, with claim 10 independent) require three common steps all using a bone plate:

- ***reducing*** the fracture to bring bone fragments in close apposition;
- ***compressing*** a bone plate against the bone with a first fastener to hold the fracture reduction; and
- ***securing*** a second fastener at a fixed angular relationship to the bone plate.

Claim 10 of the '486 patent is representative:

> A method for fracture fixation of bone comprising the steps of:
> reducing the fracture to bring bone fragments in close apposition;
> compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction; and
> securing at least one second fastener at a fixed angular relationship to the bone plate,
> wherein the at least one first fastener is inserted before the at least one second fastener and the at least one first fastener and
> the at least one second fastener remain in bone for substantially as long as the bone plate is implanted.

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

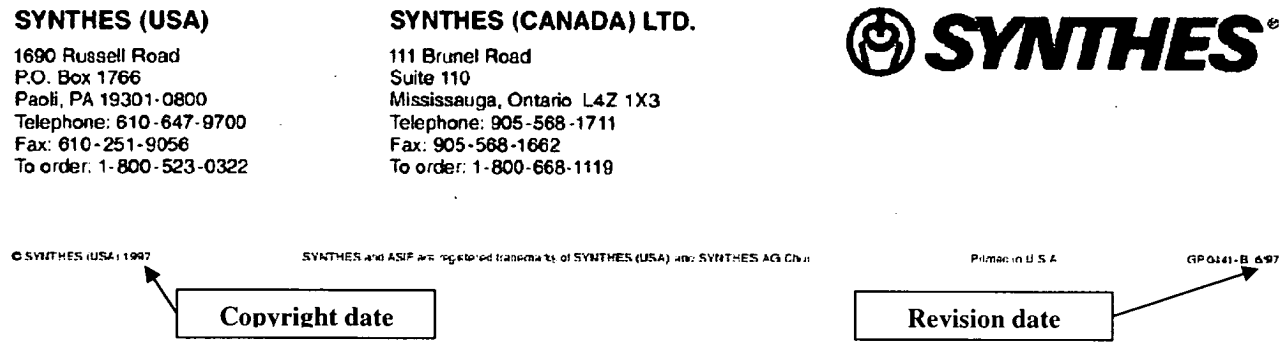
Each of the references relied upon by the Requestor qualifies as prior art to the '486 patent. The '486 patent was filed on September 12, 2000 and claims priority to a provisional patent application (No. 60/153,239) that was filed on September 13, 1999. A reference is prior art under 35 U.S.C. § 102(b) if it was published "more than one year prior" to the date the priority application was filed. 35 U.S.C. § 102(b). Accordingly, a printed publication available to the public before September 13, 1998 is prior art to the '486 patent claims. The following includes a discussion of the prior art status of the references described in this request as well as a detailed explanation of the pertinency and manner of applying the cited prior art.

1. The DRP Guide

a. The DRP Guide Is Prior Art

Requestor relies on a Synthes company sales brochure, the Titanium Distal Radius Plate Technique Guide (the "DRP Guide"), which is dated 1997. The DRP Guide discloses the features and intended use of the Synthes Distal Radius Plate.

The last page of the DRP Guide shows a copyright date of 1997 and a revision date of "6/97":



DRP Guide at 10.

"[P]ublic accessibility has been called the touchstone in determining whether a reference constitutes a 'printed publication' bar under 35 U.S.C. § 102(b)." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (en banc). "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." *Id.* "Whether an anticipatory document qualifies as a 'printed publication' under § 102 is a legal conclusion based on underlying factual determinations." *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1377 (Fed. Cir. 2006) (quoting *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1321 (Fed. Cir. 2002)).

"Accessibility goes to the issue of whether interested members of the relevant public

could obtain the information if they wanted to." *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988). Here, the relevant public would be surgeons, as they are the customers to whom bone plates are marketed and sold and they are also the hypothetical person having ordinary skill in the art for the '486 patent. Synthes' corporate representative confirmed that the distal radius plate (the "pi" plate) was available for sale in 1997, testifying as follows:

> Q. I'm going to hand you a physical plate that was previously marked as Defendant's Exhibit 84.
> A. Uh-huh.
> Q. And this is a plate with Production Numbers SYN-PHY-12.
> A. Oh, it's previously marked. Okay.
> Q. And can you identify the plate that's been identified as Defendant's –
> A. It is a –
> Q. – Deposition Exhibit Number 84?
> A. A titanium distal radius plate.
> Q. Okay. And you've been designated to offer testimony on Synthes' distal radius plates; correct?
> A. Yes.
> Q. Okay. Do you know when the – this particular distal radius plate would have first offered for sale in the United States?
> A. 1997.
> Q. Okay. And do you know when the distal radius plate that we've marked as Deposition Exhibit 84 would have first been used in the United States.
> A. It was commercially available in 1997.

Haag 5/28/08 Dep. at 71 (relevant pages attached as Exhibit E). Synthes' corporate representative later confirmed that the plate was available and disclosed to the public, "I think my testimony is that during 1997, the titanium distal radius plate was publicly disclosed." Haag 5/28/08 Dep. at 79.

"Evidence of routine business practice can be sufficient to prove that a reference was made accessible before a critical date." *Constant*, 848 F.2d at 1569. Synthes' corporate representative also confirmed that the DRP Guide would have been provided to customers (*e.g.*, surgeons and hospitals) who purchased the distal radius plate from Synthes. Haag 5/28/08 Dep. at 79. Additionally, the DRP Guide bears no confidential designation whatsoever. Synthes'

witness also admitted that Synthes would have provided copies of the DRP Guide to individuals in the medical profession upon request. Haag 5/28/08 Dep. at 215 ("Q. And Synthes would have also provided a copy of this document to interested individuals in the medical profession upon request from a Synthes consultant? A. Yes."). The fact that the DRP Guide was available to the relevant interested persons satisfies the requirements for public accessibility:

> "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 and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation."

Bruckelmyer, 445 F.3d at 1377.

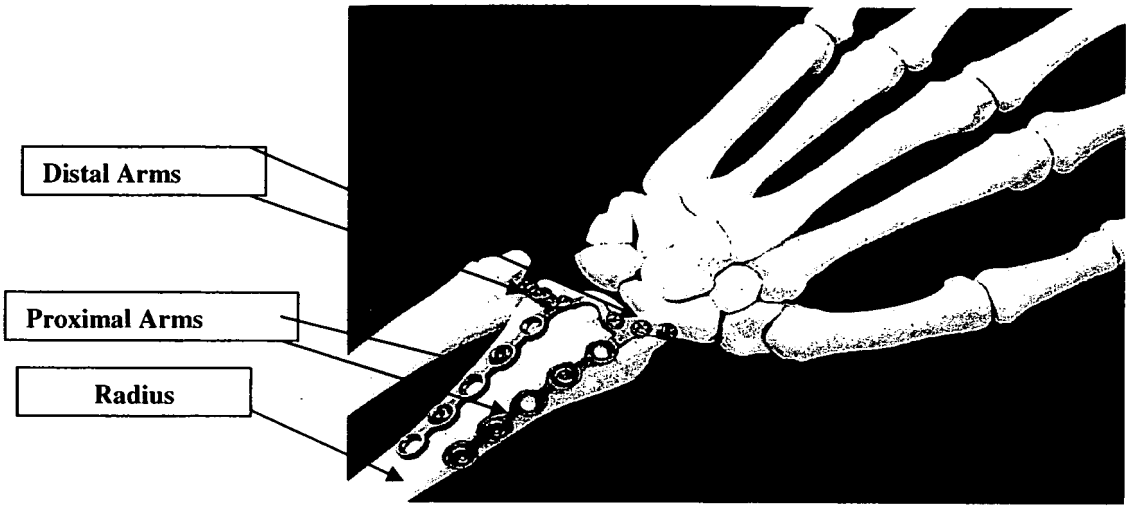
Because Synthes admitted that it would have provided interested persons in the medical field with copies of the DRP Guide upon request, public accessibility is established irrespective of the number of copies of the Guide actually disseminated. "[I]f accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Constant*, 848 F.2d at 1569. Accordingly, the DRP Guide was sufficiently accessible to those concerned with the art to constitute a printed publication and is thus prior art to the '486 patent. Requestor notes that the standards cited for accessibility and printed publications are applicable for all of the references cited herein.

The DRP Guide is not of record in the prosecution history of the '486 patent.

b. An Overview of the DRP Guide

The Synthes DRP Guide describes the features and techniques for use of a Synthes bone plate – the distal radius plate. The distal radius plate is used on fractures of the distal end of the

radius bone. The radius bone is one of the bones running from one's elbow to one's hand, and the distal end of the bone is the part of bone connecting the radius to the wrist.[3]



DRP Guide, cover page.

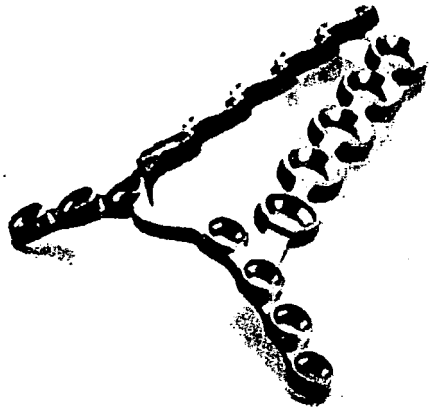
The distal radius plate is shaped similar to the Greek letter "pi" (π) and is also referred to as the "pi plate." As shown above, the distal radius plate has both proximal arms and distal arms. The distal radius plate has a head portion (the distal arms) which is configured and dimensioned to correspond to the metaphysis of the radius bone and a shaft portion (the proximal arms) which is configured and dimensioned to correspond to the diaphysis of the radius bone.

The DRP Guide discloses that the distal radius plate has an "anatomical design" and that its "precontouring reduced the need for intraoperative bending."

[3] In anatomical usage, the term "distal" refers to the far end of a bone or the part of the bone most remote from where the limb is attached to the body. The term "proximal" refers to the near end of a bone or the part of the bone most close to where the limb is attached to the body.

FEATURES

- Precontouring reduces the need for intraoperative bending.
- Anatomical design eliminates the need to remove Lister's tubercle.
- Low plate and screw profile minimizes soft tissue irritation.

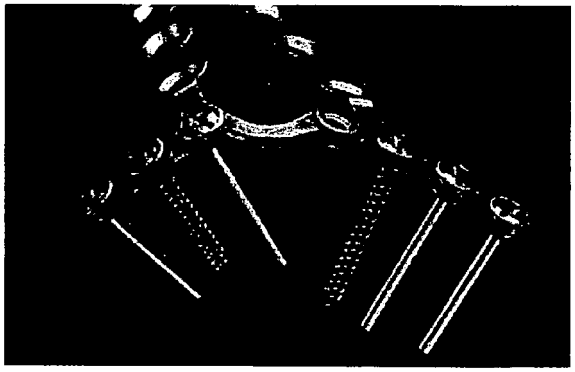


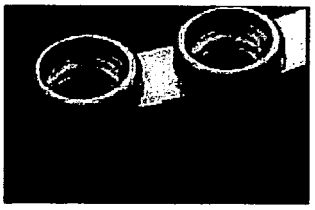
DRP Guide, inside cover page.

In other words, because the plate is precontoured to fit the anatomical shape of the radius bone, there is a reduced need to bend the plate during surgery to fit the plate to the contours of the radius bone.

The distal radius plate also has two different types of plate holes: threaded plate holes in the distal arms and unthreaded holes in the proximal arms.

The distal radius plate also uses two different types of fasteners: locking pins with threaded heads and non-locking screws:





Threaded holes in the distal arm accept 1.8 mm buttress pins or 2.4 mm self-tapping cortex screws.

DRP Guide, inside cover page.

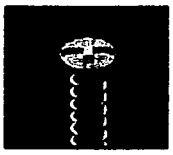
The locking pins that are used in the distal arms are described as follows:

1.8 mm Titanium Buttress Pins

- For use in the distal plate arm in comminuted articular fractures, or in poor quality bone where screw hold would be compromised.
- Threaded head locks into threaded plate hole to provide a fixed pin/plate construct and buttress for the articular surface.

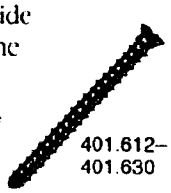
DRP Guide at 1.

The non-locking screws that can be used in the distal arm holes are described as follows:



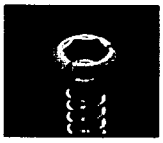
2.4 mm Titanium Self-Tapping Cortex Screws

- For use in the distal plate arm to provide alternative fixation for restoration of the articular surface when bone quality is good, lag screw technique is required, or larger fragments of poor quality bone are present.



DRP Guide at 1.

The non-locking, self-tapping cortex screws that are used with the unthreaded holes in the proximal arms are described as follows:



2.7 mm Titanium Self-Tapping Cortex Screws

- For use in the DCU (Dynamic Compression Unit) holes of the proximal plate arms.
- Self-tapping feature eliminates the need to tap.
- Small screw head provides a low profile.

DRP Guide at 1.

Thus, the distal radius plate is a device used to treat fractures in the distal radius. This plate has distal arms (the structure closest to wrist) which comprise a head portion that is configured and dimensioned to correspond to the metaphysis of a radius bone and proximal arms which comprise a shaft portion that is configured and dimensioned to correspond to the diaphysis

of a radius bone. The distal arms accept *either* locking pins or non-locking screws. The proximal arms *only* accept non-locking screws.

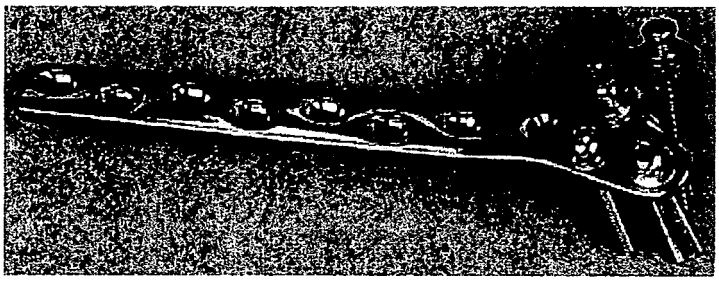
Finally, the DRP Guide discloses a method of reducing, compressing, and securing the bone plate to the bone using first and second fasteners. DRP Guide, inside cover page, 1-2, 5-8. When installed, the buttress pins lock in place to provide a fixed pin/plate construct. The shafts have elongated dynamic compression unit holes to receive self-tapping cortex screws. DRP Guide, cover illustration. The DRP Guide indicates that the bone plate is provided with a full complement of screws and buttress pins. DRP Guide, back cover. In addition, the DRP Guide indicates that the screws and buttress pins are installed and the wound closed, making it clear that the pins and screws remain in place for as long as the plate is implanted. DRP Guide at 2-9.

2. The Koval Article

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 '486 patent. The Koval Article is not of record in the prosecution history of the '486 patent.

The Koval Article describes a bone plating system developed to address severely comminuted distal femur fractures in which typical fixed-angle devices, such as blade plates or condylar screws, were not expected to be adequate, and a lateral buttress plate was typically indicated as the appropriate osteosynthesis device. *See* Koval Article at 521-22. To address

such fractures, Koval modified a standard Synthes lateral condylar buttress plate by welding threaded nuts into four of the six unthreaded holes through the bone plate head. *See, e.g.*, Koval Article at 522, Fig. 1.



"a modified lateral condylar buttress plate made by welding four tapped nuts (Richards Part #A390000, Memphis, TN, U.S.A.) into the screw holes of the distal plate flange in the identical pattern used for the standard buttress plate (Fig. 1) to create a locked screw system."

Koval Article at 522, Fig. 1.

The bone plate illustrated in Koval Figure 1 is a typical Synthes condylar buttress plate ("CBP") having dynamic compression unit ("DCU") holes along the shaft. Such devices were part of Synthes' "Dynamic Compression Plate" ("DCP") line of products, which included condylar buttress plates. The CBP plate shown in Koval includes an upper surface, and a bone contacting surface located opposite the upper surface. Koval Article at 522, Fig. 1.

The head of the Koval plate has six holes. Four of the six holes are converted to threaded holes by the inclusion of welded-in threaded nuts. Koval Article at 522. The Koval plate has seven unthreaded, elongated holes in the shaft portion of the plate. Koval Article at 522. The holes in the shaft are dynamic compression unit holes having a ramped inner surface that allows the physician to shift and compress bone fragments, depending on how the screws are inserted into the holes. The head of the Koval plate is configured and dimensioned to conform to a metaphysis of a bone and the shaft portion is configured and dimensioned to conform to a diaphysis of a bone, as clearly shown in Figure 1. Koval discloses using four 4.5-millimeter cortical screws through the threaded holes in the plate head and three 4.5-millimeter cortical screws through the unthreaded holes in the plate shaft. Koval Article at 522.

The plate disclosed in the Koval Article is very similar to the bone plates shown in Figures 7-10 of the '486 patent. In fact, the only differences are the location and number of threaded holes through the Koval plate, and the fact that the Koval plate uses welded-in threaded inserts.

Koval describes the plate as a "locked buttress plate" in which the screws lock to the plate to "act as a fixed-angle device." Koval Article at 521-22. Koval explains that the locked screws cannot toggle in the plate, reducing the likelihood of fracture displacement. Koval Article at 521-22. Ultimately, Koval concludes that "[a] condylar buttress plate with locked screws is a valid concept for improving fixation stability." Koval Article at 521-22.

Koval also describes that the holes in the bone plate may be threaded (*i.e.*, tapped) *without* the use of a nut. For example, Koval states that, in clinical situations, "bending of a locked plate with *unreinforced* tapped screw holes could distort the screw holes and prevent screw insertion. Placement of threaded inserts before bending could prevent this distortion." Koval Article at 524, emphasis added. Thus, Koval discloses a plate with threaded holes in which the holes could also be reinforced or provided with threaded inserts during bending.

3. The Haas Article

The Haas Article describes the features and use of a Synthes bone plate, the Less Invasive Stabilization System ("LISS"), for internal fixation and stabilization of distal femur fractures. The LISS plate disclosed in the Haas Article is depicted in Figure 4 (reproduced below):

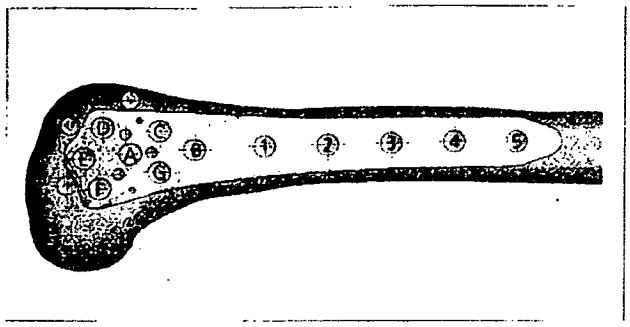


Abb.4 Im Kondylenbereich des LISS sind die Schraubenpositionen mit Buchstaben (A–F) bezeichnet. Abhängig der radiologisch bestimmten Kondylenbreite kann aus einer Tabelle die entsprechende Schraubenlänge jeder Position unmittelbar entnommen werden.

Translation:

Diag. 4 In the condyle area of the LISS the screw positions are labeled with the letters (A-F). Based on the condyle width derived from the radiological images, the respective screw lengths of each position can be obtained directly from a table.

The LISS plate disclosed in the Haas Article has only threaded holes that are capable of accepting bone screws. The screws used in the threaded holes have threads on the screw shaft and conical, threaded screw heads which mate with the threads on plate holes. Haas Article at 340 Summary, 341, Fig. 3. Figure 3 from the Haas Article details the threaded holes and corresponding threaded-head screws and is reproduced below:

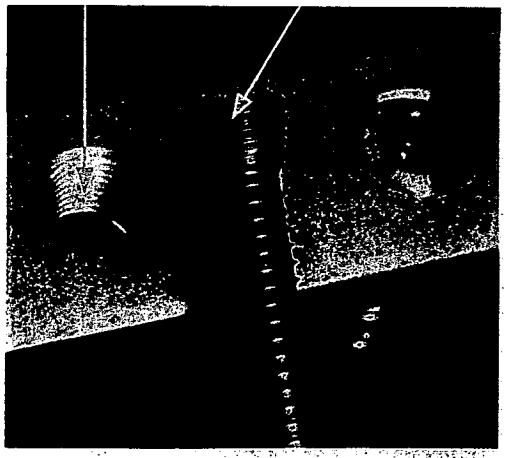


Abb.3 Eine hohe Winkelstabilität zwischen Schraube und LISS wird durch die Gewindeverbindung des Schraubenkopfes und des Fixateur-intern-Loches erzielt.

Translation:

Diag. 3 A large amount of angle stability is achieved between the screw and the LISS due to the threading connection between the screw head and the internal fixator hole.

The screw shown in Figure 3 of the Haas Article is nearly identical to the threaded head locking screw shown in Figure 2 of the '486 patent.

The Haas Article was published in a publicly available medical journal — OP Journal — in December 1997. The December 1997 edition of this journal, Vol. 13, No. 3, was cataloged at

the U.S. National Library of Medicine at the National Institute of Health on January 21, 1998. Haag Article, cover page. Accordingly, the Haas Article qualifies as a publicly available printed publication that is prior art to the '486 patent.

The Haas Article is not of record in the prosecution history of the '486 patent application.

Additionally, the original Haas Article was published in German. Accordingly, a translation and certification of the translation are provided.

C. STATEMENT OF NEW QUESTIONS OF PATENTABILITY

As detailed below, the DRP Guide, the Koval Article, and the Haas Article raise numerous substantial new question of patentability with respect to one or more of claims 1-18 of the '486 patent. None of the DRP Guide, the Koval Article, and the Haas Article was before the Patent Office during the prosecution of the '486 patent.

1. Substantial New Questions of Patentability in view of the DRP Guide

a. Substantial New Questions of Patentability Stemming From the DRP's Disclosure of a Bone Plate with "a Head Portion Configured and Dimensioned to Conform to A Metaphysis of a Bone and a Shaft Portion Configured and Dimensioned to Conform to a Diaphysis Of A Bone" and Having Both Threaded and Unthreaded Holes

As explained above, the DRP Guide discloses a distal radius plate having a head portion (the distal arms) which is configured and dimensioned to correspond to the metaphysis of the radius bone and a shaft portion (the proximal arms) which is configured and dimensioned to correspond to the diaphysis of the radius bone. The DRP Guide discloses that the distal radius plate has an "anatomical design" and that its "precontouring reduced the need for intraoperative bending." The DRP Guide also discloses two different types of plate holes: threaded plate holes in the distal arms and unthreaded holes in the proximal arms of the plate.

None of the prior art of record during the prosecution of the '486 patent discloses a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone

and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone and that has both threaded and unthreaded plate holes.

Claims 1-9 and 14-18 each require a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone and further require that the bone plate have both threaded and unthreaded plate holes. Because these features were not described in a single prior art reference that was before the Patent Office during the prosecution of the '486 patent, the disclosure of the DRP Guide raises substantial new questions of patentability with respect to claims 1-9 and 14-18 of the '486 patent.

b. Substantial New Questions of Patentability Stemming From the DRP's Disclosure of a Bone Plate with Only First (Threaded) Holes in the Head Portion of the Plate

The DRP Guide discloses a bone plate having a head portion with only threaded holes. The head portion of the distal radius plate is the part of the plate comprising the distal arms. As explained above, all of the holes in the distal arms of the distal radius plate are threaded holes.

Claim 1 of the '486 patent requires, *inter alia*, a bone plate comprising "at least one first hole . . . having a thread . . . wherein the head portion has only first plate holes." The limitation that the head has only first plate holes was originally presented in dependent application claim 12. Application claim 12 was indicated allowable in the first Office Action mailed July 17, 2002. In response, the claims were amended to include new independent application claim 23, which included this limitation. The Patent Office renumbered application claim 23 to claim 1 upon allowance. None of the references considered during prosecution of the '486 patent disclosed a plate with a head portion having only threaded plate holes. The DRP Guide discloses a bone plate having a head portion with only threaded holes. Accordingly, the DRP Guide raises substantial new questions of patentability for claim 1 of the '486 patent and claims 2-9, which

depend from claim 1.

c. Substantial New Questions of Patentability Stemming From the DRP's Disclosure of a Method for Implanting the Distal Radius Plate

Claim 10 of the '486 patent is a method of fracture fixation using a bone plate requiring, *inter alia*, compressing the bone plate against the bone with at least one first fastener and at least one second fastener, "wherein the at least one first fastener is inserted before the at least one second fastener." The limitation that the first fastener is inserted before the second fastener was originally presented in independent application claim 18. During prosecution, the Patent Office rejected method application claim 18 under 35 U.S.C. § 102(b) as being anticipated by Soviet Union Patent SU 1279626 ("Orthop"). In response, Applicants asserted that the Orthop reference failed to disclose the claim limitation of inserting the first fastener ***before*** the second fastener. Subsequently, in the Office Action mailed December 24, 2002, the Patent Office indicated application claim 18 was allowable. Upon allowance, application claim 18 was renumbered as claim 10. None of the references considered during prosecution of the '486 patent disclosed inserting the first fastener before the second fastener where the fasteners are left in the bone for as long as the plate remains implanted as required by the '486 patent claims. The DRP Guide discloses a method whereby the first fastener is inserted before the second fastener as required by the '486 patent claims. Accordingly, the DRP Guide raises substantial new questions of patentability for claim 10 of the '486 patent and claims 11 -13, which depend from claim 10.

d. Substantial New Questions of Patentability Stemming From the DRP's Disclosure of a Bone Plate with a Head Portion that Flares Outward From the Shaft of the Plate

Claim 14 of the '486 patent requires, *inter alia*, a bone plate "wherein the head portion flares outward from the shaft." The limitation that the head portion flares outward from the shaft

was originally presented in dependent application claim 16. Application claim 16 was indicated allowable in the first Office Action mailed July 17, 2002. On April 24, 2003, in response to an Office Action mailed December 24, 2002, Synthes added new application claim 27 which incorporated the subject matter of application claim 16. Application claim 27 was renumbered to claim 14 upon allowance. None of the references considered during prosecution of the '486 patent disclosed a plate with a head portion that flares outward from the shaft. The DRP Guide discloses a bone plate having a head portion that flares outward from the shaft and further has threaded and unthreaded holes. Accordingly, the DRP Guide raises substantial new questions of patentability for at least claim 14 of the '486 patent and claim 15, which depends from claim 14.

2. Substantial New Questions of Patentability in view of the Koval Article

a. Substantial New Questions of Patentability Stemming From the Koval Article's Disclosure of a Bone Plate with "a Head Portion Configured and Dimensioned to Conform to A Metaphysis of a Bone and a Shaft Portion Configured and Dimensioned to Conform to a Diaphysis Of A Bone" and Having Both Threaded and Unthreaded Holes

As explained above, the Koval Article discloses a plate having a head portion configured and dimensioned to correspond to the metaphysis of the femur bone and a shaft portion configured and dimensioned to correspond to the diaphysis of the femur bone. The Koval Article also has two different types of plate holes: four threaded plate holes in the head portion of the plate and unthreaded holes in shaft portion of the plate.

None of the prior art of record during the prosecution of the '486 patent discloses a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone and that has both threaded and unthreaded plate holes.

Claims 1-9 and 14-18 each require a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and

dimensioned to correspond to the diaphysis of a bone and further require that the bone plate have both threaded and unthreaded plate holes. Because these features were not described in a single prior art reference that was before the Patent Office during the prosecution of the '486 patent, the disclosure of the Koval Article raises substantial new questions of patentability with respect to claims 1-9 and 14-18 of the '486 patent.

b. Substantial New Questions of Patentability Stemming From the Koval Article's Disclosure of the Use of a Bone Plate Having Both Threaded and Unthreaded Holes

Claim 10 of the '486 patent is a method of fracture fixation using a bone plate requiring, *inter alia*, compressing the bone plate against the bone with at least one first fastener and at least one second fastener, "wherein the at least one first fastener is inserted before the at least one second fastener." As explained above, none of the references considered during prosecution of the '486 patent disclosed inserting the first fastener before the second fastener where the fasteners are left in the bone for as long as the plate remains implanted. Koval discloses a bone plate using both first and second fasteners. Therefore, there exist two possible ways the Koval plate could have been used: (1) a first fastener is inserted before the second fastener as required by the '486 patent claims; or (2) vice versa. With such a limited number of finite choice for using the Koval plate, the method of claim 10 is obvious in view of the Koval Article. Accordingly, the Koval Article raises substantial new questions of patentability for claim 10 of the '486 patent and claims 11-13 which depend from claim 10.

c. Substantial New Questions of Patentability Stemming From the Koval Article's Disclosure of a Bone Plate with a Head Portion that Flares Outward From the Shaft of the Plate

Claim 14 of the '486 patent requires, *inter alia*, a bone plate "wherein the head portion flares outward from the shaft." As explained above, none of the references considered during prosecution of the '486 patent disclosed a bone plate with a head portion configured and

dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone and further having both threaded and unthreaded plate holes. Koval discloses a bone plate having a head portion that flares outward from the shaft. Accordingly, the Koval Article raises substantial new questions of patentability for at least claim 14 of the '486 patent.

d. Substantial New Questions of Patentability Stemming From the Koval Article's Disclosure of a Bone Plate with a Head Portion Having a Curved Surface and an Anterior and Posterior Fork

Claim 16 of the '486 patent requires, *inter alia*, a bone plate "wherein the head portion has a curved surface, includes an anterior fork substantially parallel to an anterior side of the shaft portion, and includes a posterior fork extending out from a posterior side of the shaft portion." The limitation that the head portion has a curved surface and an anterior and posterior fork was originally presented in dependent application claim 14. Application claim 14 was indicated allowable in the first Office Action mailed July 17, 2002. On April 24, 2003 in response to an Office Action mailed December 24, 2002, Synthes added new application claim 24 which incorporated the subject matter of application claim 14. Application claim 24 was renumbered to claim 16 upon allowance. None of the references considered during prosecution of the '486 patent disclosed a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone and further having both threaded and unthreaded plate holes. Koval discloses a bone plate having a head portion has a curved surface and an anterior and posterior fork. Accordingly, the Koval Article raises substantial new questions of patentability for at least claim 16 of the '486 patent.

3. Substantial New Questions of Patentability in view of the Haas Article

The Haas Article discloses a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone. The Haas Article also discloses a plurality of threaded holes and screws with a head with a thread configured and dimensioned to mate with the thread of the threaded holes.

None of the prior art of record during the prosecution of the '486 patent discloses: (i) a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone; (ii) a plurality of threaded holes; and (iii) screws with a head with a thread configured and dimensioned to mate with the thread of the threaded holes.

Claims 1-9 and 14-18 each require a bone plate with a head portion configured and dimensioned to correspond to the metaphysis of a bone and a shaft portion configured and dimensioned to correspond to the diaphysis of a bone and further require a plurality of threaded holes and screws with a head with a thread configured and dimensioned to mate with the thread of the threaded holes. Because these features were not described in a single prior art reference that was before the Patent Office during the prosecution of the '486 patent, the disclosure of the Haas Article raises substantial new questions of patentability with respect to claims 1-9 and 14-18 of the '486 patent.

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

1. Grounds of Rejection

The following section identifies specific proposed grounds of rejection applying the prior art references listed above and on the attached PTO-1449 to the claims for which *ex parte*

reexamination is requested. Additional details regarding each proposed rejection are set forth in the accompanying claim charts attached as Exhibits A-C.

2. Proposed Rejections under 35 U.S.C. § 102(b)

a. The Law of Anticipation

"[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). To anticipate a claimed invention, the reference must show not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim. *See Net Moneyin v. Verisign*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

b. Claims 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as anticipated by the DRP Guide

(1) Overview of the Surgical Techniques Disclosed in the DRP Guide

The DRP Guide is provided by Synthes to doctors to provide guidance as to how to use the distal radius plate. The first page of the DRP Guide identifies the "indications" for the distal radius plate. It states that the plate is indicated:

> For dorsal application in:
>
> - Complex intra-articular and extra-articular fractures of the distal radius
> - Osteotomies of the distal radius

DRP Guide, inside cover page.

Dorsal application means that the plate is used on the dorsal side of the radius (*i.e.*, the top or back of the bone) rather than the lower, or ventral, side of the bone. The plate can be used on the dorsal side to treat "complex intra-articular and extra-articular fractures of the distal radius." Intra-articular factures are fractures occurring within the articular, or joint, region of

distal radius and extending to the articulating surface of the distal radius. The wrist joint is the joint at the distal end of the radius. An extra-articular fracture is a fracture that does not extend to the articular surface of the distal radius. Figure 13 from the DRP Guide shows an intra-articular fracture and an extra-articular fracture.

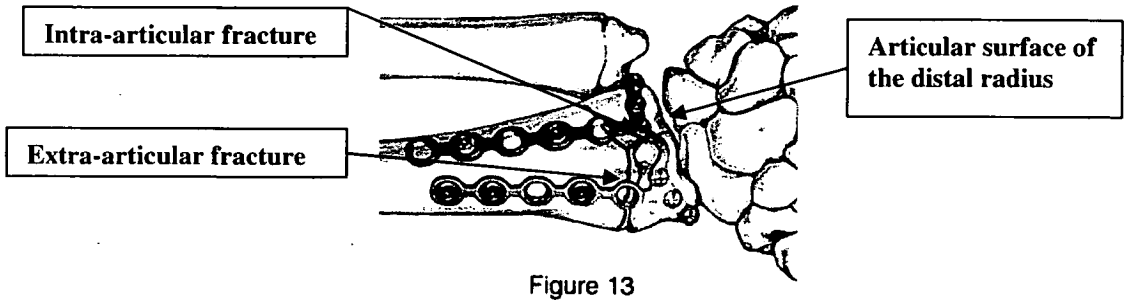


Figure 13

DRP Guide at 9.

The distal radius plate can also be used to treat osteotomies of the distal radius.[4] The present discussion will be limited to the use of the distal radius plate to treat intra-articular and extra-articular fractures of the distal radius plate.

The surgical techniques described in the DRP Guide are set forth on pages 2-9 of the Guide and are labeled with steps 1-9. The headings for steps 1-9 are as follows:

1. Shape Plate
2. Cut Plate
3. Contour distal plate arm
4. Contour proximal plate arms
5. Apply plate
6. Secure distal arms
7. Secure proximal arms
8. Closure
9. Postoperative management

DRP Guide at 3-9.

[4] An osteotomy is a cut made through the bone by a surgeon in order to change the length or alignment of the bone.

The DRP Guide does not describe a single way, or one specific order, for use of the distal radius plate. Instead, the DRP Guide makes it clear that there are, for example, at least two different techniques that can be used depending on the clinical situation. After the plate has been shaped, cut, contoured, and applied, the next step is to begin securing the plate to the bone using the various fasteners supplied. DRP Guide at 5-8. After the plate has been placed on the bone, the DRP Guide discloses that, depending on the clinical situation, the surgeon will either start with fastening the distal arms of the plate to the bone or the proximal arms of the plate to the bone.

> Place the plate on the dorsal aspect of the distal radius. Determine which holes will be used for fixation. The specific order of fixation (proximal or distal arm) depends on the fracture pattern and clinical situation (Figure 5).

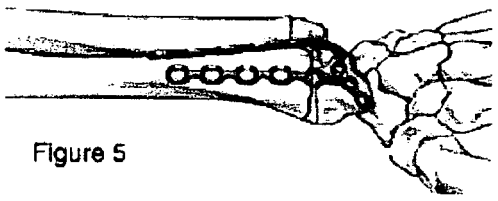


Figure 5

DRP Guide at 5.

The DRP Guide then describes how to secure the distal arms (step 6) and the proximal arms (step 7). Accordingly, the DRP Guide discloses two alternative methods for use of the distal radius plate: one where the proximal arms are secured first, and one where the distal arms are secured first. Requestor's assertions regarding anticipation of claims 10, 11, and 13 of the '486 patent are directed to the "proximal arm first" method.

(2) Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by the DRP Guide

The attached DRP Guide § 102 Claim Chart (Exhibit B) is incorporated by reference herein.

As discussed above, the DRP Guide discloses a method for use of the distal radius plate where the plate is first secured to the bone in the proximal arms, followed by securing the distal arms to the bone. This method discloses each and every limitation of claim 10.

"A method for fracture fixation of bone comprising the steps of"

The preamble of claim 10 recites "a method for fracture fixation of bone." The DRP Guide discloses a method for fracture fixation of bone, specifically a method for treating fractures of the distal radius bone.

"reducing the fracture to bring bone fragments in close apposition"

The first step of claim 10 requires reducing the fracture to bring bone fragments in close apposition. The first step in any internal fracture fixation surgery is to reduce the bone fracture to bring the broken bone fragments together and one that one skilled in the art would appreciate as being implicitly disclosed in the Guide. The DRP Guide presumes that acceptable reduction of the fracture will be accomplished in the following passage:

> Operative exposure of the fracture becomes necessary if acceptable reduction cannot be achieved by closed means . . . .

DRP Guide at 2.

In other words, the DRP Guide states that if the doctor cannot achieve acceptable reduction of the fracture by closed means (*i.e.*, without surgery), operative exposure (*i.e.*, surgery) may be required to reduce the fracture. To the extent that fracture reduction is not implicitly understood as a requisite first step in any fracture fixation surgery, the passage quoted above provides the necessary disclosure that the fracture is to be reduced to bring the bone fragments together as a preliminary, early step in virtually all distal radius fractures where the distal radius plate would be used.

Thus, the DRP Guide discloses the step of reducing the fracture to bring bone fragments in close apposition.

"compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction" and "wherein the at least one first fastener is inserted before the at least one second fastener"

The next step of claim 10 involves "compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction." This section will also address the requirement that the first fastener be inserted before insertion of the second fastener (i.e., wherein the at least one first fastener is inserted before the at least one second fastener).

Following reduction of the fracture and the shaping, cutting, contouring, and application of the distal radius plate onto the bone, the DRP Guide discloses that the next step is to apply the plate to the bone and begin securing the plate to the bone with fasteners. DRP Guide at 5-8. As discussed above, the DRP Guide states that "[t]he specific order of fixation (proximal or distal arm) depends on the fracture pattern and clinical situation." DRP Guide at 5. Accordingly, the DRP Guide discloses two methods for installation: one, the method where the proximal arms are first fixed to the bone, and two, the method where the distal arms are first fixed to the bone. The fact that the DRP Guide does not indicate which order is preferred and the fact that the Guide does not specifically go through each method in detail (the Guide happens to proceed with the next step as securing the distal arms) is of no consequence for purposes of 35 U.S.C. § 102. It is irrelevant, for purposes of anticipation, whether a specific disclosed option is emphasized relative other disclosed options. *See Leggett & Platt, Inc., v. VUTEK, Inc.*, 537 F.3d 1349 (Fed. Cir. 2008) ("[Plaintiff's] argument relies on the erroneous assumption that the disclosure of multiple examples renders one example less anticipatory); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (rejecting the argument that one example "cannot anticipate because it appears without special emphasis in a longer list).

In the proximal arms first method disclosed, the proximal arms are first secured to the bone with non-locking screws (*i.e.*, "2.7 mm Titanium Self-Tapping Cortex Screws"). The step

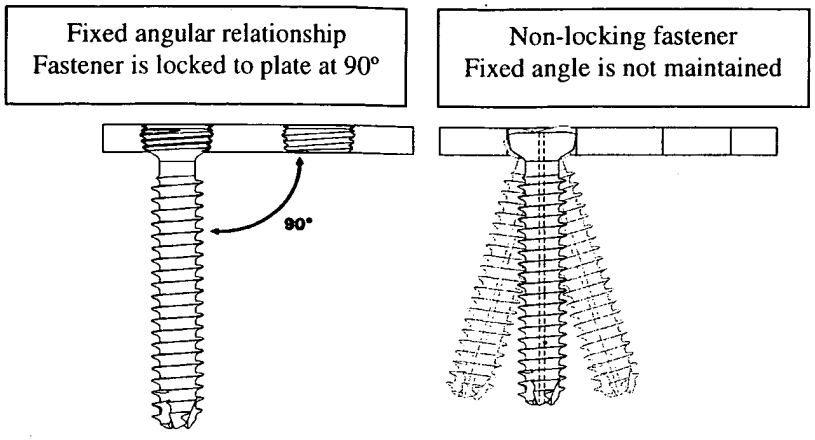
of securing the proximal arms to the bone is described in step 7 of the DRP Guide. This step describes and shows how a screwdriver is used to screw the non-locking screws into the dynamic compression holes on the proximal arms of the distal radius plate. DRP Guide at 8. Thus, the first fasteners (the non-locking 2.7 mm Titanium Self-Tapping Cortex Screws) are be installed first in the proximal arms, before the locking, second fasteners (the locking buttress pins). Accordingly, the DRP Guide discloses a method of use of the distal radius plate where the non-locking first fasteners are inserted before the locking second fasteners.

Use of the distal radius plate beginning with fixation in the proximal arms demonstrates how installation of one or more first, non-locking screws ("first fastener(s)") would compress the plate to the bone to hold a fracture reduction. As the non-locking screws are screwed into the plate, the plate is compressed to the bone to hold the fracture reduction. The use of one non-locking screw ("first fastener") in the proximal arms will maintain the fracture reduction by friction between the bone plate and bone. If additional non-locking screws are used in the proximal arms, the non-locking screws will work together to hold the fracture reduction. The first fasteners (non-locking screws in the proximal arms) will also hold a fracture reduction when the first fasteners work together with fasteners used in the distal holes. If such additional fasteners are installed in the distal arm holes, the fasteners in the proximal arms will form a construct in conjunction with the fasteners installed in the distal arm holes to hold a fracture reduction. Thus, the DRP Guide discloses at least two ways in which the distal radius plate is compressed against the bone with at least one first fastener to hold the fracture reduction.

"securing at least one second fastener at a fixed angular relationship to the bone plate"

The next step of claim 10 requires that at least one second fastener be secured at a fixed angular relationship to the bone plate. The limitation of securing the second fastener at a fixed

angular relationship to the bone plate refers to the requirement that the angle between the fastener and the plate does not change.



In the proximal arm first method, following fixation of the proximal arms, the distal arms are fixed to the plate as described in step 6 of the DRP Guide. As discussed above, the holes in the distal arms can accept either locking pins or non-locking screws. Step 6 discloses that locking pins, non-locking screws, or a combination of both fasteners can be used in the distal arm holes:

> Determine whether 1.8 mm Titanium Buttress Pins or 2.4 mm Titanium Self-Tapping Cortex Screws will be used for fixation of fragments under the distal, articular arm. A combination of both implants may be used.

DRP Guide at 5.

Accordingly, the DRP Guide discloses that 1.8 mm Titanium Buttress Pins can be used in the distal holes after the non-locking screws are installed in the proximal arms. The 1.8 mm Titanium Buttress Pins are locking pins that thread into the distal plate holes to created a locked construct where the fastener is secured to the plate at a fixed angular relationship:

Unique distal articular plate arm:

- Accepts 1.8 mm threaded buttress pins that lock into the threaded plate holes, providing a fixed-angle construct of the articular surface.
- Threaded head locks into threaded plate hole to provide a fixed pin/plate construct and buttress for the articular surface.

DRP Guide, inside cover page.

Thus, the DRP Guide discloses that the locking buttress pins installed in the distal arms are fasteners that are secured at a fixed angular relationship to the bone plate.

"the at least one first fastener and the at least one second fastener remain in bone for substantially as long as the bone plate is implanted"

Finally, all of the fasteners disclosed — the Self-Tapping Cortex Screws and the 1.8 mm Titanium Buttress Pins — are disclosed as remaining in the bone for as long as the distal radius plate is implanted. For example, the DRP Guide shows the step of wound closure immediately following the steps addressing the implantation of the fasteners and there is no disclosure in the Guide regarding removal of any previously installed fasteners. DRP Guide at 5-9.

Accordingly, the proximal arm first technique described in the DRP Guide discloses each and every limitation of claim 10 and anticipates claim 10 under 35 U.S.C. § 102.[5]

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[5] Claim 10 is a method claim, and has almost no structural requirements other than that the method be performed with a bone plate and fasteners. There is no limitation, for example, as to the type or shape of the bone plate or the type or shape of the fasteners. So while the '486 patent device claims are limited to a specific type of hybrid plating system (e.g., a plate with a head and shaft and two types of holes, which utilizes the specific, fixed-angle locking construct of threaded head screws to mate with threads in the locking holes), claim 10 broadly claims the use of any bone plate with *any* fasteners that perform the requisite steps.

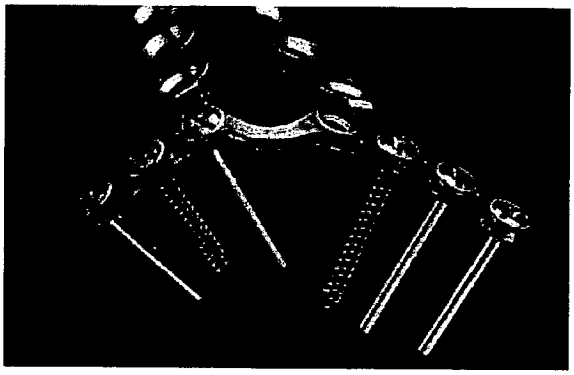
For example, claim 10 does not require the "second fastener" to be a locking screw or engage the bone. Unlike the system claims, which use the word "screw," the method claims use the term "fastener." The DRP Guide discloses that the buttress pin has a threaded head, mates with the threads of the distal plate arm holes, and provides "a fixed-angle construct of the articular surface" when secured to the plate (see the Distal Radius Plate description). Under the broadest reasonable interpretation in view of the specification without improperly importing limitations from the specification, as required by the PTO, a buttress pin is a second fastener that is "secur[ed] . . . at a fixed angular relationship to the bone plate" as required by claim 10. Notably, claim 10 does not require that the second fastener be secured to the *bone*; rather, the claim requires that the fastener be secured to the *plate*.

(3) Claim 11 is Rejected Under 35 U.S.C. 102(b) as Anticipated by the DRP Guide

Claim 11 depends from claim 10 and adds the additional limitation that the "fracture is a peri-articular fracture." Peri-articular fractures are fractures around the joint area. A fracture of the distal radius is a kind of peri-articular fracture. Additionally, as discussed above, the DRP Guide discloses that the distal radius plate can be used to treat "complex intra-articular fractures," which are fractures within the joint region. An intra-articular fracture is a peri-articular fracture. Accordingly, the DRP Guide anticipates claim 11 under 35 U.S.C. § 102.

(4) Claim 13 is Rejected Under 35 U.S.C. 102(b) as Anticipated by the DRP Guide

Claim 13 depends from claim 10 and includes the additional limitation of further securing at least one third fastener at a fixed angular relationship to the bone plate, wherein the third fastener is fixed at a different angular relationship to the bone plate than the second fastener. As shown in the following picture, the DRP Guide discloses multiple locking buttress pins (second and third fasteners) that are fixed to the bone plate at different angular relationships:



Accordingly, the DRP Guide anticipates claim 11 under 35 U.S.C. § 102.

3. Obviousness under 35 U.S.C. § 103(a)

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). "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, 127 S. Ct. 1727, 1739 (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 1739, 1742.

The Supreme Court observed that there was an "overemphasis on the importance of published articles and the explicit content of issued patents." *Id.* at 1741. 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 1742.

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 1741, 1737. 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).

"If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *KSR*, 127 S. Ct. at 1740. *KSR* teaches that "a person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 1742. 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." *Id.* at 1740.

b. The DRP Guide as a Primary Reference

The DRP Guide discloses a bone plate adapted for placement on the dorsal distal radius. DRP Guide, cover illustration. The bone plate has an upper surface and a bone contacting surface. The plate is shaped with a head, or distal arms, formed by two laterally-extending arms, and a pair of shafts extending approximately perpendicular to the shaft. The head portion is configured and dimensioned to conform to the metaphysis of the radius, and the shaft portion is configured and dimensioned to conform to the diaphysis of the radius. The head portion has seven threaded holes, *i.e.,* first holes, into which threaded-head buttress pins or self-tapping cortex screws are installed. When installed, the buttress pins lock in place to provide a fixed pin/plate construct. The shafts, or proximal arms, have elongated dynamic compression unit holes, *i.e.,* second holes, to receive self-tapping cortex screws. *See, e.g.*, DRP Guide at 1. In addition, the DRP Guide indicates that the screws and buttress pins are installed and the wound closed, making it clear that the pins and screws remain in place for as long as the plate is implanted. *See, e.g.*, DRP Guide at 9.

(1) Claims 1, 2, 5-7, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide in view of the Haas Article

The attached DRP Guide in view of Haas § 103 Claim Chart (Exhibit A) is incorporated by reference herein.

Claim 1. The DRP Guide discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of

a bone.[6] The DRP Guide discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The head portion of the plate has only threaded, first holes. The DRP Guide discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the DRP Guide discloses a threaded, locking pin configured and dimensioned to mate with the threads in the first holes, the DRP Guide arguably does not disclose a first screw having a threaded shaft for engaging bone and a threaded head that is configured and dimensioned to mate with the threaded, first holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. As shown in the attached DRP Guide in view of Haas § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article because doing so would provide the known benefit of greater stabilization of the bone fragments. Accordingly, claim 1 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 2. Claim 2 depends from claim 1 and includes the additional limitation of the first screw being a self-tapping screw. For all the reasons described above with respect to claim 1 and the additional fact that the DRP Guide discloses 2.4 mm self-tapping second screws, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article to arrive at the claimed combination, including the self-tapping first screws set forth in claim 2.

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[6] Notably, the DRP Guide is disclosed as "precontoured." *See* DRP Guide at 3. Thus, even though the plate, like the plates of the '486 patent, may be further contoured during surgery to better conform to an individual patient, the DRP Guide nevertheless discloses plates with "a head portion configured and dimensioned to conform to a metaphysis of a bone and a shaft portion configured and dimensioned to conform to a diaphysis of a bone."

Accordingly, claim 2 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 5. Claim 5 depends from claim 1 and includes the additional limitation of the second screw being a self-tapping screw. For all the reasons described above with respect to claim 1 and the additional fact that the DRP Guide discloses 2.4 mm self-tapping second screws, it would have been obvious to a person having ordinary skill in the art to combine the DRP Guide with the Haas Article to arrive at the claimed combination, including the self-tapping second screws set forth in claim 5. Accordingly, claim 5 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 6. Claim 6 depends from claim 1 and includes the additional limitation of substantially conically shaped first plate holes. For all the reasons described above with respect to claim 1 and the additional fact that the Haas Article discloses substantially conically shaped threaded, first plate holes, it would have been obvious to a person having ordinary skill in the art to combine the DRP Guide with the Haas Article to arrive at the claimed combination, including the substantially conically shaped first plate holes set forth in claim 6. Accordingly, claim 6 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 7. Claim 7 depends from claim 6 and includes the additional limitation of the first plate hole having a double lead thread. For all the reasons described above with respect to claim 6 and the additional fact that the Haas Article discloses plate holes having double lead threads, it would have been obvious to a person having ordinary skill in the art to combine the DRP Guide with the Haas Article to arrive at the claimed combination, including the first plate hole having a double lead thread as set forth in claim 7. Accordingly, claim 7 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 14. The DRP Guide discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The DRP Guide discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The head portion of the plate has only threaded, first holes. The DRP Guide discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the DRP Guide discloses a threaded, locking pin configured and dimensioned to mate with the threads in the first holes, the DRP Guide arguably does not disclose a first screw having a threaded shaft for engaging bone and a threaded head that is configured and dimensioned to mate with the threaded, first holes. The DRP Guide also arguably does not disclose a head portion that flares outward from the shaft. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. The Haas Article also discloses a plate with a head portion configured and dimensioned to conform to the metaphysis of a bone that flares outward from the shaft. As shown in the attached DRP Guide in view of Haas § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article. Accordingly, claim 14 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 15. Claim 15 depends from claim 14 and includes the additional limitation of the head portion being provided with suture holes. For all the reasons described above with respect to claim 14 and the additional fact that suture holes are disclosed in the Haas Article, it would have been obvious to a person having ordinary skill in the art to combine the DRP Guide with

the Haas Article to arrive at the claimed combination, including the head portion being provided with suture holes as set forth in claim 15. Accordingly, claim 15 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

Claim 17. The DRP Guide discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The DRP Guide discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The head portion of the plate has only threaded, first holes. The shaft portion has only unthreaded holes. The DRP Guide discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the DRP Guide discloses a threaded, locking pin configured and dimensioned to mate with the threads in the first holes, the DRP Guide arguably does not disclose a first screw having a threaded shaft for engaging bone and a threaded head that is configured and dimensioned to mate with the threaded, first holes. The DRP Guide also arguably does not disclose a shaft portion that has both first and second plate holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. The Haas Article discloses threaded holes in the shaft portion of the plate. As shown in the attached DRP Guide in view of Haas § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article. Likewise it would have been obvious to combine the unthreaded holes of the shaft shown in the DRP Guide with the threaded holes in the shaft shown in the Haas Article to arrive at the shaft portion that has

both first and second holes as set forth in claim 17. Accordingly, claim 17 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article.

(2) Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide in view of the Haas Article and Admitted Prior Art in the '486 patent

Claim 3. Claim 3 depends from claim 1 and includes the additional limitation of the first screw being a self-drilling screw. For all the reasons described above with respect to claim 1 and the additional fact that the '486 patent acknowledges that self-drilling screws were well known in the prior art (col. 4, lines 28-40), it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article and further include the well known prior art self-drilling screws. Accordingly, claim 3 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article and further in view of the self-drilling screws well known in the prior art.

Claim 9. Claim 9 depends from claim 1 and includes the additional limitation of at least one of the second plate holes being longitudinally elongated and having an edge inclined at an angle to the upper surface toward the bone-contacting surface for displacing the bone plate when engaged by the head of a second bone screw. For all the reasons described above with respect to claim 1 and the additional fact that the '486 patent acknowledges that dynamic compression holes of the type claimed in claim 9 are shown in the prior art (*e.g.*, U.S. Patent No. Re. 31,628), it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article and further include the well known prior art dynamic compression holes. Accordingly, claim 9 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article and further in view of the DCU type plate holes well known in the prior art.

(3) Claim 4 is rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide in view of the Haas Article and the Decoste prior art patent

Claim 4. Claim 4 depends from claim 1 and includes the additional limitation of the first screw being cannulated for insertion of a guide wire to guide screw placement. For all the reasons described above with respect to claim 1 and the additional fact that the Decoste prior art patent discloses cannulated screws for insertion of a guide wire to guide screw placement, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article and further include the cannulated screws for insertion of a guide wire to guide screw placement disclosed in the Decoste prior art patent. Accordingly, claim 4 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article and further in view of the Decoste prior art patent.

(4) Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide in view of the Haas Article and the Klaue prior art patent

Claim 8. Claim 8 depends from claim 1 and includes the additional limitation of the bone plate having a trapezoidal shaped cross section in regions between the first and second plate holes for minimizing contact between bone and the bone contacting surface. For all the reasons described above with respect to claim 1 and the additional fact that the Klaue prior art patent discloses a bone plate having a trapezoidal shaped cross section in regions between the plate holes for minimizing contact between bone and the bone contacting surface, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article and further include the trapezoidal shaped cross section in regions between the first and second plate holes disclosed

in the Klaue prior art patent. Accordingly, claim 8 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article and further in view of the Klaue prior art patent.

Claim 18. The DRP Guide discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The DRP Guide discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The head portion of the plate has only threaded, first holes. The DRP Guide discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the DRP Guide discloses a threaded, locking pin configured and dimensioned to mate with the threads in the first holes, the DRP Guide arguably does not disclose a first screw having a threaded shaft for engaging bone and a threaded head that is configured and dimensioned to mate with the threaded, first holes. The DRP Guide also arguably does not disclose the shaft portion having a trapezoidal shaped cross section in regions between the first and second screw holes for minimizing contact between bone and the bone contacting surface.

The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. Further, the Klaue prior art patent discloses a plate having a trapezoidal shaped cross section in regions between the screw holes for minimizing contact between bone and the bone contacting surface. As shown in the attached DRP Guide in view of Haas and in further view of Klaue § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article and further include the trapezoidal shaped cross section in regions between the screw

holes for minimizing contact between bone and the bone contacting surface disclosed in the Klaue prior art patent. Accordingly, claim 18 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article in further view of the Klaue prior art patent.

(5) Claim 12 is rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide in view of the Koval Article

Claim 12. Claim 12 depends from claim 10 and includes the additional limitation of the fracture being adjacent at least to one of the following group: a distal tibia, a proximal tibia, a distal femur, or a proximal femur. As discussed above, the DRP Guide anticipates claim 10. While the DRP Guide discloses a method for treating the radius bone with the distal radius plate, the DRP Guide arguably does not disclose a method for treating a fracture in one of a proximal tibia, a distal femur, or a proximal femur. The Koval Article discloses use of the Koval plate for fracture fixation for treating a fracture in the distal femur. The combination of the DRP Guide and the Koval plate would be a straightforward and common sense application of a method for the use of one hybrid bone plate used to treat a periarticular fracture of the radius bone to another hybrid bone plate used to treat a periarticular fracture of the femur bone. Persons of ordinary skill in the art — particularly surgeons — face diverse clinical situations with every surgery, and would be motivated to modify and combine the various available devices and tools in order to address those diverse situations. The motivation to make these modifications ultimately comes from the desire to provide the best treatment possible for the particular fracture and the particular details of the patient's anatomy, and one of skill in the art would readily grasp that the various devices and methods for using them that are described in the prior art literature could be combined to provide this treatment.

Because of the identical hybrid nature of these two plates and the similar type of fractures (*i.e.*, periarticular fractures) it would be obvious to apply the known method to another bone

fracture as set forth in claim 12. Like the distal radius plate disclosed in the DRP Guide, the Koval plate is a locking/nonlocking hybrid plate. For all the reasons described above with respect to claim 10, and the additional fact that the Koval Article discloses use of the Koval plate for fracture fixation for treating a fracture in the distal femur, it would have been obvious to a person having ordinary skill in the art to combine the method disclosed in the DRP Guide with the Koval plate disclosed in the Koval Article for fracture fixation for treating a fracture in the distal femur to arrive at the claimed method of fixation for a fracture being adjacent at least to one of the following group: a distal tibia, a proximal tibia, a distal femur, or a proximal femur, as set forth in claim 12. Accordingly, claim 12 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Koval Article.

(7) Claim 16 is rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide in view of the Haas Article and the Koval Article

Claim 16. The DRP Guide discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The DRP Guide discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The head portion of the plate has only threaded, first holes. The DRP Guide discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the DRP Guide discloses a threaded, locking pin configured and dimensioned to mate with the threads in the first holes, the DRP Guide arguably does not disclose a first screw having a threaded shaft for engaging bone and a threaded head that is configured and dimensioned to mate with the threaded, first holes. The DRP Guide also arguably does not disclose a head portion having a curved surface and including an anterior fork substantially parallel to an anterior side of the shaft portion, and further including a posterior fork

extending out from a posterior side of the shaft portion. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. The Koval Article discloses a plate with a head portion having a curved surface and including an anterior fork substantially parallel to an anterior side of the shaft portion, and further including a posterior fork extending out from a posterior side of the shaft portion. As shown in the attached DRP Guide in view of Haas and in further view of the Koval Article § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the DRP Guide with the threaded head screws disclosed in the Haas Article and further include the head structure having the anterior and posterior forks disclosed in the Koval Article. Accordingly, claim 16 is obvious under 35 U.S.C. § 103(a) over the DRP Guide in view of the Haas Article and further in view of the Koval Article.

(8) Claims 10, 11, and 13 are rejected under 35 U.S.C. 103(a) as rendered obvious by the DRP Guide

Claim 10. The DRP Guide discloses a method for use of the distal radius plate where the plate is first secured to the bone in the proximal arms, followed by securing the distal arms to the bone. As discussed above, Smith & Nephew submits that the DRP Guide discloses each and every limitation of claim 10. To the extent any ambiguity is found as to any aspect of the DRP Guide's disclosure relevant to the limitations of claim 10, however, each step or feature would have been obvious to a person having ordinary skill in the art, as explained below. A secondary reference is not necessary to render claim 10 obvious as a person having ordinary skill in the art would be motivated and possess the requisite knowledge to apply and/or modify the teachings from the DRP Guide to include each feature. *See KSR*, 127 S. Ct. at 1740 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the

same reason, 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 his or her skill."), 1742 ("a person of ordinary skill is also a person of ordinary creativity, not an automaton.").

"A method for fracture fixation of bone comprising the steps of"

As discussed above, the DRP Guide unquestionably discloses a method for fracture fixation of bone, specifically a method for treating fractures of the distal radius bone.

"reducing the fracture to bring bone fragments in close apposition"

As discussed above, the DRP Guide discloses that if a doctor cannot achieve acceptable reduction of a fracture by closed means (*i.e.*, without surgery), operative exposure (*i.e.*, surgery) may be required to reduce the fracture. To the extent any ambiguity is found as to the DRP Guide's disclosure of the reduction step, it would have been obvious to a person having ordinary skill in the art, such as a surgeon, to reduce the fracture to bring the bone fragments in close apposition when performing a surgery with the distal radius plate. A person having ordinary skill in the art would recognize and appreciate that the precise method of implanting a bone plate during surgery depends on each patient's unique circumstances. A person having ordinary skill in the art would also recognize that there may be benefits to first reducing the fracture, including allowing the bone fragments to more easily fuse together as the bone heals after surgery.

"compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction" and "wherein the at least one first fastener is inserted before the at least one second fastener"

As discussed above, the DRP Guide discloses compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction.

The DRP Guide also discloses two potential installation methods: one, the method where the proximal arms are first fixed to the bone, and two, the method where the distal arms are first

fixed to the bone. *See, e.g.*, DRP Guide at 5 ("[t]he specific order of fixation (proximal or distal arm) depends on the fracture pattern and clinical situation"). At least the first method of fixing the proximal arm to the bone using one or more first, standard, compression, non-locking screws ("first fastener(s)") compresses the plate to the bone to hold the fracture reduction.

To the extent any ambiguity is found as to the DRP Guide's disclosure of these features, it would have been obvious to a person having ordinary skill in the art, such as a surgeon, to compress the distal radius plate to the bone with one or more first fasteners to hold the fracture reduction when performing a surgery with the distal radius plate. A surgeon would know to hold a fracture reduction as part of a typical surgery and would realize that one common sense way to do so would be to compress the bone plate to the bone using a first fastener, such as a non-locking screw. Similarly, the order of the buttress pin and screw insertion in the DRP Guide is a choice to be made by the surgeon and one of ordinary skill in the art would recognize the benefits of fixing the proximal arms before the distal arms depending on the fracture pattern and clinical situation.

"securing at least one second fastener at a fixed angular relationship to the bone plate"

As discussed above, the DRP Guide discloses that in the proximal arm first method, the distal arms are fixed to the plate after fixation of the proximal arms. The distal arms may be secured to the bone using locking 1.8 mm Titanium Buttress Pins, non-locking 2.4 mm Self-Tapping Cortex Screws, or a combination of both fasteners. The 1.8 mm Titanium Buttress Pins are locking pins that thread into the distal plate holes to created a locked construct where the fastener is secured to the plate at a fixed angular relationship.

To the extent any ambiguity is found as to the DRP Guide's disclosure of the securing step, it would have been obvious to a person having ordinary skill in the art to secure a locking

buttress pin at a fixed angular relationship to the distal radius plate in situations where the proximal arms have first been secured to the bone. The benefits of securing a fastener at a fixed angular relationship to the plate would be obvious to a surgeon. In addition, it would be obvious for a person having ordinary skill in the art to modify the locking pin disclosed in the DRP Guide to include threads on the shaft of the pin.

"the at least one first fastener and the at least one second fastener remain in bone for substantially as long as the bone plate is implanted"

As discussed above, the DRP Guide discloses that the fasteners (1.8 mm Titanium Buttress Pins and Self-Tapping Cortex Screws) remain in the bone for as long as the distal radius plate is implanted because the step of wound closure in the Guide immediately follows the steps addressing the implantation of the fasteners and there is no indication that any fasteners are removed. To the extent any ambiguity is found as to the DRP Guide's disclosure of this feature, it would have been obvious to a person having ordinary skill in the art to leave the fasteners in bone for substantially as long as the distal radius plate is implanted. Doing so would be common sense for a surgeon. *See KSR*, 127 S. Ct. at 1742 ("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.").

Accordingly, claim 10 is obvious under 35 U.S.C. § 103(a) over the DRP Guide.

Claim 11. Claim 11 depends from claim 10 and adds the additional limitation that the "fracture is a peri-articular fracture." As discussed above, the DRP Guide anticipates claim 11 as it discloses that the distal radius plate can be used to treat intra-articular fractures, which are peri-articular fractures. To the extent any ambiguity is found as to the DRP Guide's disclosure of this

feature, it would have been obvious to a person having ordinary skill in the art, such as a surgeon, to perform the steps listed in the DRP Guide on a peri-articular fracture – a common type of fracture well known to surgeons. A secondary reference is not necessary to render claim 11 obvious as a person having ordinary skill in the art would be motivated and possess the requisite knowledge to apply the teachings from the DRP Guide to a peri-articular fracture. *See id.* at 1740 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."). Accordingly, claim 11 is obvious under 35 U.S.C. § 103(a) over the DRP Guide.

Claim 13. Claim 13 depends from claim 10 and includes the additional limitation of further securing at least one third fastener at a fixed angular relationship to the bone plate, wherein the third fastener is fixed at a different angular relationship to the bone plate than the second fastener. As discussed above, the DRP Guide anticipates claim 13 as it discloses multiple locking buttress pins (second and third fasteners) that are fixed to the bone plate at different angular relationships. To the extent any ambiguity is found as to the DRP Guide's disclosure of this feature, it would have been obvious to a person having ordinary skill in the art, such as a surgeon, to perform the steps listed in the DRP Guide and secure a locking buttress pin at a different angular relationship to the bone plate than another locking buttress pin. A secondary reference is not necessary to render claim 13 obvious as a person having ordinary skill in the art would be motivated and possess the requisite knowledge to apply the teachings from the DRP Guide to secure a third fastener at a different angular relationship to the bone plate than the second fastener. *See id.* at 1740 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."). Accordingly, claim 13 is obvious under 35 U.S.C. § 103(a) over the DRP Guide.

c. The Koval Article as a Primary Reference

The Koval Article discloses the use of hybrid plating with traditional fasteners and fixed angle, locking fasteners to treat fractures of the distal femur. *See, e.g.*, Koval Article at 521. The Koval Article discloses a standard Synthes lateral condylar buttress plate used to treat peri-articular fractures of the distal femur that has been modified to allow for a fixed angle locking construct in four of the six holes in the head of the plate. *See, e.g.*, Koval Article at 522, Fig. 1.

Thus, the Koval Article provides a condylar buttress plate for use on the distal femur with holes in the proximal shaft end that receive only standard non-locking screws and holes in the distal head end that can receive locking fasteners. *See, e.g.*, Koval Article at 522. The Koval plate is similar to the distal radius plate in that the distal radius plate is also a hybrid plate that receives only standard non-locking screws in the proximal shaft end and has holes in the distal head end that can receive locking fasteners. *See, e.g.*, Koval Article at 522.

(1) Claims 1, 6, 7, and 14-17 are rejected under 35 U.S.C. 103(a) as rendered obvious by the Koval Article in view of the Haas Article

The attached Koval in view of Haas § 103 Claim Chart (Exhibit C) is incorporated by reference herein.

Claim 1. The Koval Article discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The Koval Article discloses a plurality of threaded, first holes[7] and a plurality of

[7] Notably, and as further set forth in the Koval in view of Haas § 103 Claim Chart, the Koval Article specifies that the potential contouring could occur in "unreinforced tapped screw holes." Koval Article at 524. Thus, this would not occur if the screw holes were *reinforced.* Indeed, Koval notes that the built-up threaded inserts used in the study did not distort during

unthreaded, second holes. The Koval Article discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the Koval Article discloses screws with threads on the shafts to engage bone that are used in the threaded, first holes, the Koval Article arguably does not disclose a first screw having a threaded head configured and dimensioned to mate with the threads on the first holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. Additionally, while the Koval Article discloses four threaded, first holes in the head portion of a bone plate, the Koval Article arguably does not disclose a head portion that has only threaded, first holes. The Haas Article discloses a bone plate that has only threaded, first holes in the head portion. As shown in the attached Koval in view of Haas § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws and head portion having only threaded, first holes disclosed in the Haas Article because doing so would provide the known benefit of greater stabilization of the bone fragments. Accordingly, claim 1 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

Claim 6. Claim 6 depends from claim 1 and includes the additional limitation of substantially conically shaped first plate holes. For all the reasons described above with respect to claim 1 and the additional fact that the Haas Article discloses substantially conically shaped threaded, first plate holes, it would have been obvious to a person having ordinary skill in the art to combine the Koval Article with the Haas Article to arrive at the claimed combination,

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contouring. *Id.* Therefore, Koval discloses the use of tapped (*i.e.*, threaded) screw holes, and cannot be considered to teach away from such.

including the substantially conically shaped first plate holes set forth in claim 6. Accordingly, claim 6 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

Claim 7. Claim 7 depends from claim 6 and includes the additional limitation of the first plate hole having a double lead thread. For all the reasons described above with respect to claim 6 and the additional fact that the Haas Article discloses plate holes having double lead threads, it would have been obvious to a person having ordinary skill in the art to combine the Koval Article with the Haas Article to arrive at the claimed combination, including the first plate hole having a double lead thread as set forth in claim 7. Accordingly, claim 7 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

Claim 14. The Koval Article discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The Koval Article discloses a head portion that flares outward from the shaft. The Koval Article discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The Koval Article discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the Koval Article discloses screws with threads on the shafts to engage bone that are used in the threaded, first holes, the Koval Article arguably does not disclose a first screw having a threaded head configured and dimensioned to mate with the threads on the first holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. As shown in the attached Koval in view of Haas § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas

Article. Accordingly, claim 14 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

Claim 15. Claim 15 depends from claim 14 and includes the additional limitation of the head portion being provided with suture holes. For all the reasons described above with respect to claim 14 and the additional fact that suture holes are disclosed in the Haas Article, it would have been obvious to a person having ordinary skill in the art to combine the Koval Article with the Haas Article to arrive at the claimed combination, including the head portion being provided with suture holes as set forth in claim 15. Accordingly, claim 15 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

Claim 16. The Koval Article discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion with a curved surface configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The Koval Article discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The Koval Article discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. The Koval Article discloses an anterior fork substantially parallel to the anterior side of the shaft portion and a posterior fork extending out from the posterior side of the shaft portion. While the Koval Article discloses screws with threads on the shafts to engage bone that are used in the threaded, first holes, the Koval Article arguably does not disclose a first screw having a threaded head configured and dimensioned to mate with the threads on the first holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. As shown in the attached Koval in view of Haas § 103 Claim Chart, it would have been obvious to a person having

ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article. Accordingly, claim 16 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

Claim 17. The Koval Article discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The Koval Article discloses a plurality of threaded, first holes and a plurality of unthreaded, second holes. The Koval Article discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the Koval Article discloses screws with threads on the shafts to engage bone that are used in the threaded, first holes, the Koval Article arguably does not disclose a first screw having a threaded head configured and dimensioned to mate with the threads on the first holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. Additionally, while the Koval Article discloses unthreaded, second holes in the shaft portion of a bone plate, the Koval Article arguably does not disclose a shaft portion that has both threaded, first holes and unthreaded, second holes. The Haas Article discloses threaded holes in the shaft portion of the plate. As shown in the attached Koval Article in view of Haas § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the unthreaded holes of the shaft shown in the Koval Article with the threaded holes in the shaft shown in the Haas Article to arrive at the shaft portion that has both first and second holes as set forth in claim 17. Also as shown in the attached Koval Article in view of Haas § 103 Claim Chart, it would also have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in

the Koval Article with the threaded head screws disclosed in the Haas Article. Accordingly, claim 17 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article.

(2) Claims 2, 3, 5, and 9 are rejected under 35 U.S.C. 103(a) as rendered obvious by the Koval Article in view of the Haas Article and Admitted Prior Art in the '486 patent

Claim 2. Claim 2 depends from claim 1 and includes the additional limitation of the first screw being a self-tapping screw. For all the reasons described above with respect to claim 1 and the additional fact that the '486 patent acknowledges that self-tapping screws were well known in the prior art (col. 4, lines 28-40), it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the well known prior art self-tapping screws. Accordingly, claim 2 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article and further in view of the self-tapping screws well known in the prior art.

Claim 3. Claim 3 depends from claim 1 and includes the additional limitation of the first screw being a self-drilling screw. For all the reasons described above with respect to claim 1 and the additional fact that the '486 patent acknowledges that self-drilling screws were well known in the prior art (col. 4, lines 28-40), it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the well known prior art self-drilling screws. Accordingly, claim 3 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article and further in view of the self-drilling screws well known in the prior art.

Claim 5. Claim 5 depends from claim 1 and includes the additional limitation of the second screw being a self-tapping screw. For all the reasons described above with respect to

claim 1 and the additional fact that the '486 patent acknowledges that self-tapping screws were well known in the prior art (col. 4, lines 28-40), it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the well known prior art self-tapping screws. Accordingly, claim 5 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article and further in view of the self-tapping screws well known in the prior art.

Claim 9. Claim 9 depends from claim 1 and includes the additional limitation of at least one of the second plate holes is longitudinally elongated and has an edge inclined at an angle to the upper surface toward the bone-contacting surface for displacing the bone plate when engaged by the head of a second bone screw. For all the reasons described above with respect to claim 1 and the additional fact that the '486 patent acknowledges that dynamic compression holes of the type claimed in claim 9 are shown in the prior art (e.g., U.S. patent No. Re. 31, 628), it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the well known prior art dynamic compression holes. Accordingly, claim 9 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article and further in view of the DCU type plate holes well known in the prior art.

(3) Claim 4 is rejected under 35 U.S.C. 103(a) as rendered obvious by the Koval Article in view of the Haas Article and the Decoste prior art patent

Claim 4. Claim 4 depends from claim 1 and includes the additional limitation of the first screw being cannulated for insertion of a guide wire to guide screw placement For all the reasons described above with respect to claim 1 and the additional fact that the Decoste prior art patent discloses cannulated screws for insertion of a guide wire to guide screw placement, it

would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the cannulated screws for insertion of a guide wire to guide screw placement disclosed in the Decoste prior art patent. Accordingly, claim 4 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article and further in view of the Decoste prior art patent.

(4) Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as rendered obvious by the Koval Article in view of the Haas Article and the Klaue prior art patent

Claim 8. Claim 8 depends from claim 1 and includes the additional limitation of the bone plate having a trapezoidal shaped cross section in regions between the first and second plate holes for minimizing contact between bone and the bone contacting surface. For all the reasons described above with respect to claim 1 and the additional fact that the Klaue prior art patent discloses a bone plate having a trapezoidal shaped cross section in regions between the plate holes for minimizing contact between bone and the bone contacting surface, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the trapezoidal shaped cross section in regions between the first and second plate holes disclosed in the Klaue prior art patent. Accordingly, claim 8 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article and further in view of the Klaue prior art patent.

Claim 18. The Koval Article discloses a bone plate with upper and lower surfaces for fixation of bone having a head portion configured and dimensioned to conform to the metaphysis of a bone and having a shaft portion configured and dimensioned to conform to the diaphysis of a bone. The Koval Article discloses a head portion that flares outward from the shaft. The Koval Article discloses a plurality of threaded, first holes and a plurality of unthreaded, second

holes. The Koval Article discloses second screws with threaded shafts that remain seated in the plate holes as long as the bone plate is implanted. While the Koval Article discloses screws with threads on the shafts to engage bone that are used in the threaded, first holes, the Koval Article arguably does not disclose a first screw having a threaded head configured and dimensioned to mate with the threads on the first holes. The Haas Article discloses screws having threaded shafts for engaging bone and threaded heads that are configured and dimensioned to mate with threaded, first plate holes. Additionally, the Koval Article arguably does not disclose a shaft portion having a trapezoidal shaped cross section in regions between the first and second screw holes for minimizing contact between bone and the bone contacting surface. The Klaue prior art patent discloses a plate having a trapezoidal shaped cross section in regions between the screw holes for minimizing contact between bone and the bone contacting surface. As shown in the attached Koval Article in view of Haas and in further view of Klaue § 103 Claim Chart, it would have been obvious to a person having ordinary skill in the art to combine the plate and screws disclosed in the Koval Article with the threaded head screws disclosed in the Haas Article and further include the trapezoidal shaped cross section in regions between the screw holes for minimizing contact between bone and the bone contacting surface disclosed in the Klaue prior art patent. Accordingly, claim 18 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the Haas Article in further view of the Klaue prior art patent.

(5) Claims 10-13 are rejected under 35 U.S.C. 103(a) as rendered obvious by the Koval Article in view of the DRP Guide

Claim 10. The Koval Article discloses a bone plate that can be used to treat fractures of the distal femur. The Koval Article discloses a plate that has a plurality of threaded, first holes and a plurality of unthreaded, second holes. The Koval Article discloses testing the prototype plate as installed on femurs and the construct was tested using a servohydraulic testing machine.

The Koval Article also discloses potential use of the plate evaluated in the article in a clinical setting. Koval Article at 524.

It would be obvious to combine the method for use of the combination locking and non-locking plate described in the Koval Article with the method described in the DRP Guide. Because of the identical hybrid nature of these two plates and the similar type of fractures (i.e., periarticular fractures) it would be obvious to apply the known method to another bone fracture as set forth in claim 10. To the extent the Koval Article does not disclose the first step of reducing the fracture to bring bone fragments in close apposition, as described above, the DRP Guide discloses this step. The Koval Article discloses the use of non-locking compression screws (e.g., a first fastener) on the shaft portion of the plate. As these screws are installed through the shaft of the plate into the bone, the plate will be compressed to the bone and in a clinical setting such screws will hold a fracture reduction. To the extent the Koval Article does not disclose the step of compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction, as described above, the DRP Guide discloses this step.

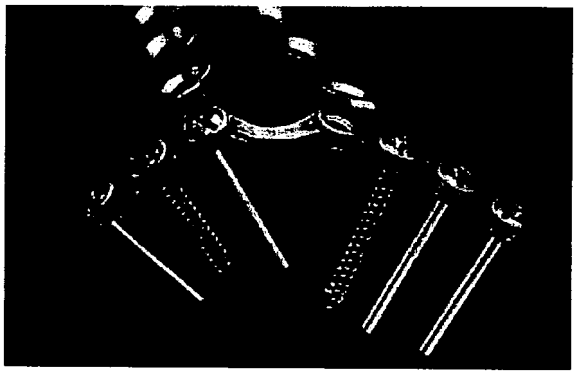
The Koval Article discloses the use of screws that are locked to the plate and installed in the threaded holes in the head portion of the plate. These screws are installed in the head portion of the plate such that the threads on the screw mate with the threads in the threaded holes and are thus secured to the plate at a fixed angular relationship (*e.g.*, second fasteners). As the construct installed in the Koval Article utilized both standard non-locking screws in the unthreaded holes and locked screws in the threaded holes, Koval must have installed a standard non-locking screw in an unthreaded hole followed by a locked screw in a threaded hole, or vice versa. To the extent that the Koval Article does not disclose inserting at least one first (non-locking) fastener before inserting at least one second (locking) fastener, as described above, the DRP Guide discloses this

step. The disclosure of the potential use of the Koval plate in a clinical setting would inform one skilled in the art that the screws used with the Koval plate (i.e., the first and second fasteners) would be left installed in the plate for substantially as long as the plate is implanted. To the extent that the Koval Article does not disclose a first fastener and a second fastener remaining in bone for substantially as long as the bone plate is implanted, the DRP Guide discloses this step. Accordingly, claim 10 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the DRP Guide.

Claim 11. Claim 11 depends from claim 10 and adds the additional limitation that the "fracture is a peri-articular fracture." Peri-articular fractures are fractures around the joint area. A fracture of the distal femur is a kind of peri-articular fracture. The Koval Article discloses the use of the Koval plate to treat periarticular fractures of the distal femur. Accordingly, for all the reasons described above with respect to claim 10, and the additional fact that the Koval Article discloses the use of the Koval plate to treat periarticular fractures of the distal femur as set forth in claim 11, claim 11 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the DRP Guide.

Claim 12. Claim 12 depends from claim 10 and includes the additional limitation of the fracture being adjacent at least to one of the following group: a distal tibia, a proximal tibia, a distal femur, or a proximal femur. The Koval Article discloses use of the Koval plate for fracture fixation for treating a fracture in the distal femur. For all the reasons described above with respect to claim 10, and the additional fact that the Koval Article discloses use of the Koval plate for fracture fixation for treating a fracture in the distal femur as set forth in claim 12, claim 12 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the DRP Guide.

Claim 13. Claim 13 depends from claim 10 and includes the additional limitation of further securing at least one third fastener at a fixed angular relationship to the bone plate, wherein the third fastener is fixed at a different angular relationship to the bone plate than the second fastener. As shown in the following picture, the DRP Guide discloses multiple locking buttress pins (second and third fasteners) that are fixed to the bone plate at different angular relationships:



For all the reasons described above with respect to claim 10, and the additional fact that the DRP Guide discloses multiple locking buttress pins (second and third fasteners) that are fixed to the bone plate at different angular relationships as set forth in claim 13, claim 13 is obvious under 35 U.S.C. § 103(a) over the Koval Article in view of the DRP Guide.

CONCLUSION

For the reasons set forth above, Smith & Nephew respectfully request reexamination and rejection of claims 1-18 of the '486 patent.

Respectfully submitted,

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Dated: January 8, 2009

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