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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Wright Medical Technology, Inc.,

Petitioner

v.

Owner of
U.S. Patent No. 6,955,677 to Dahners
Appl. No. 10/271,635 filed October 15, 2002
Issued October 18, 2005

IPR Trial No. *TBD*

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,955,677 PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108

TABLE OF CONTENTS

Page No.

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

EXHIBIT LIST

Exhibit No.	Description	Short Reference
1001	U.S. Patent No. 6,955,677	the ’677 Patent
1002	Declaration of Dr. Sayed Nassar (“Dr. Nassar”)	Nassar Declaration
1003	Curriculum Vitae of Dr. Nassar	Dr. Nassar CV
1004	List of documents reviewed by Dr. Nassar in preparing his declaration	
1005	Wolter et al., “Universal Internal Titanium Fixation Device: Developmental History, Principle, Mechanics, Implant Design And Surgical Use,” TRAUMA AND OCCUPATIONAL DISORDERS (1999) (certified English translation of Exhibit 1006)	Universal
1006	Wolter et al., “Universeller Titanfixateur interne: Entwicklungsgeschichte, Prinzip, Mechanik, Implantatgestaltung und operativer Einsatz,” TRAUMA BERUFSKRANKH (1999)	
1007	DE 198 58 889 to Wolter	
1008	DE 198 58 889 to Wolter (certified English Translation)	Wolter 889
1009	DE 43 43 117 A1 to Wolter	
1010	DE 43 43 117 A1 to Wolter (certified English translation)	Wolter 117
1011	DE 196 29 011 A1 to Wolter	
1012	DE 196 29 011 A1 to Wolter (certified English translation)	Wolter 011
1013	CA 2 626 694	Wagner
1014	U.S. Patent No. 6,206,881	Frigg ’881
1015	U.S. Patent No. 5,709,686	Talos
1016	Webster’s II New Riverside Dictionary (1996)	Webster’s Dict.
1017	Invalidity Claim Chart of U.S. Patent 6,955,677 in view of *Universal* and the Knowledge of a Person of Ordinary Skill in the Art	

1018	Complaint filed in *AngleFix Tech*, *Inc. v. Wright Medical*, *Inc.*, Case No. 2:2013-cv-02407 (W.D. Tn. June 11, 2013)	Complaint
1019	Decision: Institution of *Inter Partes* Review of U.S. Patent No. 6,955,677 (IPR2014-00112)	'677 IPR Decision

I. MANDATORY NOTICES

A. Real Party-In-Interest

Wright Medical Technology, Inc. is the real party-in-interest. Wright Medical Technology, Inc., is a wholly-owned subsidiary of Wright Medical Group, Inc.

B. Related Matters

Other matters that may affect or be affected by a decision in this proceeding include: *AngleFix Tech, LLC v. Wright Medical Technology, Inc.*, Civil Action No. 2:13-cv-02407-JPM-tmp (W.D. Tenn.); and *AngleFix Tech, LLC v. Smith & Nephew, Inc.*, Civil Action No. 2:13-cv-02281-JPM-tmp (W.D. Tenn.).

C. Counsel And Service Information

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II. CERTIFICATION OF GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Wright Medical Technology, Inc. ("Wright Medical") certifies that U.S. Patent No. 6,955,677 ("the '677 patent") is available for *inter partes* review and that Wright Medical is not barred or estopped

from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

III. OVERVIEW OF THE CHALLENGE AND RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b)(1)-(2), Wright Medical respectfully requests *inter partes* review of Claims 1-4, 9, 11-12, 18, 21-25, 28, 30-31, 33-34, 39-44, 47-48, 54-57, 60, 62-63, 65-66, and 71-74 of the '677 patent (Ex. 1001) and requests that each challenged claim be canceled. The earliest priority date of the '677 patent is October 15, 2002.

A. Prior Art

Wright Medical relies upon the following patents, published patent applications, and published non-patent literature:

1. "Universal Internal Titanium Fixation Device: Developmental History, Principle, Mechanics, Implant Design And Surgical Use" by Wolter et al. ("*Universal*") (Ex. 1005), which was published in 1999 in Trauma and Occupational Disorders, published by Springer-Verlag, and is prior art under 35 U.S.C. § 102(b).

This reference was not before the Examiner during the prosecution of the '677 patent.

B. Grounds for Challenge

Wright Medical requests cancellation of Claims 1-4, 9, 11-12, 18, 21-25, 28, 30-31, 33-34, 39-44, 47-48, 54-57, 60, 62-63, 65-66, and 71-74 ("Challenged

Claims") as unpatentable under 35 U.S.C. § 103. Attached to this petition is the declaration of Dr. Sayed Nassar ("Dr. Nassar") (Ex. 1002), his Curriculum Vitae (Ex. 1003), and a list of documents he considered (Ex. 1004). Dr. Nassar's declaration supports the grounds in this petition showing that there is a reasonable likelihood that Wright Medical will prevail and that each challenged claim is not patentable.

IV. OVERVIEW OF THE '677 PATENT

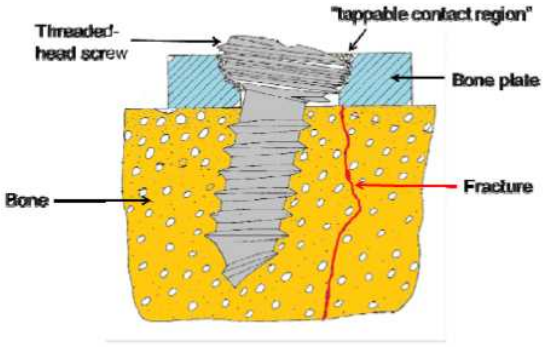
A. The '677 Patent Specification

The '677 patent is directed to orthopedic bone screw/plate fixation systems, i.e., orthopedic fixation systems comprising a bone plate and at least one bone screw. Ex. 1001 at Col. 1:17-11. As admitted in the Background Art section of the '677 patent, these fixation systems were known to come in two types: non-locking and locking. *Id*. at 1:15-27. In non-locking systems, a bone plate is provided that defines a plurality of non-threaded holes each sized and configured to receive a bone screw therein. *Id*. at 1:15-21. These non-locking systems enable screws to be inserted in the holes defined by the bone plates in a number of angles.

Locking systems also include a bone plate defining a plurality of holes each sized and configured to receive a respective bone screw therein. *Id*. at 1:21-35. However, the bone screws of the locking systems include threaded heads that are configured to mate with a thread formed on the inner surface of the holes defined

by the bone plates. *Id*. These systems are designed such that the screws are to be inserted into the respective holes at a predetermined angle. *Id*.

The specification of the ’677 patent acknowledges the advantages of locking systems over non-locking systems, but states “there remains the disadvantage that currently available screw/plate systems are unidirectional” and “[i]t would therefore be advantageous to provide a screw/plate system that allows the surgeon to choose the angle at which the screw is inserted through, and rigidly affixed in, an aperture of the plate.” *Id*. at 1:48-63. The ’677 patent specification presents the subject matter as if the inventor, Laurence Dahners, was the first to achieve rigid fixation with variable angles in a bone plate system. As set forth below, the claimed subject matter was in the prior art.



The ’677 patent specification describes the alleged invention as a surgical plate having apertures “bounded by a region structured to enable the fastener, and particularly a threaded head portion of the fastener, to be tapped into the material constituting the region.” *Id*. (2:16-26). With reference to FIG. 3 (annotated by Petitioner for clarity), the specification refers to this region as the “tappable contact region” and states that “[b]y providing this tappable region, the fastener can be inserted at any desired angle in relation to the aperture.” *Id*. at 2:26-29.

The '677 patent specification discloses two different embodiments having tappable contact regions. With reference to FIG. 2B (annotated by Petitioner for clarity), the first embodiment of a tappable contact region of a fastener receiving member (e.g., bone plate) consists of a matrix of protrusions and interstices (or spaces) between the protrusions. The specification states that the protrusions can be provided in "any protruding form." *Id*. at 7:23-24. It further states that the matrix of protrusions and interstices can be formed by "any suitable means," including "forming ridges or grooves [in the bone plate hole] and subsequently cutting transversely through the ridges to discretize the ridges into protrusions." *Id*. at 7:51-56. It states that the density and size of individual protrusions are not limited by the invention and that the protrusions "may or may not be deformable." *Id.* at 7:38-8:3.

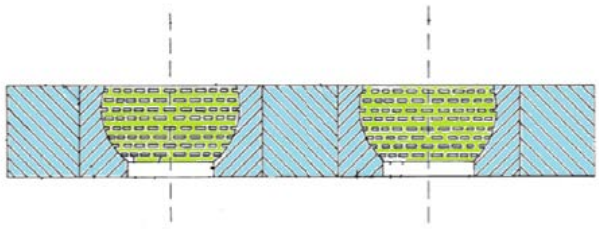


Fig. 2B

With reference to FIG. 6 (annotated by Petitioner for clarity), the second embodiment of a tappable contact region of a fastener receiving member consists of a

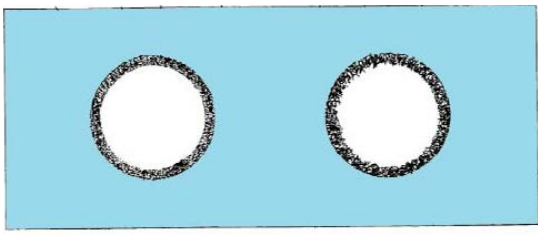


Fig. 6

mesh of metal fiber where the metal fibers "will deflect" and some of the fibers "may be cut" in response to driving a threaded-head fastener into the contact region. *Id.* at 9:63-10:4.

B. Person of Ordinary Skill in the Art ("POSA") And State of the Art

A POSA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. As of October 15, 2002, the effective filing date of the '677 patent, a POSA would have at least a bachelor's degree in the field of mechanical engineering, biomedical engineering, or a related discipline and at least 3-5 years of practical work experience in the field of orthopedic surgical fasteners, including the design, construction, and implantation of surgical bone plates and screws. Ex. 1002 ¶ 30. Alternatively, a POSA could have an advanced degree such as a Masters, Ph.D., M.D., or D.O. in one of the above disciplines and 1-2 years of experience in one of the above fields. *Id*. A POSA would have had familiarity with the extant literature on the use of surgical bone plate and screw systems to achieve stable bone plate fixation in the treatment of fractures and other techniques. *Id*. A POSA may work as part of a multi-disciplinary team and draw upon not only his or her own skills, but also take advantage of certain specialized skills of others in the team, to solve a given problem. *Id*.

As of October 15, 2002, the state of the art pertinent to the '677 patent was such that use of orthopedic bone plates and screws were known. Typically made of metal, orthopedic fixation systems including bone plates and screw come in many different shapes and sizes, depending on the type and size of the fractured bone and the nature of the fracture. Ex. 1002 ¶ 13. As the '677 patent acknowledges, bone plates have long been "used to stabilize the site of a bone fracture, and one or more bone screws are inserted through apertures of the plate and threaded into the bone material." Ex. 1001 at 1:17-21; Ex. 1002 ¶ 13.

Early bone plates typically included numerous holes each having a smooth inside surface. Ex. 1002 ¶ 14. In order to compress the bone plate against the bone, a surgeon would place the bone plate against a fractured bone and insert bone screws into the smooth holes. *Id*. These bone screws contained a thread on the screw shaft, but not on the screw head. *Id.* The thread made it possible for the surgeon to screw the threaded elongate shafts of the screws into the bone. *Id.* The surgeon could insert the standard screws at whatever angle was necessary to reach the bone fragments, within an angular range allowed by the requirement that the screw pass through the hole in the plate. *Id*.

With standard screws, the screws are not rigidly fixed to the plate. *Id*. ¶ 15. As the '677 patent acknowledges, "some types of small bone fragments tend to change position relative to the plate over time. This deleterious condition can

result from the 'toggling' of the screws affixed to the plate." Ex. 1001 at 1:37-40; Ex. 1002 ¶ 15. Thus, over time, as the patient moves about post-operatively, the screws can toggle relative to the plate. Ex. 1001 at 1:37-40; Ex. 1002 ¶ 15. For this reason, these types of bone screws are now often referred to as "non-locking" screws. Ex. 1002 ¶ 15.

To overcome that drawback, the art developed designs to rigidly affix, or "lock," the screw to the plate by modifying the plate holes and screw heads. Ex. 1002 ¶ 16. These designs were known as locking systems. *Id*. The '677 patent discusses locking systems in the Background Art section. Ex. 1001 at 1:21-47; Ex. 1002 ¶ 16. The '677 patent explains that some locking screw systems have a thread on the head of the bone screw and locking holes have a thread on the inside surface to receive the threads of the screw head in a mating fashion. Ex. 1001 at 1:21-26; Ex. 1002 ¶ 16. As a result of that mating the "screw becomes rigidly affixed to the plate, in effect locking to the plate rather than simply bearing against the plate." Ex. 1001 at 1:26-32; Ex. 1002 ¶ 16. The '677 patent further explains, locking screws do not toggle in the plate. Ex. 1001 at 1:40-47; Ex. 1002 ¶ 16. Locking screws only can be inserted into holes at a single pre-determined angle for the thread on the screw head to mate with the thread in the plate hole. Ex. 1002 ¶ 17. This is because "the thread formed on the inside surface of the plate is

structurally fixed at a constant helical angle with respect to the central axis passing through the center point of the aperture." Ex. 1001 at 1:48-58; Ex. 1002 ¶ 17.

Beginning at least as early as the 1990s, however, Professor Dietmar Wolter ("Wolter"), published ways to overcome the unidirectional disadvantage of the prior art locking systems mentioned in the '677 patent. *See generally* Exs. 1005-1012; *see also* Ex. 1002 ¶ 18. Wolter disclosed bone plate holes that allowed surgeons to insert the bone screw at variable angles with respect to the bone plate hole axis, while still holding the screw in rigid fixation with the plate. Ex. 1002 ¶ 18. Wolter's fixation systems allow a surgeon to insert a screw with a threaded head at various different introduction angles that can be selected freely by the surgeon. *Id*. The fixation systems allow rigid fixation between bone screws that can be inserted into bone plates at various insertion angles because the inner walls of the plate holes do not contain a continuous helical thread like those used in the unidirectional locking systems. *Id*. Rather, the fixation systems are designed in such a way that a screw thread can tap directly into the hole walls as it is driven into the hole. *Id*.

One plate hole designed by Wolter contains multiple separated thread segments, i.e., four sets of ridges with four smooth spaces between each set of ridges. Ex. 1010 at 8:16-21, FIG. 8; Ex. 1002 ¶ 19. Upon insertion of the screw, the thread segments deform or adapt to the thread on the screw head to mate with

it, thereby providing rigid fixation of the screw at whatever angle the surgeon selected. Ex. 1010 at 4:25-35, 7:9-18; Ex. 1002 ¶ 19. Other plate holes designed by Professor Wolter are formed in a softer material than the thread on the head of the screw, and/or include deformable projections, ridges, lips, or raised areas. Ex. 1008 at 15:13-16, 24-32, FIG. 2; Ex. 1002 ¶ 19. These designs allow a surgeon to insert bone screws into the holes at whatever angle he or she chooses, and tap the thread into the hole wall with minimal force achieving maximum stability and fixation. Ex. 1002 ¶ 19.

C. The '677 Patent Claims and Claim Construction

The challenged claims are directed to either a surgical plate adapted for fixation with a bone screw (*i.e.*, a bone plate having holes), a fastening apparatus (*i.e.*, a bone plate and a fastener), or a method for affixing a fastener to a fastener receiving member (*i.e.*, a method of applying the bone plate to a bone and inserting the fastener).

In an *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the patent specification. 37 C.F.R. § 42.100(b). Any claim term that lacks a definition in the specification is therefore also given a broad interpretation. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). The following discussion proposes constructions of terms in the Challenged Claims under the broadest reasonable construction

standard. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art. Moreover, should the patent owner, in order to avoid the prior art, contend that the claims have a construction different from their broadest reasonable interpretation, the appropriate course is for the patent owner to seek to amend the claims to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012). Any such amendment would only be permissible if the proposed amended claims comply with 35 U.S.C. § 112.

1. "Tappable contact region"

Each of the claims requires a bone plate having a "tappable contact region." Wright Medical does not believe that under the broadest reasonable interpretation standard that any special meanings apply to "tappable contact region."

The specification explains that the "tappable contact region" is formed so as to allow for being tapped by a fastener to rigidly affix the fastener at a selected one of a plurality of different insertion angles. Ex. 1001 (*e.g.*, Cols. 10:46-51; 3:9-17). The specification further explains:

> The term "tappable" is used herein to denote that contact region 85 is structured such that it can be tapped by second thread 51 of head section 40 of fastener 10 in response to forceful insertion and rotation

> of head section 40 into the material of contact region 85. As described below in connection with FIG. 3, this enables the user to manipulate second thread 51 of head section 40 to form, in effect, a custom internal thread in contact region 85 sufficient to maintain fastener 10 at an arbitrary orientation in relation to receiving member 60 selected by the user.

Id. at 7:3-7. The '677 patent discloses that tapping "is accomplished by threading [a thread from a threaded-head fastener] into the tappable contact region while the [fastener] is oriented at the selected insertion angle." *Id.* at 3:35-39.

The '677 also instructs that "[i]t is another object of the present invention to provide such fastener receiving member with an aperture that ***does not require*** a ***pre-tapped***, fixed-position thread structure with which a threaded fastener is to be interfaced." *Id*. at 3:57-60 (emphasis added). Further, the '677 patent states:

> . . . the invention departs from conventional use of a thread formed on inside surface 81 of aperture A for mating with the thread of a screw head. That is, apertures A of fastener receiving member 60 ***do not contain a permanent helical thread structure*** of fixed orientation. Instead, ***a tappable contact region***, generally designated 85, is disposed on each inside surface 81 of fastener receiving member 60.

Id. at 6:63-7:3 (emphasis added). *See also* 2:19-23 ("Notably absent from these apertures [and the tappable contact region disposed therein] are any forms of permanent internal thread structures . . .").

Claims 1-4, 9, 11-12, 18, 21-25, 28, 30-31, 33-34, 39-44, 47-48, 54-57, 60, 62-63, 65-66, and 71-74 do not recite any particular type of "tappable contact region" (although some claims recite that it is non-threaded and non-rotatable). Thus, under the broadest reasonable construction, any untapped (i.e., not "pre-tapped") region of material, formed integrally with the plate and disposed on the inside surface of the aperture, that is structured to make contact with a fastener upon forceful insertion and rotation and secure it at an angle selected by the user (other than a traditional helical thread), would satisfy the "tappable contact region" limitation. Put another way, under the broadest reasonable interpretation a "tappable contact region" is "an untapped contact region that is capable of being modified to form an internal screw thread by means of a tap."[1]

[1] This construction is consistent with the interpretation set forth in the Decision of Institution of *Inter Partes* Review issued April 8, 2014 in connection with IPR2014-00112 concerning the '677 patent except for the inclusion of "untapped." The inclusion of "untapped" is believed to be proper and Petitioner directs the PTAB to pages 10-11 of the '677 IPR Decision in connection with IPR2014-0112. Ex. 1019 at pp. 10-11 (noting the disclaimer or disavowal of claim scope of

2. "Protrusions"

Claims 11-12, 33-34, 43-44, 47-48, 65-66, and 73-74 further require that the tappable contact region comprise "a plurality of protrusions extending generally radially inwardly from the inside surface and a plurality of interstices between the protrusions." Ex. 1001 at 11:13-16-18. "Protrusions" are raised areas that extend from a surface and "interstices" are spaces or interruptions between those raised areas. Ex. 1016 ("protrusion" and "interstice"). The claims do not limit the type or number of protrusions and interstices and the specification states that the protrusions are not limited in density, size, dimension, or origination. *See* Ex. 1001 at 7:38-56. Indeed, the specification states that the protrusions can be provided in "any protruding form." *Id.* at 7:23-24.

As noted in the previous section, the specification makes clear, however, that there is a difference between "protrusions" and "threads" as those words are used in the patent. Specifically, the specification states that while the tappable contact region many comprise protrusions and interstices, such protrusions do not include the use of threads. *Id*. at 2:19-23 ("Notably absent from these apertures are any form of permanent internal thread structures a found in the prior art and which,

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threaded holes). With respect to this construction, Wright Medical believes that a screw having a thread formed on its head can be a "tap."

as indicated above, are a limitation in applications such as the treatment of bone trauma."). Thus, the proper construction of "protrusion" is "any protruding form not forming a thread."

3. "Substantially Cylindrical Vertical Profile" and "Substantially Frusto-Conical Vertical Profile"

Claim 4 recites that the "the tappable contact region has a substantially cylindrical vertical profile," and claims 28 and 60 recite that "the head section has a substantially frusto-conical vertical profile." These terms do not have an ordinary meaning to one of ordinary skill in the art as they describes a profile, which one of ordinary skill in the art would understand as a two-dimensional view, of a three-dimensional object, i.e., a cylinder or a frustum of a cone.

The term "vertical profile" is never used in the specification, but the word "vertical" is used several times when describing the cross-sectional view of various objects. *See* Ex. 1001 at 4:23-39. The word "profile" also is used repeatedly in connection with the term "cross-sectional." *Id*. at 5:1-3; 8:4-11. Thus, based on the specification, the broadest reasonable interpretation of the term "substantially cylindrical vertical profile" is "having the same appearance as a cross-sectional view of a cylinder taken along the longitudinal (vertical) axis of the cylinder," and the broadest reasonable interpretation of the term "substantially frusto-conical profile" is "having the same appearance as a cross-sectional view of a frustum of a cone taken along the longitudinal (vertical) axis of the frustum."

V. THE CHALLENGED CLAIMS ARE NOT PATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(4)-(5), specific grounds identified below and discussed in the Nassar Declaration (Ex. 1002) show in detail the prior art disclosures that render the challenge claims unpatentable.

A. The Challenged Claims are Unpatentable Over *Universal* in View of the Knowledge of a POSA

Attached hereto as Exhibit 1017 is a claim chart setting forth where each of the claimed features is disclosed by the *Universal* reference and would have been unpatentable over *Universal* in view of the knowledge of a POSA.

1. Independent Claims 1, 21, 39, 47, 54 and 71 Are Not Patentable Over *Universal* in View of the Knowledge of a POSA

Universal discloses many if not all of the claimed features of claims 1, 21, 39, 47, 54, and 71. Ex. 1002 ¶¶ 24, 37, 54, 55, 70, 71, 94, and 98; *see also* Ex. 1017. To whatever extent that *Universal* does not disclose each feature of any of the challenged claims, then *Universal* in combination with the knowledge of one of ordinary skill in the art would have rendered obvious each of such features. *Id*. As set forth in the Nassar Declaration, all of the features of the challenged claims were within the knowledge of one of ordinary skill in the art prior to the priority date of the ’677 patent. *See generally* Ex. 1002; Ex. 1017.

The test for obviousness is “expansive and flexible,” such that a patent challenger need “not seek out precise teachings directed to the specific subject

matter of the challenged claim." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007); *see also Plasmart, Inc. v. Kappos*, 482 Fed. Appx. 568, 572 (Fed. Cir. May 22, 2012) (unpublished) ("minor distinctions" do not preclude a finding of obviousness).

In the following analysis, claims 1 and 47 have been analyzed together as these claims are both directed to surgical plates and are of similar scope. For the same reason, claims 21 and 47, which disclose fastening apparatus, and claims 39 and 71, which disclose methods, are analyzed together. To aid in the discussion, the following sections include claim charts/tables in which like elements of the independent claims have been paired together.

a. Independent Claims 1 and 47

Claims 1 and 47 are rendered obvious by the *Universal* reference. *See* Ex. 1002 ¶¶ 37, 54; *see also* Ex. 1017. For example, claims 1 and 47 recite:

Claim 1	Claim 47
1. A surgical plate adapted for fixation with a bone screw, comprising	47. A surgical plate adapted for fixation with a bone screw, comprising

Universal discloses "internal fixator systems" including bone plates (i.e., surgical plates) that are adapted for fixation with a bone screw. For example, *Universal* teaches that in order to address the need for internal fixator systems

"implants made out of titanium were developed that develop angular stability by exploiting the friction created by fixing self-tapping screws of harder titanium in plates made from softer titanium . . . ." Ex. 1005 at 308 (Abstract); *see also id*. at 312 (FIGS. 9a-10b). Numerous systems are disclosed by the *Universal* article, including fixation devices for the distal femur (FIG. 13); Lower leg (FIG. 14a); subcapital humerus fractures (FIG. 15); lower arm for ulna and radius (FIG. 16); cervical vertebra (FIG. 18); thoracic and lumbar vertebra (FIG. 19); calcaneus (FIG. 20); and lower talocalcanean (FIG. 21), to identify only a few disclosed fixation systems. *Id*. at 314-315.

Claims 1 and 47 further recite:

Claim 1	Claim 47
first and second opposing major surfaces, an inside surface extending between the first and second major surfaces and defining an aperture generally coaxially disposed about an aperture axis, and	first and second opposing major surfaces, an inside surface extending between the first and second major surfaces and defining an aperture generally coaxially disposed about an aperture axis, and

The bone plates of the fixation devices disclosed by *Universal* have opposed first and second major surfaces and an inside surface that extends between the first

and second major surfaces as illustrated in FIGS. 13-21. Ex. 1005 at 314-315. Each of these bone plates are shown as including at least one aperture (i.e., a hole) that is disposed about an aperture axis as each hole inherently includes an aperture axis. *Id*.; *see also* Ex. 1002 ¶ 40.

Claims 1 and 47 further require:

Claim 1	Claim 47
a non-rotatable, non-threaded tappable contact region disposed on the inside surface of the aperture, the tappable contact region having an inside diameter large enough to permit a bone screw to pass therethrough at a variable insertion angle defined between the longitudinal axis of the bone screw and the aperture axis, and	a non-threaded tappable contact region disposed on the inside surface, wherein the tappable contact region has a minimum inside diameter large enough to permit a bone screw to pass therethrough at an insertion angle defined between a longitudinal axis of the bone screw and the aperture axis, and

The apertures defined by the bone plates of the disclosed fixation systems in *Universal* include a tappable contact region on the inner surface of the aperture (hole). Ex. 1002 ¶ 42. For example, *Universal* teaches that in initial prototypes a thread was first formed (i.e., tapped) in the material defining an aperture (i.e., in a

"tappable contact region"). Ex. 1005 at 313 ("A hexagonal thread forcer was made. By forcing a thread into the hole as an intermediate step in the respective screw canal direction, the problem was solved.") However, *Universal* also discloses that "[t]his thread forming process ***is not required*** when the implant has a lesser thickness; a solid screw to plate connection is created simply due to the penetration of the head." *Id*. (emphasis added). When a thread is not formed by the hexagonal thread forcer, a "tappable contact region" (i.e., inner surface of material defining the hole) of a bone plate disclosed by *Universal* is "non-threaded."[2] Dr. Wolter also recognized that "[i]n order to ensure free selectability, only either the screw head or the plate hole can have a preformed thread" *Id*. at 310-311. One of ordinary skill in the art would have understood this disclosure as providing "non-threaded tappable contact regions" as required by claims 1 and 47. Ex. 1002 ¶¶ 42-43.

Further, as the material of the bone plate (i.e., surgical plate) that defines the hole (i.e., aperture) is continuous with the remainder of the plate material, the

[2] The PTAB has construed "non-threaded" as "not containing any forms of permanent internal thread structures" in IPR2014-00112, which also concerns the '677 patent.

tappable contact region is "non-rotatable" as required by claim 1 as the "tappable contact region" cannot rotate relative to the rest of the plate. Ex. 1002 ¶ 44.

The holes (apertures) defined by the bone plates (surgical plates) in *Universal* have an inside diameter that is large enough to permit a bone screw to pass therethrough at a variable insertion angle defined between the longitudinal axis of the bone screw and the aperture axis. *Id*. at ¶¶ 45-48. Indeed, one of the primary objectives of Dr. Wolter's work was to provide fixation systems with "freely determinable screw direction." Ex. 1005 at 310; *see also id*. at 312 (FIG. 9b). One of ordinary skill in the art would have understood from these teachings that the diameter of the holes (apertures) defined by the bone plates disclosed in *Universal* had to have a diameter that is sufficient to allow bone screws to be received at various angles. Ex. 1002 ¶¶ 45-48.

Claims 1 and 47 further recite:

Claim 1	Claim 47
the tappable contact region is formed so as to allow for being tapped by an external thread of the bone screw to rigidly affix the bone screw to the tappable contact region at a selected one of a plurality of different insertion	the tappable contact region is adapted for being tapped by an external thread of the bone screw to affix the bone screw to the tappable contact region at the insertion angle and wherein the tappable contact region comprises a plurality of

angles that can be selectively formed between the axis of the bone screw and the aperture axis.	protrusions extending generally radially inwardly from the inside surface and a plurality of interstices between the protrusions.

The inner surfaces of the material defining the holes (i.e., the "tappable contact regions") of the bone plates disclosed in *Universal* allow for being tapped by a thread of a bone screw at the insertion angle. Ex. 1002 ¶ 50. For example, *Universal* describes the solution to providing fixation systems with freely determinable screw directions as "making the screw head from a harder material and having it bear a thread, while the plate hole is made from a softer material" such that "[w]hen the bone screw is turned in, a material reshaping process occurs when the thread bearing screw head enters the plate hole, forcing a thread [to] form in the hole wall." Ex. 1005 at 311. Not only does a reshaping process of the plate occur (i.e., tapping), but "[t]he penetration of the thread bearing screw head into the plate hole injures the titanium oxide surface layers, so that contact occurs between native titanium surfaces" to provide suitable rigid fixation between the plate, bone screw, and bone. *Id*. at 313 ("In particular, the solidity of this connection at an alternating load of 140,000 and up to 248,000 was surprising (Fig. 11 a, b"). These claimed features were also within the knowledge of a person of ordinary skill in the art. *See* Ex. 1002 ¶ 51.

With respect to claim 47, Dr. Wolter realized that "[t]he force which is required to introduce the screw head into the plate hole – and therefore the torque which acts on the implant itself – depends on the amount of material which is to be reshaped." Ex. 1002 at 313. This lead Dr. Wolter to include a plurality of protrusions that extend radially inwardly from the inside surface of the hole (aperture) of the plate in the form of "lips or raised areas which were formed in various thicknesses" in order "to use as little force as possible to place the screw head in the plate hole with sufficient overall stability of the connection" as required by claim 47. *Id*. FIG. 12 of *Universal* provides a cross-sectional view of a plate hole having a single lip in its center. *Id*. at 312. Further, increasing the number of protrusions and interstices was well within the skill of a POSA. Ex. 1002 ¶ 53. For example, FIG. 2 of DE 198 58 889 (Exs. 1007, 1008) illustrates numerous examples of bone plates including multiple lips or raised areas. *See* Ex. 1002 ¶ 53. This reference also teaches that "[t]he preshaped thread 5 [on the head of the bone screw] reshapes the projections 12 or 12' and 12" [formed on the inner surface of the holes], respectively, such that a threaded connection is formed between the screw 1 and the through hole 9, which ***is oriented precisely in the screwing-in axis***." Ex. 1008 at 13:11-16 (emphasis added); Ex. 1002 ¶ 53.

Thus, one of ordinary skill in the art would have understood that *Universal* discloses the claimed plurality of protrusions and interstices under the broadest reasonable interpretation of these terms. Ex. 1002 ¶¶ 52-53.

As each of the features of claims 1 and 47 are disclosed in Universal and was within the knowledge and skill of a person of ordinary skill in the art, these claims are not patentable and should be canceled. *Id*. ¶ 54.

b. Independent Claims 21 and 54

Claims 21 and 54 are rendered obvious by the *Universal* reference. *See* Ex. 1002 ¶¶ 55, 70. For example, claims 21 and 54 recite:

Claim 21	Claim 54
21. A fastening apparatus adapted for multi-angular insertion, comprising:	54. A fastening apparatus adapted for multi-angular insertion, comprising:

Universal discloses "internal fixator systems" (i.e., fastening apparatuses) that are adapted for multi-angular insertion. Ex. 1002 ¶ 56. For example, *Universal* teaches that in order to address the need for internal fixator systems, "implants made out of titanium were developed that develop angular stability by exploiting the friction created by fixing self-tapping screws of harder titanium in plates made from softer titanium . . . ." Ex. 1005 at 308 (Abstract); *see also id*. at 312 (FIGS. 9a-10b). As noted above, one of the primary objectives of Dr.

Wolter's work was to provide a fixation system (i.e., fastening apparatuses) with a "freely determinable screw direction," i.e., being adapted for multi-angular insertion. *Id*. at 310; *see also id*. at 312 (FIG. 9b).

Claims 21 and 54 further recite:

Claim 21	Claim 54
(a) a fastener comprising an elongate section and an adjoining head section disposed along a fastener axis, the head section comprising a thread; and	(a) a fastener comprising an elongate section and an adjoining head section disposed along a fastener axis, the head section comprising a thread, said fastener comprising a surgical bone screw; and

Universal discloses fasteners in the form of bone screws having threaded heads and that include an elongate section that is disposed along a fastener axis. Ex. 1002 ¶ 58. For example, *Universal* explicitly teaches the use of "bone screws" having "thread bearing screw head[s]" and the reference illustrates numerous examples of bone screws having elongate sections. Ex. 1005 at 311; 312 (FIGS. 9a, 10b); 314 (FIGS. 12, 14b); 317 (FIG. 25). The elongated section of the illustrated bone screws include a thread. *Id*.; *see also id*. at 312 ("Differing

inclines of the bone [e.g., elongate section of screw] and screw head threads make it possible to pull the implant against the bone surface.")

The remaining elements of claims 21 and 54 are similar to the elements of claims 1 and 47, which were analyzed above. For example, claims 21 and 54 further require:

Claim 21	Claim 54
(b) a fastener receiving member comprising first and second opposing major surfaces, an inside surface extending between the first and second major surfaces and defining an aperture generally coaxially disposed about an aperture axis, and	(b) a fastener receiving member comprising first and second opposing major surfaces, an inside surface extending between the first and second major surfaces and defining an aperture generally coaxially disposed about an aperture axis, and

As noted above with respect to claims 1 and 47, the bone plates (i.e., fastener receiving members) of the fixation systems (i.e., fastening apparatuses) disclosed by *Universal* have opposed first and second major surfaces and an inside surface that extends between the first and second major surfaces as illustrated in FIGS. 13-21. Ex. 1005 at 314-315. Each of these bone plates is shown as

including at least one aperture (i.e., a hole) that is disposed about an aperture axis as each hole inherently includes an aperture axis. *Id*; *see also* Ex. 1002 ¶ 60.

Claims 21 and 54 further require:

Claim 21	Claim 54
a non-rotatable tappable contact region disposed on the inside surface of the aperture, the tappable contact region having an inside diameter large enough to permit the elongate section of the fastener to pass therethrough at a variable insertion angle defined between the fastener axis and the aperture axis, and	a tappable contact region disposed on the inside surface, wherein the tappable contact region has a minimum inside diameter large enough to permit the elongate section to pass therethrough at an insertion angle defined between the fastener axis and the aperture axis, and

Again, as set forth above, *Universal* teaches that the plate hole is made from a softer material such that "[w]hen the bone screw is turned in, a material reshaping process occurs when the thread bearing screw head enters the plate hole, forcing a thread form in the hole wall." Ex. 1005 at 311; Ex. 1002 ¶ 62. *Universal* further discloses that "[i]in order to ensure free selectability, only either the screw head or the plate hole can have a preformed thread." Ex. 1005 at 310-311. As the material of the plate (i.e., surgical plate) that defines the hole (i.e., aperture) is

continuous with the remainder of the plate material, the tappable contact region is "non-rotatable" as required by claim 21 because the "tappable contact region" cannot rotate relative to the plate. Ex. 1002 ¶ 63.

The holes (apertures) defined by the bone plates (surgical plates) in *Universal* have an inside diameter that is large enough to permit a bone screw to pass therethrough at a variable insertion angle defined between the longitudinal axis of the bone screw and the aperture axis. *Id*. ¶ 64. As noted above, one of the primary objectives of Dr. Wolter' work was to provide fixation systems with "freely determinable screw direction." Ex. 1005 at 310; *see also id*. at 312 (FIG. 9b); Ex. 1002 ¶¶ 64-65. One of ordinary skill in the art would have understood from these teachings that the diameter of the holes (apertures) defined by the bone plates disclosed in *Universal* had to have a diameter that is sufficient to allow bone screws to be received in various angles. Ex. 1002 ¶¶ 64-65. Bone screws inherently include a "fastener axis" and apertures (holes) inherently include and "aperture axis."

Claims 21 and 54 also recite:

Claim 21	Claim 54
the tappable contact region is formed so as to allow for being tapped by the thread of the head section to rigidly	the tappable contact region is adapted for being tapped by the thread of the head section to affix the head section to

affix the head section to the tappable contact region at a selected one of a plurality of different angles that can be selectively formed between the axis of the fastener and the aperture axis.	the tappable contact region at the insertion angle.

As demonstrated above, *Universal* teaches that "making the screw head from a harder material and having it bear a thread, while the plate hole is made from a softer material" such that "[w]hen the bone screw is turned in, a material reshaping process [i.e., tapping] occurs when the thread bearing screw head enters the plate hole, forcing a thread form [i.e., tapping] in the hole wall [i.e., tappable contact region]" enables the hole to be tapped at a selected one of a plurality of different angles between an inherent fastener axis and an inherent aperture axis. Ex. 1005 at 311; *see also id* at 310 (disclosing that a "freely determinable screw direction" is a "prerequisite" of the disclosed fixation systems). The use of "cold welding" between the plate and the screw creates "a permanently stable bond that also enables various screw angles and positions." *Id*. at 308 (Abstract); 311. Further some embodiments include "lips or raised areas [i.e., protrusions] . . . formed in various thicknesses" can be included on the inner surface of the hole (i.e., a "tappable contact region") in order "to use as little force as possible to place the screw head in the plate hole with sufficient overall stability [i.e., rigid affixation]

of the connection," i.e., rigid affixation. *Id*. at 313. A "close connection of the titanium contact surfaces between the screw head and [a] lip in the plate hole" is shown in FIG. 12. *Id*. at 314.

As each of the features of claims 21 and 54 are disclosed in *Universal* and was within the knowledge and skill of a person of ordinary skill in the art, these claims are not patentable and should be canceled. *See* Ex. 1002 ¶¶ 55, 67-70.

c. Independent Claims 39 and 71

Independent claims 39 and 71 are unpatentable over the *Universal* article. *See id*. ¶¶ 71, 94, 98. For example, claims 39 and 71 recite:

Claim 39	Claim 71
39. A method for affixing a fastener to a fastener receiving member at a desired orientation, comprising the steps of:	71. A method for affixing a fastener to a fastener receiving member at a desired orientation, comprising the steps of:

The *Universal* reference discloses a "minimally invasive surgical technique" (i.e., a method) for using the disclosed fixation devices in the thigh region. Ex. 1005 at 315; *see also* Ex. 1002 ¶ 72. As demonstrated above with respect to claims 21 and 54, *Universal* discloses numerous fixation systems including a fastener in the form of a bone screw. Ex. 1005 at 311; 312 (FIGS. 9a, 10b); 314 (FIGS. 12, 14b); 317 (FIG. 25). These fixation systems also include a bone plate (i.e., a fastener receiving member) that can take one of the many forms illustrated in

FIGS. 12-21. Ex. 1005 at 314-315. A prerequisite of the fixation systems disclosed by *Universal* is that they provide for "freely determinable screw direction" (i.e., the ability to affix a fastener to a fastener receiving member at a desired orientation). *Id*. at 310.

Claims 39 and 71 further require:

Claim 39	Claim 71
(a) providing a fastener comprising an elongate section and an adjoining head section disposed along a fastener axis, the head section comprising a thread;	(a) providing a fastener comprising a threaded elongate section and an adjoining head section disposed along a fastener axis, the head section comprising a thread;

As noted above with respect to element (a) of claims 21 and 54, *Universal* explicitly teaches the use of "bone screws" having "thread bearing screw head[s]" and illustrates numerous examples of bone screws having elongate sections. Ex. 1005 at 311; 312 (FIGS. 9a, 10b); 314 (FIGS. 12, 14b); 317 (FIG. 25); *see also* Ex. 1002 ¶ 73. The elongate section of the illustrated bone screws include a thread. Ex. 1005 at 311; 312 (FIGS. 9a, 10b) ("Differing inclines of the bone [i.e., elongate section of the screw] and screw head threads make it possible to pull the implant against the bone surface."); 314 (FIGS. 12, 14b); 317 (FIG. 25).

Claims 39 and 71 further require:

Claim 39	Claim 71
(b) providing a fastener receiving member comprising first and second opposing major surfaces, an inside surface extending between the first and second major surfaces and defining an aperture generally coaxially disposed about an aperture axis, and	(b) providing a fastener receiving member comprising first and second opposing major surfaces, an inside surface extending between the first and second major surfaces and defining an aperture generally coaxially disposed about an aperture axis, and

As set forth above with respect to element (b) of claims 21 and 54, the fixation systems disclosed by *Universal* include bone plates (i.e., fastener receiving members) having opposed first and second major surfaces and an inside surface that extends between the first and second major surfaces as illustrated in FIGS. 13-21. Ex. 1005 at 314-315. Each of these bone plates are shown as including at least one hole (i.e., aperture) that is disposed about an aperture axis as each hole inherently includes an aperture axis. *Id.*; *see also* Ex. 1002 ¶¶ 40, 75.

Claims 39 and 71 further recite:

Claim 39	Claim 71
a non-rotatable tappable contact region disposed on the inside surface of the	a tappable contact region disposed on the inside surface;

aperture, the tappable contact region having an inside diameter large enough to permit the elongate section of the fastener to pass therethrough at a variable insertion angle defined between the fastener axis and the aperture axis, and	

As demonstrated above, *Universal* teaches that the plate hole is configured such that "[w]hen the bone screw is turned in, a material reshaping process occurs when the thread bearing screw head enters the plate hole, forcing a thread form [i.e., tapping] in the hole wall [i.e., tappable contact region]." Ex. 1005 at 311. *Universal* further discloses that "[i]in order to ensure free selectability, only either the screw head or the plate hole can have a preformed thread." *Id*. at 310-311. One of ordinary skill in the art would have understood this teaching as disclosing a "tappable contact region" as required by claim 39. Ex. 1002 ¶ 77. As the material of the plate (i.e., fastener receiving member) that defines the hole (which includes a tappable contact region) is continuous with the remainder of the plate material, the tappable contact region is "non-rotatable" as required by claim 39. *Id*. ¶ 78.

The "tappable contact region" formed on the inner surface of the holes (apertures) defined by the bone plates (fastener receiving members) in *Universal*

have an inside diameter that is large enough to permit a bone screw to pass therethrough at a variable insertion angle defined between the longitudinal axis of the bone screw and the aperture axis in order to meet the identified prerequisite of providing "freely determinable screw direction." Ex. 1005 at 310; *see also* Ex. 1002 ¶¶ 79-80.

Element (b) of claim 39 further requires:

Claim 39
the contact region is formed so as to allow for being tapped by the thread of the head section to rigidly affix the head section to the tappable contact region at a selected one of a plurality of different angles that can be selectively formed between the axis of the fastener and the apertur [sic] axis;

The inner surfaces of the holes formed in the bone plates disclosed in *Universal* include contact regions that allow for being tapped by a thread of a section of a bone screw. Ex. 1002 ¶¶ 72, 82, 83. For example, *Universal* teaches that the plate hole is configured such that "[w]hen the bone screw is turned in, a material reshaping process occurs when the thread bearing screw head enters the plate hole, forcing a thread form [i.e., tapping] in the hole wall [i.e., tappable contact region]." Ex. 1005 at 311. Again, it was a prerequisite of the fixation systems disclosed in *Universal* that they provide a "freely determinable screw

direction," i.e., enable a user to select one of a plurality of different insertion angles between an axis of a fastener (bone screw) and an aperture axis (hole axis). *Id*. at 310.

Claims 39 and 71 further recite:

Claim 39	Claim 71
(c) selecting one of the plurality of different insertion angles at which the fastener is to be inserted in relation to the fastener receiving member;	(c) selecting an insertion angle at which the fastener is to be inserted in relation to the fastener receiving member, wherein the insertion angle is defined between the fastener axis and the aperture axis;

The fixation systems disclosed by *Universal* provide for a "freely determinable screw direction" relative to the bone plate (i.e., fastener receiving member) such that the installation of such systems inherently requires the selection of one of a plurality of different insertion angles or the selection of an insertion angle at which the fastener (i.e., bone screw) is inserted in relation to the fastener receiving member (i.e., bone screw). Ex. 1005 at 310; Ex. 1002 ¶ 85. FIGS. 9a, 9b, 10b, 12, and 22-23b of *Universal* show an insertion angle that has been selected. Ex. 1005 at 312; 314; 316. With respect to claim 71, a fastener axis and an aperture axis are inherent to a fastener and an aperture. Ex. 1002 ¶ 86.

Claims 39 and 71 further require:

Claim 39	Claim 71
(d) inserting the elongate section through the aperture until the thread of the head section contacts the non-rotatable tappable contact region; and	(d) inserting the elongate section through the aperture until the thread of the head section contacts the tappable contact region;

Universal illustrates the insertion of an elongate section of a fastener (i.e., bone screw) through a hole (i.e., aperture) until the thread of the head section contacts a [non-rotatable] tappable contact region in FIG. 9a. Ex. 1005 at 312. In particular, the elongate section of the bone screw at left in FIG. 9a is being inserted and the head of another bone screw (at center) in FIG. 9a is shown as being placed in contact with the inner surface of a hole. Further, one of ordinary skill in the art would understand that this step is performed in the proper use of the fixation system disclosed in *Universal*. Ex. 1002 ¶¶ 88-90.

Claims 39 and 71 also require:

Claim 39	Claim 71
(e) tapping the fastener into the receiving member such that the fastener is rigidly oriented at the selected	(e) tapping the fastener into the receiving member such that the fastener is oriented at the selected insertion angle

insertion angle by threading the thread of the head section into the non-rotatable tappable contact region while the fastener is oriented at the selected insertion angle.	by threading the thread of the head section into the tappable contact region while the fastener is oriented at the selected insertion angle; and

As provided above, *Universal* teaches that the plate hole is configured such that "[w]hen the bone screw is turned in, a material reshaping process occurs when the thread bearing screw head enters the plate hole, forcing a thread form [i.e., tapping] in the hole wall [i.e., tappable contact region]." Ex. 1005 at 311. This material reshaping process results in the "penetration of the thread bearing screw head into the plate hole [which] injures the titanium oxide surface layers, so that contact occurs between native titanium surfaces." *Id*. at 313. Further, *Universal* teaches that "a solid screw to plate connection is created simply due to the penetration of the head" (i.e., rigid fixation) as a result of the reshaping (tapping) process. *Id*. As the aim of the disclosed fixation systems in *Universal* is to provide for a "freely determinable screw direction," the fixation occurs while the fastener (bone screw) is oriented at the selected insertion angle. *Id*. at 310; *see also* Ex. 1002 ¶ 92. Element (e) of claims 39 and 71 also was within the skill and knowledge of a person of ordinary skill in the art. *See id*. ¶ 93.

Claim 71 further requires:

Claim 71
(f) comprising the step of placing one of the major surfaces of the receiving member against bone material, and inserting the elongate section of the fastener into the bone material by threading the elongate section into the bone material.

Universal explicitly teaches "the plate must be pressed against the bone during implantation," i.e., placing one of the major surfaces of the receiving member (i.e., bone plate) against bone material, "in order to avoid fatigue fractures of the screw neck." Ex. 1005 at 311. Additionally, *Universal* discloses "[d]iffering inclines of the bone [i.e., elongate section of screw] and screw head threads make it possible to pull the implant against the bone surface," which can only occur when the threads of the elongate section of the fastener (i.e., bone screw) is threaded into bone material. *Id*. at 312; *see also* Ex. 1002 ¶ 96. FIG. 12b illustrates a schematic depiction bone screw (fastener) having been threaded into bone. Ex. 1005 at 311. FIGS. 22a-23b are x-ray images of the fixation systems disclosed by *Universal* after implantation, i.e., after the elongate section of a bone screw has been threaded into bone material.

As each of the features of claims 39 and 71 are disclosed in *Universal* and was within the knowledge and skill of a person of ordinary skill in the art, these claims are not patentable and should be canceled. *See* Ex. 1002 ¶¶ 94, 96-98.

2. The Dependent Claims Recite Additional Features That Are Not Patentable In View Of *Universal*

The dependent claims recite additional features of the surgical plates of claims 1 and 47 (dependent claims 2-4, 9, 11-12, 18, 48), the fastening apparatuses of claims 21 and 54 (dependent claims 22-25, 28, 30-31, 33-34, 55-57, 60, 62-63, 65-66), and the methods of claims 39 and 71 (dependent claims 40-44, 72-74). As discussed below, *Universal* renders obvious all of the additional features of dependent claims 2-4, 9, 11-12, 18, 22-28, 30-31, 33-34, 40-44, 48, 55-60, 62-63, 65-66, and 72-74. *See generally* Ex. 1002 ¶¶ 99-121, Ex. 1017.

Claims 2-4 depend from independent claim 1, which as discussed *supra* is unpatentable over *Universal*. Claim 2 further limits claim 1 by reciting "the first and second major surfaces [of the surgical plate] are disposed generally transversely in relation to the aperture axis." *Universal* shows that the bone plate holes are perpendicular to the bone plate. Ex. 1005 at 312 (FIGS. 9 and 10); Ex. 1002 ¶¶ 100-101. Thus, claim 2 is unpatentable over *Universal*.

Claim 3 further limits claim 1 by requiring that the plate comprise "a plurality of inside surfaces, each inside surface defining a respective aperture generally coaxially disposed about a respective aperture axis, and a plurality of tappable contact regions disposed on the inside surfaces." *Universal* discloses a bone plates having a plurality of holes (i.e., at least two holes). Ex. 1005 at 312 (*e.g.*, Fig. 10, showing 6 holes); 318 (describing 4-, 3-, and 2-hole plates); *see also*

Ex. 1002 ¶ 102. *Universal* discloses that the holes are made from a relatively "softer titanium" which is "penetrated" by "self-tapping screws of harder titanium," resulting in a "'weld' form[ing] between the contact surfaces." Ex. 1005 at 311. As set forth above with respect to the independent claims, the holes of the fixation systems disclosed by *Universal* include "tappable contact regions" under the broadest reasonable interpretation of this term. *Id*. at 307-308, 311; Ex. 1002 ¶ 102. Thus, *Universal* renders unpatentable claim 3.

Claim 4 further limits claim 1 by requiring that the tappable contact region have a "substantially cylindrical vertical profile." The holes, which include "tappable contact regions" as detailed above, are shown in *Universal* as having a substantially cylindrical form in Figures 9a and 9b. Ex. 1005 at 312, 314-15. The cross-sectional view of the substantially cylindrical holes taken along a longitudinal axis of the holes (i.e., along the aperture axis) would have the same visual appearance of a cross-sectional view of a cylinder. Ex. 1002 ¶ 103. Consequently, claim 4 is unpatentable over *Universal*.

Claims 9, 31, and 63 respectively depend from independent Claims 1, 21, and 54, which as discussed *supra* are unpatentable over *Universal*. Claims 9, 31, and 63 further limit those independent claims by reciting that "the tappable contact region is formed in the inside surface" of the hole. *Universal* describes that angular stability is "buil[t] in the plate hole," "[d]ue to the penetration of a thread

bearing screw head . . . into a plate hole which is made from a softer titanium" causing a direct weld "between the contact surfaces." Ex. 1005 at 307, 311. *Universal* further teaches that the plate hole is configured such that "[w]hen the bone screw is turned in, a material reshaping process occurs when the thread bearing screw head enters the plate hole, forcing a thread form [i.e., tapping] in the hole wall [i.e., tappable contact region]." *Id*. at 311. Thus, claims 9, 31, and 63 are unpatentable over *Universal*. Ex. 1002 ¶ 104.

Claims 11, 33, 43, 65, and 73 respectively depend from independent claims 1, 21, 39, 54, and 71, which as discussed above are unpatentable over *Universal*. Claims 11, 33, 43, 65, and 73 further limit those independent claims by reciting that "the tappable contact region comprises a plurality of protrusions extending generally radially inwardly from the inside surface and a plurality of interstices between the protrusions." As discussed above, *Universal* describes "equipping the wall of the hole with lips or raised areas which were formed in various thicknesses." Ex. 1005 at 313. These raised areas or lips are "protrusions" under the broadest reasonable interpretation of this term and extend radially inwardly from the inside surface. Ex. 1002 ¶¶ 51-53, 105. Between raised areas or lips would be "interstices," i.e., spaces, otherwise the lips or raised areas would be a single lip or raised area. *Id*. Thus, the feature added by claims 11, 33, 43, 65, and 73 are unpatentable over *Universal*.

Claims 12, 34, 48, and 66 respectively depend from claim 11 (which in turn depends from independent claim 1), claim 33 (which in turn depends from independent claim 21); claim 47; and claim 65 (which in turn depends from independent claim 54). As discussed above, each of these claims is unpatentable over *Universal*. Claims 12, 34, 48, and 66 further limit those claims by reciting that "the protrusions are constructed from a metal-containing material." *Universal* discloses that bone plates, the plate hole walls, and the lips or raised areas in the hole walls are formed from titanium. Ex. 1005 at 307-08, 311, 313-14. Titanium is a "metal-containing material" and one of the preferred metal alloys listed in the '677 patent. Ex. 1001 at 6:22-26; 7:33-37. Thus, the features of claims 12, 34, 48, and 66 are disclosed by *Universal*. *See also* Ex. 1002 ¶ 106.

Claim 18 requires that "the minimum inside diameter of the tappable contact region ranges from approximately 0.5 to approximately 10 mm." It would have been common sense to one of ordinary skill for the tappable contact region to have a minimum inside diameter to accommodate commercially available bone screws, which typically have a diameter between 0.5 and 10 mm. Ex. 1002 at ¶¶ 107-108. Indeed, the *Universal* reference discloses various screw sizes, including screws having "a core or external diameter of 4.2 or 5.5 mm" for use in the "upper and lower leg regions, screws with a diameter of 2.5 or 4.0 mm" for the lower arm and cervical spine, as well as screw sizes "with a diameter of 3.2 and 4.2 mm." Ex.

1005 at 316. *Universal* further discloses the following sizes for "[s]crews of the titanium fixation system: Mini: Core diameter of 2.5 mm, outer diameter 4.0 mm; Midi: Core diameter of 3.2 mm, outer diameter of 4.2 mm; Maxi: Core diameter of 4.2 mm, outer diameter of 5.5 mm." *Id*. at 317. These features would have also been within the knowledge of a person of ordinary skill in the art. Ex. 1002 ¶ 109.

One of ordinary skill in the art would have understood from this disclosure of bone screw sizes that the "minimum inside diameter of the tappable contact region" of the bone plates disclosed in *Universal* would have ranged "from approximately 0.5 to approximately 10 mm" in order to function properly with the disclosed range of screw sizes. Ex. 1002 ¶¶ 107-108. Indeed, even if the precise range were not disclosed, no criticality of the range is taught other than common sense of sizing the holes to mate with the screws being used. *See KSR*, 550 U.S. at 418 (The obviousness "analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."). Thus, claim 18 is not patentable over *Universal* in view of the knowledge of one of ordinary skill in the art. Ex. 1002 ¶ 109.

Claim 22 depends from independent claim 21, which, as discussed above, is unpatentable over *Universal*. Claim 22 further limits claim 21 by reciting that "the fastener is a bone screw." The fasteners disclosed throughout *Universal* are bone

screws as detailed above. *See also* Ex. 1005 (*e.g.*, Figure 9(b), showing a screw in a bone). Thus, claim 22 is not patentable over *Universal*. *See also* Ex. 1002 ¶ 110.

Claims 23 and 55 depend respectively from independent claims 21 and 54, which, as discussed above, are not patentable over *Universal*. Claims 23 and 55 respectively further limit claims 21 and 54 by reciting that "the elongate section [of the fastener] comprises a thread." *Universal* shows several fasteners wherein the elongate section comprises a thread. Ex. 1005 at 312 (FIGS. 9a, 9b); 314 (FIG. 14b). Further, as detailed above, *Universal* explicitly teaches that [d]iffering inclines of the bone [i.e., the elongate section of the screw] and screw head threads make it possible to pull the implant against the bone surface." *Id*. at 312. Thus, claims 23 and 55 are not patentable over *Universal*. *See also* Ex. 1002 ¶ 111.

Claims 24 and 56 respectively depend from claim 23 (which in turn depends from independent claim 21), and claim 55 (which in turn depends from independent claim 54), which, as discussed above, are not patentable over *Universal*. Claims 24 and 56 further limit claims 21, 23, 54, and 55 by reciting that "the elongate section [of the fastener] comprises a first outer surface, and the thread of the elongate section extends along a length of the first outer surface in generally helical relation to the fastener axis." All of the fasteners shown in *Universal* include an elongate section having a thread extending along the outer surface of the elongate section in generally helical relation to the fastener axis. *Id*.

at 312 (FIGS. 9a, 9b); 314 (FIG. 14b). A screw thread, by definition, winds around the elongate section of the screw in helical relationship to the screw axis. Ex. 1002 ¶ 112. Thus, claims 23 and 55 are not patentable over *Universal*.

Claim 25 depends from claim 24 (which in turn depends from claim 23, which in turn depends from independent claim 21), and claim 56 depends from claim 55 (which in turn depends from independent claim 54). As set forth above, claims 21, 23, 24, 54, 55, and 56 are not patentable over *Universal*. Claims 25 and 57 further limit claims 21, 23, 24, 54, 55, and 56 by reciting that "the head section [of the fastener] comprises a second outer surface, and the thread of the head section extends along a length of the second outer surface in generally helical relation to the fastener axis." *Universal* discloses a screw with a head section having a helical thread. Ex. 1005 at 312 (FIGS. 9a, 9b, 10b showing a helically threaded screw head); *see also* Ex. 1002 ¶ 113. Further, as noted above, *Universal* explicitly teaches that [d]iffering inclines of the bone and screw head threads make it possible to pull the implant against the bone surface." Ex. 1005 at 312. Thus, claims 25 and 57 are disclosed by *Universal*.

Claims 28 and 60 require that "the head section [of the fastener] has a substantially frusto-conical vertical profile." The '677 patent does not disclose that there is anything critical in a head section of a fastener, such as a bone screw, having a substantially frusto-conical vertical profile. *KSR*, 550 U.S. at 418.

Further, several of the bone screws in *Universal* appear to have a "substantially frusto-conical vertical profile" within the broadest reasonable interpretation of this term. For example, the bone screws shown in FIGS. 14b, 20, and 25 appear to show bone screws having heads with a "substantially frusto-conical vertical profile." Ex. 1005 at 314-315; 317. In view of these figures, one of ordinary skill in the art would have understood that *Universal* to have disclosed the limitations of claims 28 and 60. Ex. 1002 ¶ 114.

Claims 30 and 62 respectively depend from independent claims 21 and 54, which as discussed above are not patentable over *Universal*. Claims 30 and 62 further limit claims 21 and 54 by reciting that "the first and second major surfaces of the fastener receiving member define a surgical plate." The plates described in *Universal* (i.e., fastener receiving members) are part of "internal fixator systems [for] body regions," that are "pressed against the bone during implantation." Ex. 1005 at 308, 311. Put simply, the plates disclosed in *Universal* are surgical plates. Ex. 1002 ¶ 115. Thus, claims 30 and 62 are not patentable over *Universal*.

Claim 40 depends from independent claim 39, which, as discussed above is not patentable over *Universal*. Claim 40 further limits claim 39 by reciting the step of "placing one of the major surfaces of the receiving member against bone material, and inserting the elongate section of the fastener into the bone material." *Universal* discloses that "the plate must be pressed against the bone during

implantation." Ex. 1005 at 311. Further, in FIG. 9b, *Universal* shows one of the major surfaces of a bone plate (i.e., receiving member) placed against bone material, with the elongate section of the fastener implanted within the bone material. *Id*. Thus, claim 40 is disclosed by *Universal*. *See also* Ex. 1002 ¶ 116.

Claim 41 depends from claim 40, which depends from independent claim 39. As discussed above, claims 39 and 40 are not patentable over *Universal*. Claim 41 further limits claims 40 and 39 by reciting "the elongate section is threaded, and inserting the elongate section into the bone material comprises threading the elongate section into the bone material." *Universal* shows several fasteners wherein the elongate section comprises a thread. Ex. 1005 at 312 (FIGS. 9a, 9b); 314 (FIG. 14b). Further, as detailed above, *Universal* explicitly teaches that [d]iffering inclines of the bone [i.e., elongate section of the bone screw] and screw head threads make it possible to pull the implant against the bone surface." *Id*. at 312. Thus, claim 41 is disclosed by *Universal*. These features were also known to a person of ordinary skill in the art. *See* Ex. ¶ 117.

Claims 42 and 72 respectively depend from claim 41 (which depends from claim 40, which depends from independent claim 39) and claim 71, which are not patentable over *Universal* for the reasons set forth above. Claims 42 and 72 further limit those claims by reciting that "threading of the elongate section further into the bone material causes threading of the thread of the head section into the tappable

contact region of the receiving member." *Universal* describes "pressing" the plate "against the bone during implantation," and "penetration of a thread bearing screw head made from a harder pure titanium into a plate hole which is made from a softer titanium," which corresponds to the claimed threading the head section into the tappable contact region. Ex. 1005 at 311; 308. Universal also shows a fastener implanted with the elongate section threaded into bone, and the head section tapped into the plate contact region. *Id*. at 312 (FIG. 9b). *Universal* also teaches, as noted above, that [d]iffering inclines of the bone and screw head threads make it possible to pull the implant against the bone surface." *Id*. at 312. Where the plate is pressed against bone, screwing the screw further into the bone would result in threading the thread on the screw head into the tappable contact region. Ex. 1002 ¶¶ 92-94, 118. Thus, claims 42 and 72 are disclosed by *Universal*.

Claims 43 and 73 further recite that "tapping the fastener comprises driving the thread of the head section through a series of the interstices and into contact with a series of the protrusions." As discussed above, *Universal* describes "equipping the wall of the hole with lips or raised areas which were formed in various thicknesses." Ex. 1005 at 313. These raised areas or lips are "protrusions" under the broadest reasonable interpretation of this term and extend radially inwardly from the inside surface. Ex. 1002 ¶ 119. *Universal* further teaches that a connection is formed between the contact surfaces of the screw head and the lips

(or raised areas). Ex. 1005 at 313-314. When a threaded-head screw as disclosed in *Universal* is threaded into a plate having "lips" or "raised areas" as taught in *Universal*, the thread of the screw head will be driven through the spaces between the lips or raised areas that will contact the thread. Ex. 1002 ¶ 119. Thus, the additional feature of claims 43 and 73 is disclosed by *Universal* and therefore these claims are not patentable over *Universal*. *See also id*. ¶ 120.

Claim 44 depends from claim 43, which depends from independent claim 39), and claim 74 depends from claim 73, which in turn depends from independent claim 71. As discussed above, claims 39, 43, 71, and 73 are not patentable over *Universal*. Claims 44 and 74 further limit those claims by reciting that "driving the thread of the head section into contact with the series of protrusions deforms at least some of the protrusions." *Universal* explains that "[t]he force which is required to introduce the screw head into the plate hole . . . depends on the amount of material which is to be reshaped." Ex. 1005 at 313. In order to minimize the required insertion force, *Universal* teaches that in this can be accomplished by "equipping the wall of the hole with lips or raised areas." *Id.* FIG. 12 of *Universal* provides a cross-sectional view of the "close connection of the titanium contact surfaces between the screw head and the lip in the plate hole." *Id*. at 312. Therefore, the lips or raised areas are reshaped by the contact resulting from the

penetration of the screw head thread in this embodiment. Ex. 1002 ¶ 119-121). Thus, claims 44 and 74 are disclosed by *Universal*.

VI. CONCLUSION

Wright Medical submits that issues have been presented that demonstrate a reasonable likelihood that Claims 1-4, 9, 11-12, 18, 21-25, 28, 30-31, 33-34, 39-44, 47-48, 54-57, 60, 62-63, 65-66, and 71-74 of the '677 patent are unpatentable as being obvious over *Universal* and the knowledge of a person of ordinary skill in the art. The reference cited above was never considered by the original Examiner, and if they had been, the '677 patent would not have issued. Wright Medical therefore requests that the Board grant *inter partes* review to cancel those claims.

Please charge any fees or credit overpayment to Deposit Account No. 08933.

Respectfully submitted,

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Dated: April 14, 2014

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,955,677 PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108** was served on April 14, 2014, via **FedEx Priority Overnight** service to the correspondence address of record for the subject patent pursuant to 37 C.F.R. § 42.105:

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