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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. Petitioner

v.

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL Patent Owner

Case IPR2014-00112 Patent 6,955,677 B2

Before GRACE KARAFFA OBERMANN, RICHARD E. RICE, and MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

RICE, Administrative Patent Judge.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Smith & Nephew, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74 of U.S. Patent No. 6,955,677 B2 (Ex. 1001, "the '677 patent"). The University of North Carolina at Chapel Hill ("Patent Owner") filed a Preliminary Response (Paper 11, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

Institution of an *inter partes* review is authorized by statute when:

the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. We determine that the information provided in the Petition demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims, and accordingly institute an *inter partes* review.

A. Related Proceedings

Petitioner discloses the following district court proceedings as matters that may affect or be affected by a decision in this proceeding: *AngleFix Tech, LLC v. Smith & Nephew, Inc.*, Civ. No. 2:13-cv-02281-JPM-tmp (W.D. Tenn.); *AngleFix Tech, LLC v. Nuvasive, Inc.*, Civ. No. 3:13-cv-00983-BEN-RBB (S.D. Cal.);

¹ Paper 11 is titled "PATENT OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,955,677." As Paper 11 was filed by Patent Owner in response to the Petition, and within the time specified in 37 C.F.R. § 42.107(b), we view Paper 11 as a patent owner preliminary response under 37 C.F.R. § 42.107(a).

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AngleFix Tech, LLC v. Wright Medical Technology, Inc., Civ. No. 2:13-cv-02407-JPM-tmp (W.D. Tenn.).

B. The '677 Patent

The '677 patent, titled "MULTI-ANGULAR FASTENING APPARATUS AND METHOD FOR SURGICAL BONE SCREW/PLATE SYSTEMS," issued October 18, 2005, from an application filed October 15, 2002. Ex. 1001, cover page. The '677 patent discloses, as background, that in known bone screw/plate systems the head of the screw has a thread, in addition to the thread on the shaft of the screw, that is received matingly by threads in an aperture of the plate, such that the screw head is capable of being threaded into the plate aperture as the screw shaft is threaded into bone material. Ex. 1001, 1:21-29. A problem with such conventional screw/plate systems is that:

the head of a conventional threaded-head screw can only be rigidly affixed to the plate by mating its thread with that of the aperture, such that the bone screw is always inserted and threaded in one direction, e.g., perpendicularly or coaxially with respect to the plate.

Id. at 1:55-59. A goal of the '677 patent, therefore, is "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 1:60-63. Figure 3, reproduced below, depicts an embodiment of the claimed invention:

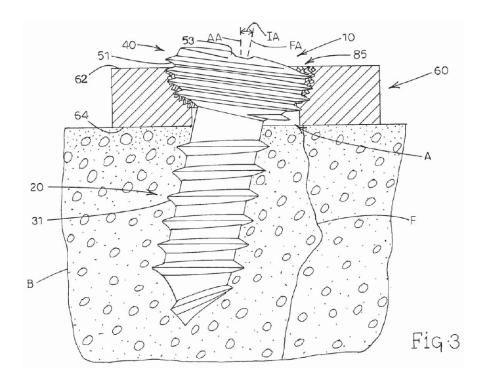


Figure 3 shows fastener 10 affixed in aperture A of fastener receiving member 60, and anchored to bone material B, at angle IA between fastener axis FA and aperture axis AA. *Id.* at 4:22-26; 7:7-14. It is disclosed that angle IA is a direction that was selected by the surgeon, after mounting receiving member 60 against bone material B in relation to bone fracture F, along which to drive fastener 10 into a target section of bone material B. *See id.* at 9:15-27. Figure 3 shows fastener 10 affixed rigidly in tappable contact region 85 of aperture A of fastener receiving member 60. *Id.* at 9:35-49; Fig. 3.

According to the '677 specification, "the invention departs from the conventional use of a thread formed on inside surface 81 of aperture A for mating with the thread of a screw head." *Id.* at 6:63-65. The specification discloses that "apertures A of fastener receiving member 60 do not contain a permanent helical thread structure of fixed orientation." *Id.* at 6:66-7:1. "Instead, a tappable contact region, generally designated 85, is disposed on each inside surface 81 of fastener receiving member 60" (*id.* at 7:1-3) and "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." *Id.* at 7:4-7. The specification discloses that tappable contact region 85 can be formed as a matrix of protrusions and interstices between protrusions, or as a matrix or mesh of fiber metal. *Id.* at 7:20-23; 8:44-49.

C. Exemplary Claims

Claims 1, 21, 39, 47, 54, and 71 are independent and are drawn to a surgical plate adapted for fixation with a bone screw (claims 1 and 47), a fastening apparatus adapted for multi-angular insertion (claims 21 and 54), and a method for affixing a fastener receiving member at a desired orientation (claims 39 and 71). Ex. 1001, 10:36-51; 11:41-61; 12:44-13:9; 13:40-55; 14:4-22; 15:4-16:3. Claims 2-20 depend directly or indirectly from claim 1. *Id.* at 10:52-11:40. Claims 22-38 depend directly or indirectly from claim 21. *Id.* at 11:62-12:43. Claims 40-46 depend directly or indirectly from claim 39. *Id.* at 13:10-39. Claims 48-53 depend directly or indirectly from claim 47. *Id.* at 13:56-14:3. Claims 55-70 depend directly or indirectly from claim 54. *Id.* at 14:23-15:3. Claims 72-76 depend directly or indirectly from claim 71. *Id.* at 16:4-26.

The independent claims require, *inter alia*, "a non-rotatable, non-threaded tappable contact region" (claim 1), "a non-rotatable tappable contact region" (claims 21 and 39), "a non-threaded tappable contact region" (claim 47), and "a tappable contact region" (claims 54 and 71). *Id.* at 10:40-41; 11:50-51; 12:53-54; 13:44-45; 14:14; 15:13-14. Claim 47 additionally requires, *inter alia*, that "the tappable contact region comprises a plurality of protrusions . . . and a plurality of interstices." *Id.* at 13:52-55.

Claim 1 is reproduced below (emphasis added):

1. A surgical plate adapted for fixation with a bone screw, 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 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 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 angles that can be selectively formed between the axis of the bone screw and the aperture axis.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references:

Wolter '117	DE 43 43 117 A1	June 22, 1995	Ex. 1005
		Translation	Ex. 1006
Wolter '011	DE 196 29 011 A1	Jan. 22, 1998	Ex. 1007
		Translation	Ex. 1008
Wolter '889	DE 198 58 889 A1	June 21, 2000	Ex. 1009
		Translation	Ex. 1010
Wagner	CA 2 626 694	Sept. 14, 2000	Ex. 1011
Frigg	US 6,206,881 B1	Mar. 27, 2001	Ex. 1012

E. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 13-60):

Reference(s)	Basis	Claims Challenged
Wolter '117	§ 102(b)	1-7, 9, 11, 12, 21-27, 30, 31, 33, 34, 39-44, 47, 48, 54-59, 62, 63, 65, 66, and 71-74

Reference(s)	Basis	Claims Challenged
Wolter '117	§ 103(a)	1-7, 9, 11, 12, 21-27, 30, 31, 33, 34, 39-44, 47, 48, 54-59, 62, 63, 65, 66, and 71-74
Wolter '117 and Wolter '889	§ 103(a)	4-8, 24, and 56
Wolter '117 and Wagner	§ 103(a)	18
Wolter '117 and Frigg ²	§ 103(a)	28 and 60
Wolter '117 and Wolter '011	§ 103(a)	1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74
Wolter '889	§ 102(b)	1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74
Wolter '889	§ 103(a)	1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74
Wolter '889 and Wolter '117	§ 103(a)	4-8, 24, and 56
Wolter '889 and Wagner	§ 103(a)	18
Wolter '889 and Frigg	§ 103(a)	28 and 60
Wolter '011	§ 102(b)	1-3, 9, 21-25, 28, 30, 31, 39-42, 54- 57, 60, 62, 63, 71, and 72

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide,

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² Petitioner also argues that claims 28 and 60 are unpatentable as obvious over Wolter '177 in combination with either Wolter '011 or Wolter '889. *Id.* at 42.

77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech.*, *Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes specific constructions for "tappable contact region" and "non-threaded." Pet. 10-13. We will address each claim term identified by Petitioner in turn.

1. Tappable contact region

Petitioner proposes that we give "tappable contact region" its ordinary and customary meaning as "any contact region structured to receive a fastener and secure it at an angle selected by the user." Pet. 10-12. In support of this construction, Petitioner argues that "[t]he '667 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 11 (citing Ex. 1001, 3:35-39).

Patent Owner disagrees, and argues that "'tappable contact region[,]' does not have a plain and ordinary meaning" in the art, because that term "is not a common ordinary phrase." Prelim. Resp. 6. Patent Owner further argues that the '667 patent explains that a "tappable contact region . . . is a treatment of the inner surface of the hole which provides for a region which can be deformed or deflected by the entry of the head of a screw" at a desired angle. *Id.* Patent Owner quotes from the '667 patent specification several descriptions of treatments formed on the inner surface of the hole, arguing that "[t]here is nothing permanent nor 'tapped' about the tappable contact region." *Id.* at 7. For example, Patent Owner quotes the

description that "protrusions 87 contacting second thread 51 may or may not deform or otherwise move in response to driving of second thread 51 into contact region 85." *Id.* (citing Ex. 1001, 9:60-63).

Patent Owner further argues that, "[w]hen the term tapping is used in its ordinary meaning, the material is permanently cut away to form a thread," and such "permanent removal is quite different from 'may or may not deform or otherwise move," as described in the specification. *Id.* (quoting Ex. 1001, 9:60-63). Patent Owner also argues that "no permanent thread" is formed in the tappable contact region of the '677 patent, and "[t]he lack of true 'tapping' is one of the elements that distinguishes the '677 patent from the prior art which is inherently limited by the dependence on traditional tapping." *Id.* at 8.

We do not agree fully with either party's proposed claim construction. In the context of screw/plate systems, the plain meaning of the verb "tap" is "to form an internal screw thread in by means of a tap [i.e., a tool for forming an internal screw thread]." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 1205 (10th ed. 1993). The specification of the '677 patent uses the term "tappable" in a manner consistent with the ordinary meaning of "tap," for example, where it describes that 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." Ex. 1001, 2:50-53. Similarly, the '677 patent states: "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." *Id.* at 7:3-7. That the protrusions of the tappable contact region, in one embodiment, "may or may not deform or otherwise move" on contact with the second thread of the fastener does not signify that a permanent thread cannot be

formed in the tappable contact region, contrary to Patent Owner's argument. *See* Prelim. Resp. 7-8 (citing Ex. 1001, 9:60-63). Indeed, the patent discloses that the driving of the second thread through the aperture "in effect forms a custom internal thread in [the] contact region " Ex. 1001, 10:3-8.

Accordingly, the broadest reasonable construction of the claim term "tappable contact region," consistent with the specification, is a contact region that is capable of being modified to form an internal screw thread by means of a tap.

2. Non-threaded

Petitioner requests that we give "non-threaded" its ordinary meaning as "does not contain a thread, *i.e.*, does not contain a continuous ridge that wraps around in the form of a helix." Pet. 13. Patent Owner disagrees, and proposes that "[n]on-threaded means not having a thread or a partial thread that functions as a thread." Prelim. Resp. 8. The claim construction issue presented by the parties' respective arguments, therefore, is whether the term "non-threaded" excludes only a continuous helical thread (Petitioner's position), or whether that term also excludes a partial thread that functions as a thread (Patent Owner's position).

We determine that the specification of the '677 patent supports Patent Owner's position, because it disparages "any forms of permanent internal thread structures." Ex. 1001, 2:16-23. Specifically, the specification states:

The present invention in broad terms provides a plate or other component suitable for affixation by a fastener. The plate has one or more apertures through which one or more corresponding fasteners can be inserted. *Notably absent from these apertures are any forms of permanent internal thread structures* as found in the prior art and which, as indicated above, are a limitation in applications such as the treatment of bone trauma.

Ex. 1001, 2:16-23 (emphasis added). Reading this statement as a disclaimer or disavowal is consistent with the criticism in the specification, discussed above, of

pre-tapped, fixed-position thread structures that constrain the orientation of a bone screw to a bone plate such that the screw must be inserted and threaded perpendicularly, or coaxially, with respect to the plate. *See id.* at 1:51-59. It is also consistent with the explicit goal of the '677 patent to provide a structure that permits affixing the bone screw to the bone plate without use of a pre-tapped, fixed-position thread structure:

It is another object of the present invention to provide [a] 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). The plate embodiments described in the specification lack internal thread structures of any kind and, therefore, are also consistent with the disclaimer or disavowal of internal thread structures. *See, e.g.*, *id.* at 6:63 – 8:67.

In conclusion, Petitioner's proposed construction of the limitation "non-threaded" is inconsistent with the specification, because it does *not* exclude a partial (e.g., spaced apart, or interrupted) helical thread that, although lacking a *continuous* helical ridge, is capable of matingly receiving a threaded fastener. *See* Pet. 13. Patent Owner's proposed claim construction, however, does exclude such a partial helical thread (*see* Prelim. Resp. at 8) and, therefore, is consistent with the disclaimer or disavowal in the specification of any forms of permanent internal thread structures.

The broadest reasonable construction of the claim term "non-threaded," consistent with the specification, is "not containing any forms of permanent internal thread structures." This construction of the "non-threaded" limitation excludes both a continuous thread in the form of a helical ridge and a partial thread that functions as a thread.

B. Anticipation by Wolter '117

Petitioner contends that Wolter '117 anticipates claims 1-7, 9, 11, 12, 21-27, 30, 31, 33, 34, 39-44, 47, 48, 54-59, 62, 63, 65, 66, and 71-74 of the '677 patent. Pet. 14-38. We are persuaded that Wolter '117 anticipates only a subset of those claims, as discussed below.

1. Wolter '117

Wolter '117 discloses a fixation system in which the respective seat surfaces of the bone plate and the bone screw allow for mutual alignment in various angular positions. Ex. 1006, 2:38-42. In a preferred embodiment, a through-hole of the bone plate comprises a partial thread in the form of "spaced-apart," or interrupted, thread segments; it is disclosed that the empty regions between the thread segments permit "penetration of a counter-thread at various screw-in angles." *Id.* at 3:33-37.

Figures 3 and 7 of Wolter '117, reproduced below, illustrate compatible bone screw and bone plate embodiments (*id.* at 8:33-35).

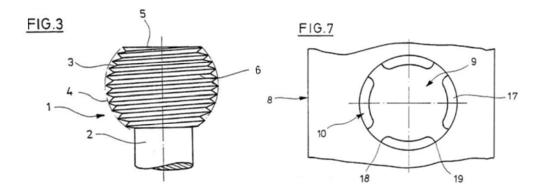


Figure 3 discloses a bone screw, and Figure 7 discloses a bone plate. As illustrated in Figure 3, bone screw 1 has screw head 3 disposed on shank 2, with spherical seat surface 4 on the underside of the screw head. *Id.* at 6:28-33; 7:28-30. Continuous external thread 6 is pre-formed in seat surface 4 of bone screw 1.

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Id. at 6:33-34; 7:28-32.

As illustrated in Figure 7, bone plate 8 has through-hole 9 with "an internal thread 10 comprising spaced-apart thread segments 17." *Id.* at 8:16-25. Wolter '117 discloses that bone plate 8 in Figure 7 can be used with bone screw 1 in Figure 3, and that the empty spaces or regions separating thread segments 17 of bone plate 8 (Figure 7) allow penetration by thread 6 of bone screw 1. *Id.* at 8:33-37.

2. Anticipation Analysis

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In support of its assertion that Wolter '117 anticipates claims 1-7, 9, 11, 12, 21-27, 30, 31, 33, 34, 39-44, 47, 48, 54-59, 62, 63, 65, 66, and 71-74 of the '677 patent, Petitioner provides discussion and detailed claim charts explaining how each claim limitation is allegedly disclosed in Wolter '117, and provides the declaration of Michael Voor, Ph.D., in support of its contentions. Pet. 14-38; Ex. 1002 ("Voor Decl."), ¶¶ 42-69.

a. Independent Claims 21, 39, 54, and 71

Upon review of Petitioner's analysis and the evidence of record, Petitioner has demonstrated that there is a reasonable likelihood that it will prevail in showing that Wolter '117 anticipates claims 21-27, 30, 31, 33, 34, 39-44, 54-59, 62, 63, 65, 66, and 71-74. For example, with respect to the "tappable contact region" limitation of independent claims 21, 39, 54, and 71, Petitioner persuasively argues that Wolter '117 discloses a "tappable contact region" (spaced-apart thread segments) on the inside surface of the bone plate aperture of Figure 7 that permits

passage of the bone screw at various screw-in angles. *See* Pet. 20, 21, 24, 25. Patent Owner's opposing argument that "[c]ylindrical threads are not a 'non-threaded tappable contact region'" (*see* Prelim. Resp. 9) is not commensurate with the scope of claims 21, 39, 54, and 71, or dependent claims 22-27, 30, 31, 33, 34, 40-44, 55-59, 62, 63, 65, 66, and 72-74, which do not include the "non-threaded" limitation. We are persuaded that Wolter '117 discloses all of the limitations of those claims.

b. Independent Claims 1 and 47

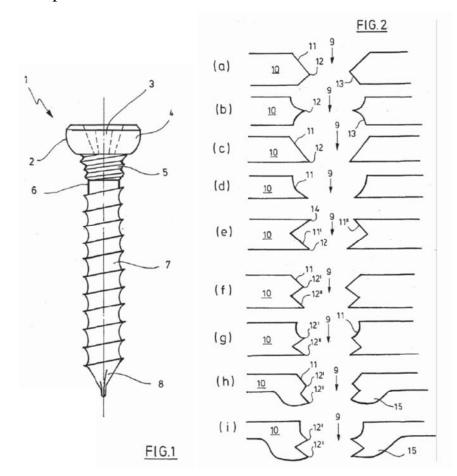
We are not persuaded, however, that Wolter '117 anticipates independent claim 1, and its dependent claims 2-7, 9, 11, 12, or independent claim 47, and its dependent claim 48, at least because those claims include the "non-threaded" limitation. Petitioner's arguments—that "[h]oles with thread segments . . . differ from threaded holes" and "[t]hreaded holes have a continuous thread or ridge that wraps around the circumference of the hole" (Pet. 15)—do not explain adequately why the spaced-apart thread segments illustrated in Figure 7 of Wolter '117 do not amount to a partial thread that functions as a thread. To the contrary, we are persuaded that the partial thread segments of Wolter '117 function as a thread. *See* Prelim. Resp. 8-10. Because we interpret the "non-threaded" limitation to exclude a partial thread that functions as a thread, Petitioner has not established that Wolter '117 teaches the "non-threaded" limitation. Accordingly, we are not persuaded that Wolter '117 anticipates claims 1-7, 9, 11, 12, 47, and 48.

C. Anticipation by Wolter '889

Petitioner contends that Wolter '889 anticipates claims 1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74 of the '677 patent. Pet. 43-51. Wolter '889 discloses a fixation system in which the threaded

connection between a bone screw and a connection support (e.g., a bone plate) is not formed in the respective seats of the bone screw and the connection support, but rather below the seats. Ex. 1010, 3:41-4:10; 8:17-19.

Figures 1 and 2a to 2i of Wolter '889, reproduced below, illustrate bone screw/bone plate embodiments.



As illustrated in Figure 1, bone screw 1 includes screw head 2, with spherical seat 4 on the bottom of the screw head, and short, pre-shaped thread 5 disposed underneath seat 4. *Id.* at 11:22-26. Adjoining thread 5 from underneath is screw shaft 6 bearing bone thread 7 and self-tapping screw tip 8. *Id.* at 11:26-32. Figures 2a to 2i illustrate various embodiments of through holes 9 in bone plates 10. *Id.* at 11:32-35. Through hole 9 in bone plate 10 of Figure 2g, for example, is

delimited by two projections, 12' and 12", and disposed below spherical seat 11. *Id.* at 12:28-31. Wolter '889 discloses that, in the embodiments of Figures 2a to 2i, "preshaped thread 5 reshapes the projections 12 or 12' and 12", respectively, such that a threaded connection is formed between the screw 1 and through hole 9, which is oriented precisely in the screwing-in axis." *Id.* at 13:11-15.

In support of its assertion that Wolter '889 anticipates claims 1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74 of the '677 patent, Petitioner provides discussion, detailed claim charts, and the Voor declaration, to explain how each claim limitation is allegedly disclosed in Wolter '889. Pet. 43-51; Ex. 1002, ¶¶ 70-99. Petitioner argues, for example, that Wolter '889 satisfies the "non-threaded" limitation of claims 1 and 47 because, in contrast to a continuous thread in the form of a helical ridge, or a partial thread in the form of spaced-apart thread segments, "each projection 'is arranged symmetrically on a circular line around the hole axis.'" Pet. 45 (quoting Ex. 1010, 4:40-43). Based on the record developed at this preliminary stage of the proceeding, we are persuaded that the projections of Wolter '889 (Figure 2) satisfy the "non-threaded" limitation, as construed above.

Patent Owner argues that Wolter '889 does not anticipate the challenged claims for a number of reasons. Prelim. Resp. 10-12. We have considered all of Patent Owner's arguments, but we do not find them persuasive at this stage of the proceeding.

Patent Owner argues, for example, that Wolter '889 "does not teach any cylindrical holes or vertical profiles," but "rather teaches slots," and does not disclose "defining an aperture generally coaxially disposed about an aperture axis," as required by the '677 patent claims. *Id.* at 10-11 (relying on Ex. 1010, Fig. 3). Patent Owner's arguments relying on the slot-shaped aperture of the Figure 3 plate

embodiment of Wolter '889, however, are not responsive to Petitioner's positions relying on the plate embodiments of Figure 2, illustrated above. *Compare* Prelim. Resp. 10-11 (relying on Figure 3) *with* Pet. 45-49 (relying on Figure 2); *see also* Ex. 1010, 4:40-43 ("The projection . . . can . . . be arranged symmetrically on a circular line around the hole axis.'"). Similarly, Patent Owner's arguments regarding non-disclosure and non-enablement of insertion angles (Prelim. Resp. 11) do not acknowledge or address the disclosure in Wolter '889 that "[a] bone screw 1 can be screwed in in various angular positions with respect to the axis of the through holes 9 of the embodiments of a connection support 10 according to Figures 2a to 2i." Ex. 1010, 13:7-11.

Upon review of Petitioner's analysis and the evidence of record, we determine that Petitioner has demonstrated that there is a reasonable likelihood that it will prevail in showing that Wolter '889 anticipates claims 1-3, 5-9, 11, 12, 21-25, 30, 31, 33, 34, 39-44, 47, 48, 54-57, 62, 63, 65, 66, and 71-74.

We are not persuaded, however, that Wolter '889 anticipates claims 4, 18, 26-28, or 58-60. Petitioner's chart omits claim 18. *See* Pet. 50-51. Petitioner's conclusory argument (*id.* at 50, chart) does not persuade us that Figure 2f (depicting two projections below a conical seat) discloses a tappable contact region having "a substantially cylindrical vertical profile" (claim 4). Nor do Petitioner's conclusory arguments (*id.* at 51, chart) persuade us that the "head section" of the bone screw depicted in Figure 1 discloses the various shapes recited in claims 26-

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³ As recited in independent claim 21 of the '677 patent, the "head section" of the fastener adjoins the elongate section of the fastener and comprises a thread. Ex. 1001, 11:43-45. We understand Petitioner to read the "head section" limitation on the entire structure disposed above bone thread 7 in Figure 1 of Wolter '889, specifically, the structure comprising screw head 2 and pre-shaped thread 5. Pet. 46 (chart, citing Fig. 1).

28 and 58-60. Figure 1, reproduced above, depicts a bone screw "head section" having a screw head with a flat top and a spherical bottom disposed above a preshaped thread section. The head section (structure above bone thread 7) depicted in Figure 1 does not have "a rounded vertical profile" (claims 26 and 58), "a substantially hemispherical vertical profile" (claims 27 and 59), or "a substantially frusto-conical vertical profile" (claims 28 and 60). *See id.* at 51, chart (relying on Fig. 1 as to each of the recited shapes).

D. Obviousness over Wolter '117

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, so-called secondary considerations. Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966). "[H]owever, the 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." KSR, 550 U.S. at 418; see also In re Preda, 401 F.2d 825, 826 (CCPA 1968) ("[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom."). The level of ordinary skill in the art usually is evidenced by the references

themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

Petitioner contends that the challenged claims of the '677 patent are unpatentable as obvious over Wolter '117 and the knowledge of one of ordinary skill in the art. *Id.* at 38. For essentially the same reasons discussed above with respect to anticipation by Wolter '117, we determine that there is a reasonable likelihood that Petitioner will prevail in showing that claims 21-27, 30, 31, 33, 34, 39-44, 54-59, 62, 63, 65, 66, and 71-74 would have been obvious over Wolter '117, but not in showing that claims 1-7, 9, 11, 12, 47, and 48 would have been obvious over Wolter '117.

E. Obviousness over Wolter '117 and Wagner

Petitioner contends that claim 18 of the '677 patent is unpatentable as obvious over Wolter '117 in view of Wagner. *Id.* at 41. Claim 18 depends from claim 1. Petitioner does not allege that Wagner remedies the deficiencies of Wolter '117 with respect to the "non-threaded" requirement of claim 1, discussed above. Accordingly, Petitioner has not demonstrated that there is a reasonable likelihood that it will prevail in showing that claim 18 of the '677 patent is unpatentable as obvious over Wolter '117 and Wagner.

F. Obviousness over Wolter '117 and Frigg

Petitioner contends that claims 28 and 60 of the '677 patent are unpatentable as obvious over Wolter '117 in view of Frigg. *Id.* at 42. Claims 28 and 60 depend directly or indirectly from claims 21 and 54, respectively.

Claims 28 and 60 each recites that "the head section [of the fastener] has a substantially frusto-conical vertical profile." As specified in the independent

claims, the "head section" adjoins the elongate section of the fastener and comprises a thread. Petitioner argues that Frigg "discloses bone screws having a substantially frusto-conical vertical profile." *Id.* (citing Ex. 1012, Fig. 1).⁴

Figure 1 of Frigg, reproduced below, is a longitudinal section through a bone plate:

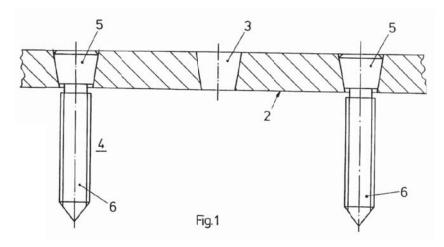


Figure 1 depicts bone screws 4 formed with conical heads 5. Ex. 1012, 1:61-64. The conical heads have structured or textured lateral surfaces 7, not identified in Figure 1, for inserting into matching conical plate holes 3, along with threads 6 for anchoring into bone. *Id.* at 1:61-67. Frigg discloses that structured or textured lateral surface 7 of head 5 has greater hardness than the material in the vicinity of plate holes 3 in bone plate 1, such that, "even when bone screws 4 are inserted in an imperfectly coaxial manner into plate holes 3, optimal geometric locking is achieved because the harder, structured lateral surface 7 is able to penetrate the softer material of plate hole 3." *Id.* at 2:1-7. In a preferred embodiment, the lateral

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⁴ Petitioner also argues that claims 28 and 60 are unpatentable as obvious over Wolter '177 in combination with either Wolter '011 or Wolter '889. *Id.* In particular, Petitioner argues that Figure 3 of Wolter '011 and Figure 1 of Wolter '889 each depicts a screw with a head section having a substantially frustoconical vertical profile. *See id.* at 42. Those contentions are redundant to Petitioner's contention regarding Frigg.

surfaces of head 5 of bone screw 4 are fitted with thread 9. *Id.* at 2:20-22; Fig. 2. We are persuaded that Frigg discloses a bone screw with a head section having a substantially frusto-conical vertical profile," as recited in claims 28 and 60.

For a reason to combine Wolter '117 and Frigg, Petitioner relies on Dr. Voor's testimony that one of ordinary skill would have known to use a bone screw having a substantially frusto-conical vertical profile, such as disclosed in Frigg, with the bone plates disclosed in Wolter '117. *See* Pet. 42 (citing Ex. 1002, ¶ 124). We understand Petitioner's position to be that using Frigg's bone screw with Wolter '117's bone plates would have been obvious as a combination of familiar elements according to known methods to yield predictable results. *See KSR*, 550 U.S. at 416 ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

In response, Patent Owner argues that "Frigg fails to teach tapping or angled fixation." Prelim. Resp. 12. As we understand Petitioner's contention, however, Petitioner does not rely on Frigg as teaching tapping or angled fixation, but rather as teaching a bone screw having a substantially frusto-conical vertical profile. Patent Owner's attack on the individual disclosure of Frigg does not effectively rebut Petitioner's position regarding what the combined teachings of Frigg and Wolter '117 would have suggested to a person of ordinary skill in the art.

On this record, we determine that there is a reasonable likelihood that Petitioner will prevail in showing that claims 28 and 60 are unpatentable as obvious over Wolter '117 and Frigg.

G. Obviousness over Wolter '889 alone or in combination with other references

Petitioner contends that the challenged claims of the '677 patent are unpatentable as obvious over Wolter '889 and the knowledge of one of ordinary skill in the art. Pet. 52. For essentially the same reasons discussed above with respect to anticipation by Wolter '889, we determine that there is a reasonable likelihood that Petitioner will prevail in showing that claims 1-3, 5-9, 11, 12, 21-25, 30, 31, 33, 34, 39-44, 47, 48, 54-57, 62, 63, 65, 66, and 71-74 would have been obvious over Wolter '889, but not in showing that claims 4, 18, 26-28, or 58-60 would have been obvious over Wolter '889.

Petitioner contends that claims 4-8, 24, and 56 of the '677 patent are unpatentable as obvious over Wolter '889 in view of Wolter '117. *Id.* (citing Ex. 1002, ¶¶ 121, 122). Dr. Voor's declaration supports Petitioner's contentions. *See* Ex. 1002, ¶¶ 121, 122. At this preliminary stage of the proceeding, Patent Owner does not dispute Petitioner's contentions or Dr. Voor's opinions regarding the limitations added to claim 1 by dependent claims 4-8, to claim 23 (which depends from claim 21) by claim 24, or to claim 55 (which depends from claim 54) by claim 56. *See* Prelim. Resp. 10-13. On this record, we determine that there is a reasonable likelihood that Petitioner will prevail in showing that claims 4-8, 24, and 56 are unpatentable as obvious over Wolter '889 and Wolter '117.

Petitioner contends that claim 18 of the '677 patent is unpatentable as obvious over Wolter '889 in combination with Wagner and/or the knowledge of one of ordinary skill in the art. Pet. 52 (citing Ex. 1002, ¶ 123). Dr. Voor's declaration supports Petitioner's contention. *See* Ex. 1002, ¶ 123. At this preliminary stage of the proceeding, Patent Owner does not dispute Petitioner's contentions or Dr. Voor's opinions regarding the limitations added to claim 1 by

dependent claim 18. On this record, we determine that there is a reasonable likelihood that Petitioner will prevail in showing that claim 18 is unpatentable as obvious over Wolter '889 and Wagner.

Petitioner contends that claims 28 and 60 of the '677 patent are unpatentable as obvious over Wolter '889 in combination with Frigg and/or the knowledge of one of ordinary skill in the art. Pet. 52-53 (citing Ex. 1002, ¶ 124). For essentially the same reasons as those discussed above with respect to Petitioner's assertion that the same claims would have been obvious over the combination of Wolter '117 and Frigg, we determine that there is a reasonable likelihood that Petitioner will prevail in showing that claims 28 and 60 are unpatentable as obvious over Wolter '889 and Frigg.

I. Remaining Grounds of Unpatentability

Petitioner also contends that claims 4-8, 24, and 56 of the '677 patent are unpatentable as obvious over Wolter '117 in view of Wolter '889. *Id.* at 39-41. This contention is redundant to Petitioner's almost identical contention (*id.* at 52), discussed above, that the same claims are unpatentable as obvious over Wolter '889 in view of Wolter '117. We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claims 4-8, 24, and 56 are unpatentable as obvious over Wolter '889 in view of Wolter '117. Therefore, we deny the petition on the redundant ground that claims 4-8, 24, and 56 are obvious over Wolter '117 in view of Wolter '889.

Petitioner also contends that Wolter '011 anticipates claims 1-3, 9, 21-25, 28, 30, 31, 39-42, 54-57, 60, 62, 63, 71, and 72 of the '677 patent. Pet. 53-60. Those claims, however, are a subset of those asserted to be anticipated by Wolter '889. *See id.* at 43-51. Petitioner has not asserted or shown that Wolter '011

remedies any deficiency, or potential deficiency, in Wolter '889. Accordingly, this remaining ground of unpatentability is redundant to the ground of unpatentability based on Wolter '889, and, therefore, we do not authorize an *inter partes* review on this ground.

Petitioner also contends that, if "the tappable contact region disclosed in Wolter '117 somehow did not meet the non-threaded limitation of Claims 1 and 47," then the limitation would have been obvious over Wolter '117 combined with Wolter '011 and the knowledge of one of ordinary skill in the art. Pet. 42. This contention is redundant to Petitioner's contention (*id.* at 52), discussed above, that claims 1 and 47 are either anticipated by, or unpatentable as obvious over, Wolter '889. We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claims 1 and 47 are either anticipated by, or obvious over, Wolter '889. Therefore, we deny the petition on the redundant ground that claims 1 and 47 are obvious over Wolter '117 and Wolter '011.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner will prevail in showing unpatentability of claims 1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74 of the '677 patent. At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is granted and an inter partes review is hereby

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instituted as to claims 1-9, 11, 12, 18, 21-28, 30, 31, 33, 34, 39-44, 47, 48, 54-60, 62, 63, 65, 66, and 71-74 of the '677 patent on the following grounds of unpatentability:

Claims 21-27, 30, 31, 33, 34, 39-44, 54-59, 62, 63, 65, 66, and 71-74, unpatentable under 35 U.S.C. § 102(b) or § 103(a) as anticipated by or obvious over Wolter '117;

Claims 1-3, 5-9, 11, 12, 21-25, 30, 31, 33, 34, 39-44, 47, 48, 54-57, 62, 63, 65, 66, and 71-74, unpatentable under 35 U.S.C. § 102(b) or § 103(a) as anticipated by or obvious over Wolter '889;

Claims 28 and 60, unpatentable under 35 U.S.C. § 103(a) as obvious over Wolter '117 and Frigg;

Claims 4-8, 24, and 56, unpatentable under 35 U.S.C. § 103(a) as obvious over Wolter '889 and Wolter '117;

Claim 18, unpatentable under 35 U.S.C. § 103(a) as obvious over Wolter '889 and Wagner; and

Claims 28 and 60, unpatentable under 35 U.S.C. § 103(a) as obvious over Wolter '889 and Frigg.

FURTHER ORDERED that no other grounds of unpatentability alleged in the Petition for any claim is authorized for this *inter partes* review;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 11 AM Eastern Time on May 12, 2014. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered

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herewith and any motions the parties anticipate filing during the trial.

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