Paper No.

# UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INSTRADENT USA, INC. Petitioner v.

# NOBEL BIOCARE SERVICES AG

Patent No. 8,764,443 Issue Date: July 1, 2014 Title: METHOD FOR PRODUCING A SURFACE STRUCTURE ON AN IMPLANT, AND SUCH AN IMPLANT

Inter Partes Review No. Unassigned

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# PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET. SEQ*.

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# EXHIBIT LIST

Ex. #	Exhibit
1001	U.S. Patent No. 8,764,443 ("'443 Patent")
1002	Declaration of Dr. Michel Dard
1003	U.S. Patent No. 6,364,663 ("Dinkelacker")
1004	U.S. Patent No. 6,129,730 ("Bono")
1005	U.S. Patent No. 6,129,730 ("Bono") as annotated during Deposition of Dr. Sinan Müftü
1006	Deposition Transcript of Dr. Sinan Müftü
1007	Decision On Appeal of the Patent Trial and Appeal Board entered on November 15, 2013 in the prosecution of U.S. Patent Application No. 10/583,817 in the name of Lars Jorneus
1008	Declaration of Jan Hall under 37 CFR § 1.132 Submitted During Prosecution of '443 Patent
1009	U.S. Patent No. 8,714,977 ("Fromovich")
1010	U.S. Patent No. 422,307 ("Libbey")
1011	Transcript of Oral Hearing of June 18, 2013 in Application Ser. No. 10/499,930
1012	U.S. Patent No. 6,371,709 ("Papafotiou")
1013	U.S. Patent No. 4,103,422 ("Weiss Patent")
1014	Charles M. Weiss, D.D.S. and Adam Weiss, BA, <i>Principles and</i> <i>Practice of Implant Dentistry</i> (1st ed. 2001), ch. 19, pp. 347-61 (" <i>Implant Dentistry</i> ")
1015	U.S. Patent No. 3,466,748 ("Christensen")
1016	U.S. Patent No. 3,813,779 ("Tosti")
1017	Complete CV of Dr. Dard

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#### **NOTICE OF EACH REAL-PARTY-IN-INTEREST**

The real-parties-in-interest are Instradent USA, Inc., Instradent AG, Straumann Holding AG, Institut Straumann AG and JJGC Indústria e Comércio de Materiais Dentários S/A. The sole shareholder of Instradent USA, Inc. is Instradent AG, a Swiss corporation whose sole shareholder is Straumann Holding AG, a Swiss corporation. Instradent USA, Inc. imports and sells dental implants manufactured by JJGC Indústria e Comércio de Materiais Dentários S/A, which is wholly owned by Straumann Holding AG.

### **NOTICE OF RELATED MATTERS**

U.S. Patent No. 8,764,443 ("the '443 Patent") is asserted in *Certain Dental Implants*, Inv. No. 337-TA-934, in which a Final Initial Determination is expected to be entered on October 27, 2015, as well as in the Central District of California in the case captioned *Nobel Biocare Services AG and Nobel Biocare USA, LLC, v. Neodent USA, Inc.,* Civil Action No. 14-1322 DOC (DFMx)(C.D. CA.), which is

stayed pending resolution of the International Trade Commission Investigation, and within which the Complaint was served on Instradent USA, Inc. (formerly known as Neodent USA, Inc.) on August 21, 2014.

## **NOTICE OF SERVICE INFORMATION**

Please address all correspondence to the lead counsel at the address above. Petitioner consents to electronic service at: <u>phunter@foley.com</u>; <u>npisano@foley.com</u>; and <u>acheslock@foley.com</u>.

### **GROUNDS FOR STANDING**

Petitioner hereby **certifies** that the patent for which review is sought is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting an *inter partes* review. Petitioner has paid all fees believed to be due for this Petition. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this Petition under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741.

# **STATEMENT OF MATERIAL FACTS**

 The '443 Patent matured from U.S. patent application Serial No. 10/499,430, filed February 7, 2005, which claims priority to PCT/SE02/023261 ("the PCT International Application"), which itself claims priority to Swedish Patent Application No. 0104350 ("Swedish National Application"), filed December 21, 2001. (Ex. 1001.) 2. Petitioner is not aware of any specific evidence that would support a finding that the dates of conception and reduction to practice predate the filing of the application that resulted in the issuance of the '443 Patent, and Nobel Biocare Services AG has not identified any such specific evidence throughout the course of concurrent litigation.

3. The date of conception and reduction to practice of the claims of the '443 Patent is December 21, 2001, the filing date of the Swedish National Application, to which the '443 Patent ultimately claims priority.

4. All references dated prior to December 21, 2001 are available as prior art.

5. Further, for purposes of qualifying prior art under 35 U.S.C. § 102(b), the filing date of the PCT Application is relevant, and thus, any prior art that published or issued more than one year before that filing date – December 18, 2002 – is prior art under § 102(b). *See* 35 U.S.C. § 102(b).

6. The '443 Patent was filed before the enactment of America Invents Act, and therefore the pre-AIA version of the statutes referenced within this Petition are applicable.

7. Nobel Biocare Services AG is the purported patent owner by virtue of an assignment executed on July 1, 2005 and recorded at the United States Patent Office at Reel/Frame 25722-114.

#### STATEMENT OF PRECISE RELIEF REQUESTED

The Petitioner respectfully requests the Board initiate an *inter partes* review and cancel Claims 15, 17-19, 21, 25-27, and 30-32 of the '443 Patent as unpatentable pursuant to 35 U.S.C. § 311(b) based on the following five grounds of unpatentability that are discussed in detail herein (including relevant claim constructions).

**Ground 1.** Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as obvious by Bono (Ex. 1004) in view of Dinkelacker (Ex. 1003).

**Ground 2** Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as obvious over Libbey (Ex. 1010) in view of Dinkelacker (Ex. 1003).

**Ground 3.** Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as obvious over Papafotiou (Ex. 1012) in view of Dinkelacker (Ex. 1003).

**Ground 4.** Claims 15, 17, 30, and 32 are unpatentable as anticipated over the Weiss Patent (Ex. 1013) (as evidenced by the *Implant Dentistry* text (Ex. 1014), Christensen (Ex. 1015), or Tosti (Ex. 1016)).

**Ground 5.** Claims 18-19, 21, 25, and 26 are unpatentable as obvious over the Weiss Patent (Ex. 1013) (as evidenced by the *Implant Dentistry* text (Ex. 1014), Christensen (Ex. 1015), or Tosti (Ex. 1016)) in view of Dinkelacker (Ex. 1003).

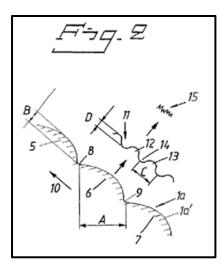
### THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW

A petition for *inter partes* review must demonstrate "a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition." (35 U.S.C. § 314(a).) The Petition meets this threshold. Each of the elements of Claims 15, 17-19, 21, 25-27, and 30-32 of the '443 Patent are taught in the prior art as explained below in the proposed grounds of unpatentability. Also, the reasons to combine are established for each ground under 35 U.S.C. § 103(a).

#### **STATEMENT OF REASONS FOR RELIEF REQUESTED**

### I. Introduction to the Technology of the '443 patent

The '443 Patent is directed to a dental device having a thread with a wave pattern with at least one trough that follows the spiral trajectory of the thread on the dental device. (Ex. 1001 at Claim 15.) The claimed trough has a depth of 25 to 200  $\mu$ m. (*Id.*) The '443 patent purports to achieve "substantial stability of the implant incorporation in the bone in a short time, for example just 1 to 5 days." (Ex. 1001 at col. 2, lns. 35-37.) An example of the claimed "wave pattern" is shown directly below, as sourced from Figure 2 of the '443 Patent.



As is demonstrated by each ground of unpatentability presented below, the structure of the dental device recited in claims 15, 17-19, 21, 25-27, and 30-32 of the '443 Patent having a trough with a depth of between 25 to 200  $\mu$ m was neither novel nor inventive.

# II. Construction of the Claims

## a. Legal Overview

A claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." (*See*, 37 C.F.R. § 42.100(b).) For the purposes of this proceeding, claim terms are presumed to take on their broadest reasonable ordinary meaning. As stated in the case *In re ICON Health and Fitness, Inc.* at 496 F.3d 1374, 1379 (Fed. Cir. 2007): "the PTO must give claims their broadest reasonable construction consistent with the specification."

# i. Preamble language of "dental implant" (Claim 15)

Petitioner anticipates that Nobel Biocare Services AG will attempt to argue that the preamble of claim 15 is a limitation. That is incorrect.

A preamble that does not recite an essential structural limitation, and is not "necessary to give life, meaning, and vitality to the claim," is not limiting. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). That is, "a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Id.

The preamble of independent claim 15 recites "a dental implant comprising." The balance of the actual claim limitations of that claim do not reference a "dental implant," but instead define the structurally complete features of an "implant body" without reference to the "dental implant" of the preamble. (Ex. 1002, ¶ 18.) Indeed, the actual claim limitations directed to an "implant body" are not limited to a "dental implant," but instead can be read to include any type of "implant" or fastener having the particularly claimed structure of a trough (Ex. 1002, ¶ 19), under the Broadest Reasonable Interpretation standard applied by the Board.

As such, under the Broadest Reasonable Interpretation standard, the preamble of independent claim 15 is not a limitation.

# III. One of Ordinary Skill in the Prior Art

The relevant time for assessing the level of ordinary skill in the art is as of the time of the invention – in this case, December 21, 2001, the filing date of the Swedish National Application, to which the '443 Patent ultimately claims priority. To assess the level of ordinary skill in the art at that time, one should consider factors such as: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field. Daiichi Sankyo v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007). Considering all of those factors, Petitioner's expert believes that one of ordinary skill in the art of the '443 patent prior to December 21, 2001 would have been a person having at least a bachelor-level degree in mechanical or bio-medical engineering and three years of experience in the design and development of dental implants, or a dental provider trained in the practice of implanting dental implants. (Ex. 1002, ¶ 13.)

#### **IV.** Claim-By-Claim Explanation of Grounds for Unpatentability

Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as shown in the following Grounds.

# Ground 1. Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as being obvious over Bono in view of Dinkelacker

Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as being obvious over U.S. Patent No. 6,129,730 ("Bono") (Ex. 1004) in view of U.S. Patent No.

6,364,663 ("Dinkelacker") (Ex. 1003) under § 103(a). Bono issued on October 10, 2000, and constitutes prior art to the '443 patent under § 102(b). Dinkelacker was filed on December 3, 1999, and issued on April 2, 2002, making it prior art under § 102(e).

# i. Introduction to the Dinkelacker Reference

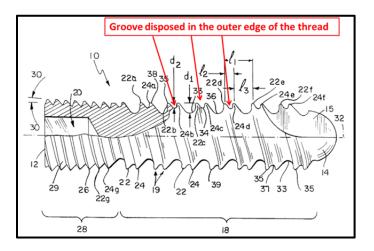
The Dinkelacker reference is directed to a dental implant, and further discloses having a trough or groove with a depth in the claimed range of 25 to 200 um. In particular, Dinkelacker discloses that: "The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows)....The groove-shaped recesses are 20-300 µm wide and 10-150 um deep." (Ex. 1003, col. 3, lns. 36-42.) The sizing of the grooves is not *coincidental*; rather, Dinkelacker teaches that the dimensions correspond with those of the osteons of the bone to help the bone grow directly into the implant. (Ex. 1003, col. 3, lns. 42-45.) In particular: "The groove-shaped surface of the implant causes the osteons 110 of the bone to collect in the grooves on the perimeter of the steps 106. This produces a tight connection between the bone and implant. The grooved structure allows the osteons to grow directly into the implant. This improves the transmission of force to the anatomical/histological bone components, in particular to the osteons, and causes a pressure-induced formation of compact bone 112 around the implant in the area of the spongiosa.

This biomechanical integration shortens the healing phase for the implant and lengthens the time of the implant in the bone due to the decrease in bone resorption." (Ex. 1003, col. 6, lns. 23-35.)

#### ii. Introduction to the Bono Reference

Bono is directed to an orthopedic bone screw that is used for attaching medical devices such as plates to bones. (Ex. 1004, col. 1, lns. 5-8.)

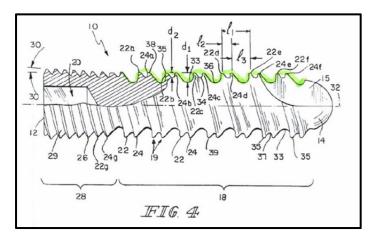
As shown in FIG. 4 (reproduced below) and further described in the patent, Bono discloses an implant body having a helical thread disposed thereon: "Referring to FIGS. 3 and 4, dual lead threaded section 18 includes a dual lead thread 19. Dual lead thread 19 comprises a first lead 22 and a second lead 24. Each lead 22, 24 is provided in the form of a helix, which is disposed around shaft 16 along an axis 32." (Ex. 1004, col. 3, lns. 5-9.)



As shown above in the annotated version of FIG. 4 (annotations in red), dual lead thread 19 of Bono creates a wave pattern, when seen in side view, including a small groove in the outer face of the thread that extends generally in the direction

of the longitudinal axis of the implant body: "Large groove 36 of bone screw 10 has a thread depth d1. Thread depth d1 is the radial distance from a peak position 35 to a position at a trough 33 of lead 13. Small groove 37 has a thread depth d2, which is the radial distance from peak position 35 to a position at a trough 34 of lead 12. In the illustrative embodiment, thread depth d1 is at least twice thread depth d2." (Ex. 1004, col. 3, lns. 39-46.)

Significantly, Nobel Biocare Services AG's own expert, during the course of concurrent litigation, admitted that Bono discloses a "wave pattern" that includes a "trough" in connection with an annotated version of FIG 4. presented directly below (annotation in green):



(Ex. 1005, Figure 4 (as annotated).)

Q: Can you explain to me how it is, if you consider the wave that I've drawn in figure 4, that figure 4 doesn't show a wave pattern with at least one trough, the wave pattern extending generally in the direction of the longitudinal axis of the implant body? A: *There's a wave pattern here definitely.* 

Q: Okay. And if you consider what I drew there, then there would be troughs. Isn't that right?

Q: *There would be troughs*. That's right. If -- I could -- yes.

(Ex. 1006, Dep. Tr. of Dr. Müftü, 66:24-67:11 (emphasis added).)

#### iii. Reasons to Combine Bono with Dinkelacker

Bono discloses a threaded bone screw having a groove disposed in the outer edge of the thread. (Ex. 1004, col. 3, ln. 39-46 & FIG. 4) (Ex. 1002, ¶ 25.) That groove is admittedly a "wave pattern" as recited in independent claim 15. (Ex. 1005, Figure 4 (as annotated); Ex. 1006, Dep. Tr. of Dr. Müftü, 66:24-67:11) (Ex. 1002, ¶ 25.) Bono does not explicitly teach that the groove has a depth within the range of 25 to 200  $\mu$ m claimed by independent claim 15. (Ex. 1002, ¶ 25.) Dinkelacker, on the other hand, discloses grooved surfaces on the body of a dental implant having a depth within the range of 25 to 200  $\mu$ m, as recited in independent claim 15, which grooves are sized to correspond with the osteons in the bone to promote the bone to grow directly into the implant. (Ex. 1003, col. 3, ln. 42-45) (Ex. 1002, ¶ 25.)

It is well accepted that bone screws and dental implants are within the same technical field. (Ex. 1002, ¶ 26.) That is, when developing a dental implant, one of skill in the art would have looked to orthopedic screws such as that disclosed by Bono, because orthopedic screws are implanted within bone having characteristics similar to that of the jaw bone in which a dental implant is placed. (Ex. 1002, ¶ 26.) In fact, Nobel Biocare Services AG's own patents directed to dental implants describe that those implants may be used in other bony structures. (See, e.g., Ex. 1009, Fromovich, col. 2, lines 23-27 ("This invention is of a skeletal screw that can be easily inserted inside bone and can be used in soft bone and hard bone. The following description will focus on dental implants but all the details can be implemented also in orthopedics for other regions of the body.")) (emphasis added) (Ex. 1002, ¶ 26.) Thus, persons of ordinary skill in the field of dental implants knew that many of the early dental implants were adapted from bone screws similar to that disclosed by Bono, as it was well known that titanium was an exceptional material for use in medical devices inserted into bone. (Ex. 1002, ¶ 26.) Notably, the similarity of such bone screws to dental implants was also recognized by the inventor of the '443 Patent, who performed research to evaluate the effectiveness of grooves on dental implants through *in vivo* investigations in rabbit femoral bone. (Ex. 1008, Jan Hall Decl., at 14) (Ex. 1002, ¶ 26.) As a result, it is typical for one of ordinary skill in the art of dental implants to look to both

orthopedic screws and dental implants when developing aspects of dental implants to improve the interaction between the implant and the bone. (Ex. 1002,  $\P$  26.)

Moreover, one of skill in the art would have recognized the benefit of the depth of the grooves disclosed by Dinkelacker as being sized to correspond with the dimensions of bone osteons, and would have been motivated to modify the grooves formed in the outer surface of the threads of the Bono bone screw to have a similar depth as that taught by Dinkelacker. (Ex. 1002, ¶ 27.) That is, the osteons of the bone are "agnostic" as to the location of the groove, and Dinkelacker's teachings to provide a specific groove depth are readily applicable to Bono to "cause[] the osteons 110 of the bone to collect in the grooves []. This produces a tight connection between the bone and implant." (Ex. 1003, col. 6, lns. 23-27) (Ex. 1002, ¶ 27.) Here, the known technique is the dimension of the grooves taught by Dinkelacker, which when applied to the spiral groove of Bono would result in the same and predictable benefit of promoting osteon growth into the groove of the Bono, thereby creating a tight connection between the implant and the bone that facilitates prompt fixation, and promotes the longevity of the implant and the health of the bone. (Ex. 1002, ¶ 27.) See KSR Int'l v. Teleflex, Inc., 127 S. Ct. 1727, 1740 (2007) (discussing obviousness of predictable improvements).

As further evidence of the obviousness of relocating grooves, such as taught in Dinkelacker, to other areas of a dental implant, one may look to other applications prosecuted by the Nobel Biocare Services AG. For example, during prosecution of U.S. Patent Application No. 10/583,817 in the name of Lars Jorneus ("the Jorneus application"), which was owned by the Swedish affiliate of the Nobel Biocare Services AG and prosecuted by the attorney who prosecuted the '443 Patent, the applicant argued that the Examiner improperly used hindsight reasoning to combine Dinkelacker with U.S. Patent No. 6,419,491 ("Ricci"), which discloses a dental implant having a lower "anchor" portion. (Ex. 1007 at 7) (Ex. 1002, ¶ 28.) Specifically, the prosecuting attorney argued that the Examiner's application of the "crosswise groove-shaped recesses" of Dinkelacker to the anchor portion of the Ricci implant was improper. (*Id.*) (Ex. 1002, ¶ 28.) On appeal, the PTAB found that relocating the grooves of Dinkelacker from the body of the implant to another portion of the implant would have been obvious to one of ordinary skill:

We conclude that an artisan of ordinary skill would have found it obvious to combine the teachings of Ricci and Dinkelacker such that the lower portion 152 of the implant of Ricci (which is in contact with bone and which bear a pattern of grooves) is modified with the grooves of Dinkelacker, which correspond to the grooves recited in claim 1. We conclude further that an artisan of ordinary skill would have been motivated to combine the cited prior art references due to the teachings of Dinkelacker that the grooves taught therein promote movement and collection by osteons on the perimeter of the implant.

(Ex. 1007 at 6-7) (Ex. 1002,  $\P$  28.) Accordingly, one of skill in the art would have found that the grooves disclosed by Dinkelacker could be applied to other portions of an implant, such as to the outer surface of the thread. (Ex. 1002,  $\P$  29.)

# iv. Combination of Bono and Dinkelacker

The elements of claims 15, 17-19, 21, 25-27, and 30-32 are mapped to the

teachings of Bono in view of Dinkelacker in the following claim chart, as

II.11.2442 D.4	Design in the of Distribution
Hall '443 Patent	Bono in view of Dinkelacker
15. A dental implant	"The present invention relates to a fastener for coupling a
comprising:	medical device to a bone; more particularly to a <u>bone</u>
	screw; and most particularly to a bone screw that has a
	desirable pullout value." (Ex. 1004, Bono, col. 1, ln. 5-8)
	(emphasis added) (Ex. 1002, ¶ 32.)
	"Additionally, bone screw 10 may be used alone in certain
	circumstances, without the use of other prosthetic
	appliances." (Ex. 1004, Bono, col. 3, ln. 2-4) (Ex. 1002, ¶
	33.)
	"The invention concerns a <u>tooth implant</u> that can be
	inserted in the jaw in an operation with a rotationally
	symmetrical implant body that has a rough surface, and a
	method to make the implant." (Ex. 1003, Dinkelacker,
	col. 1, ln. 5-8) (emphasis added.) (Ex. 1002, ¶ 34.)
an implant body	"Referring now to FIG. 3, bone screw 10 of the present
defining a	invention includes a head 12, a tip 14, and a shaft 16
longitudinal axis and	extending between head 12 and tip 14." (Ex. 1004, Bono,

Hall '443 Patent	Bono in view of Dinkelacker
an exterior surface;	col. 2, ln. 49-51) (Ex. 1002, ¶ 36.)
	"The tooth implant in FIG. 1 comprises a cylinder 11 that consists of titanium which has a head 12 with a polished surface Below the head 12 is a collar 16 that has numerous small troughs or lagoons 17 in its perimeter. Abutting the collar 16 is a body area 18 that extends over the majority of the length of the implant cylinder 11. The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows)." (Ex. 1003, Dinkelacker, col. 3, ln. 28- 38) (Ex. 1002, ¶ 37.) $I = \int_{\frac{1}{2}} \int_{\frac{1}{2}} \frac{1}{2} \int_{\frac{1}{2}} F_{19,1}$ (Ex. 1003, Dinkelacker, Figure 1; Ex. 1002, ¶ 38.)
and <b>a thread</b> extending about the	Bono discloses the outer surface of the implant has a wave pattern with at least one trough:
implant body in a spiral trajectory, the thread defining an outer surface,	"Referring to FIGS. 3 and 4, dual lead threaded section 18 includes <u>a dual lead thread 19</u> . Dual lead thread 19 comprises a first lead 22 and a second lead 24. Each lead

Hall '443 Patent	Bono in view of Dinkelacker
wherein when seen	22, 24 is provided in the form of a helix, which is disposed
in side view, <b>the</b>	around shaft 16 along an axis 32." (Ex. 1004, Bono, col.
outer surface of the	3, ln. 5-9) (emphasis added) (Ex. 1002, ¶ 40.)
thread comprises a	
wave pattern with	"Still referring to FIG. 4, bone screw 10 has a large groove
at least one trough,	36 and a small groove 37. Large groove 36 of bone screw
the wave pattern	10 has a thread depth d1. Thread depth d1 is the radial
extending generally	distance from a peak position 35 to a position at a trough
in the direction of the	33 of lead 13. Small groove 37 has a thread depth d2,
longitudinal axis of	which is the radial distance from peak position 35 to a
the implant body, the	position at a trough 34 of lead 12. In the illustrative
trough extending in a	embodiment, thread depth d1 is at least twice thread depth
course that	d2." (Ex. 1004, Bono, col. 3, ln. 39-46) (Ex. 1002, ¶ 41.)
substantially follows	$30$ $22a$ $38$ $35$ $d_1$ $d_2$ $d_1$ $d_2$ $d_1$ $d_2$
the spiral trajectory	$\begin{array}{c} 2^{24} \\ 1 \\ 3^{3} \\ 3^{3} \\ 3^{3} \\ 3^{3} \\ 1 \\ 1 \\ 1^{3} \\ 3^{3} \\ 3^{3} \\ 1^{3} \\ 1^{3} \\ 2^{4} \\ 2^{4} \\ 2^{4} \\ 2^{4} \\ 1^{5} \\ 1^$
of the thread, <b>the</b>	$\frac{1}{22b} \frac{1}{24b} \frac{1}{24c} \frac{1}{24d} $
wave pattern	
having a respective	29 $26$ $249$ $24$ $19$ $22$ $24$ $39$ $31$ $33$ $35$ $229$
trough depth in the	28 IFIG 4
range of between	Dinkelacker discloses the trough or groove depth in the
approximately 25 to	required range:
200 μm.	required range.
	"The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows)The groove-shaped recesses are 20-300 $\mu$ m wide and <u>10-150 <math>\mu</math>m deep</u> . During the healing phase, the osteons of the bone tissue can collect in the groove-shaped recesses. The width of the grooves corresponds to the dimensions of the osteons." (Ex. 1003, Dinkelacker, col. 3, ln. 36-45) (emphasis added) (Ex. 1002, ¶ 43.)
	"The groove-shaped surface of the implant causes the osteons 110 of the bone to collect in the grooves on the perimeter of the steps 106. This produces a tight connection between the bone and implant. <u>The grooved</u> <u>structure allows the osteons to grow directly into the</u>

Hall '443 Patent	Bono in view of Dinkelacker
	implant. This improves the transmission of force to the anatomical/histological bone components, in particular to the osteons, and causes a pressure-induced formation of compact bone 112 around the implant in the area of the spongiosa. This biomechanical integration shortens the healing phase for the implant and lengthens the time of the implant in the bone due to the decrease in bone resorption." (Ex. 1003, Dinkelacker, col. 6, ln. 23-35) (emphasis added) (Ex. 1002, ¶ 44.)
17. The implant as in claim 15, wherein the <b>troughs of the</b> <b>wave pattern follow</b> <b>the spiral trajectory</b> of the thread <b>along a</b> <b>crest of the thread</b> .	FIG. 3 and FIG. 4 in Bono show the implant has trough, such as 37, along a crest 35 of the thread. (Ex. 1004, Bono, FIGS. 3-4) (Ex. 1002, ¶ 45.) See claim [15] (Ex. 1002, ¶ 46.)
18. The implant as in claim 15, wherein the wave pattern varies along the implant.	<ul> <li>FIG. 3 and FIG. 4 in Bono show the implant has a wave pattern that varies along the implant:</li> <li>"Referring now to FIG. 3, bone screw 10 of the present invention includes a head 12, a tip 14, and a shaft 16 extending between head 12 and tip 14. In addition, <u>bone screw 10 has two threaded sections, a dual lead threaded section 18 positioned to extend within bone, and a second threaded section 28 adjacent to head 12." (Ex. 1004, Bono, col. 2, ln. 49-54) (emphasis added) (Ex. 1002, ¶ 48.)</u></li> <li>"As best seen in FIGS. 4, second threaded section 28 lies adjacent to head 12. As illustrated, second thread 29 is a triple thread, with leads starting about 120° apart. First lead 22 and second lead 24 of dual lead thread 19 continue through second threaded section 28, and they are joined by a third lead 26, to form second thread 29." (Ex. 1004, Bono, col. 4, ln. 17-22) (Ex. 1002, ¶ 49.)</li> <li>"Still referring to FIG. 4, bone screw 10 has a large groove</li> </ul>

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	36 and a small groove 37. Large groove 36 of bone screw 10 has a thread depth $d_1$ . Thread depth $d_1$ is the radial distance from a peak position 35 to a position at a trough 33 of lead 1 <sub>3</sub> . Small groove 37 has a thread depth $d_2$ , which is the radial distance from peak position 35 to a position at a trough 34 of lead 1 <sub>2</sub> . In the illustrative embodiment, thread depth $d_1$ is at least twice thread depth $d_2$ ." (Ex. 1004, Bono, col. 3, ln. 39-46) (emphasis added) (Ex. 1002, ¶ 50.) Additionally, Dinkelacker separately discloses an implant with a wave pattern that varies along the implant: "FIG. 17 shows an embodiment of the tooth implant according to the invention as in FIG. 14 in which at least one part of the steps has different groove structures. The body of the implant in FIG. 17 is divided into ten steps 84- 93 that are connected by transition areas 94. The perimeter of the two top steps 84 and 85 have crosswise grooves as in FIG. 7C. Of the steps 86 and 87 that follow below, step 86 has grooves that run left at a sharp angle to the lengthwise axis of the implant, and step 87 has grooves that run right at a sharp angle to the lengthwise axis of the implant. The surface structure of the next steps 88 and 89 corresponds to that of steps 86 and 87, while all the other steps 90-93 have grooves 95 that run in an axial direction." (Ex. 1003, Dinkelacker, col. 5, ln. 52-64) (Ex. 1002, ¶ 52.)

Hall '443 Patent	Bono in view of Dinkelacker
	"The sections have grooves 63 that run in the lengthwise direction of the cone and follow the lengthwise direction of the cone and follow the same width at the start of each section 61 viewed from top to bottom, and their width and depth decrease downward." (Ex. 1003, Dinkelacker, col. 5, ln. 14-19) (emphasis added) (Ex. 1002, ¶ 53.)
19. The implant as in claim 15, wherein the trough varies along the spiral trajectory.	See claim [18] (Ex. 1002, ¶ 54.)
26. The implant as in claim 15, wherein the wave pattern is formed by <b>laser</b>	"The material removing process is advantageously carried out with a digitally-controlled laser beam." (Ex. 1003, Abstract) (Ex. 1002, ¶ 58.)
bombardment.	"A procedure to manufacture a tooth implant according to the invention provides that numerous groove-shaped recesses that run along the lengthwise axis are created in the surface of the implant body by a material removal process in one of the smooth implant bodies preformed

Hall '443 Patent	Bono in view of Dinkelacker
	into the desired shape. The material removal process is advantageously carried out by a digitally-controlled laser beam." (Ex. 1003, col. 2, lns. 35-42) (Ex. 1002, ¶ 59.)
27. The implant as in claim 15, wherein the trough depth is <b>approximately 75</b> μm.	See claim [15] (Ex. 1002, ¶ 60.)
30. The implant as in claim 15, wherein the trough has a depth of between approximately 50 to 150 µm.	See claim [15] (Ex. 1002, ¶ 61.)
31. The implant as in claim 30, wherein the trough has a depth of <b>approximately up</b> <b>to 75 μm.</b>	See claim [15] (Ex. 1002, ¶ 62.)
32. The implant as in claim 15, wherein the <b>at least one</b> <b>trough</b> of the wave pattern <b>extends</b> <b>along an apex of the</b> <b>thread</b> .	See claim [15] (Ex. 1002, ¶ 63.)

As to claim 21, which recites "[t]he implant as in claim 15, wherein the implant forms part of a set of implants, the set including implants with wave patterns having different trough depths," Dinkelacker discloses two different embodiments with two different types of grooves in Figures 12 and 17, and their accompanying

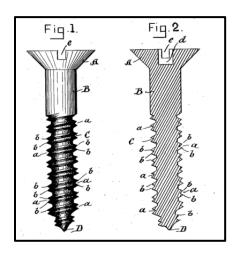
text as described in detailed above. (Ex. 1003, Figures 12 and 17, col. 5, ln. 52-64, col. 5, ln. 14-19) (Ex. 1002, ¶ 55.) One of skill in the art would have appreciated that dental implant procedures involve the placement of a "set of dental implants," and Dinkelacker itself provides expression motivation to use implants, that, between them, "[have] different wave patterns having different trough depths." (Ex. 1002, ¶ 56.) In particular, Dinkelacker explains the advantage of providing varying grooved structures on the surface of dental implant to "account [for] the different density of the bone that surrounds the implant over its length," such that a "combination of different surface structures over the implant body also helps to secure the implant during the healing and healed phases against axial shifting and rotation, and also to better conduct pressure into the bone." (Ex. 1003, col. 6, lns. 4-6 and 11-14) (Ex. 1002, ¶ 56.) As such, claim 21 is obvious over the teachings of Bono combined with Dinkelacker. (Ex. 1002, ¶ 56.) The foregoing rationale is equally applicable to claim 25 that similarly recites "[t]he implant as in claim 15, wherein the implant forms part of a set of implants, the implants in the set having a range of wave pattern structures for complying with a specific jaw bone structure." (Ex. 1002, ¶ 57.)

# Ground 2. Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as obvious by Libbey in view of Dinkelacker.

Claims 15, 17-19, 21, 25-27, and 30-32 are unpatentable as obvious over U.S. Patent No. 422,307 ("Libbey") (Ex. 1010) in view of Dinkelacker (Ex. 1003) under § 103(a). Libbey issued February 25, 1890, and is therefore prior art under 35U.S.C. § 102(b).

# i. <u>Introduction to Libbey</u>

Libbey discloses an improved wood screw. (Ex. 1010, col. 1, lns. 5-6.) Libbey's disclosed wood screw includes a "V-shaped groove a, thus forming two cutting-edges b, or as it were, a double thread." (Ex. 1010, col. 1, lns. 34-36.) Libbey's double-threaded wood screw is reproduced directly below.



Notably, during the oral argument at the Board that ultimately lead to issuance of the '443 patent, Nobel Biocare Services AG distinguished the claims over a regular screw by stating such a screw would only have a single thread:

JUDGE BRADEN: So how is the invention different than a screw?

MR. NARULA: Well, that's why we claim both. I mean, I have a screw. I mean, I do have one -- I'm claiming one thread and another thread, and then this -- sorry, I'm just claiming a thread and then a groove on top of the thread that is spiral. So a screw wouldn't have my spiral microgroove on there.

JUDGE BRADEN: So you have -- so your threads that are on a screw are -- is different than the spiral trajectory?

MR. NARULA: No. You said how is this different than a screw? If I had a screw in front of me, a screw might have threads on it, but it wouldn't have threads and a microgroove 25 to 200 microns with -- following a spiral trajectory in addition to the regular threads. Right? So a thread just – I mean, a regular screw would just have one thread on it.

(Ex. 1011, Transcript of Oral Hearing of June 18, 2013 at 12.)

Libbey's improved screw is precisely what Mr. Narula's was arguing the pending claims were directed to when he stated "[i]'m just claiming a thread and then a groove on top of the thread that is spiral." (*Id*.)

#### ii. <u>Reasons to Combine Libbey and Dinkelacker</u>

Persons of ordinary skill in the art recognize that behavior of dental implants can be modelled using various types of wood. (Ex. 1002,  $\P$  67.) Accordingly, much like the bone screw of Bono, one of skill in the art would look to other fasteners, including wood fasteners, when developing aspects of a dental implant to

improve the interaction between the implant and the bone. (Ex. 1002,  $\P$  67.) Here, Nobel Biocare Services AG's own representative made a binding admission on the record that the only difference between what was claimed and a regular screw was a regular screw had a single thread, whereas Nobel Biocare Services AG was "claiming a thread and then a groove on top of the thread that is spiral." (Ex. 1011 at 12) (Ex. 1002,  $\P$  67.) *See E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1438 (Fed. Cir. 1988) ("arguments made during the prosecution history are relevant in determining the meaning of [the claims]. Those arguments, and other aspects of the prosecution history, as well as the specification and other claims, must be examined to ascertain the true meaning of what the inventor intended to convey in the claims."); *see also Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 876 (Fed. Cir. 1998).

In addition, Libbey itself explains its thread structure results in a better hold "because as there is at least one-third more lateral surface with which the wood is in contact the screw is easier forced home and has better drawing and holding capacity," which thread structure would be equally applicable to a dental implant. (Ex. 1009, col. 1, ln. 39 – col. 2, ln. 2) (Ex. 1002, ¶ 68.)

Similar to the Bono bone screw, Libbey does not explicitly teach that its thread groove has a depth within the range of 25 to 200  $\mu$ m claimed by independent claim 15. (Ex. 1002, ¶ 69.) Dinkelacker, on the other hand, discloses grooved surfaces

on the body of a dental implant having a depth within the range of 25 to 200  $\mu$ m claimed by independent claim 15, which are sized to correspond with the osteons in the bone to promote the bone to grow into the grooves of the implant. (Ex. 1003, col. 3, ln. 42-45) (Ex. 1002, ¶ 69.) Application of the Dinkelacker teachings directed to the depth of the groove on the outer edge of a thread are equally applicable to the threaded structure disclosed in Libbey, and for the same reasons. (Ex. 1002, ¶ 69.) In particular, as noted above, the Board found that applying the grooves of Dinkelacker from the body of the implant to another portion of the implant would have been obvious to one of ordinary skill. (Ex. 1007 at 6-7) (Ex. 1002, ¶ 69.) Accordingly, one of skill in the art would have found that the grooves disclosed by Dinkelacker could be applied to other portions of an implant, such as to the outer surface of the threads. (Ex. 1002, ¶ 70.)

# iii. Combination of Libbey and Dinkelacker

The elements of claims 15, 17-19, 21, 25-27, and 30-32 are mapped to the teachings of Libbey in view of Dinkelacker in the following claim chart, as supported by the declaration of Dr. Michel Dard.

Hall '443 Patent	Libbey in view of Dinkelacker
15. A dental implant comprising:	"[A] certain new and useful Improvements in Wood- Screw" (Ex. 1010, Libbey, col. 1, lns. 5-6) (Ex. 1002, ¶ 73.)
	"So how is this invention different than a screw?" to which applicant's counsel stated " I have a screwI'm just

Hall '443 Patent	Libbey in view of Dinkelacker
	claiming a thread and then a groove on top of the thread that is spiral. So a screw wouldn't have my spiral microgroove on there." (Ex. 1011, Hearing Transcript at 12) (Ex. 1002, ¶ 74.) "The invention concerns a <u>tooth implant</u> that can be
	inserted in the jaw in an operation With a rotationally symmetrical implant body that has a rough surface, and a method to make the implant." (Ex. 1003, Dinkelacker, col. 1, lns. 5-8) (Ex. 1002, ¶ 75.)
an implant body defining a longitudinal axis and an exterior	"Figure 1 represents a side view of a wood-screw." (Ex. 1010, Libbey, col. 1, lns. 20-21) (Ex. 1002, ¶ 77.)
axis and an exterior surface;	"A represents the head; B, the barrel or stem; C, the thread, and D the point. (Ex. 1010, Libbey, col. 1, lns. 30-31) (Ex. 1002, ¶ 78.) Fig.1 Fig.2 B B B B B B B B B B
	"The tooth implant in FIG. 1 comprises a cylinder 11 that consists of titanium which has a head 12 with a polished surface Below the head 12 is a collar 16 that has numerous small troughs or lagoons 17 in its perimeter. Abutting the collar 16 is a body area 18 that extends over the majority of the length of the implant cylinder 11. The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows) ." (Ex. 1003, Dinkelacker, col. 3, lns. 28- 38) (Ex. 1002, ¶ 79.)

Hall '443 Patent	Libbey in view of Dinkelacker
	(Ex. 1003, Dinkelacker, Figure 1) (Ex. 1002, ¶ 80.)
and a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface, wherein when seen in side view, the outer surface of the thread comprises a wave pattern with at least	"The thread is slightly thicker than the thread of an ordinary wood-screw, and <u>its periphery is divided by a V-</u> <u>shaped groove</u> a, thus forming two cutting-edges b, or as it were, a double thread, by reason of which the screw will much more readily enter the wood and consequently lessen the liability of splitting the same, while <u>a better hold is</u> <u>obtained</u> , because as there is at least one-third more lateral <u>surface with which the wood is in contact the screw is</u> <u>easier forced home and has better drawing and holding</u> <u>capacity</u> ." (Ex. 1010, Libbey, col. 1, ln. 32 – col. 2, ln. 43) (emphasis added) (Ex. 1002, ¶ 81.)
one trough, the wave pattern extending generally in the direction of the	Dinkelacker discloses the trough or groove depth in the required range:
longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread, the wave pattern having a respective trough depth in the range of	"The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows)The groove-shaped recesses are 20-300 $\mu$ m wide and <u>10-150 <math>\mu</math>m deep</u> . During the healing phase, the osteons of the bone tissue can collect in the groove-shaped recesses. The width of the grooves corresponds to the dimensions of the osteons." (Ex. 1003, Dinkelacker, col. 3, ln. 36-45) (emphasis added) (Ex. 1002, ¶ 83.)
between approximately 25 to 200 μm.	"The groove-shaped surface of the implant causes the osteons 110 of the bone to collect in the grooves on the perimeter of the steps 106. This produces a tight connection between the bone and implant. The grooved <u>structure allows the osteons to grow directly into the</u> <u>implant. This improves the transmission of force to the</u> <u>anatomical/histological bone components, in particular to</u> <u>the osteons, and causes a pressure-induced formation of</u> <u>compact bone 112 around the implant in the area of the</u> <u>spongiosa. This biomechanical integration shortens the</u> <u>healing phase for the implant and lengthens the time of the</u>

Hall '443 Patent	Libbey in view of Dinkelacker
	implant in the bone due to the decrease in bone resorption." (Ex. 1003, Dinkelacker, col. 6, ln. 23-35) (emphasis added) (Ex. 1002, ¶ 84.)
17. The implant as in claim 15, wherein the <b>troughs of the wave</b> <b>pattern follow the</b> <b>spiral trajectory</b> of the thread <b>along a</b> <b>crest of the thread</b> .	FIG. 1 of Libbey shows its trough in the form of a "v-shaped groove a." (Ex. 1002, ¶ 85.) See claim [15] (Ex. 1002, ¶ 86.)
18. The implant as in claim 15, wherein the wave pattern varies along the implant.	<ul> <li>See claim [15].</li> <li>Dinkelacker separately discloses an implant with a wave pattern that varies along the implant:</li> <li>"FIG. 17 shows an embodiment of the tooth implant according to the invention as in FIG. 14 in which at least one part of the steps has different groove structures. The body of the implant in FIG. 17 is divided into ten steps 84-93 that are connected by transition areas 94. The perimeter of the two top steps 84 and 85 have crosswise grooves as in FIG. 7C. Of the steps 86 and 87 that follow below, step 86 has grooves that run left at a sharp angle to the lengthwise axis of the implant, and step 87 has grooves that run right at a sharp angle to the lengthwise axis of the implant, and step 88 and 89 corresponds to that of steps 86 and 87, while all the other steps 90-93 have grooves 95 that run in an axial direction." (Ex. 1003, Dinkelacker, Figures 12 and 17) (Ex. 1002, ¶ 88.)</li> <li>"The sections have grooves 63 that run in the lengthwise direction of the cone and follow the lengthwise d</li></ul>

Hall '443 Patent	Libbey in view of Dinkelacker
	arranged so that they have the same width at the start of each section 61 viewed from top to bottom, and <u>their width</u> <u>and depth decrease downward</u> ." (Ex. 1003, Dinkelacker, col. 5, ln. 14-19) (emphasis added) (Ex. 1002, ¶ 89.)
19. The implant as in claim 15, wherein <b>the</b> <b>trough varies along</b> <b>the spiral trajectory</b> .	See claim [18] (Ex. 1002, ¶ 90.)
26. The implant as in claim 15, wherein the wave pattern is formed by <b>laser</b>	"The material removing process is advantageously carried out with a digitally-controlled laser beam." (Ex. 1003, Abstract) (Ex. 1002, ¶ 94.)
bombardment.	"A procedure to manufacture a tooth implant according to the invention provides that numerous groove-shaped recesses that run along the lengthwise axis are created in the surface of the implant body by a material removal process in one of the smooth implant bodies preformed into the desired shape. The material removal process is advantageously carried out by a digitally-controlled laser beam." (Ex. 1003, col. 2, lns. 35-42) (Ex. 1002, ¶ 95.)
27. The implant as in claim 15, wherein the trough depth is <b>approximately 75</b> μm.	See claim [15]. (Ex. 1002, ¶ 96.).
30. The implant as in claim 15, wherein the <b>trough has a depth of</b> <b>between</b> <b>approximately 50 to</b> <b>150 μm</b> .	See claim [15]. (Ex. 1002, ¶ 97.)
31. The implant as in claim 30, wherein the trough has a depth of	See claim [15]. (Ex. 1002, ¶ 98.)

Hall '443 Patent	Libbey in view of Dinkelacker
approximately up to	
75 μm.	
32. The implant as in	<i>See</i> claim [15]. (Ex. 1002, ¶ 99.)
claim 15, wherein the	
at least one trough of	
the wave pattern	
extends along an	
apex of the thread.	

As to claim 21, Dinkelacker discloses two different embodiments with two different types of grooves in Figures 12 and 17, and their accompanying text as described in detailed above. (Ex. 1003, Figures 12 and 17, col. 5, ln. 52-64, col. 5, In. 14-19) (Ex. 1002, ¶91.) One of skill in the art would have appreciated many dental implant procedures involve the placement of a "set of dental implants," and Dinkelacker itself provides expression motivation to use implants, that, between them, "[have] different wave patterns having different trough depths." (Ex. 1002, ¶ 92.) In particular, Dinkelacker explains the advantage of providing varying grooved structures on the surface of dental implant to "account [for] the different density of the bone that surrounds the implant over its length," such that a "combination of different surface structures over the implant body also helps to secure the implant during the healing and healed phases against axial shifting and rotation, and also to better conduct pressure into the bone." (Ex. 1003, col. 6, lns. 4-6 and 11-14) (Ex. 1002, ¶ 92.) As such, claim 21 is obvious over the teachings

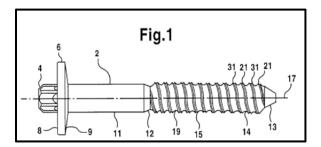
of Libbey combined with Dinkelacker. (Ex. 1002,  $\P$  92.) The foregoing rationale is equally applicable to claim 25, which recites claim language similar to that of claim 21. (Ex. 1002,  $\P$  93.)

# Ground 3. Claims 15, 17-19, 25-27, and 30-32 are unpatentable as obvious by Papafotiou in view of Dinkelacker.

Claims 15, 17-19, 25-27, and 30-32 are unpatentable as obvious by U.S. Patent No. 6,371,709 ("Papafotiou") (Ex. 1012) in view of Dinkelacker (Ex. 1003) under § 103(a). Papafotiou is a continuation application of Application Ser. No. 09/341,296, filed October 4, 1999, and issued on April 16, 2002, and is therefore prior art under § 102(e).

#### i. <u>Introduction to Papafotiou</u>

Papafotiou discloses a "screw thread having a threadform including a ridge rising from the root to the crest with the crest having two peaks, separated by a trough." (Ex. 1012, Abstract.) Papafotiou's disclosed threaded configuration is reproduced directly below.

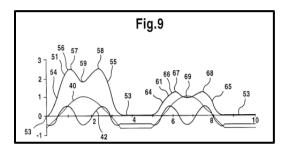


## ii. <u>Reasons to Combine Papafotiou and Dinkelacker</u>

Similar to Libbey, Papafotiou discloses a fastener that is a particularly useful for fastening to wood or timber. (Ex. 1012, col. 1, 7-10) (Ex. 1002,  $\P$  101.) Papafotiou explains that, "[a]lthough developed particularly for rail track application, the thread has much wider applications." (Ex. 1012, col. 1, lns. 21-23) (Ex. 1002,  $\P$  101.) As described at col. 6, lines 7-35, the threadform of Papafotiou advantageously increases compression of the workpiece, while reducing the degree of cutting. (Ex. 1002,  $\P$  101.)

Accordingly, one of skill in the art would seek to combine Papafotiou with Dinkelacker for the same reasons provided for the combination of Libbey with Dinkelacker. (Ex. 1002,  $\P$  101.)

Furthermore, Papafotiou discloses a trough having a depth in the range of 25 to 200  $\mu$ m (25 to 250 microns). (Ex. 1002, ¶ 102.) In particular, Papafotiou discloses the scales of its various "threadforms" in Figure 9, as follows:



Papafotiou explains Figure 9's disclosure as: "The scales on the axes of FIG. 9 indicate the dimensions in mm for the threadform. <u>The higher ridge 51 rises 2.5</u> <u>mm from the root while the lower ridge 61 rises 1.25 mm. The higher trough 59 is</u> 0.7 mm deep while the lower trough 69 is 0.25 mm deep." (Ex. 1012, col. 4, lns.

46-51) (emphasis added) (Ex. 1002, ¶ 103) Papafotiou also discloses screw threads for screws with an external diameter around 18mm, as shown by reference to the "head" of Figure 1 at column 2, lines 60-65. (Ex. 1002, ¶ 103.)

Here, the '443 patent's disclosure is relative to implants in the diameters of 3.5mm to 5.0mm, which was a well-known range of dental implant diameters at the time of the priority of the '443 Patent – December 21, 2001. (Ex. 1002, ¶ 104.) Using these known diameters, one of skill in the art could readily the groove depths of Papafotiou to arrive at the ranges 49 - 136 microns when scaling to a 3.5mm implant, and 69 - 194 microns when scaling to a 5.0mm implant, each of which are in the range claimed of 25 to 200 µm (25 to 250 microns). (Ex. 1002, ¶¶ 104-106.)

Accordingly, application of Dinkelacker's teachings directed to a groove of a particular depth is even further applicable to Papafotiou whose groove or trough is already within the claimed range. (Ex. 1002,  $\P$  107.)

## i. <u>Combination of Papafotiou and Dinkelacker</u>

The elements of claims 15, 17-19, 21, 25-27, and 30-32 are mapped to the teachings of Papafotiou in view of Dinkelacker in the following claim chart, as supported by the declaration of Dr. Michel Dard.

Hall '443 Patent	Papafotiou in view of Dinkelacker
15. A dental implant comprising:	Fasteners incorporating the threadform may also be screwed into dense fibrous or fiber reinforced materials and

Hall '443 Patent	Papafotiou in view of Dinkelacker
	non fibered materials. (Ex. 1012, Papafotiou, col. 6, lns. 24-35) (Ex. 1002, ¶ 110.)
	"So how is this invention different than a screw?" to which applicant's counsel stated " I have a screwI'm just claiming a thread and then a groove on top of the thread that is spiral. So a screw wouldn't have my spiral microgroove on there." (Ex. 1011, Hearing Transcript at 12) (Ex. 1002, ¶ 111.)
	"The invention concerns a <u>tooth implant</u> that can be inserted in the jaw in an operation With a rotationally symmetrical implant body that has a rough surface, and a method to make the implant." (Ex. 1003, Dinkelacker, col. 1, lns. 5-8) (Ex. 1002, ¶ 112.)
an implant body defining a longitudinal axis and an exterior surface;	"Referring to FIG. 1, the rail fastening screw 2 has a head 4, flange 6, plain shank 11, tapered shoulder 12 and tip 13. Between the shoulder 12 and tip 13 the screw has a portion into which a thread 15 is rolled." (Ex. 1012, Papafotiou, col. 2, lns. 50-55) (Ex. 1002, ¶ 114.)
	Fig.1 4 31 21 31 21 17 31 21 31 21 17 11 11 12 19 15 14 13 15 14 15 15 14 15 15 14 15 15 14 15 15 14 15
	"The tooth implant in FIG. 1 comprises a cylinder 11 that consists of titanium which has a head 12 with a polished surface Below the head 12 is a collar 16 that has numerous small troughs or lagoons 17 in its perimeter. Abutting the collar 16 is a body area 18 that extends over the majority of the length of the implant cylinder 11. The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows)." (Ex. 1003, Dinkelacker, col. 3, lns. 28- 38) (Ex. 1002, ¶ 115.)

Hall '443 Patent	Papafotiou in view of Dinkelacker
	(Ex. 1003, Dinkelacker, Figure 1) (Ex. 1002, ¶ 116.)
and a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface, wherein when seen in side view, the outer surface of the thread comprises a wave pattern with at least one trough, the wave pattern extending generally in the direction of the longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread, the wave pattern having a respective trough depth in the range of between approximately 25 to 200 µm.	"[T]he present invention provides <u>a screw thread</u> having a threadform comprising a ridge rising from root to crest with the crest having two peaks separated by a trough the depth of which is less than the height of the ridge from root to crest." (Ex. 1012, Papafotiou, col. 1, lns. 25-30) (emphasis added) (Ex. 1002, ¶ 117.) Papafotiou discloses screw threads for screws with an external diameter around 18 mm. Referring to FIG. 1, the rail fastening screw 2 has a head 4, flange 6, plain shank 11, tapered shoulder 12 and tip 13. Between the shoulder 12 and tip 13 the screw has a portion into which a thread 15 is rolled. Tor the embodiment shown, the screw has the following approximate dimensions: $\frac{125 \text{ mm}}{14.5 \text{ mm}} \frac{125 \text{ mm}}{14.5 \text{ mm}} \frac{14.5 \text{ mm}}{18 \text{ mm}} \frac{14.5 \text{ mm}}{14.5 \text{ mm}} 14.5 \text{$
	"The scales on the axes of FIG. 9 indicate the dimensions in mm for the threadform. The higher ridge 51 rises 2.5 mm from the root while the lower ridge 61 rises 1.25 mm. The higher trough 59 is 0.7 mm deep while the lower trough 69 is 0.25 mm deep." (Ex. 1012, Papafotiou, col. 4, lns. 46- 51) (emphasis added) (Ex. 1002, ¶ 119.)

Hall '443 Patent	Papafotiou in view of Dinkelacker
	Dinkelacker also discloses the trough or groove depth in the required range, in the context of a dental implant: "The body area 18 has closely adjacent groove-shaped recesses 20 in its perimeter that run in an axial direction (also termed furrows)The groove-shaped recesses are 20-300 µm wide and <u>10-150 µm deep</u> . During the healing phase, the osteons of the bone tissue can collect in the groove-shaped recesses. The width of the grooves corresponds to the dimensions of the osteons." (Ex. 1003, Dinkelacker, col. 3, ln. 36-45) (emphasis added) (Ex. 1002, ¶ 121.) "The groove-shaped surface of the implant causes the osteons 110 of the bone to collect in the grooves on the perimeter of the steps 106. This produces a tight connection between the bone and implant. <u>The grooved</u> structure allows the osteons to grow directly into the implant. This improves the transmission of force to the anatomical/histological bone components, in particular to the osteons, and causes a pressure-induced formation of compact bone 112 around the implant in the area of the spongiosa. This biomechanical integration shortens the healing phase for the implant and lengthens the time of the implant in the bone due to the decrease in bone resorption." (Ex. 1003, Dinkelacker, col. 6, ln. 23-35) (emphasis added) (Ex. 1002, ¶ 122.)
17. The implant as in claim 15, wherein the <b>troughs of the wave</b> <b>pattern follow the</b> <b>spiral trajectory</b> of the thread <b>along a</b> <b>crest of the thread</b> .	Papafotiou Troughs 53, 59, and 69 in Fig. 9 are along a crest of the thread. (Ex. 1002, ¶ 123.)
18. The implant as in claim 15, wherein <b>the</b>	"Working from the left side of FIG. 9, the threadform profile rises from a root 53 to the ridge 51 by way of a

Hall '443 Patent	Papafotiou in view of Dinkelacker
wave pattern varies along the implant.	flank 54 which rises to a crest 56. This crest carries two peaks 57 and 55 with a trough 59 between them. From peak 58 the ridge falls down a flank 55 to the root 53 which is of the same depth as the root on the other side of the ridge 51. The threadform profile then rises to the ridge 61 by way of a flank 64 which rises to a crest 66. The ridge 61 is significantly lower than the ridge 51. The crest 66 carries two peaks 67 and 68 with a trough 69 between them. From the peak 68 the ridge falls down a flank 65 to the root 53 from where the threadform repeats its sequence. The trough 69 has a shallower form than trough 59." (Ex. 1012, col. 4, lns. 33-46) (Ex. 1002, ¶ 124.)
	Fig.9
	$\begin{array}{c} 3\\3\\2\\1\\5\\4\\40\\5\\3\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\-1\\$
	(Ex. 1012, Figure 9) (Ex. 1002, ¶ 125.)
	Dinkelacker separately discloses an implant with a wave pattern that varies along the implant:
	"FIG. 17 shows an embodiment of the tooth implant according to the invention as in FIG. 14 in which at least one part of the steps has different groove structures. The body of the implant in FIG. 17 is divided into ten steps 84- 93 that are connected by transition areas 94. The perimeter of the two top steps 84 and 85 have crosswise grooves as in FIG. 7C. Of the steps 86 and 87 that follow below, step 86 has grooves that run left at a sharp angle to the lengthwise axis of the implant, and step 87 has grooves that run right at a sharp angle to the lengthwise axis of the implant. The surface structure of the next steps 88 and 89 corresponds to that of steps 86 and 87, while all the other steps 90-93 have grooves 95 that run in an axial direction." (Ex. 1003,

Hall '443 Patent	Papafotiou in view of Dinkelacker
	Dinkelacker, col. 5, ln. 52-64) (Ex. 1002, ¶ 127.)
	(Ex. 1003, Dinkelacker, Figures 12 and 17) (Ex. 1002, ¶ 127.)
	"The sections have grooves 63 that run in the lengthwise direction of the cone and follow the lengthwise direction of the conical surface. The grooves 63 are preferably arranged so that they have the same width at the start of each section 61 viewed from top to bottom, and <u>their width and depth decrease downward</u> ." (Ex. 1003, Dinkelacker, col. 5, ln. 14-19) (emphasis added) (Ex. 1002, ¶ 128.)
19. The implant as in	<i>See</i> claim [18] (Ex. 1002, ¶ 129.)
claim 15, wherein <b>the</b>	
trough varies along	
the spiral trajectory.	
26. The implant as in	"The material removing process is advantageously carried
claim 15, wherein the	out with a digitally-controlled laser beam." (Ex. 1003,
wave pattern is formed	Abstract) (Ex. 1002, ¶ 133.)
by laser	
bombardment.	"A procedure to manufacture a tooth implant according to the invention provides that numerous groove-shaped recesses that run along the lengthwise axis are created in the surface of the implant body by a material removal process in one of the smooth implant bodies preformed into the desired shape. The material removal process is advantageously carried out by a digitally-controlled laser beam." (Ex. 1003, col. 2, lns. 35-42) (Ex. 1002, ¶ 134.)
27. The implant as in	<i>See</i> claim [15]. (Ex. 1002, ¶ 135.)
claim 15, wherein the	
trough depth is	
approximately 75	
$\mu$ m. 30. The implant as in	<i>See</i> claim [15]. (Ex. 1002, ¶ 136.)
claim 15, wherein the	See Gamm [15]. (LA. 1002, ∥ 150.)

Hall '443 Patent	Papafotiou in view of Dinkelacker
between approximately 50 to 150 μm.	
31. The implant as in claim 30, wherein the trough has a depth of <b>approximately up to 75 μm.</b>	See claim [15]. (Ex. 1002, ¶ 137.)
32. The implant as in claim 15, wherein the <b>at least one trough</b> of the wave pattern <b>extends along an</b> <b>apex of the thread</b> .	See claim [15]. (Ex. 1002, ¶ 138.)

As to claim 21, Dinkelacker discloses two different embodiments with two different types of grooves in Figures 12 and 17, and their accompanying text as described in detailed above. (Ex. 1003, Figures 12 and 17, col. 5, ln. 52-64, col. 5, ln. 14-19) (Ex. 1002, ¶ 130.) One of skill in the art would have appreciated that many dental implant procedures involve the placement of a "set of dental implants," and Dinkelacker itself provides expression motivation to use implants, that, between them, "[have] different wave patterns having different trough depths." (Ex. 1002, ¶ 131.) In particular, Dinkelacker explains the advantage of providing varying grooved structures on the surface of dental implant to "account [for] the different density of the bone that surrounds the implant over its length,"

such that a "combination of different surface structures over the implant body also helps to secure the implant during the healing and healed phases against axial shifting and rotation, and also to better conduct pressure into the bone." (Ex. 1003, col. 6, lns. 4-6 and 11-14) (Ex. 1002, ¶ 131.) As such, claim 21 is obvious over the teachings of Papafotiou combined with Dinkelacker. (Ex. 1002, ¶ 131.) The foregoing rationale is equally applicable to claim 25, which recites language similar to that of claim 21. (Ex. 1002, ¶ 132.)

# Ground 4. Claims 15, 17, 30, and 32 are unpatentable as anticipated by the Weiss Patent (as evidenced by the *Implant Dentistry* text, Christensen, or Tosti).

Claims 15, 17, 30, and 32 are unpatentable as anticipated by U.S. Patent No. 4,102,422 ("Weiss Patent") (Ex. 1013) (as evidenced by the *Implant Dentistry* text (Ex. 1014), Christensen (Ex. 1015), or Tosti (Ex. 1016)). The Weiss Patent issued August 1,1978, making it prior art under § 102(b).

#### ii. <u>Introduction to the Weiss Patent Reference</u>

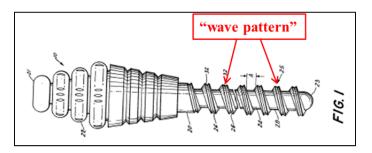
The Weiss Patent discloses "a threaded self-tapping endodontic stabilizer for insertion in the jawbone of the patient's mouth through an aperture in a loose tooth to stabilize the tooth comprises an elongated member." (Ex. 1013 at Claim 1.) That disclosure of the Weiss Patent is expanded in the Specification, as follows:

> [A] threaded self-tapping endodontic stabilizer for insertion in the jawbone of the patient's mouth through an aperture in a loose tooth to stabilize the tooth

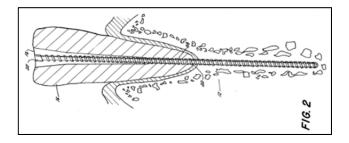
comprises an elongated penetrating member. As is conventional in such stabilizers, the coronal end of the stabilizer comprises a head adapted for manual rotation by the dental practitioner (during the tapping and insertion process), and the apical end comprises a shaft having an external thread defining a plurality of lands and intervening grooves.

(Ex. 1013, col. 3, ln. 24-39.)

The Weiss Patent further teaches: "The lands 26 preferably have a shallow recess 32 extending along the peripheral edge thereof, so that the lands 26 have a generally W-shaped cross-section. The presence of the recess 32 on the lands 26 increases the surface area of the lands 26, and hence the area of contact between the lands 26 and the perio-stabilizer ligament 30." (Ex. 1013, col. 4, ln. 11-19.) The Weiss endodontic stabilizer having the recess formed on the outer edge of the thread is shown in Figure 1 of the Weiss Patent, reproduced below (annotations in red):



The Weiss Patent illustrates its endodontic stabilizer with the apical end inserted well into the jawbone 12, as shown in reproduced Figure 2 below.



#### iii. Nobel Biocare Services AG's Anticipated Arguments

# (1) The Weiss Patent's Endodontic Stabilizer is a "Dental Implant"

As noted above in Section II.a.i, Petitioner anticipates that Nobel Biocare Services AG will attempt to argue that the preamble of independent claim 15 reciting a "dental implant" is a limitation, which Petitioner has demonstrated is not an appropriate construction of that preamble under the Broadest Reasonable Interpretation standard applied by the Board. Nevertheless, Petitioner further anticipates that Nobel Biocare Services AG will argue that the Weiss Patent does not anticipate claim 15 – and likewise its dependent claims 17, 30, and 32 – because it is not a "dental implant."

In view of that potential argument by Nobel Biocare Services AG, Petitioner notes there is ample evidence that the endodontic stabilizer disclosed in the Weiss Patent would have been considered a "dental implant" at the time of the priority date of the '443 Patent – December 21, 2001. For example, the endodontic

stabilizer described in the Weiss Patent is also further depicted and described in the "Implant Dentistry" text (Ex. 1014). It seems unlikely that Dr. Weiss, the author of the Implant Dentistry textbook, would have included something that is not a dental implant in a book that is focused exclusively on dental implants. An endodontic stabilizer is designed to be implanted into a patient's jawbone, similar to any other type of dental implant. (Ex. 1002, Dard Decl., ¶ 143.) Indeed, the Weiss Patent provides a detailed description that the endodontic stabilizer is implanted into a patient's jawbone. (Ex. 1013, col. 2, ln. 21-25 ("[A] threaded self-tapping endodontic stabilizer for insertion in the jawbone of the patient's mouth through an aperture in a loose tooth to stabilize the tooth comprises an elongated member.")) (Ex. 1002, ¶ 143.) Further, Dr. Dard, who has been practicing and teaching in the dental implant field for over 20 years also opines that the endodontic stabilizer disclosed in the Weiss Patent would have been considered a "dental implant" (Ex. 1002, ¶ 144) at the time of the priority date of the '443 Patent, including confirming that the *Implant Dentistry* text is a reliable authority on the field of dental implants, and what types of dental devices would be within that field. (Ex. 1002,  $\P$  144.)

The foregoing view is supported by both Christensen and Tosti, each of which describes a device similar to that of Weiss. (Ex. 1002,  $\P$  145.) In particular, focusing first on Christensen, it discloses a titanium anchor, similar to that of the

Weiss Patent, and includes threads for anchoring the device in the jaw. (Ex. 1015, col. 4, lns. 8-18 ("[w]hen the anchor screw has been secured in place, no further steps are taken until bone surrounding the root socket has regenerated and grown into the spaces between the tapered threads in section 18. During this period of bone growth, the anchor screw is solidly locked in place by the straight threads of the first threaded section which are engaged with the walls of the pilot hole.")) (Ex. 1002, ¶ 145.) Tosti discloses a similar device as shown in Figure 4 (Ex. 1016). (Ex. 1002, ¶ 145.)

Accordingly, even under Nobel Biocare Services AG's anticipated incorrect claim construction that requires the preamble of claim 15 to be a limitation, the Weiss Patent anticipates independent claim 15, and each of claims 17, 30, and 32 that ultimately depend therefrom.

# (2) The Weiss Patent's Groove or Recess 32 Promotes Osseointegration

Petitioner also expects Nobel Biocare Services AG to argue that the recess or groove 32 of the Weiss Patent is intended to hold dental cement and therefore would not promote osseointegration, which is the intended purpose of the claimed grooves in the '443 patent. Nobel Biocare Services AG's anticipated argument is not accurate, because cement is applied only to the "apical control point" and a portion of the stabilizer 3 millimeters coronal, or above, the apical control point. (Ex. 1013, col. 4, ln. 53-58) (Ex. 1002, ¶ 146.) The portion of the endodontic

stabilizer below the apical control point is anchored into the *patient's jawbone*, where the grooves would increase the surface area of the portion of the endodontic stabilizer placed within the bone, thereby promoting osseointegration and the effective retention of the stabilizer to occur. (Ex. 1013, col. 6, ln. 1-4) (Ex. 1002, ¶ 146.) Moreover, the Weiss Patent describes that ligaments first grow into the grooves (col. 4, ln. 11-19), which is a stage of bone remodeling and osseointegration. (Ex. 1002, ¶ 146.) The Weiss Patent also discloses it can be used to support a prosthetic such as a crown or cap. (Ex. 1013, Figure 7 and col. 4, ln.  $66 - 5 \ln 3$  ("Referring now to FIGS. 6 and 7, therein illustrated is a stabilizer 10' adapted for use where the crown portion of the tooth 16 has been broken away or otherwise removed and will eventually be replaced by an artificial crown or cap 50 (as illustrated in phantom line in FIG. 7).") (Ex. 1002, ¶ 146.)

Moreover, as taught in Christensen and Tosti, the device of the Weiss Patent need not be cemented in place, but could instead be anchored in the jaw entirely by the thread. (*See e.g.* Ex. 1015, Christensen, col. 3, ln. 60 – col. 4, ln. 20) (Ex. 1016, Tosti, Figure 4), and could be used to support a prosthetic, such as crown 25 shown in Christensen FIG. 3. (Ex. 1002, ¶ 147.) As such, a person of skill in the art would have understood from Christensen and Tosti that the endodontic stabilizer disclosed in Weiss could be directly anchored in bone without cement. (Ex. 1002, ¶ 148.)

# (3) Figure 1 Reliably Discloses a Trough with a Depth of Between 25 to 200 μm

In addition to the foregoing, Petitioner also anticipates that Nobel Biocare Services AG will assert that Figure 1 of the Weiss Patent is a patent drawing that cannot be relied upon because it does not explicitly disclose the depth of the "shallow recess 32." However, the Weiss Patent discloses that "[t]he stabilizer 10 of the present invention is characterized by a thread 25 in which the groove 28 has a longitudinal height (designated by the reference numeral A in FIG. 1) of at least 0.20 millimeters and preferably about 0.25-0.38 millimeters." (Ex. 1013, col. 3, lns. 40-44.) Furthermore, Dr. Michel Dard confirms Figure 1 is a fair representation of an endodontic stabilizer, and that one of skill in the art could reliably determine the depth of the "shallow recess 32" using that Figure. (Ex. 1002, ¶ 149; 159-163.)

As such, Figure 1 of the Weiss Patent is a reliable source from which one of skill in the art could determine the depth of its disclosed trough.

# iv. How the Weiss Patent (as evidenced by the *Implant Dentistry* text, Christensen, or Tosti) Anticipates Claims 15, 17, 30, and 32

- (1) Claim 15
  - (a) **Preamble**

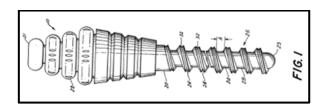
While not required by the claims, the Weiss Patent discloses a "dental implant." (Ex. 1013, col. 2, ln. 21-25) ("[A] threaded self-tapping <u>endodontic stabilizer for</u>

<u>insertion in the jawbone</u> of the patient's mouth through an aperture in a loose tooth to stabilize the tooth comprises an elongated member.") (emphasis added) (Ex.  $1002, \P 151.$ )

Petitioner also provided a detailed description of why the Weiss Patent discloses a "dental implant" above in Section I.A.iii(1).

#### (b) Element (a)

Claim 15 – element (a) recites "an implant body defining a longitudinal axis and an exterior surface." The Weiss Patent discloses such an "implant body," as follows:



The Weiss Patent explains Figure 1 as:

"[A] threaded self-tapping endodontic stabilizer for insertion in the jawbone of the patient's mouth through an aperture in a loose tooth to stabilize the tooth <u>comprises an elongated member</u>." (Ex. 1013, col. 2, ln. 21-25) (Ex. 1002, ¶ 153.)

"FIG. 1 is a fragmentary side elevation view of a threaded, self-tapping endodontic stabilizer according to the present invention." (*Id.* at col. 2, ln. 64-66) (Ex. 1002, ¶ 154.)

## (c) Element (b)

Claim 15 – element (b) recites "and **a thread** extending about the implant body in a spiral trajectory, the thread defining an outer surface, wherein when seen in side view, **the outer surface of the thread comprises a wave pattern with at least one trough**, the wave pattern extending generally in the direction of the longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread, **the wave pattern having a respective trough depth in the range of between approximately 25 to 200 µm**."

The Weiss Patent discusses its thread and its trough or "shallow recess 32" as follows:

"[T]he coronal end of the stabilizer comprises a head adapted for manual rotation by the dental practitioner (during the tapping and insertion process), and the apical end comprises <u>a shaft having an external thread defining a plurality of</u> <u>lands and intervening grooves</u>. In order to secure the advantages of the present invention, a plurality of the grooves have a longitudinal height (measured parallel to the shaft axis) of at least 0.20 millimeters, and preferably from 0.25 to 0.38 mm. The aforementioned thread design provides adequate groove surface (between lands) onto which the perio-stabilizer ligament may generate". (Ex. 1013, col. 2, ln. 25-37) (emphasis added) (Ex. 1002, ¶ 156.)

"The stabilizer 10 of the present invention is characterized by a thread 25 in which the groove 28 has a longitudinal height (designated by the reference numeral A in FIG. 1) of at least 0.20 millimeters and preferably about 0.25-0.38 millimeters. The groove 28 preferably extends substantially parallel to the longitudinal axis of shaft 24 for substantially the entire longitudinal height A. Thus adequate space is provided intermediate lands 26 into which perio-stabilizer ligament 30 (see FIG. 5) may generate. Any vertical motion of the stabilizer 10 exercises and works the generated portion of the ligament 30 intermediate lands 26 and thus encourages further generation of the ligament. As the ligament 30 is what effectively secures the stabilizer 10 within the jawbone 12, the overall result is enhanced retention of the stabilizer 10 within the jawbone 12." (Ex. 1013, col. 3, In. 40-55) (emphasis added) (Ex. 1002, ¶ 157.) In addition, as one of skill in the art would have understood based on familiarity with the similar devices in Christensen and Tosti, the device of Weiss could be readily anchored in the jawbone, as discussed more fully above in Section I.A.iii.

As to the depth of the trough or "shallow recess 32" disclosed in Figure 1, the Weiss Patent discloses that the dimension "A" shown in Figure 1, which it describes as the "longitudinal height" between threads, is "at least 0.20 millimeters and preferably about 0.25-0.38 millimeters." (Ex. 1013, col. 3, ln. 43-44) (Ex. 1002, ¶ 159.)

As explained in the declaration of Dr. Michel Dard, a measurement can be made of the dimension marked "A" in Figure 1, which is the distance between threads, and a measurement can also be made of the depth of the recess in the thread. (Ex. 1002, ¶ 160.) Those measurements are 5.5mm, and 0.77mm, respectively. (Ex. 1002, ¶ 160.) Dr. Dard compared the measured dimension "A" to the range stated in the Weiss Patent, which is 0.2 - 0.38 mm, and Dr. Dard used that same proportion to determine that Figure 1 shows the groove in the threads as having a depth between 28 – 53 microns. (Ex. 1002, ¶ 160-162.)

The depth of between 28 - 53 microns is well within the claimed range of "25 to 200 µm" or between 25 and 200 microns. (Ex. 1002, ¶ 163)

#### (2) Claim 17

Claim 17 depends from independent claim 15 and recites "wherein the **troughs** of the wave pattern follow the spiral trajectory of the thread along a crest of the thread."

Figures 1 and 5 of the Weiss Patent show its implant has a trough or shallow recess, such as 32, extending along a crest of a thread. (Ex. 1013, Figs. 1, 5) (Ex. 1002, ¶ 164.)

The Weiss Patent explains those shallow recesses as follows:

"Preferably, a plurality of the lands of <u>the thread contain a shallow recess</u> <u>extending along their peripheral edge</u>, the shallow recesses further promoting the

working and exercise of the perio-stabilizer ligament by increasing the surface area of the stabilizer, and hence the area of contact between the stabilizer and the ligament." (Ex. 1013, col. 2, ln. 43-48) (Ex. 1002, ¶ 166.)

"<u>The lands 26 preferably have a shallow recess 32 extending along the</u> peripheral edge thereof, so that the lands 26 have a generally W-shaped crosssection. The presence of the recess 32 on the lands 26 increases the surface area of the lands 26, and hence the area of contact between the lands 26 and the periostabilizer ligament 30. As a result of the increased area of contact the ligament 30 undergoes increased exercising as a result of any motion on the part of the stabilizer 10." (Ex. 1013, col. 4, ln. 11-19) (Ex. 1002, ¶ 167.)

#### (3) Claim 30

Claim 30 depends from independent claim 15 and recites "wherein the **trough** has a depth of between approximately 50 to 150 μm."

Dr. Dard compared the measured dimension "A" to the range stated in the Weiss Patent, which is 0.2 - 0.38 mm, and Dr. Dard used that same proportion to determine that Figure 1 shows the groove in the threads as having a depth between 28 - 53 microns (0.77 x 0.0364 = 0.028mm and 0.77 x 0.0691 = 0.0532mm). (Ex. 1002, ¶ 168.)

The depth of between 28 - 53 microns is well within the claimed range of "50 to 150 µm" or between 50 and 150 microns. (Ex. 1002, ¶ 169.)

### (4) Claim 32

Claim 32 depends from independent claim 15 and recites "wherein the **at least one trough** of the wave pattern **extends along an apex of the thread**."

Figures 1 and 5 of the Weiss Patent show its implant has troughs or shallow recesses, such as 32, extending along an *apex* of a thread. (Ex. 1013, Figs. 1, 5) (Ex. 1002, ¶ 170.)

"Preferably, a plurality of the lands of <u>the thread contain a shallow recess</u> <u>extending along their peripheral edge</u>, the shallow recesses further promoting the working and exercise of the perio-stabilizer ligament by increasing the surface area of the stabilizer, and hence the area of contact between the stabilizer and the ligament." (Ex. 1013, col. 2, ln. 43-48) (Ex. 1002, ¶ 171.)

"<u>The lands 26 preferably have a shallow recess 32 extending along the</u> peripheral edge thereof, so that the lands 26 have a generally W-shaped crosssection. The presence of the recess 32 on the lands 26 increases the surface area of the lands 26, and hence the area of contact between the lands 26 and the periostabilizer ligament 30. As a result of the increased area of contact the ligament 30 undergoes increased exercising as a result of any motion on the part of the stabilizer 10." (Ex. 1013, col. 4, ln. 11-19) (Ex. 1002, ¶ 172.)

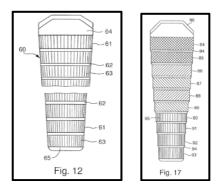
Ground 5. Claims 18-19, 21, 25, and 26 are unpatentable as anticipated by the Weiss Patent (as evidenced by the *Implant Dentistry* text, Christensen, or Tosti), in view of Dinkelacker. Claims 18-19, 21, 25, and 26 are unpatentable as obvious the Weiss Patent (Ex.

1013) (as evidenced by the Implant Dentistry text (Ex. 1004), Christensen (Ex.

1015), or Tosti (Ex. 1016)), in view of U.S. Patent No. 6,364,663 ("Dinkelacker") (Ex. 1003).

#### i. <u>Further Introduction to the Dinkelacker Reference</u>

As discussed in detail above, the Dinkelacker reference is directed to a dental implant, and demonstrates that implants having "a wave pattern that varies over the implant" were well known. (Ex. 1003, Abstract and Figures 12 and 17.) In particular, Figures 12 and 17 of Dinkelacker and their accompanying disclosure demonstrate that exact understanding in the prior art well before the priority date of the '443 Patent, as reproduced below:



As to Figure 12 Dinkelacker states "[t]he sections have grooves 63 that run in the lengthwise direction of the cone and follow the lengthwise direction of the conical surface. The grooves 63 are preferably arranged so that they have the same width at the start of each section 61 viewed from top to bottom, and <u>their width and</u> <u>depth decrease downward</u>." (Ex. 1003, col. 5, ln. 14-19 (emphasis added)) (Ex. 1002, ¶ 174.) With regard to Figure 17, Dinkelacker explains that "FIG. 17 shows an embodiment of the tooth implant according to the invention as in FIG. 14 in which at least one part of the steps has different groove structures." (Ex. 1003, col. 5, lns. 52-54.) (Ex. 1002, ¶ 175.)

#### ii. <u>Reasons to Combine the Weiss Patent with Dinkelacker</u>

Dinkelacker itself explains the advantage of providing varying grooved structures on the surface of dental implants to "account [for] the different density of the bone that surrounds the implant over its length," such that a "combination of different surface structures over the implant body also helps to secure the implant during the healing and healed phases against axial shifting and rotation, and also to better conduct pressure into the bone." (Ex. 1003, col. 6, lns. 4-6 and 11-14; Ex. 1002, ¶ 175.) Accordingly, one of skill in the art would recognize the benefit of such groove variations, and would have been motivated to modify the grooves disclosed in the Weiss Patent to "vary" along the surface to "account [for] the different density of the bone that surrounds the implant over its length" of Weiss Patent upon insertion. (Ex. 1002, ¶ 175.) Here, the known technique is the groove variation as disclosed by Dinkelacker, which when applied to grooves of the endodontic stabilizer of the Weiss Patent would result in the same and predictable benefit of helping to secure the implant in view of "different density of the bone

that surrounds the implant over its length." (Ex. 1002, ¶ 175.) See KSR Int'l v.

*Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007) (discussing obviousness of predictable improvements).

# iii. <u>Combination of the Weiss Patent (as evidenced by the</u> <u>Implant Dentistry text, Christensen, or Tosti) and Dinkelacker</u>

The elements of claims 18-19, 21, 25, and 26 are mapped to the teachings of the

Weiss Patent (as evidenced by the Implant Dentistry text) in view of Dinkelacker

in the following claim chart, as supported by the Declaration of Dr. Michel Dard.

Hall '443 Patent	Weiss Patent (as evidenced by the Implant Dentistry text,
	Christensen, or Tosti) in view of Dinkelacker
18. The implant as in	See discussion of claims [15] and [17] with regard to the
claim 15, wherein	Weiss Patent above.
the wave pattern	
varies along the	"FIG. 17 shows an embodiment of the tooth implant
implant.	according to the invention as in FIG. 14 in which at least one part of the steps has different groove structures. The body of the implant in FIG. 17 is divided into ten steps 84-93 that are connected by transition areas 94. The perimeter of the two top steps 84 and 85 have crosswise grooves as in FIG. 7C. Of the steps 86 and 87 that follow below, step 86 has grooves that run left at a sharp angle to the lengthwise axis of the implant, and step 87 has grooves that run right at a sharp angle to the lengthwise axis of the implant. The surface structure of the next steps 88 and 89 corresponds to that of steps 86 and 87, while all the other steps 90-93 have grooves 95 that run in an axial direction." (Ex. 1003, col. 5, ln. 52- 64) (Ex. 1002, ¶ 178.) (Ex. 1003, Dinkelacker, Figures 12 and 17) (Ex. 1002, ¶ 178.) "The sections have grooves 63 that run in the lengthwise direction of the cone and follow the lengthwise direction of

Hall '443 Patent	Weiss Patent (as evidenced by the <i>Implant Dentistry</i> text, Christensen, or Tosti) in view of Dinkelacker
	the conical surface. The grooves 63 are preferably arranged so that they have the same width at the start of each section 61 viewed from top to bottom, and <u>their width and depth</u> <u>decrease downward</u> ." (Ex. 1003, col. 5, ln. 14-19) (Ex. 1002, ¶ 179.)
19. The implant as in claim 15, wherein the trough varies along the spiral trajectory.	See claim [18]. (Ex. 1002, ¶ 180.)
26. The implant as in claim 15, wherein the wave pattern is formed by <b>laser</b>	"The material removing process is advantageously carried out with a digitally-controlled laser beam." (Ex. 1003, Abstract) (Ex. 1002, ¶ 184.)
bombardment.	"A procedure to manufacture a tooth implant according to the invention provides that numerous groove-shaped recesses that run along the lengthwise axis are created in the surface of the implant body by a material removal process in one of the smooth implant bodies preformed into the desired shape. The material removal process is advantageously carried out by a digitally-controlled laser beam." (Ex. 1003, col. 2, lns. 35-42) (Ex. 1002, ¶ 185.)

As to claim 21, Dinkelacker discloses two different embodiments with two different types of grooves in Figures 12 and 17, and their accompanying text as described in detailed above. (Ex. 1003, Figures 12 and 17, col. 5, ln. 52-64, col. 5, ln. 14-19) (Ex. 1002, ¶ 181.) One of skill in the art would have appreciated that many dental implant procedures involve the placement of a "set of dental implants," and Dinkelacker itself provides expression motivation to use implants,

that, between them, "[have] different wave patterns having different trough depths." (Ex. 1002, ¶ 182.) In particular, Dinkelacker explains the advantage of providing varying grooved structures on the surface of dental implant to "account [for] the different density of the bone that surrounds the implant over its length," such that a "combination of different surface structures over the implant body also helps to secure the implant during the healing and healed phases against axial shifting and rotation, and also to better conduct pressure into the bone." (Ex. 1003, col. 6, lns. 4-6 and 11-14) (Ex. 1002, ¶ 182.) As such, claim 21 is obvious over the teachings of the Weiss Patent combined with Dinkelacker. (Ex. 1002, ¶ 182.) The foregoing rationale is equally applicable to claim 25, which recites language similar to that of claim 21. (Ex. 1002, ¶ 183.)

#### **CONCLUSION**

For the foregoing reasons, Petitioner respectfully requests that Trial be instituted and that Claims 15, 17-19, 21, 25-27, and 30-32 be canceled.

Respectfully submitted,

Dated: August 20, 2015

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# **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a CD containing a copy of the foregoing

Petition for Inter Partes Review together with all exhibits and other papers filed

therewith was served on August 20, 2015, by Federal Express directed to the

attorneys of record for the patent at the following address:

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