Paper No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INSTRADENT USA, INC.
Petitioner
v.

NOBEL BIOCARE SERVICES AG

Patent No. 8,714,977
Issue Date: May 6, 2014
Title: CONDENSING SKELETAL IMPLANT THAT FACILITATE INSERTIONS

_____

Inter Partes Review No. Unassigned

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

TABLE OF CONTENTS

EXHIBIT LIST

Ex. #	Exhibit
1001	U.S. Patent No. 8,714,977 ("the '977 Patent")
1002	Image File Wrapper for '977 Patent
1003	U.S. Pat. Application Publication US2005/0100683 ("Chang")
1004	U.S. Patent No. 4,738,623 ("Driskell")
1005	Selected Redacted Pages of Staff's Post-Hearing Opening Brief
1006	U.S. Patent No. 7,597,557 ("the '557 Patent")
1007	Declaration of Mr. Michel Dard
1008	March 2003 Product Catalog, Alpha Bio Tec Ltd. ("2003 Catalog")
1009	No. 63 Jan-Feb 2003 Israeli Dental Update Journal ("Update Journal")
1010	Certified English Translation of Ex-1009
1011	Israeli Patent Application No. 156033, filed May 21, 2003
1012	PCT International Application Publication No. WO2004/103202 A1
1013	Statement of Relevance by Ophir Fromovich dated June 28, 2009
1014	2002 Product Catalog of Anthogyr SAS ("Anthogyr")
1015	Declaration of Martin Vogt on authenticity of Ex-1014
1016	Das ITI-Schraubenimplantat (TPS), circa 1987
1017	Certified English translation of Ex-1016
1018	Photos of TPS 3.5 mm implant kit by Institut Straumann AG
1019	Declaration of Martin Vogt on authenticity of Ex-1016 and Ex-1018
1020	Curriculum Vitae of Mr. Michel Dard
1021	Non-confidential Deposition Transcript of Ophir Fromovich

NOTICE OF LEAD AND BACKUP COUNSEL

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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. 8,714,977 ("the '977 patent") is asserted in *Certain Dental Implants*, Inv. No. 337-TA-934 (Int'l Trade Comm'n), in which the Final Initial Determination is expected to be entered on October 27, 2015, as well as in a case captioned *Nobel Biocare Services AG and Nobel Biocare USA, LLC, v. Neodent USA, Inc.*, Civil Action No. 14-1322 DOC (DFMx)(C.D. Cal.), 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: phunter@foley.com; npisano@foley.com; and acheslock@foley.com.

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

1. The '977 patent matured from U.S. Patent Application Serial No. 12/685,388, filed November 26, 2012, which is a continuation of Application Serial No. 12/687,072, filed on Jan. 13, 2010, which is a continuation of Application Serial No. 12/552,211, filed on Sep. 1, 2009, which is a continuation of Application Serial No. 10/558,260, filed as International Application No. PCT/IL2004/000438 on May 23,

2004. The International Application claims the benefit of priority to Israeli Application No. 156033, filed May 21, 2003. (Ex. 1012 at p.1.) The thread step range of 1.5-2.5 mm recited in each of independent claims 1 and 9 was first added, along with additional disclosure and figures, to the International Application. (Ex. 1012 at p. 20, lines 5-8). Accordingly, the earliest effective filing date of the claims of the '977 patent is May 23, 2004.

2. The Alpha Bio Tec Ltd. advertisement contained in the Israeli Dental Update Journal No. 63 was published in Israel no later than February 2003 and is § 102(b) prior art to the claims of the '977 patent. (Ex. 1009; "Update Journal"). The March 2003 Product Catalog of Alpha Bio Tec Ltd. was published and distributed in training courses by inventor Ophir Fromovich in or around March 2003, and is prior art to the claims of the '977 patent under § 102(b). (Ex. 1008; "2003 Catalog".) The 2002 Product Catalog of Anthogyr SAS is prior art under § 102 (b), as is the ITI Manual, each of which is discussed in detail herein. (Ex. 1014 ("Anthogyr"); Ex. 1016 ("ITI Manual").)

3. Nobel Biocare Services AG ("Nobel") is the purported patent owner by virtue of an assignment executed on October 31, 2006 and recorded at the United States Patent Office at Reel/Frame 18534/618.

STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner respectfully requests the Board initiate an *inter partes* review and cancel

Claims 1-7, 9 and 13-20 of the '977 as unpatentable pursuant to 35 U.S.C. § 311(b) based on the three grounds of unpatentability discussed in detail herein.

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 1-7, 9 and 13-20 of the '977 patent are taught in the prior art as explained below in the proposed grounds of unpatentability. Also, where the claims are rendered obvious by combinations of prior art, the reasons to combine are established under 35 U.S.C. § 103(a).

STATEMENT OF REASONS FOR RELIEF REQUESTED

I. Introduction to the Technology of the '977 patent

The '977 Patent, entitled "Condensing Skeletal Implant That Facilitate Insertions," is directed to dental implants, generally of titanium, that are surgically placed into a hole drilled into a patient's jawbone ("osteotomy") to support a dental prosthesis, such as a crown or an overdenture bar. (Ex. 1007 at ¶ 17.) The dental implants described in the '977 Patent generally have an elongated "body" including a "coronal" end, disposed adjacent to the crest of the patient's jaw when the implant is fully inserted into the osteotomy, and an "apical" end opposite the coronal end. (Ex. 1001, Abstract; Ex. 1007 at ¶ 18.) The implant includes a pair of helical threads spaced 180^{o} around

the circumference of the body, which begin at the apical end, and extend axially (upwards) towards the coronal end. (Ex. 1001, col. 12, ln. 29-36; Ex. 1007 at ¶ 19.) As defined in the '977 Patent, each helical thread has a "thread step" (or pitch), measured longitudinally between adjacent turns of the same thread, having a range between 1.5 and 2.5 mm. (Ex. 1001, col. 12, ln. 26-29; Ex. 1007 at ¶ 20.) Certain claims (*e.g.*, claims 1 and 19) of the '977 Patent require a "coronal region" that extends coronally from the tops of the helical threads and includes a frustoconical shape or inverse taper, such that the coronal region is narrower at its coronal end than at its apical end. (Ex. 1001, col. 12, ln. 44-56 and FIGS. 5, 8, 12; Ex. 1007 at ¶ 21.)

II. Independent Claim 1 of the '977 Patent

The "dental implant" of Claim 1 includes "a body," "a coronal region of the body, the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region," "an apical end …having a core with a tapered region..," "a pair of helical threads extending along the body…" and "a bone tap," "wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is between 1.5-2.5 mm." (Ex. 1001.) As shown in FIGS. 5, 8, and 12, the frustoconical shape may extend along part or all of the coronal region. *Id.*

III. Independent Claim 9 of the '977 Patent

The dental implant of Claim 9 includes "a body," "a coronal end of the body," and an "apical end having a tapered core… includ[ing] at least one region having two tapered variable profile helical threads," "wherein the core is more tapered than the threads and wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is 1.5-2.5 mm." Claim 9 does not require a "coronal region having a frustoconical shape" as recited in Claim 1; instead claim 19 (which depends from claim 9) requires that "a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge."

IV. Construction of the Claims

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. Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation." In addition to this presumption, Petitioner provides a more detailed explanation of the broadest reasonable meaning of certain claim terms.

i. "Coronal Region Having a Frustoconical Shape" (Claim 1)

The phrase "the coronal region having a frustoconical shape" appears only in independent Claim 1 and nowhere else in the specification. FIG. 12 depicts an embodiment described as having "a coronally tapered coronal region." (FIG. 12, col. 6, ll. 59-61; col. 12, ll. 10-16; Ex. 1007 at ¶ 23.) The phrase was readily understood by the Patent Examiner during prosecution of the '977 patent as referring to a coronal region as depicted in FIGS. 5, 8 and 12, and the Patent Examiner made prior-art based rejections, including citation of Chang and Driskell. (Ex. 1002 at 73, 163; Ex. 1003 and 1004; Ex. 1007 at ¶ 23.)

Applicants did not challenge the prior art-based rejections based on Chang or Driskell, nor did they dispute that the cited references showed implants having frustoconical coronal regions. Instead, applicants acquiesced in those rejections and amended the claims to include bone tap and thread step range limitations. (Ex. 1002 at 35-37, 51-53, 152; Ex. 1007 at ¶ 24.) Those amendments were deemed by the Patent Examiner to distinguish over the cited prior art. (Ex. 1002 at 15; Ex. 1007 at ¶ 24.)

In the ITC, the parties proposed the following constructions (Ex. 1005 at 22):

Claim Term	Nobel's Construction	Petitioner's and Staff's Construction
"the coronal region having a frustoconical shape"	the coronal region as a whole has a frustoconical shape that permits bone to relapse upon implant insertion	the coronal region has, partly or entirely, a frustoconical shape

In the construction argued by the Petitioner and Investigative Commission Staff, the phrase "having a frustoconical shape" should be construed to mean "the coronal region has, partly or entirely, a frustoconical shape." Nobel, however, (i) disputes the interpretation of "having" is open-ended and (ii) insists the functional limitation "that permits bone to relapse upon implant insertion" should be read into the claims. *Id.*

(1) "having" Is Open-Ended

The term "having" in the dispute phrase should be construed as open-ended, as the terms "comprising" and "including" are construed, thereby allowing some portion of the coronal region to have other shapes in addition to a frustoconical shape. *See, e.g., Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376 (Fed. Cir. 2000) (the term "having" was interpreted as open-ended, allowing the inclusion of other components in addition to those cited); *Pehr v. Rubbermaid, Inc.*, 87 F. Supp. 2d 1222 (D. Kan. 2000) ("having" — "means to hold, include, or contain as a part or whole.") This construction is proper—especially in view of the Figures and description provided in the specification of the '977 patent.

By contrast, Nobel seeks to construe "having" as closed (essentially as "consisting of"), thereby requiring that the *whole* coronal region have a frustoconical shape, such that the claimed "coronal region" consists entirely of a "frustoconical shape" and cannot have any additional shapes. The intrinsic evidence does not support such a construction. (Ex. 1007 at ¶ 35.)

As required, analysis of the intrinsic evidence begins with the claims. *Sunovion Pharm., Inc., v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013) ("When construing claim terms, we first look to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive.") (internal citation omitted).

The language of Claim 1 neither requires that the *whole* coronal region have a frustoconical shape nor excludes the coronal region from having additional shapes (besides a frustoconical shape). (Ex. 1007 at ¶ 29.) In other words, the claim language itself does not mandate that the term "having" is closed. *Phillips v. AWH Corp.*, 415 F.3d at 1314 ("the claims themselves provide substantial guidance as to the meaning of particular claim terms."). And the claim language does not use the term "having" in a manner that indicates an objective intent to require that the entire coronal region have a frustoconical shape. (*Id*.) *Innova/Pure Water, Inc., v. Safari Water Filtration Sys., Inc*., 381 F.3d 1111, 1116 (Fed. Cir. 2004) ("The inquiry into the meaning that claim terms would have to a person of skill in the art at the time of the invention is an objective one.")

Moreover, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Phillips v. AWH Corp.*, 415 F.3d at 1314. Indeed, the language of claim 9 shows that the patentee knew how to indicate that a whole region had a certain structure. (Ex.

1007 at ¶ 30.) *See Takeda Pharm. Co. Ltd. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1365 (Fed. Cir. 2014) ("the remainder of Claim 1 demonstrates that the inventors knew how to express ambiguity in claim language when they so desired" by claiming a hardness strength "about" a certain range). Claim 9 recites a thread having a variable height along the "entire threaded region." (Ex. 1007 at 30; Ex. 1001, col. 18:53.) Therefore, had the patentee desired to limit Claim 1 to require that the *entire* coronal region have a frustoconical shape, the patentee could have easily included the word "whole" (or "entire") in the claim. (*Id.*) The patentee did not to do so. *Phillips v. AWH Corp.*, 415 F.3d at 1314 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms."). The PTAB should reject Nobel's construction, which effectively rewrites the claim. *See Takeda Pharm.*, 743 F.3d at 1365 (court refused to construe claim term to include the word "about" because the inventors knew how to express ambiguity in the claim, but decided not to).

Next, the rest of the intrinsic evidence, that is, the written description and the prosecution history must be considered. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). Petitioner's proposed construction is supported by the figures and description of the invention in the specification. *Phillips v. AWH Corp.*, 415 F.3d at 1315. As an initial matter, the parties agreed that the claim term "coronal region" (within the phrase "the coronal region having a frustoconical shape") means "a region of the implant body closer to the crest of the jawbone when

the implant is fully implanted." (Ex. 1007 at ¶ 31.) The specification confirms and adds precision to this construction, generally describing the coronal region as the region of the implant above the threads (*i.e.*, the apical region). This is consistent with the claims. For example, Claim 3 recites that the "coronal region" ends at the threads:

> **Claim 3.** The implant of claim 1, wherein the apical end of the coronal region defines an upper limit of the threads.

(Ex. 1001, col. 18:21–22; Ex. 1007 at ¶ 31.)

Likewise, regarding the embodiment shown in FIG. 8, the specification generally defines the "coronal region" as the region above the threads that is to be inside the bone—a region that includes the frustoconical region 48. (*Id.*, col. 11:33–35 ("The most coronal part of the coronal region is even preferably inversed tapered 48 as illustrated in FIG. 8.); col. 11:44–47 ("FIG. 8 illustrates such an embodiment with a narrow region 71 between the part of the implant that is to be inside the bone 72 and the abutment part 73 which is tapered to allow connection to a prosthetic element like a crown."); Ex. 1007 at ¶ 32.)

In view of Claim 3 and the specification, one of ordinary skill in the art would understand "coronal region" to mean "a region of the implant body closer to the crest of the jawbone when the implant is fully implanted" and to refer specifically to the region above the threads. (Ex. 1007 at ¶ 34.) The specification makes clear to one of ordinary skill in the art that the claimed coronal region may include other shapes (or

angles) besides a frustoconical shape. (*Id.* at ¶ 33.) For example, Figs. 5, 8, and 9 disclose implants with coronal regions with additional shapes (or angles) besides a frustocone. (*Id.*; Ex. 1001 at FIGS. 5, 8, 9.) Petitioner's proposed construction covers at least these embodiments and those shown in Figs. 12, 17, and 18 (whole coronal region has a frustoconical shape). (Ex. 1007 at ¶ 34; Ex. 1001 at 12–15.)

Thus, in the context of the '977 patent, one of ordinary skill in the art would construe the claim term "the coronal region having a frustoconical shape" to mean "the coronal region has, partly or entirely, a frustoconical shape." This interpretation is consistent with Claim 3 and the specification; and does not impermissibly exclude embodiments. *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) ("[a]t leas[t] where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary.") (Ex. 1007 at ¶ 35.)

In contrast, Nobel's construction improperly attempts to read one embodiment (generally disclosed in FIG. 12) into Claim 1. *Electro Med. Sys. S.A. v. Cooper Life Sci.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994) ("Particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments.") Relying on *Lexington Luminance LLC v. Amazon.com Inc.*, No. 2014-1384, 2015 WL 524270 (Fed. Cir. Feb. 9, 2015) ("*Lexington Luminance*") and other cases, the Staff concluded that Nobel's expert's testimony at the evidentiary

hearing conducted in the ITC conflicts with the specification, and should be accorded little or no weight. (Ex. 1005 at 28.) "There is a strong presumption against a claim construction that excludes a disclosed embodiment . . . ." *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011).

Accordingly, the evidence shows that the claim term "having" should be construed as open ended and embodiments disclosed in at least Figs. 5, 8, and 9 should not be excluded from the construction of "a coronal region having a frustoconical shape." (Ex. 1007 at ¶ 35.)

(2) The Functional Limitation "that permits bone to relapse upon implant insertion" Should Not Be Read Into Claim 1

Nobel's proposed construction also includes a functional limitation – the coronal region allegedly "permits bone to relapse upon implant insertion." The testimony of Nobel's expert, Steve Hurson, at the ITC evidentiary hearing, confirmed this, as discussed in the Staff Attorney's brief. (Ex. 1005 at 29.)

In the ITC, Nobel contended that one of ordinary skill in the art would understand that the "frustoconical coronal region" requires "more" than a small edge break or bevel and that the claim term "should be construed to require a coronal taper that is large enough to allow the bone to relapse over the implant." (*See, e.g.*, Ex. 1005 at p. 30.) In other words, Nobel attempted to import in the guise of a functional limitation ("permits bone to relapse upon implant insertion") an ambiguous size limitation ("large

enough to allow the bone to relapse over the implant") into Claim 1. Nobel's proposed construction should be rejected. (Ex. 1007 at ¶ 36.)

First, the claim term is clear and reference to the size of the frustoconical region or to alleged bone relapse should not be read into the claim from the specification. *See Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1371 (Fed. Cir. 2001) ("[L]imitations from elsewhere in the specification will not be read in where, as here, the claim terms are clear."); *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116 (1895) ("[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty . . . .")

Second, because the claim term "the coronal region having a frustoconical shape" is written in structural terms, it is improper to construe it as having a functional limitation. *See Schwing GMBH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002) ("Where a claim uses clear structural language, it is generally improper to interpret it as having functional requirements."); *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1371 (Fed. Cir. 2001). Indeed, "apparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990).

Third, injecting a functional/use limitation ("permits bone to relapse upon implant insertion") into Claim 1 confuses rather than clarifies the meaning of the term. The specification states at col. 2, ll. 62-66:

> The coronal region of the implant is preferably converging coronally. This region is to be placed below the bone level and the bone is covering this region because the implant is designed to allow insertion with a small diameter drill and to allow elastic expansion of the cortical bone.

Thus, the specification links the ability of the bone to allegedly relapse with the size of the osteotomy, not with the size of the frustocone. (Ex. 1007at ¶ 37.)

Under Nobel's proposed construction, infringement depends on whether the bone relapses; and whether the bone relapses depends, in part, on the size of the osteotomy. "It is usually improper to construe non-functional claim terms in system claims in a way that makes infringement or validity turn on their function." *Superior Indus., Inc. v. Masaba, Inc.*, No. 2013-1302, 2014 WL 163046, at *5 (Fed. Cir. Jan. 16, 2014) (unpublished); *see also Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008); *Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1090 (Fed. Cir. 2009).

Finally, Nobel's contention that the file history supports its construction is incorrect. Nobel argues that because the parent U.S. Application No. 12/552,211 (U.S. Patent No. 8,197,255) includes a claim directed to a method claim of installing a dental implant with a frustoconical coronal region that "allows the bone to relapse to cover the coronal region," a similar functional limitation should be read into apparatus Claim 1 of the '977 patent. But instead, this shows that the patentee understood how to write

a functional limitation when the patentee wanted to claim such a limitation. *Takeda Pharm. Co. Ltd. v. Zydus Pharms. USA, Inc.*, 743 F.3d at 1365.

Unlike the method claim of U.S. Patent No. 8,197,255, apparatus Claim 1 of the '977 patent does not recite any such functional/use limitation and none should be improperly imported. In sum, the evidence shows that one of ordinary skill in the art at the time of the invention would interpret the claim term "the coronal region having a frustoconical shape" to mean "the coronal region has, partly or entirely, a frustoconical shape." (Ex. 1007 at ¶ 38.)

ii. "A Most Coronal Aspect" / "A Most Coronal Aspect Of The Coronal End Is Tapered Coronally" (Claim 19)

The phrases "a most coronal aspect" and "a most coronal aspect of the coronal end is tapered coronally" appears only in dependent Claim 19, which depends from independent Claim 9. Unlike the word "frustoconical," which appears nowhere except in claim 1, several portions of the '977 patent discuss having "a coronally tapered coronal region." (Ex-1001 at FIGS. 8, 12, col. 4, ll. 5-7; col. 5, l. 66-col. 6, ll. 10; col. 6, ll. 47-49 and ll. 59-61; col. 11, ll. 34-36 and 44-47; col. 12, ll. 10-16 and col. 12, l. 42-col. 13. l. 9.) The phrase was first introduced in an Amendment filed October 21, 2013, and simultaneous with amendment of the claims to include the bone tap and thread step range limitations. (Ex. 1002 at 35-37, 51-53, 152.)

In the ITC, the parties proposed the following constructions (Ex. 1005 at 34):

Claim Term	Nobel's Construction	Petitioner's and Staff's Construction
"a most coronal aspect" and "a most coronal aspect of the coronal end is tapered coronally"	the most coronal end tapers in the coronal direction and permits bone to relapse upon implant insertion	a furthermost portion of the coronal end (from the apical end) has a width that is reduced in the direction of the coronal end of the implant

As with the construction of "the coronal region having a frustoconical shape" in Claim 1, the dispute here is whether the functional limitation "permits bone to relapse upon implant insertion" (as proposed by Nobel) should be read into Claim 19. For the reasons set forth above in connection with Claim 1, the evidence shows that Nobel's construction is improper and not supported by the intrinsic evidence. Therefore, this clearly structural claim term should be construed to mean "a furthermost portion of the coronal end (from the apical end) has a width that is reduced in the direction of the coronal end of the implant." (Ex. 1007 at ¶ 41.)

"Claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." MPEP § 2114. "[A]pparatus claims cover what a device *is,* not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim." MPEP § 2114(II) (citing *Ex parte Masham,* 2 USPQ2d 1647 (Bd. Pat. App. & Inter.

1987)). A claim element that describes how an apparatus should be used to achieve the desired result is not given patentable weight because an apparatus claim is differentiated from the prior art by structure alone. *Ex Parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Interf. 1987) ("The apparatus disclosed [ ] does not undergo a metamorphosis to a new apparatus merely by affixing instructions thereto indicating" how to use the apparatus.).

Indeed, functional language has long been ignored by courts. *See, e.g.*, *General Electric Co. v. Wabash Appliance Co.,* 304 U.S. 364, 371-72 (1938); *In re Fuller*, 35 F.2d 62 (CCPA 1929) ("It [the claimed element] is also functional, describing a result only, and not a process, and can, therefore, have no standing here."). Although there is "nothing intrinsically wrong with" using functional claim language, if a claim element merely recites the outcome of a step (rather than a step itself) or what a structure does, such an element should be ignored. *See In re Swineheart*, 439 F.2d 210, 212-13 (CCPA 1971).

V. Claim-By-Claim Explanation of Grounds for Unpatentability

Unpatentability of claims 1-7, 9, and 16-20 of the '977 Patent are set forth below and discussed in the declaration by Mr. Michel Dard, whose *curriculum vitae* is presented in Ex. 1020. (Ex. 1007).

Ground 1. Claims 1-5, 9 and 16-19 of the '977 are unpatentable as anticipated by the 2003 Alpha Bio Tec Catalog.

Claims 1-5, 9 and 16-19 of the '977 patent are unpatentable under 35 U.S.C. § 102(b) as anticipated by a March 2003 product catalog published by Alpha Bio Tec Ltd. ("the 2003 Catalog"; Ex. 1008), an Israeli company founded by inventor Dr. Ophir Fromovich. Section 2 of the 2003 Catalog describes 5 mm and 6 mm SPI dental implants that anticipate each of claims 1-7, 9 and 16-19. Other sizes of the implants described in the 2003 Catalog appear identical to FIGS. 7A and 7B of the '977 patent. As established at the ITC evidentiary hearing, and discussed in detail below, the 2003 Catalog was published and distributed to persons of skill in the art more than a year before the May 23, 2004 effective filing date of the '977 patent and is prior art under 35 U.S.C. § 102(b). (Ex. 1005 at 43-48.)

i. <u>The 2003 Catalog is Prior Art Under 35 U.S.C. § 102(b)</u>

In the ITC, Nobel, which acquired Alpha Bio Tec Ltd. in 2008, and has access to all of the records for that company (but produced virtually none of those records), contended that there was "no evidence" that the 2003 Catalog constitutes a "printed publication."

However, Inventor Fromovich testified that he had hundreds of copies of the 2003 Catalog printed, in roughly the same proportion as the number of Alpha Bio Tec Ltd.'s customers at the time. (Ex. 1021 at 124:22 – 127:2; 131:23 – 133:13.) He testified that he handed out the 2003 Catalog, without confidentiality restriction, as a "training

aid" for groups of clinicians when showing them how to use the implants disclosed in the catalog. (*Id.* at 123:20 – 124:5; 133:14 – 134:18.) Dr. Fromovich also admitted that another document, an advertisement in the Israeli Dental Update Journal No. 63 for Jan-Feb. 2003 ("Update Journal") (Ex. 1009), was published no later than March 2003. (Ex. 1021 at 188:6 – 191:23.) The Alpha Bio Tec Ltd. advertisement in the Update Journal (Ex. 1009) includes a picture and description of the SPI Implants identical to those described in the 2003 Catalog (Ex. 1008 at 16).

Despite Nobel's protestations that there was "no evidence" that the 2003 Catalog or Update Journal were published or distributed, the Staff attorney readily concluded that "[i]n the Staff's view, there is ***clear and convincing evidence*** that the catalog discloses to one of ordinary skill in the art all of the limitations of [asserted] claims 1, 3–5 and 19 of the '977 patent. Therefore, the 2003 Alpha Bio Tec Catalog renders the [sic] these claims invalid under § 102." (Ex. 1005 at 44 (emphasis added).) The 2003 Catalog plainly meets the lesser "preponderance of evidence" standard applicable in this proceeding.

In the ITC matter, the Staff's post-hearing brief concludes that (Ex. 1005 at 45):

> "the evidence shows that the catalog qualifies as prior art under § 102. The 2003 Alpha Bio Tec Catalog was 'publicly accessible' more than one year before the effective filing date (May 23, 2004) of the '977 patent. … In particular, the evidence demonstrates that the 2003 Alpha Bio Tec Catalog was publicly accessible before May 23, 2003—the critical date

> for the '977 patent. The 2003 Alpha Bio Tec Catalog, entitled "Product Catalog March 2003," includes a 2003 copyright designation. …

There is no genuine issue that the 2003 Catalog was not published or distributed more than a year before the May 23, 2004 effective filing date of the '977 patent. Nobel, ***who was in possession, custody or control of the records of Alpha Bio Tec Ltd. since 2008***, provided no documentary evidence suggesting that the 2003 Catalog was not, in fact, "actually" published or distributed later than May 23, 2003. Dr. Fromovich acknowledged that he placed the advertisement for the SPI implant in the Update Journal which was published more than a year before the effective filing date. *See In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013) *cert. denied sub nom. Morsa v. Patent & Trademark Office*, 134 S. Ct. 1317, 188 L. Ed. 2d 306 (2014).

Moreover, the Patent Office is entitled to rely upon Nobel's ***admission*** in the Information Disclosure Statement filed December 20, 2012 that references as should be "consider[ed] published before May 21, 2003." (Ex. 1002 at 196 (2012-12-20 Information Disclosure Statement at Sheet 5).) Although citation of a reference in an IDS is not itself an admission that the reference constitutes prior art, *ResQNet.com, Inc. v. Lansa, Inc*., 594 F.3d 860, 866 (Fed. Cir. 2010), an ***admission in an IDS that the reference is prior art*** certainly cannot later be retracted. Nobel's contention that its admission in the IDS was "conditional" because it was "for purposes of examination" is absurd – if a reference is specifically identified as prior art "for

purposes of examination" it is inconceivable that it should subsequently be considered anything else.

ii. Independent Claims 1 and 9

Independent Claims 1 and 9 are each directed to a dental implant, which are shown on pages 16 and 17 of the 2003 Catalog. The 3.7 mm and 4.2 mm SPI implants illustrated on page 16 of the 2003 Catalog are indistinguishable from FIGS. 7A and 7B of the '977 patent, and except for the presence of a frustoconical shape on the coronal region of the implant, as defined in Section IV.i above, meet all of the other limitations of claim 1 and all of the limitations of claim 9 of the '977 patent. An example of an SPI implant having an exterior diameter of 3.75 mm, as shown in the 2003 Catalog, is reproduced below (on the right), and appears identical to the device depicted in FIG. 7A of the '977 patent (left, below):

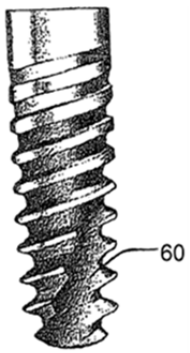
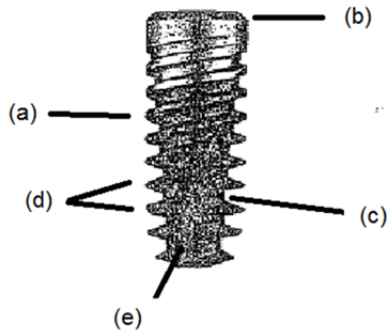


FIG. 7A

2003 Catalog

The 2003 Catalog also discloses SPI implants having a frustoconical shape on the most coronal part of the implant. An example of the SPI implant having an exterior diameter of 5 mm and having a frustoconical coronal region (labeled "b" in the figure below), from the 2003 Catalog, is reproduced below and annotated with reference

letters corresponding to the elements of claim 1 of the ’977 patent:



As indicated by the arrows and reference letters in the preceding figure, the 5 mm diameter SPI implant disclosed in the 2003 Catalog includes each of elements (a) through (e) of claim 1 of the ’977 patent.

The SPI implant disclosed in the 2003 Catalog also discloses element (f) of claim 1 of the ’977 patent in text describing key features of the SPI implants, i.e., that the implants have a “double thread” design with a thread step of “2.1 mm”:

SPI SPIRAL

A tapered implant with large variable thread design double thread 2x2.1mm. Spiral tap condense bone for improved stabilization. Special development of Alpha Bio for immediate loading and immediate extraction for bone qualitie types II,III,IV and I. The tapered design allows the implant to be placed in the ideal position for improved esthetics and better load distribution.

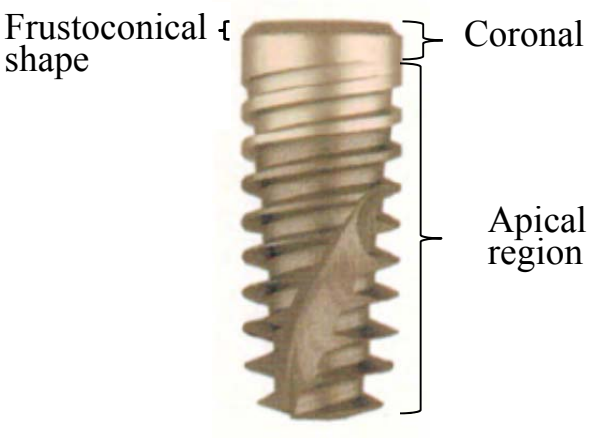
(Ex. 1008 at 17.) The ’977 patent, at column 12, line 29, states “preferably the step is 2.1mm” – the identical distance disclosed for the thread step in the 2003 Catalog, as shown above. (Ex. 1001 at col. 12, ln. 26-29.) The disclosure of a thread step having a range of 1.5-2.5 mm – the limitation added to independent application claims 1 and 10 to secure allowance of the application for the ’977 patent – first appeared in the

PCT application filed May 23, 2004.

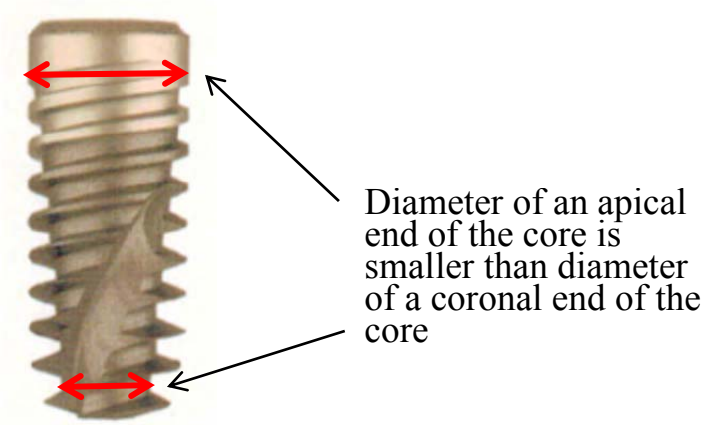
Nobel's recognition of the materiality of the 2003 Catalog is confirmed by its efforts to downplay the significance of that prior art. In a "Statement of Relevance of Ophir Fromovich," submitted during prosecution of U.S. Patent Application Serial No. 10/558,260, which matured as U.S. Patent No. 7,597,557 ("the '557 Patent") (Ex-1006), Dr. Fromovich emphasized that the 2003 Catalog did not disclose the "gradually condensing core" feature depicted in FIG. 3 of that application (also FIG. 3 of the '977 Patent). (Ex. 1002 at 196 (2012-12-20 Information Disclosure Statement at Sheet 5); Ex. 1013 at ¶¶ 3, 7.) The Statement was also submitted during prosecution of the '977 Patent, even though the distinction argued therein did not apply to the claims sought and obtained in the '977 Patent. *Compare* Ex. 1013 with Ex. 1001.

Each of elements (a) through (f) of claim 1 of the '977 Patent are disclosed and described by the SPI implant disclosed in the 2003 Catalog (Ex. 1008), as shown with particularity as follows.

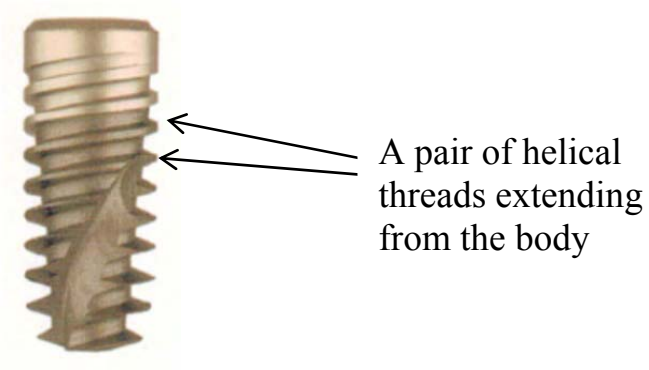
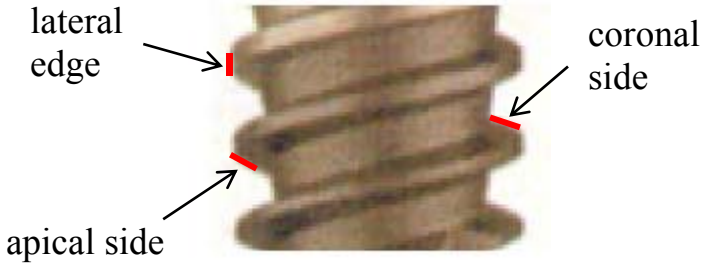
The '977 Patent	**Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)**
A dental implant comprising:	"A tapered implant with large variable thread design double thread 2x2.1mm." (Ex. 1008 at 17; Ex. 1007 at ¶ 51.)

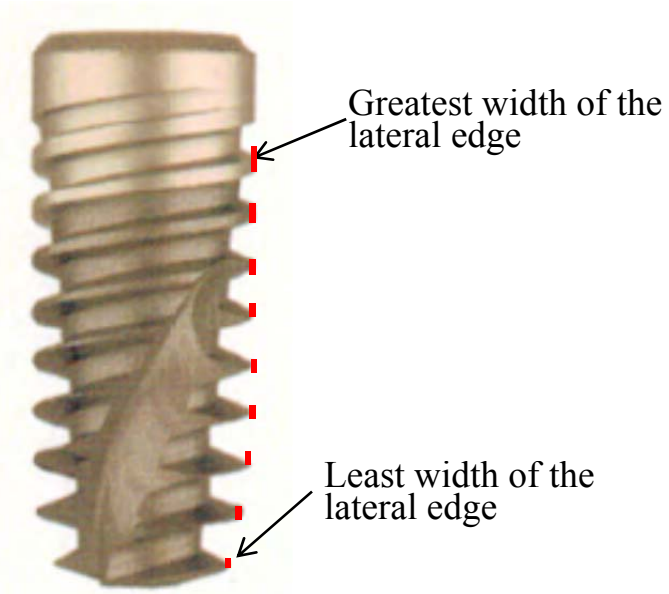
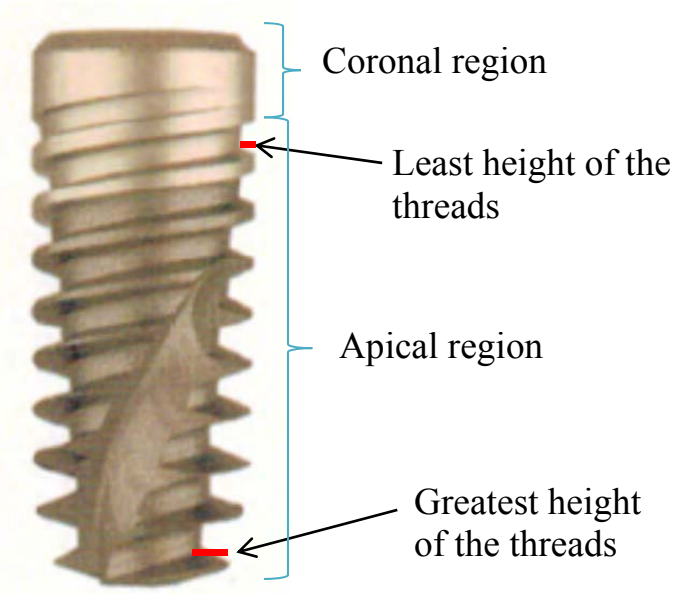
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
(a) a body; (b) a coronal region of the body, the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region;	

As demonstrated above, the 5 mm SPI implant disclosed in the 2003 Catalog includes element (a), an implant body, and element (b), a coronal region, wherein the coronal region includes a frustoconical shape such that the diameter at the apical end is smaller than the diameter at the coronal end. (Ex. 1007 at ¶ 52.)

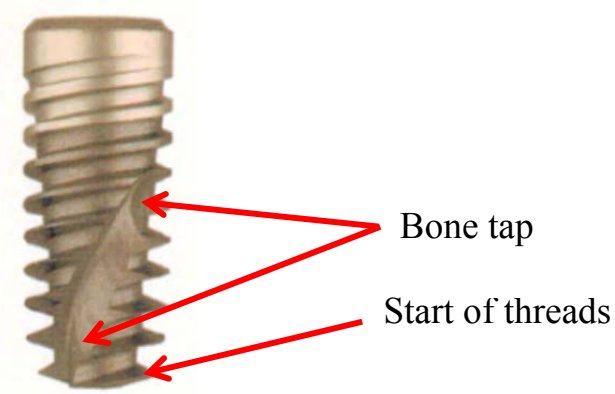
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog" (Ex-1008)
(c) an apical region of the body, the apical region having a core with a tapered region wherein a diameter of an apical end of the core is smaller than a diameter of a coronal end of the core and the apical end of the core is substantially flat; and	 "The tapered design allows the implant to be placed in the ideal position for improved esthetics and better load distribution." (Ex. 1008 at 17.)

As demonstrated above, the SPI implant disclosed in the 2003 Catalog includes element (c), an apical region of the body that is tapered such that the diameter at the apical end is smaller than the diameter at the coronal end. (Ex. 1007 at ¶ 53.)

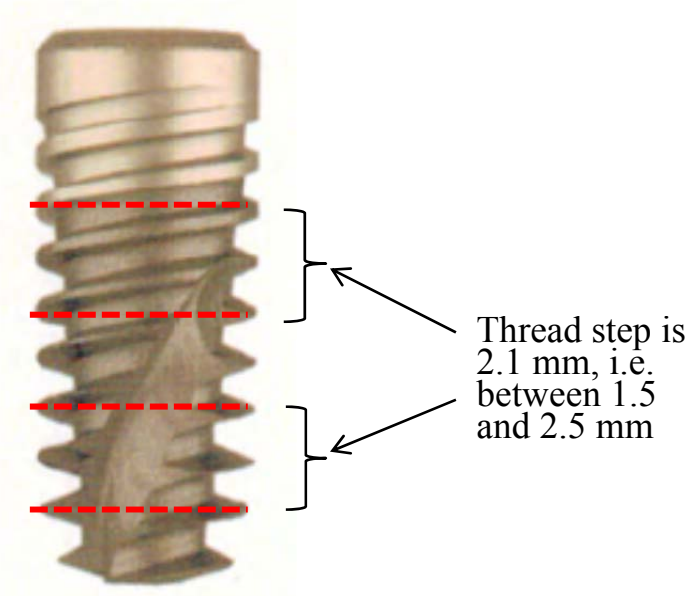
The '977 Patent	**Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)**
(d) a pair of helical threads extending from the body along at least a portion of the apical region,	
each of the threads comprising an apical side, a coronal side, and a lateral edge connecting the apical side and the coronal side, a base connecting the threads to the core, a thread height defined between the lateral edge and the base,	

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
the lateral edge having a variable width that is expanded along a segment in the direction of the coronal end of the apical region, so that a least width of the lateral edge of the threads is adjacent the apical end of the apical region and a greatest width of the lateral edge of the threads is adjacent the coronal end of the apical region,	
and the threads having a variable height that is expanded substantially along the segment of the implant in the direction of the apical end of the apical region, so that a least height of the threads is adjacent the coronal end of the apical region and a greatest height at apical end of the apical region; and	

As demonstrated above, the SPI implant disclosed in the 2003 Catalog includes element (d), a pair of helical threads. (Ex. 1007 at ¶ 54.)

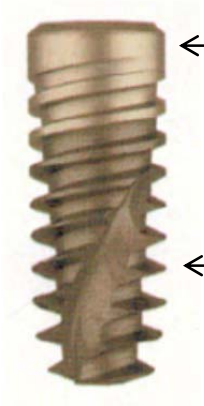
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog" (Ex-1008)
(e) a bone tap, wherein the helical threads starts at said bone tap and said substantially flat apical end of the core;	 "Spiral tap condense bone for improved stabilization." (Ex-1008 at 17.)

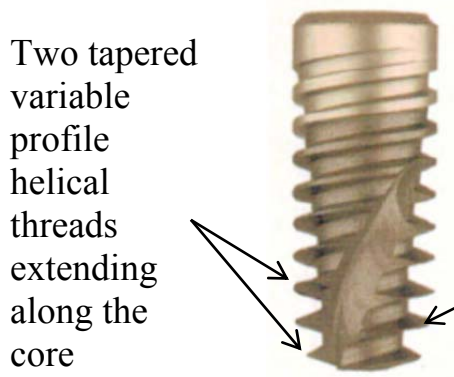
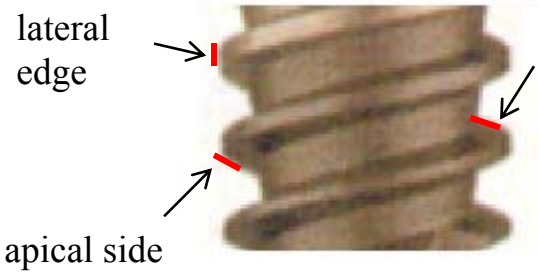
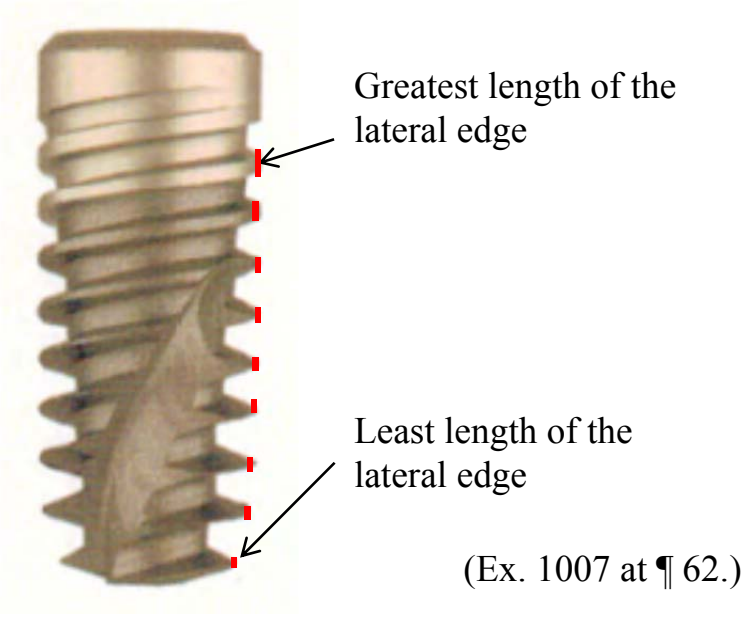
The SPI implant disclosed in the 2003 Catalog includes element (e), a bone tap. (Ex. 1007 at ¶ 55.)

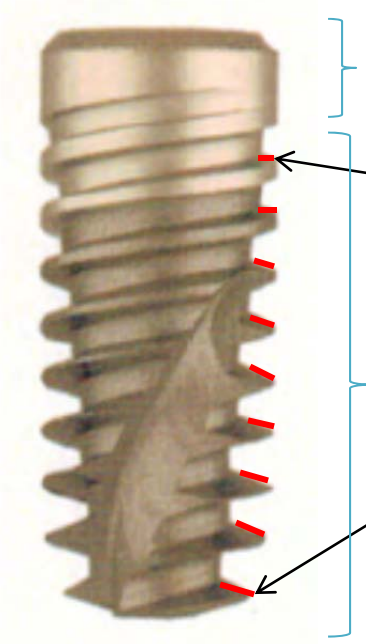
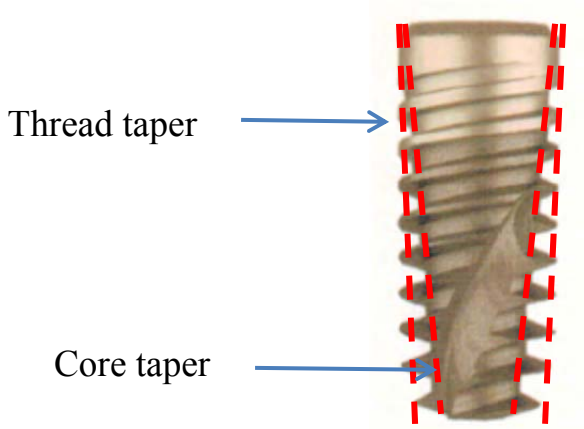
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
(f) wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is between 1.5-2.5 mm.	 "A tapered implant with large variable thread design double thread 2x2.1mm." (Ex-1008 at 16-17.)

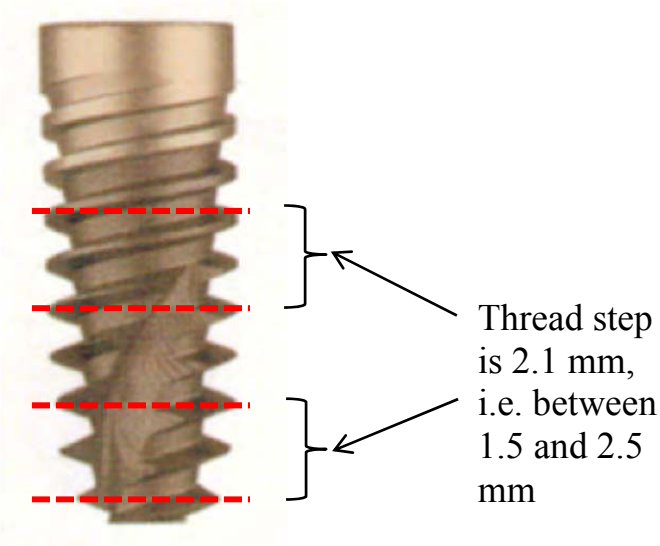
As demonstrated above, the SPI implant disclosed in the 2003 Catalog includes element (f), a thread step within the range of 1.5-2.5 mm (Ex. 1007 at ¶ 56), which is the claim limitation added during prosecution of the '977 Patent to obtain allowance. In view of the foregoing, all limitations of independent claim 1 of the '977 Patent are disclosed by the SPI implant described by the 2003 Alpha Bio Tec Catalog.

Independent claim 9 also is fully anticipated by the SPI implant disclosed in the 2003 Catalog as shown below.

The '977 Patent	**Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)**
(9) A dental implant comprising:	"A tapered implant with large variable thread design double thread 2x2.1mm." (Ex. 1008 at 17; Ex. 1007 at ¶ 57.)
(9a) body; a coronal end of the body; and an apical end of the body;	 Coronal end Apical end (Ex. 1007 at ¶ 58.)
(9b) the apical end having a tapered core,	 Diameter of an apical end of the core is smaller than diameter of a coronal end of the core Apical region having a core with a tapered region (Ex. 1007 at ¶ 59.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
	"The tapered design allows the implant to be placed in the ideal position for improved esthetics and better load distribution." (Ex. 1008 at 17.)
(9c) the apical end includes at least one region having two tapered variable profile helical threads extending along the core,	 (Ex. 1007 at ¶ 60.)
(9d) each thread having an apical side, a coronal side, a lateral edge connecting the apical side and the coronal side, a base touching the core, a height defined between the lateral edge and the base,	 (Ex. 1007 at ¶ 61.)
(9e) a variable length of the lateral edge being progressively expanded substantially along the region of the apical end in the direction of the coronal end, so that a least length of the lateral edge of the thread is adjacent the apical end and a greatest length of the lateral edge of the thread is adjacent the coronal end,	 (Ex. 1007 at ¶ 62.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
(9f) and a variable height being progressively expanded substantially along the entire threaded region of the implant in the direction of the apical end, so that a least height of the thread is adjacent the coronal end and a greatest width of the thread is adjacent the apical end,	 (Ex. 1007 at ¶ 63.)
(9g) wherein the core is more tapered than the threads and	 (Ex. 1007 at ¶ 64.)

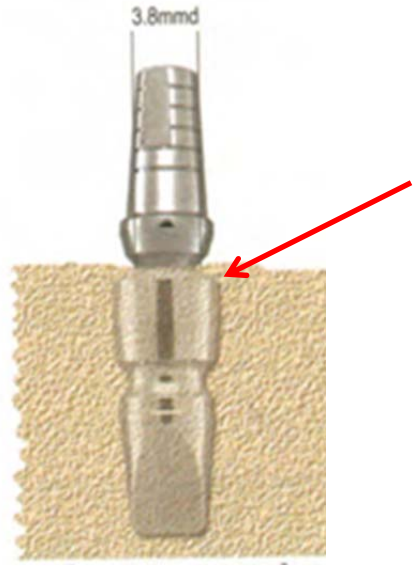
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
(9h) wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is 1.5-2.5 mm.	 "A tapered implant with large variable thread design double thread 2x2.1mm." (Ex-1008 at 17.) (Ex-1007 at ¶ 65.)

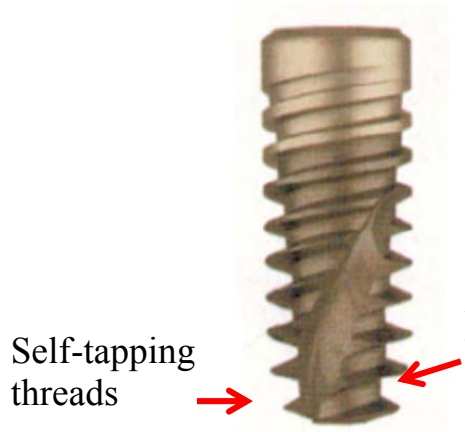
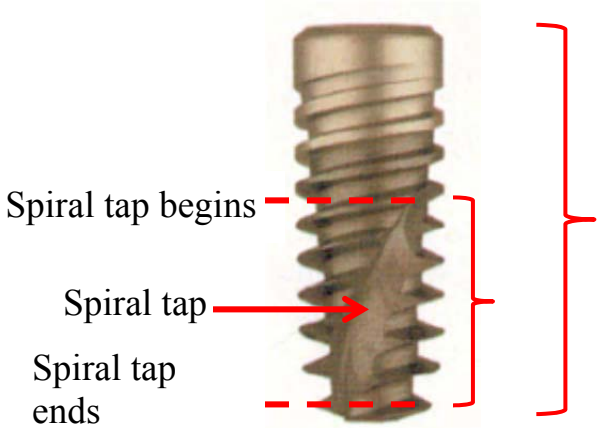
As shown above, all of the limitations of claims 1 and 9 are disclosed by the 2003 Catalog. (Ex. 1007 at ¶¶ 57-65.) Accordingly, both claims 1 and 9 of the '977 Patent are anticipated by the SPI implant disclosed in the 2003 Alpha Bio Tec Catalog and therefore are invalid under 35 U.S.C. §§ 102. *Zenith*, 522 F.3d at 1363.

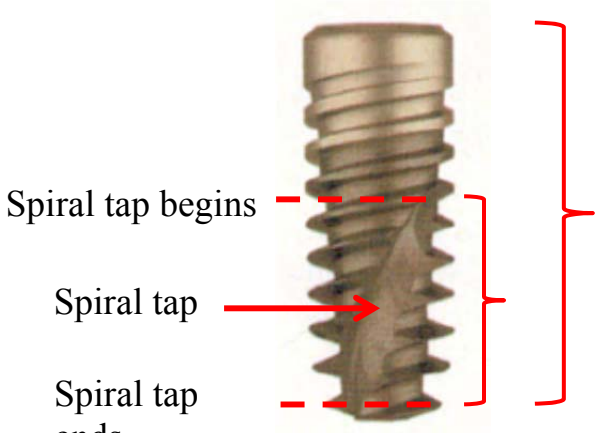
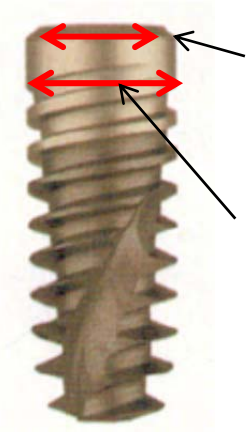
iii. Dependent Claims 2-5 and 16-19

Because allowance of the claims of the '977 Patent turned on the addition of element (f) of independent claims 1 and 9, and the dependent claims had been either previously rejected over the prior art (claims 2-5) or merely recite known features (claims 16-19), those claims also fail as invalid under 35 U.S.C. §§ 102 or 103 once claims 1 and 9 are shown to not patentably distinguish over the prior art. Nonetheless,

invalidity of dependent claims 2-5 and 16-19 as disclosed by the SPI implant of the 2003 Catalog is described with particularity as follows:

The '977 Patent	**Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)**
(2) The implant of claim 1, wherein the coronal region has a surface configured to be in contact with bone.	"Implant surface: 'Hybrid' design 2/3 apically S.L.A. (macro) 20-40µ + (micro) 2µ, 1/3 coronary [sic] Acid Etched 5-10µ. Increases clot retention and is conducive to bone healing." (Ex. 1008 at 17, 31; Ex. 1007 at ¶ 66.)  Coronal region surface configured to in contact bone
(3) The implant of claim 1, wherein the apical end of the coronal region defines an upper limit of the threads.	 Coronal region Upper limit of threads Apical region (Ex. 1007 at ¶ 67.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
(4) The implant of claim 1, wherein the threads adjacent the apical end of the body are self-tapping.	 "Clinical Benefits" include "self-drilling, super self tapping features" and "self condensing." (Ex. 1008 at 17; Ex. 1007 at ¶ 68.)
(5) The implant of claim 1, wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant.	 (Ex. 1007 at ¶ 69.)
(16) A dental implant according to claim 9, wherein the lateral edge is parallel to the long axis of the implant.	 (Ex. 1007 at ¶ 70.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the 2003 Catalog (Ex-1008)
(17) A dental implant according to claim 9, wherein the thread adjacent the apical end is self-tapping and adapted to 15 cut bone.	 "Clinical Benefits" include "self-drilling, super self tapping features" and "self condensing." (Ex. 1008 at 17; Ex. 1007 at ¶ 71.)
(18) A dental implant according to claim 9, wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant.	 (Ex. 1007 at ¶ 72.)
(19) A dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge.	 (Ex. 1008 at 16; Ex. 1007 at ¶ 73.)

Ground 2. Claims 9 and 16-18 of the '977 Patent are anticipated by the Update Journal, and Claims 1-5, 19 and 20 of the '977 are unpatentable as obvious over the Update Journal in view of the 2002 Anthogyr Catalog.

i. <u>The Update Journal is Prior Art Under 35 U.S.C. §102(b)</u>

As discussed in Section (i) of Ground 1 *supra*, the Alpha Bio Tec Ltd. SPI Implants were described not only in the 2003 Catalog, but also described in an advertisement placed in the Jan-Feb. 2003 edition of the Israeli Dental Update Journal ("Update Journal"), a publication circulated in the Israeli dental community. (Ex. 1009). As established at the evidentiary hearing in the ITC matter, the Update Journal was published no later than March 2003, and the copy admitted into evidence included a "Received" stamp of March 6, 2003. Publication of the Alpha Bio Tec Ltd. advertisement in the Update Journal was confirmed by Dr. Fromovich, co-inventor of the '977 patent. The advertisement included the following description of the SPI Implants (with English translation from Hebrew):

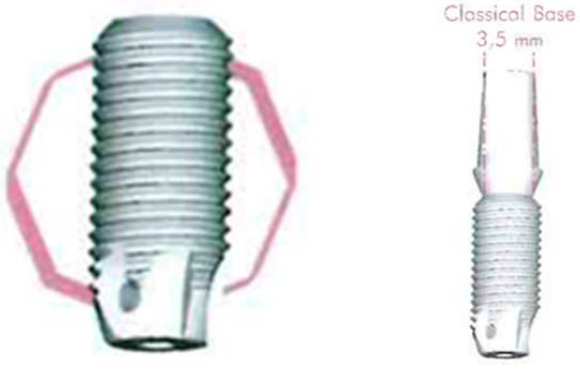
"SPI Spiral
Conical implant with dual thread, enlarged pinions along the length of the implant.
Thread height 2 x 2.1. Serves as a helical and compressor and anchor.
Suitable for immediate implantations after extraction and for immediate loading.
Suitable for bone types II, III and IV
A world exclusive and unique development by Alpha Bio Serves as an inspiration to other companies."

The text of the advertisement establishes that the SPI implant has a dual thread with a thread height of 2.1 mm, the same as the preferred thread of 2.1 mm stated at col. 12,

ln. 36-39 of the ’977 patent, and squarely within the claimed thread step range of 1.5-2.5 mm recited in independent claims 1 and 9 of the ’977 patent.

ii. The 2002 Anthogyr Catalog is Prior Art Under 35 U.S.C. §102(b)

The 2002 Anthogyr Catalog (“Anthogyr”), published by Anthogyr SAS, discloses a number of “Octagon” dental implants, including a 5 mm implant shown at page 16. (Ex. 1014 at 16.) As shown in the attached declaration from Martin Vogt, the Anthogyr catalog was received by Institut Straumann in January 2002, where it has been maintained in Institut Straumann’s document archives. (Ex. 1015). The 5 mm Octagon implant disclosed in Anthogyr includes a spiral thread, a flat apical end, and axially extending flutes that form a bone tap. (Ex. 1014 at 16.) The 5 mm Octagon implant also includes a frustoconical coronal region having an inverse taper, such that a coronal end of the coronal region has a narrower diameter than an apical end of the coronal region, as shown in the figure reproduced below. *Id.*

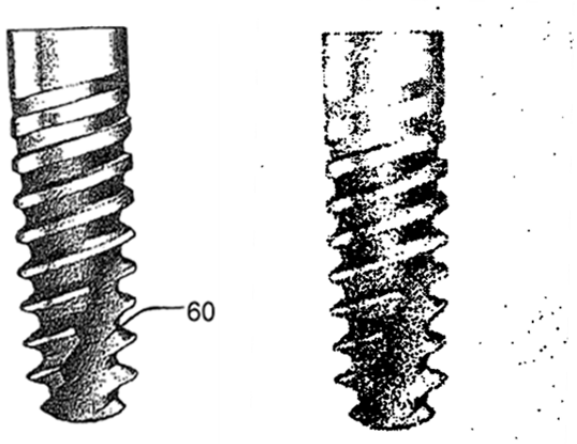


The 5 mm implant is implanted so that the top coronal edge is disposed at or below the surface of the bone. *Id.* When a “classical base” abutment is attached to the

implant, the abutment does not cover the coronal region, such that the coronal region contacts the bone after the abutment has been placed. *Id.*

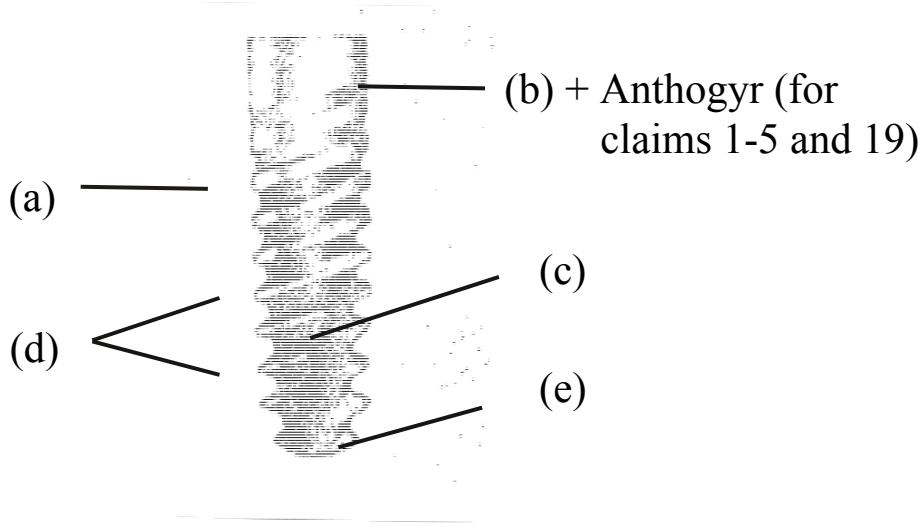
iii. Independent Claims 1 and 9

Independent Claims 1 and 9 are each directed to a dental implant, which is disclosed in the Update Journal. (Ex. 1009.) FIG. 7A of the '977 Patent is indistinguishable from the SPI implant illustrated in the Update Journal. Except for the presence of a frustoconical shape on the coronal region of the implant, as defined in Section IV.i above, the SPI implant disclosed in the Update Journal meets all of the other limitations of claim 1 and all of the limitations of claim 9 of the '977 patent. The depiction of the SPI Implant in the Update Journal is reproduced below (on the right), for comparison to FIG. 7A (left, below):



Anthogyr threaded dental implants having a frustoconical shape that extends over the entire coronal region of the implant. (Ex. 1014 at 16.) It would have been obvious to a person of ordinary skill in the art of dental implant design to modify the SPI

implant shown in the Update Journal to include a frustoconical coronal region, as shown for the Octagon 5 mm implant, disclosed in Anthogyr. (Ex. 1007 at ¶ 80.) As shown in the 2003 Catalog, this is exactly what Alpha Bio Tec Ltd. did for its 5 mm and 6 mm diameter implants, which have a taller frustoconical coronal region than the smaller 3.7 mm and 4.2 mm SPI implants. An example of the SPI implant having an exterior diameter of 5 mm and having a frustoconical coronal region (labeled "b" in the figure below), illustrated in the Update Journal, is reproduced below and annotated with the reference letters corresponding to the elements of claim 1 of the '977 patent:



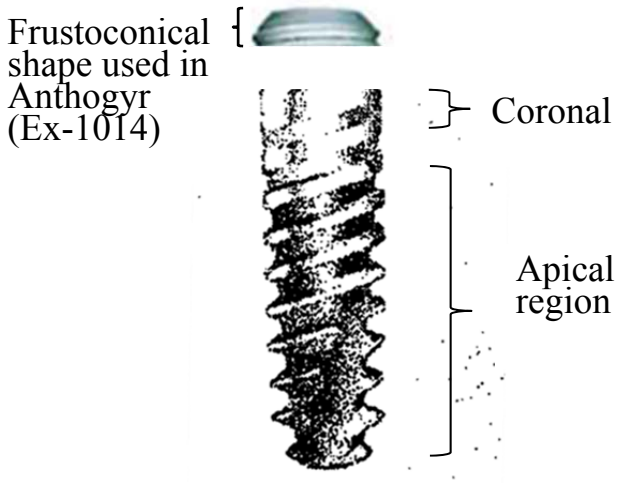
As indicated by the arrows and reference letters in the preceding figure, the SPI implant disclosed in the Update Journal, in combination with the coronal region of the 5 mm Octagon implant of Anthogyr includes each of elements (a) through (e) of claim 1 of the '977 patent. (Ex. 1007 at ¶ 81.)

The SPI implant disclosed in Update Journal also discloses element (f) of claim 1 of the '977 patent in a section of text describing key features of the SPI implants, namely,

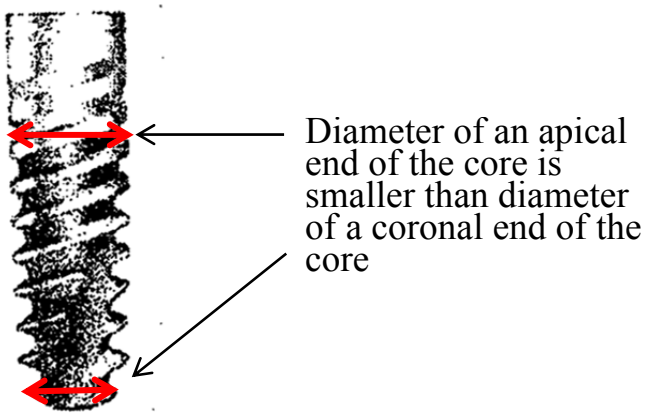
that the implants include a "double thread" design having a thread step of "2.1 mm" (Ex. 1009):

> *"SPI Spiral*
> *Conical implant with dual thread, enlarged pinions along the length of the implant.*
> *Thread height 2 x 2.1. Serves as a helical and compressor and anchor.*

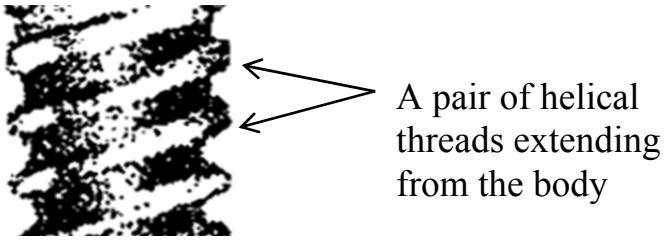
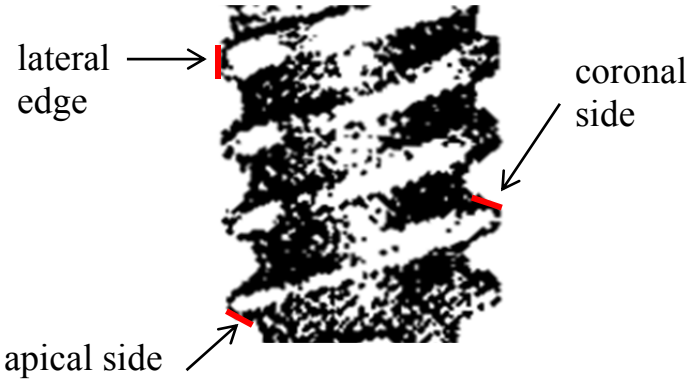
Each of elements (a) through (f) of claim 1 of the '977 Patent are disclosed and described by the SPI implant disclosed in Update Journal (Ex. 1009) in Combination with Anthogyr (Ex. 1014), as shown with particularity as follows.

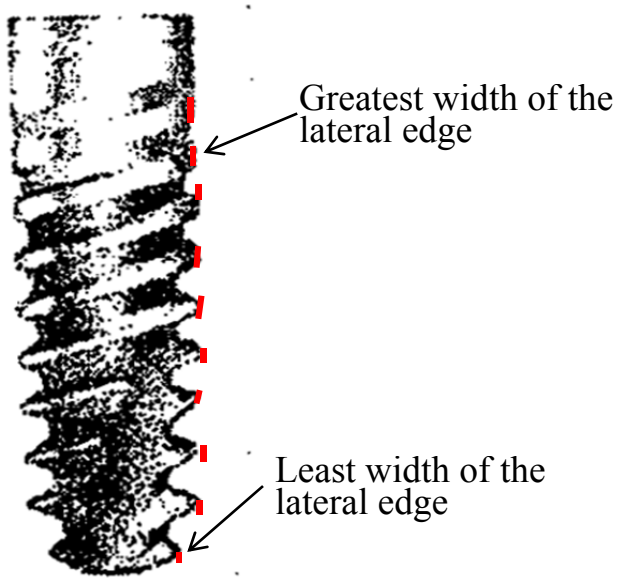
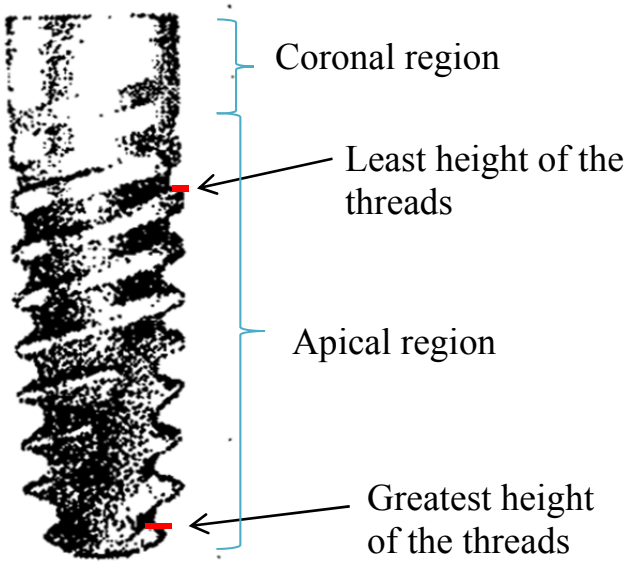
The '977 Patent	**Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr**
A dental implant comprising:	"Conical implant with dual thread …" (Ex. 1009; Ex-1010; Ex. 1007 at ¶ 86.)
(a) a body; (b) a coronal region of the body, the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region;	

As shown, the SPI implant disclosed in the Update Journal meets element (a), an implant body and has a coronal region, element (b), wherein the coronal region may include a frustoconical shape as disclosed in Anthogyr. (Ex. 1007 at ¶ 87.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr
(c) an apical region of the body, the apical region having a core with a tapered region wherein a diameter of an apical end of the core is smaller than a diameter of a coronal end of the core and the apical end of the core is substantially flat; and	

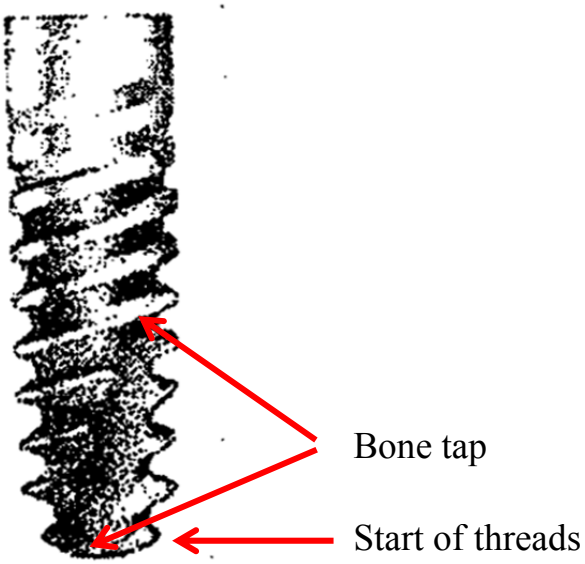
As demonstrated above, the SPI implant disclosed in the Update Journal includes element (c), an apical region of the body that is tapered such that the diameter at the apical end is smaller than the diameter at the coronal end. (Ex. 1007 at ¶ 88.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr
(d) a pair of helical threads extending from the body along at least a portion of the apical region,	
each of the threads comprising an apical side, a coronal side, and a lateral edge connecting the apical side and the coronal side, a base connecting the threads to the core, a thread height defined between the lateral edge and the base,	

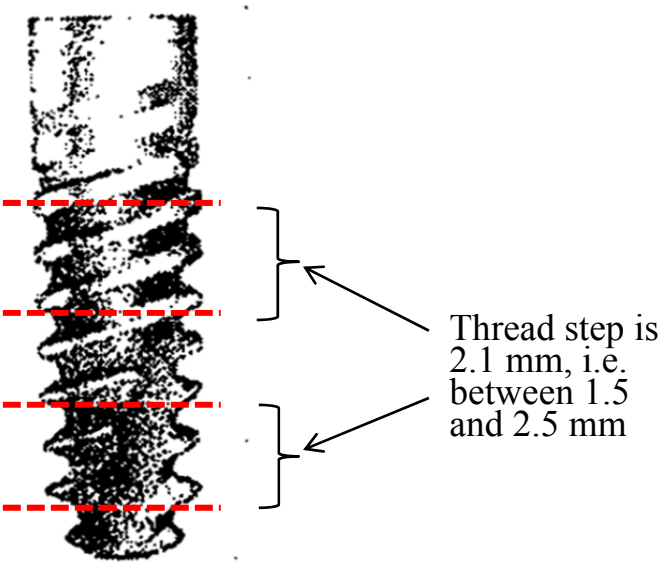
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr
the lateral edge having a variable width that is expanded along a segment in the direction of the coronal end of the apical region, so that a least width of the lateral edge of the threads is adjacent the apical end of the apical region and a greatest width of the lateral edge of the threads is adjacent the coronal end of the apical region,	
and the threads having a variable height that is expanded substantially along the segment of the implant in the direction of the apical end of the apical region, so that a least height of the threads is adjacent the coronal end of the apical region and a greatest height at apical end of the apical region; and	

As demonstrated above, the SPI implant disclosed in the Update Journal includes element (d), a pair of helical threads. (Ex. 1007 at ¶ 89.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr
(e) a bone tap, wherein the	

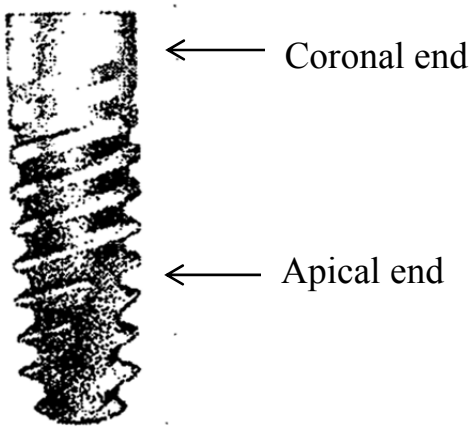
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr
helical threads starts at said bone tap and said substantially flat apical end of the core;	

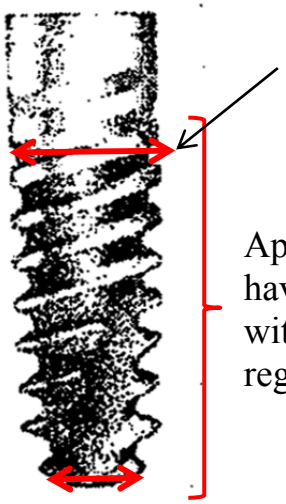
The SPI implant disclosed in the Update Journal includes element (e), a bone tap. (Ex. 1007 at ¶ 90.)

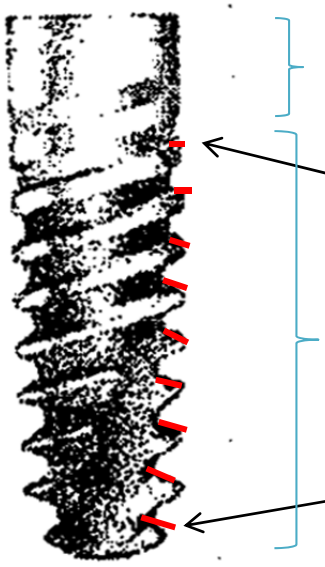
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009) + Anthogyr
(f) wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is between 1.5-2.5 mm.	 "Thread height 2 x 2.1." (Ex-1009, Ex-1010.)

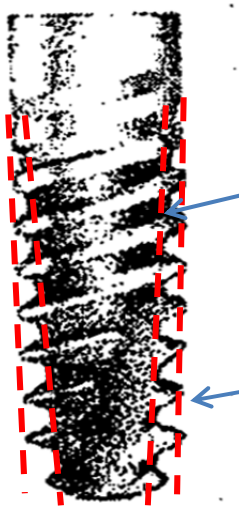
As demonstrated above, the SPI implant disclosed in the Update Journal includes element (f), a thread step within the range of 1.5-2.5 mm. (Ex. 1007 at ¶ 91.) In view of the foregoing, all limitations of independent claim 1 of the '977 Patent are disclosed by the SPI implant described by the Update Journal having a coronal region modified as disclosed in Anthogyr.

Independent claim 9 is not just obvious, but rather fully anticipated by, the SPI implant disclosed in the Update Journal as shown below.

The '977 Patent	**Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009)**
(9) A dental implant comprising:	"Conical implant with dual thread…" (Ex. 1009; Ex. 1010; Ex. 1007 at ¶ 92.)
(9a) body; a coronal end of the body; and an apical end of the body;	 (Ex. 1007 at ¶ 93.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009)
(9b) the apical end having a tapered core,	 Diameter of an apical end of the core is smaller than diameter of a coronal end of the core. Apical region having a core with a tapered region. (Ex. 1007 at ¶ 94.)
(9c) the apical end includes at least one region having two tapered variable profile helical threads extending along the core,	 Two tapered variable profile helical threads extending along the core. Apical end. (Ex. 1007 at ¶ 95.)
(9d) each thread having an apical side, a coronal side, a lateral edge connecting the apical side and the coronal side, a base touching the core, a height defined between the lateral edge and the base,	 lateral edge. coronal side. apical side. (Ex. 1007 at ¶ 96.)

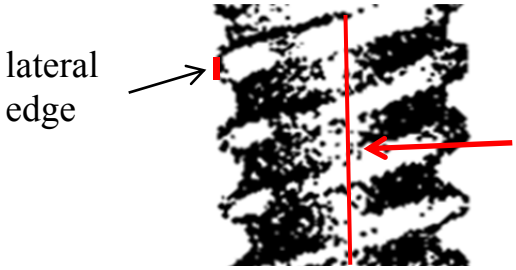
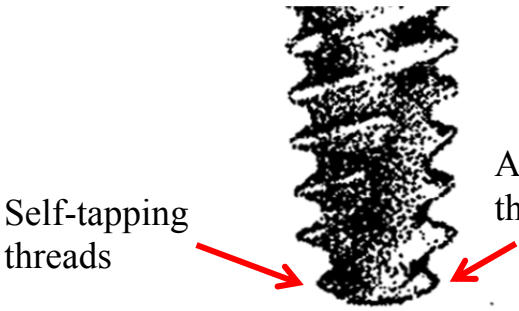
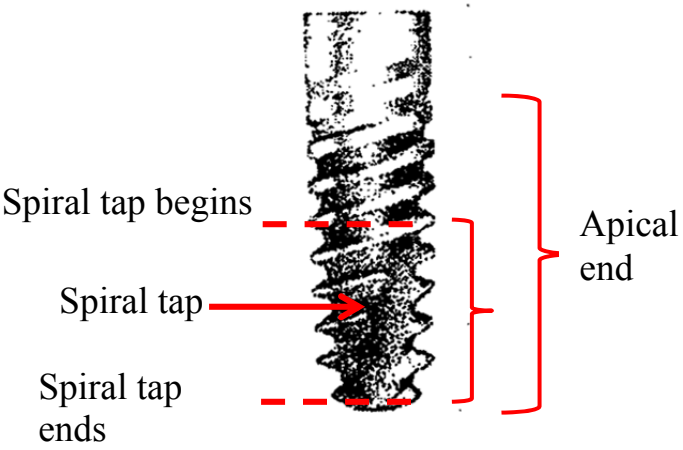
The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009)
(9e) a variable length of the lateral edge being progressively expanded substantially along the region of the apical end in the direction of the coronal end, so that a least length of the lateral edge of the thread is adjacent the apical end and a greatest length of the lateral edge of the thread is adjacent the coronal end,	 (Ex. 1007 at ¶ 97.)
(9f) and a variable height being progressively expanded substantially along the entire threaded region of the implant in the direction of the apical end, so that a least height of the thread is adjacent the coronal end and a greatest width of the thread is adjacent the apical end,	 (Ex. 1007 at ¶ 98.)

The '977 Patent	Alpha Bio Tec SPI Implant disclosed in the Update Journal (Ex-1009)
(9g) wherein the core is more tapered than the threads and	 Core taper Thread taper (Ex. 1007 at ¶ 99.)
(9h) wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is 1.5-2.5 mm.	 Thread step is 2.1 mm, i.e. between 1.5 and 2.5 mm "Thread step 2 x 2.1..." (Ex-1009; Ex-1010; Ex. 1007 at ¶ 100.)

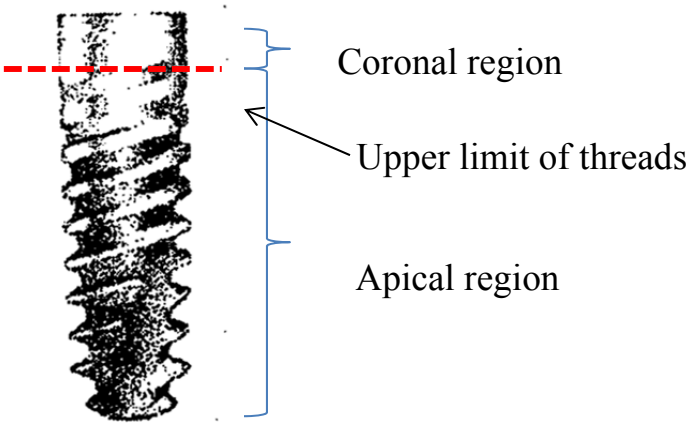
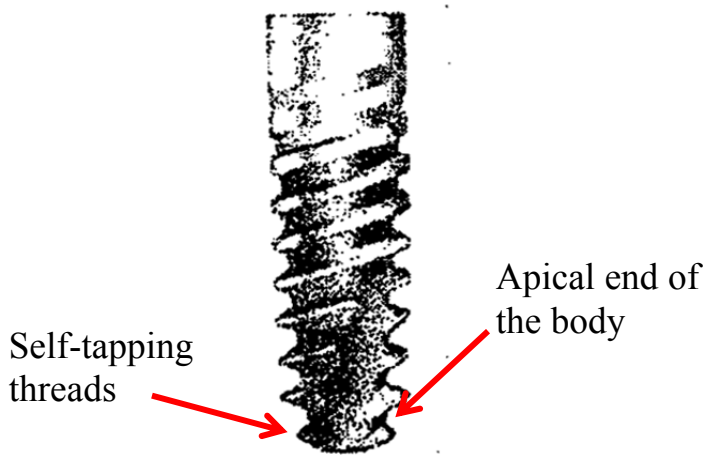
As shown above, all of the limitations of claim 9 are disclosed by the Update Journal. (Ex. 1007 at ¶¶ 92-100.) Accordingly, independent claim 9 of the '977 Patent is anticipated by the SPI implant disclosed in the Update Journal and therefore is invalid under 35 U.S.C. § 102. *Zenith*, 522 F.3d at 1363.

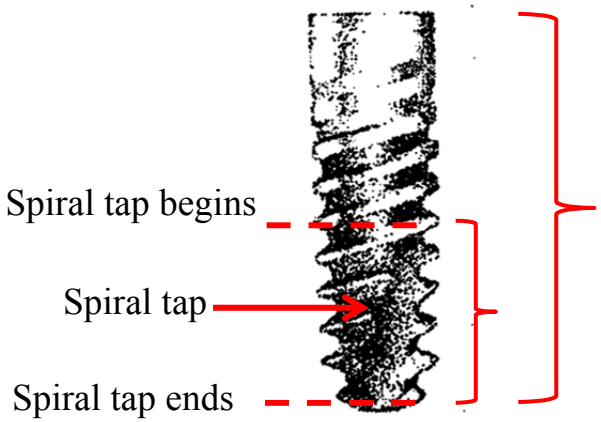
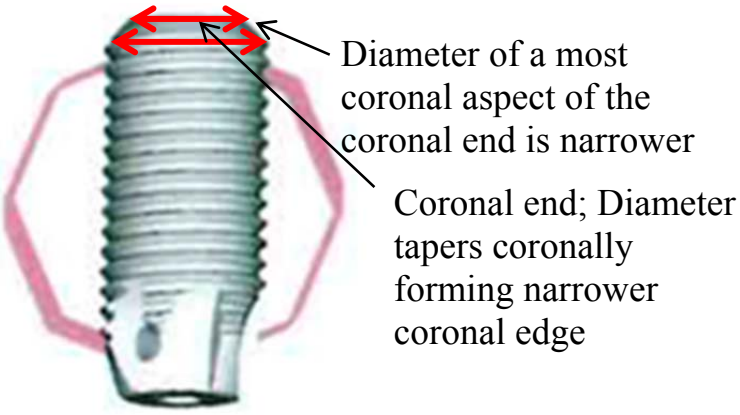
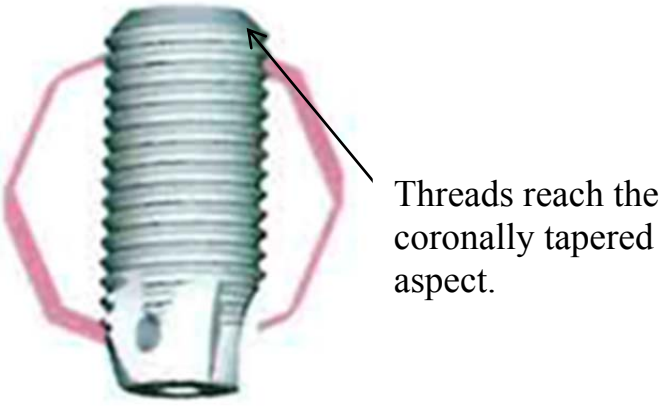
iv. Dependent Claims 2-5 and 16-20

Dependent claims 16-18 are ***anticipated*** by the SPI implant disclosed in the Update Journal under 35 U.S.C. §102(b).

The '977 Patent	Alpha Bio Tec SPI Implant Update Journal (Ex-1009)
(16) A dental implant according to claim 9, wherein the lateral edge is parallel to the long axis of the implant.	 (Ex. 1007 at ¶ 101.)
(17) A dental implant according to claim **9,** wherein the thread adjacent the apical end is self-tapping and adapted to 15 cut bone.	 (Ex. 1007 at ¶ 102.)
(18) A dental implant according to claim 9, wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant.	 (Ex. 1007 at ¶ 103.)

Claims 2-5, 19, and 20 are invalid as rendered obvious under §103 by the SPI implant disclosed in the Update Journal in view of Anthogyr, as shown below.

The '977 Patent	**Alpha Bio Tec SPI Implant Update Journal (Ex-1009) + Anthogyr (Ex-1014)**
(2) The implant of claim 1, wherein the coronal region has a surface configured to be in contact with bone.	(Ex-1014 at 16.)  (Ex. 1007 at ¶ 104.)
(3) The implant of claim 1, wherein the apical end of the coronal region defines an upper limit of the threads.	 (Ex. 1007 at ¶ 105.)
(4) The implant of claim 1, wherein the threads adjacent the apical end of the body are self-tapping.	 (Ex. 1007 at ¶ 106.)

The '977 Patent	Alpha Bio Tec SPI Implant Update Journal (Ex-1009) + Anthogyr (Ex-1014)
(5) The implant of claim 1, wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant.	 (Ex. 1007 at ¶ 107.)
(19) A dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge.	 (Ex. 1007 at ¶ 108.)
(20) A dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally, and wherein the threads reach the coronally tapered aspect.	 (Ex. 1007 at ¶ 109.)

As demonstrated above, Claims 9 and 16-18 are anticipated by the SPI implant disclosed in the Update Journal alone, while claims 2-5, 19, and 20 are invalid as rendered obvious under §103 by the Update Journal in view of Anthogyr. (Ex. 1007 at ¶ 92-109.)

v. Reasons to Combine The Update Journal and Anthogyr

At least one rationale to support a conclusion that the aforementioned claims would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). The '977 Patent relates to the field of skeletal implants, and in particular, to the design of implants for supporting dental prostheses. (Ex. 1007 at ¶¶ 14, 111.) A person of ordinary skill in the art of the '977 Patent, prior to May 23, 2004, would have had at least a bachelor-level degree in mechanical or bio-medical engineering and three years of experience in design and development of dental implants, or a dental provider trained in the practice of implanting dental implants. (*Id.*)

Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). As suggested by the 5.0 mm Octagon implant shown at page 16 of Anthogyr, a person of ordinary skill

in the art would have been motivated to combine a frustoconical coronal region on implant diameters of 5 mm and larger to provide a transition between the coronal end of the implant and the typical abutment base and to obtain the other expected benefits of that combination. (Ex. 1014; Ex. 1007 at ¶¶ 112-117.)

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). At the time of the effective filing date of the '977 Patent, there was a reasonable expectation of success for combining the frustoconical coronal region of the 5 mm Octagon implant disclosed in Anthogyr with the SPI implant disclosed in the Update Journal. (Ex. 1007 at ¶ 118.) The resulting combination would have worked precisely as expected, as suggested by the illustration of the abutment joined to the 5 mm Octagon implant in Anthogyr. *Id.* When considering obviousness of a combination of known elements, the operative question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *See KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). Indeed, "when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *Id*. Modifying the SPI implant of the Update Journal to include the

frustoconical coronal region of Anthogyr would have been just such a mere substitution or design choice. (Ex. 1007 at ¶ 118.)

Ground 3. Claims 1-7 and 13-15, 19, and 20 are unpatentable as obvious over the Update Journal in view of the ITI Manual.

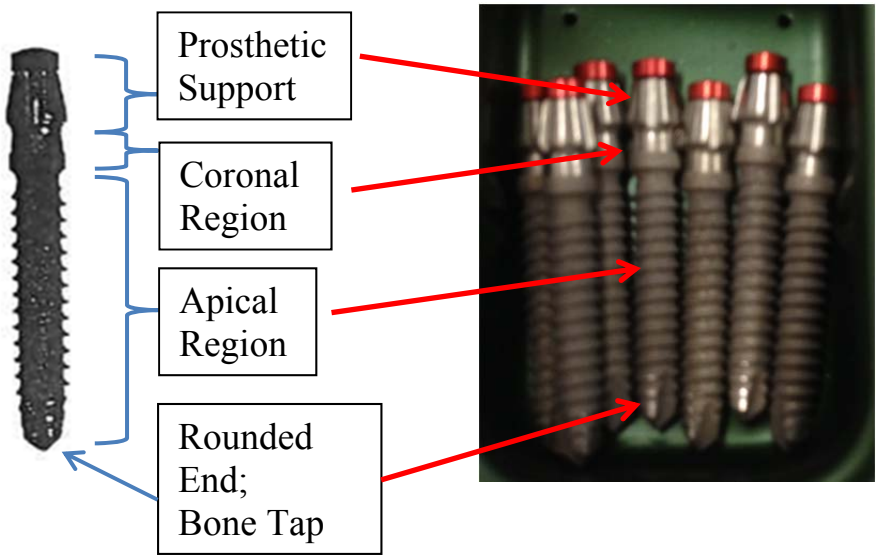
i. The Update Journal is Prior Art Under 35 U.S.C. §102(b)

There can be no genuine dispute that the Alpha Bio Tec Ltd advertisement describing the SPI implant, contained in the Update Journal constitutes prior art to the '977 patent under 35 U.S.C. §102(b) as discussed in Section (i) of Ground 2 *supra*. As discussed above, the SPI implant described in the Update Journal anticipates independent claim 9, and dependent claims 16-18 that depend from claim 9. *See* pp. 44-50, *supra*. As further shown above, except for the claimed frustoconical coronal region of element (b) of claim 1, the SPI implant of the Update Journal meets all of the limitations of independent claim 1 and dependent claims 3-5.

ii. The ITI-Schraubenimplantat (TPS) Manual is Prior Art Under 35 U.S.C. §102(b)

The ITI-Schraubenimplantat manual ("ITI manual"), published circa 1987, discloses dental implant kits used support overdenture bars. (Ex. 1016.) A certified English translation of the ITI manual is provided as Ex. 1017. Photos of a TPS 3.5 mm kit, depicted on page 25 of Ex. 1016 are provided in Ex. 1018. Exhibit 1019 is a Declaration of Martin Vogt attesting to the authenticity of Ex. 1016 and the kit shown in Ex. 1018. The ITI manual describes plasma-coated titanium threaded dental

implants available in lengths from 11 to 20 mm having diameters of either 3.5 mm or 4.0 mm. (Ex. 1017 at 2-3, 6, 24-25.) The kit that include 4.0 mm diameter dental implants includes 3.2 mm spiral drills, while the kit that includes the 3.5 mm diameter dental implants includes 2.7 mm spiral drill. (*Id.* at 24-25.) An annotated picture of the 3.5 mm diameter TPS implant from the ITI manual is reproduced below (Ex. 1016 at 6), and for enhanced clarity, a photo of the actual product. (Ex. 1018 at 2.)



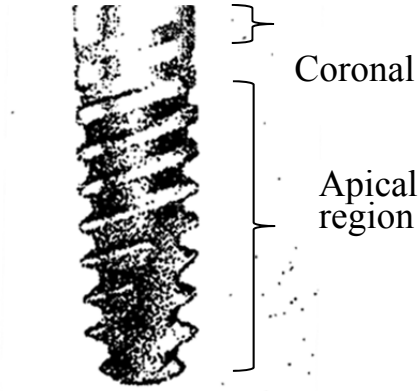
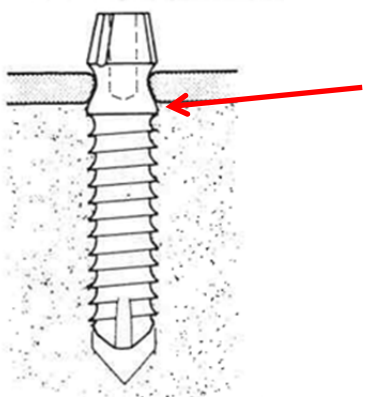
As shown above, the TPS implant disclosed in the ITI manual includes a threaded apical region, a frustoconical coronal region (partially roughened by plasma treatment) and a pillar structure designed to protrude above the patient's gum to engage to support a prosthetic. (Ex. 1017 at 6, Ex. 1018 at 2). The implant includes a rounded apical end and a self-tapping thread. (*Id*. at 6, 14.) As disclosed in the ITI manual, the TPS implants are designed for immediate loading (Ex. 1017 at 4) and are inserted into undersized osteotomies (the 4.0 mm implant is inserted into a hole formed in the jaw

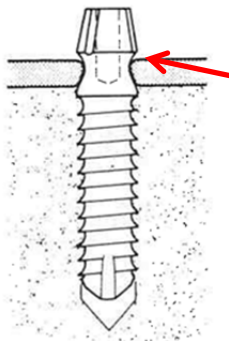
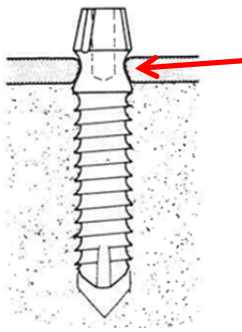
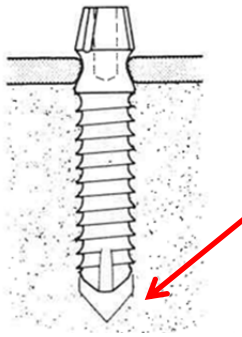
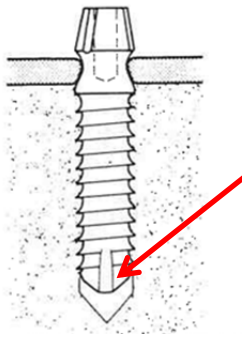
using a 3.2 mm diameter spiral drill, while the 3.5 mm implant is inserted into a hole formed using a 2.7 mm diameter spiral drill) (*Id.* at 10, 24, 25). The ITI manual teaches that the implant should be inserted into the osteotomy with a ratchet and guide wrench so that the transition between the thread and coronal region ("shoulder") is disposed "at least 2 mm below the bone surface." (*Id*. at 13-14.) This portion includes the plasma-treated portion of the frustoconical coronal region. (Ex. 1017 at 6, 14; Ex. 1018) Notably, because the 4.0 mm diameter TPS implant is inserted into a hole that is (4.0 mm -3.2 mm) 0.8 mm smaller than the diameter of the implant itself, even if "bone relapse" as theorized by Nobel exists (and there is no evidence it does), than the TPS implant disclosed in the ITI Manual inherently would "relapse" as claimed by Nobel. (Ex. 1016 at 14.)

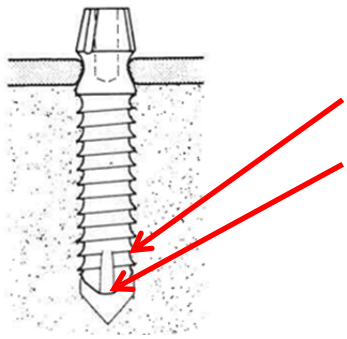
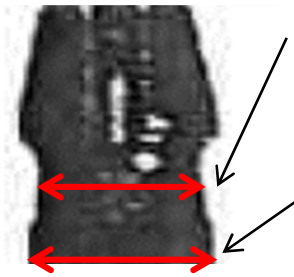
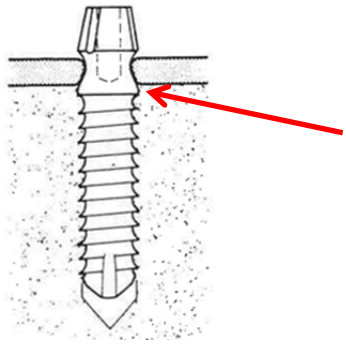
iii. Claims 1-7, 13-15, 19, and 20 of the '977 Patent are unpatentable as obvious over the Update Journal in view of the ITI Manual

As noted above, the SPI implant described in the Update Journal anticipates claim 9, 16-18 and meets all of the limitations of claims 1 and 3-5, except for the claimed frustoconical coronal region of element (b) of claim 1. The TPS implant disclosed in the ITI manual discloses a threaded dental implant having a frustoconical coronal region configured to contact bone, self-tapping threads and a rounded apical end. (Ex. 1007 at ¶ 121.) One of ordinary skill in the art of dental implant design would have found substitution of the such features from the ITI manual into the SPI implant of the

Update Journal a matter of mere design choice, rendering the following limitations and claims obvious (Ex. 1007 at ¶ 123):

The '977 Patent	**SPI Implant disclosed in the Update Journal (Ex-1009) + ITI Manual (Ex-1016)**
Claim 1 (b) a coronal region of the body, the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region; (All other limitations of claim 1 and claims 3-5 met by the SPI implant of Ex-1009, as shown in Section (iii) of Ground 2 *supra*, pp. 40-43; Ex. 1007 at ¶¶ 124, 126-129, 131-133.)	Frustoconical coronal region of TPS implant (Ex. 1016)   (Ex. 1007 at ¶ 125; *Cf.*, FIGS. 8 and 9 of Ex. 1001.)
(2) The implant of claim 1, wherein the coronal region has a surface configured to be in contact with bone.	

The '977 Patent	SPI Implant disclosed in the Update Journal (Ex-1009) + ITI Manual (Ex-1016)
(6) The implant of claim 1, wherein the implant includes a protruding element configured to protrude through the gums to allow connection to a dental prosthesis.	 Pillar that protrudes through gum to allow connection to dental prosthesis (Ex. 1016 at 14, 17-20; Ex. 1007 at ¶ 134.)
(7) The implant of claim 6, wherein the protruding element and the implant are one piece.	 Pillar and implant at one piece (Ex. 1016 at 14; Ex. 1007 at ¶ 135.)
(13) A dental implant according to claim 9, wherein the apical end includes a rounded region.	 Apical end is rounded (Ex. 1016 at 14; Ex. 1007 at ¶ 136.)
(14) A dental implant according to claim 13, wherein the thread is self-tapping adjacent the apical end.	 Apical end includes bone tap and self-tapping thread (Ex. 1016 at 14; Ex. 1007 at ¶ 137.)

The '977 Patent	SPI Implant disclosed in the Update Journal (Ex-1009) + ITI Manual (Ex-1016)
(15) A dental implant according to claim 14, wherein the self-tapping thread is spaced from the rounded region.	 Apical end self-tapping thread and spaced apart rounded region (Ex. 1016 at 14; Ex. 1007 at ¶ 138.)
(19) A dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge.	 Diameter of a most coronal aspect of the coronal end is narrower Coronal end; Diameter tapers coronally forming narrower coronal edge (Ex. 1007 at ¶ 139.)
(20) A dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally, and wherein the threads reach the coronally tapered aspect.	 Threads reach the coronally tapered aspect. (Ex. 1016 at 14, 17-20; Ex. 1007 at ¶ 140.)

As shown above, the TPS implant disclosed in the ITI manual, in combination with the SPI Implant of the Update Journal, renders obvious claims 1-7, 13-15, 19, and 20 of the '977 Patent. (Ex. 1007 at ¶¶ 124-140.)

iv. Reasons to Combine the Update Journal and the ITI Manual

As discussed in Section (v) of Ground 2 *supra* for the prior combination of the disclosures of the Update Journal and Anthogyr, one rationale that the aforementioned combination of the Update Journal and the ITI Manual would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). Indeed, a person of ordinary skill in the art would have been motivated to combine the features of TPS implant described in the ITI Manual with the SPI implant of the Update to obtain the benefits expected from such a combination of known elements. (Ex. 1007 at ¶ 141.)

As discussed above, a person of ordinary skill in the art of the '977 Patent, prior to May 23, 2004, would have had at least a bachelor-level degree in mechanical or bio-medical engineering and three years of experience in design and development of dental implants, or a dental provider trained in the practice of implanting dental implants. (Ex. 1007 at ¶¶ 14, 110.)

Here, there was more than a reasonable expectation that combining features of the implant disclosed in the ITI Manual with the SPI implant of the Update Journal would be successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). At the time of the effective filing date of the '977 Patent, use of frustoconical

coronal regions on threaded implants inserted into undersized osteotomies, along with use of rounded apical ends and self-tapping threads, have been known in the art for more than a decade. (Ex. 1007 at ¶ 148; Ex. 1016 at 6, 14.)

Indeed, one of ordinary skill in the art of dental implant design would have been motivated to modify the SPI implant of the Update Journal to incorporate these features disclosed in the ITI Manual as a matter of routine design choice, to obtain precisely the features identified in the ITI Manual associated with such features. (Ex. 1007 at ¶ 149.) In particular, as described in the ITI Manual, it is beneficial to insert the plasma-treated portion of the frustoconical coronal region at least 2 mm below the crest of the bone "so as to prevent the screw thread from unscrewing," whether by "bone relapse" theorized by Nobel to occur when using an undersized osteotomy, or simply as a result of bone ingrowth. (Ex. 1007 at ¶¶ 143-149.)

CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that Trial be instituted and that Claims 1-7, 9 and 13-20 of the '977 Patent be canceled.

Respectfully submitted,

Dated: August 20, 2015 By: */Paul S. Hunter/*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a CD containing copies of the foregoing Petition for *Inter Partes* Review together with all exhibits and other papers filed therewith was served on August 20, 2015, via Federal Express, directed to the attorneys of record for the patent at the following address:

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