

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Institut Straumann AG and
Dental Wings Inc.,
Petitioners

v.

Sirona Dental Systems GmbH
Patent Owner

Case IPR2015-01190
U.S. Patent No. 6,319,006

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,319,006
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.***

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EXHIBITS CITED

Exhibit	Description
1001	U.S. Patent No. 6,319,006 to Scherer et al.
1002	Declaration of Dr. Lewis Benjamin
1003	Fortin et al., <i>Computer-Assisted Dental Implant Surgery Using Computed Tomography</i> , 1 J. IMAGE GUIDED SURGERY 53 (1995) (Fortin '95)
1004	French Patent FR 2 705 027 A1 to Fortin (Fortin Patent)
1005	Translation of FR 2 705 027 to Fortin
1006	Declaration of Tessa Progner
1007	U.S. Patent No. 5,562,448 to Mushabac (Mushabac)
1008	U.S. Patent No. 5,842,858 to Truppe (Truppe)
1009	German Patent DE 195 10 294 A1 to Bannuscher (Bannuscher)
1010	Translation of DE 195 10 294 to Bannuscher
1011	Declaration of Tessa Progner
1012	Preliminary Opinion concerning German Patent Right of European Patent 1 101 451 dated April 8, 2014
1013	Translation of April 8, 2014 Preliminary Opinion
1014	Declaration of Tessa Progner
1015	Adell et al., <i>A 15-Year Study of Osseointegrated Implants in the Treatment of the Edentulous Jaw</i> , 10 INT. J. ORAL SURG. 387 (1981).
1016	Israelson et al., <i>Barium-Coated Surgical Stents and Computer-Assisted Tomography in the Preoperative Assessment of Dental Implant Patients</i> , 12 INT'L J. PERIODONTICS RESTORATIVE DENT. 61 (1992).

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1017	Kraut, <i>Utilization of 3D/Dental Software for Precise Implant Site Selection Clinical Reports</i> , 1 IMPLANT DENT.134 (1992).
1018	Klein, <i>A Computerized Tomography (CT) Scan Appliance for Optimal Presurgical and Preprosthetic Planning of the Implant Patient</i> , 5 PRACT. PERIODONTICS AESTHETIC DENT. 33, 38 (1993).
1019	Fellingham, et al., <i>Interactive Graphics and 3-D Modelling for Surgical Planning and Prosthesis and Implant Design</i> , NAT. COMP. GRAPHICS ASS'N CONF. EXPO., 132-142, 133-134 (May 11-15 1986).
1020	U.S. Patent No. 5,967,777 to Klein
1021	Int'l Pat. App. Pub. No. WO 95/28688 (1995) to Swaelens
1022	Verstreken, et al., <i>An Image Guided Planning System for Oral Implant Surgery</i> , CAR, PROC. INT'L SYMP. COMP. COMM. SYS. IMAGE GUIDED DIAG. THERAPY, pp. 888-93 (1996).
1023	Prosecution history of the U.S. Patent No. 6,319,006
1024	European Patent No. EP1101451 to Scherer et al.

I. INTRODUCTION

Pursuant to 35 U.S.C. § 311-319 and 37 C.F.R. §§ 42.100 *et seq.*, Institut Straumann AG and Dental Wings Inc. (“Petitioners”) request *inter partes* review of all claims of U.S. Patent No. 6,319,006 (“the ‘006 patent,” Ex. 1001) assigned on its face to Sirona Dental Systems GmbH (“Patent Owner”). The ‘006 patent describes and claims a method for producing a drill assistance device for a tooth implant in a person’s jaw. Claim 1, the only independent claim, recites a method of determining an optimal bore hole for the implant and a pilot hole in a drill template through the use of x-ray data, three-dimensional optical measurement data, and a correlation of this data.

The Patent and Trademark Office (“PTO”) granted the ‘006 patent on a first-action allowance. However, the applicants did not disclose, and the PTO did not consider, prior art that described the use of x-ray data, three-dimensional optical measurement data, and correlations between such data, for the identical purpose of producing a drill assistance device. In sum, previously unconsidered prior art anticipates or renders obvious the alleged invention.

This petition, including the supporting evidence, establishes that claims 1-10 of the ‘006 patent are unpatentable under either 35 U.S.C. § 102 or 35 U.S.C. §

103. Petitioners respectfully request that claims 1-10 of the '006 patent be held unpatentable and canceled.

II. COMPLIANCE WITH REQUIREMENTS FOR AN *INTER PARTES* REVIEW PETITION

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioners certify that the '006 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting *inter partes* review of the claims of the '006 patent.

B. Payment of Fee for *Inter Partes* Review

This petition for *Inter Partes* Review of claims 1-10 of U.S. Patent No. 6,319,006 is accompanied by the fee set forth in 37 C.F.R. §§ 42.15(a) and 42.103. Please charge or credit Deposit Account No. 12-1216 with any shortage or overpayment of fees associated with this petition.

C. Mandatory Notices

1. Real Party-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioners certify that the real parties-in-interest are Institut Straumann AG of Basel, Switzerland and its affiliated companies, and Dental Wings Inc., of Montreal, Canada. Implant Solutions, LLC, and 3D Diagnostix, Inc. are also real parties-in-interest.

2. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioners state that the '006 patent is currently involved in patent infringement litigation, *Sirona Dental Systems GmbH, et al. v. Dental Wings Inc., et. al.*, C.A. No. 1:14-cv-460 (D. Del.), filed April 11, 2014. Waivers of service were filed on August 1, 2014. The Complaint alleges infringement of the '006 patent by Dental Wings Inc., Implant Solutions, LLC, and 3D Diagnostix, Inc. Petitioner, Institut Straumann AG is a shareholder of Dental Wings Inc.

The Patent Owner is a Plaintiff in four separate lawsuits asserting infringement of the '006 patent, *Sirona Dental Systems GmbH, et al. v. Dentsply IH Inc.*, C.A. No. 1:14-cv-538 (D. Del.), filed April 24, 2014, *Sirona Dental Systems GmbH, et al. v. OnDemand3D Technology, Inc.*, C.A. No. 1:14-cv-539 (D. Del.), filed April 24, 2014, *Sirona Dental Systems GmbH, et al. v. Anatomage, Inc.*, C.A. No. 1:14-cv-540 (D. Del.), also filed April 24, 2014, and *Sirona Dental Systems GmbH et al. v. 3Shape A/S et al*, C.A. No. 1:15-cv-00278 (D. Del.), filed March 30, 2015. These actions are now pending in the United States District Court for the District of Delaware.

On April 15, 2015, Anatomage, Inc. filed a Petition requesting *inter partes* review of claims 1-10 of the '006 patent, *Anatomage, Inc. v. Sirona Dental Systems GmbH*, IPR2015-01057.

3. Lead and Back-Up Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioners designate the following counsel:

Lead Counsel: Wesley O. Mueller, Reg. No. 33,976

Backup Counsel: Thomas P. Canty, Reg. No. 44,586

Pursuant to 37 C.F.R. § 42.10(b), Petitioners have filed a power of attorney with the above designation of counsel.

4. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), Petitioners provide the following service information for designated counsel. Petitioners further consent to electronic service by email at the email addresses of the counsel provided below.

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III. STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b), Petitioners request *Inter Partes Review* of claims 1-10 of the '006 patent. The precise relief requested is that each claim of the '006 patent be found unpatentable for the following reasons.

A. Identification of Prior Art and Challenged Claims

Ground 1: Claims 1-4 and 9-10 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Fortin '95 (Ex. 1003).

Ground 2: Claims 1-4 and 9-10 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Mushabac (Ex. 1007).

Ground 3: Claims 1-10 are unpatentable under 35 U.S.C. § 103 as being obvious over Fortin '95 (Ex. 1003) in view of Truppe (Ex. 1008).

Ground 4: Claims 1-10 are unpatentable under 35 U.S.C. § 103 as being obvious over Bannuscher (Ex. 1009, trans. Ex. 1010) in view of Truppe (Ex. 1008).

B. Supporting Evidence Relied Upon

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b)(4) and (5), a full statement of the reason why each of claims 1-10 of the '006 patent should be held unpatentable under 35 U.S.C. §§ 102(b) and 103(a) is provided in Section VIII. Petitioners rely on the exhibits identified above and on the expert Declaration of Dr. Lewis Benjamin (Ex. 1002). Dr. Benjamin has been active in the field of

dental implantology for over twenty-five years as a practitioner, researcher, and author. His expertise includes the use of computer-aided imaging and modeling for surgical implant procedures, and the design and fabrication of surgical templates for carrying out dental implant surgery. (Ex. 1002 at ¶¶ 4-5). Dr. Benjamin's *curriculum vitae* is attached to his Declaration as Appendix A.

IV. SUMMARY OF PETITION

The '006 patent claims a method for producing a drill assistance device for a tooth implant in a person's jaw. The patent specification asserts that an x-ray image used to determine the implant position in the jaw cannot be "exactly transferred" to a surgical site during the implant procedure. The patent claims purportedly differ from the prior art through the steps of "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth" and correlating a measured data record thereof with a measured data record of an x-ray picture.

Registration of x-ray data to optical image data, however, was well known in the prior art. For example, Fortin '95 (Ex. 1003), Mushabac (Ex. 1007), Truppe (Ex. 1008) and Bannuscher (Ex. 1009, trans. Ex. 1010) disclose correlating x-ray data with acquired three-dimensional measurements with respect to the patient's jaw and teeth to position a pilot hole in the drill template. The PTO did not consider any of these prior art references during the original examination of the

'006 patent. The correlation described in these references enabled a dental surgeon to consider the bone and nerve structure in a patient's jaw in determining the appropriate location and orientation of the drill template. Therefore, at least claims 1-4 and 9-10 are anticipated by Fortin '95 or Mushabac.

Fortin '95 and Bannuscher disclose obtaining data from an impression or a model of a jaw and teeth. Truppe (Ex. 1008) discloses an implant preparation method that superimposes an optical image of the jaw and teeth with an x-ray data set. According to Truppe, the optical image can be captured either from the actual jaw of the patient or from a model of the jaw to provide a "positionally correctly superimposed data set" for operation planning and simulation. A substitution of the optical scan disclosed by Truppe for the three-dimensional measurements of either Fortin '95 or Bannuscher also would have been obvious because the combination yields a "predictable result." *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012) (quoting *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007)). Therefore, all claims of the '006 patent are obvious based on either Fortin '95 in combination with Truppe or Bannuscher in combination with Truppe.

V. OVERVIEW OF THE '006 PATENT

The '006 patent issued on November 20, 2001, from U.S. Application No. 09/699,363, filed October 31, 2000. The application that became the '006 patent claims priority to German application 199 52 962, filed on November 3, 1999. The

prior art presented with these grounds is well before both of these filing dates.

Accordingly, solely for purposes of this Petition, Petitioners do not address whether the claims of the '006 patent would be entitled to priority to the November 3, 1999 filing date of the German application.

A. Background of the Relevant Technology

The art related to the '006 patent concerns the fields of dental implants and restorations and computer-aided design and manufacture based on images of the teeth and jaw. (Ex. 1002 at ¶ 18). Dental implants are rigid structures that are embedded in or fastened to the jaw bone to provide an anchor for a false tooth, dental bridge or other dental prosthesis. (*Id.* at ¶ 20). A hole corresponding to a planned implant position can be drilled in the jaw bone to permit the dental implant to be fastened to the jaw bone. (*Id.* at ¶ 20-21). As explained in more detail by Dr. Benjamin, numerous dental implant technologies had been widely used long before the '006 patent application was filed. (*Id.* ¶¶ 17-32).

The '006 patent refers to a “drill assistance device,” which is a type of surgical template. Surgical templates have also been widely used in medical procedures. (*Id.* at ¶ 25-28). In dental implant surgery, the surgical template can be a device that is secured in the patient’s mouth to direct a drill apparatus to drill the hole at the planned implant position. (*See* Ex. 1016 at pp. 54, 59; Ex. 1002 at ¶ 24). In this context, the surgical template is sometimes referred to as a drill

template. (Ex. 1002 at ¶ 24). The hole in the template is sometimes referred to as a surgical guide or a drill guide. (*Id.*).

Although the '006 patent uses the terms “bore hole” and “pilot hole” in an inconsistent manner, “bore hole” as used herein refers to the hole drilled into the jaw bone at the planned implant position. “Pilot hole” as used herein refers to the drill guide prepared in the drill template to position and guide the drill apparatus. (*Id.*).

B. Person of Ordinary Skill in the Art

Because the art related to the '006 patent spans the fields of dental surgery and research in computer-aided design and manufacture, a person of ordinary skill in the art would have knowledge and experience in different areas of expertise. (*Id.* at ¶ 18). A person of ordinary skill in the art at the time of the effective filing date of the '006 patent claims would have either a doctorate degree in dentistry from an accredited institution or a degree in biomedical, electrical or computer engineering or a related field and several years of experience in planning and placing dental implants and related structures and/or would have familiarity with computer-aided design processes and systems. (*Id.*).

C. The '006 Patent Specification

The '006 patent discloses and claims a method for producing a drill template that is used in a tooth implant procedure. The drill template is used to make a bore hole for a tooth implant relative to other teeth that remain in the jaw.

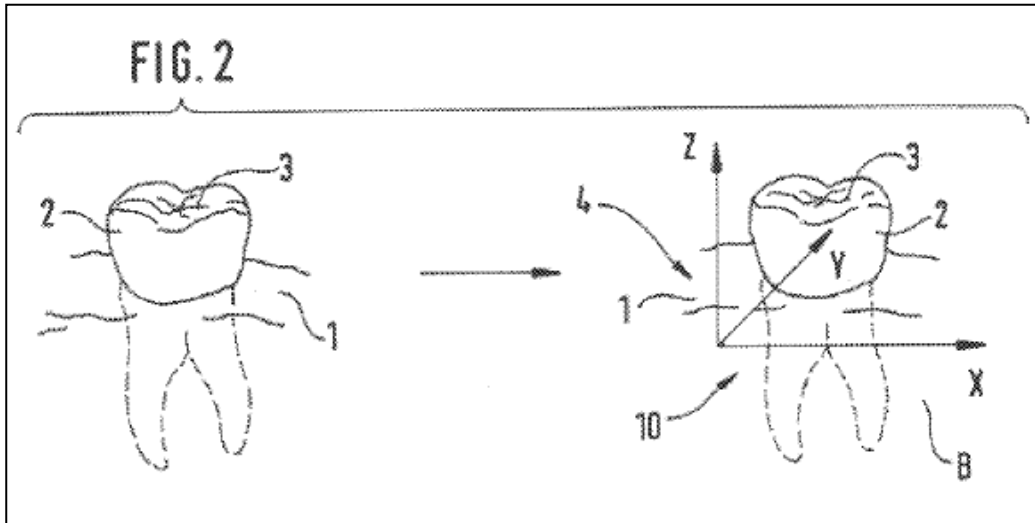
The specification acknowledges prior art drill templates for tooth implants. For one known example, the specification explains that a computer generated “three-dimensional image is modeled using an image of the jaw relative to an imprint surface.” (Ex. 1001 at 1:13-14). One or more implant bore holes are specified in three dimensions, and the coordinates are provided to a computer-controlled precision machine tool. (*Id.* at 1:13-14). In this way, a drill guide may be produced that includes “corresponding bore hole position and bore hole orientation previously determined using the section of the jaw.” (*Id.* at 1:25-27).

According to this prior art method, a dentist locates the bore hole for the implant relative to the jaw with the use of x-ray pictures. (*Id.* at 1:30-32). Although the position and orientation of the bore hole is known from the created computer model, it was allegedly difficult to determine the position of the bore hole during the surgical procedure because the “information that is contained in the x-ray cannot be exactly transferred to the optical images which the physician sees while drilling.” (*Id.* at 1:34-35, 38-39). Therefore, according to the specification,

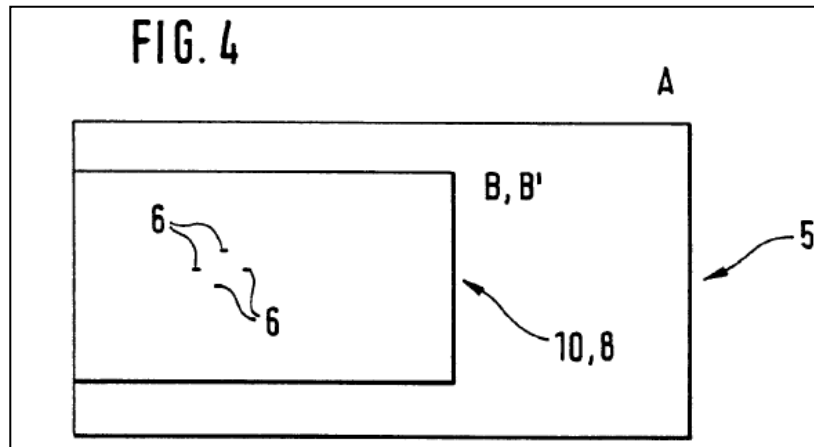
the dentist relied on individual experience to perform the implant procedure even though the implant itself was very precisely manufactured. (*Id.* at 1:39-46).

To overcome this alleged problem, the specification discloses a method for producing a drill assistance device that allowed “the exact drilling of a pilot hole for a tooth implant” relative to other teeth remaining in the jaw. (*Id.* at 2:8-10). To plan the drill assistance device, an x-ray picture of the jaw is taken, and “corresponding measured data records” produced from the x-ray are compiled. (*Id.* at 2:15-16). The specification contemplates different x-ray types, including a panoramic tomography picture, a tomosynthetic image or a computer tomography image. (*Id.* at 2:46-48). Using the x-ray, a position of the bore hole for the dental implant, including its orientation, is planned by observing the location of the nerve tracts in the jawbone. (Ex. 1001 at FIG. 5; 4:17-23).

The method also generates three-dimensional optical measurement data of the visible surfaces of the jaw and teeth. (*Id.* at 2:17-20). While it refers to a “three-dimensional optical image,” the specification does not provide any details as to what imaging apparatus should be used or how such an image is acquired. (*Id.* at 3:50-53). In any event, this step somehow provides an image of the surface structure, such as the occlusal surface 3 of a molar 2 as shown in FIG. 2 reproduced below.

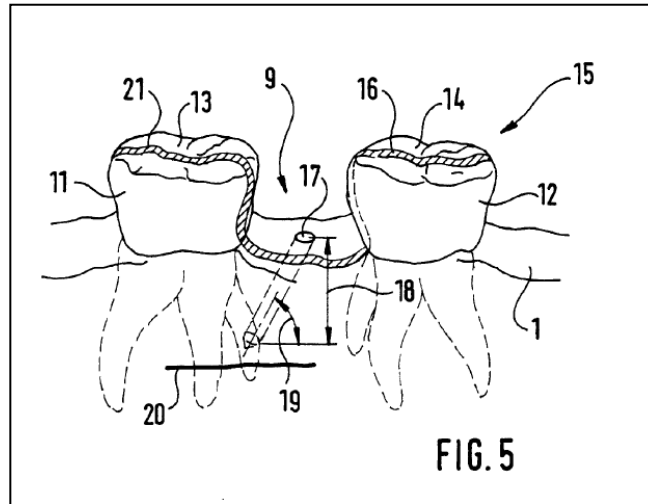


The measurement data records of the x-ray picture and the three-dimensional optical measuring data are then correlated. Without providing any mathematical algorithms or other implementation detail, the specification broadly states that such correlation “can be achieved in different ways.” (*Id.* at 3:60-61). It describes the goal of an x-ray picture superimposed on a three-dimensional image by using “markers 6, that are attached to the teeth 2 (FIG. 3), in order to create fixed points that make possible to superimpose an x-ray picture A and a three-dimensional image B,” but the details of how the superimposition is actually made are not disclosed. (*Id.* at 3:66-67, 4:1-2; FIG. 4). The specification also describes a pseudo-x-ray B’ generated from the surface data of the three-dimensional image. (*Id.* at 4:3-8; FIG. 4). A user then overlaps the x-ray 5 and the pseudo-x-ray 8, preferably in different orthogonal directions, as shown in FIG. 4 reproduced below. (*Id.* at 4:8-9; FIG. 4).



The records also can be correlated by extracting the surface shapes “from the x-ray pictures as they are recorded in the optical image, and then they are superimposed with the data of the optical image.” (*Id.* at 3:8-10). In any case, the correlation between the two types of data is either “accomplished automatically or interactively.” (*Id.* at 3:11).

Once the data records are correlated, the position of the implant relative to occlusal surfaces of the adjacent teeth can be planned and created, as shown in FIG. 5. (*Id.* at 4: 31-36; FIG. 5). The implant bore hole location and depth also can be established.



The implant is determined and positioned “in ways that are known in the art.” (*Id.* at 3:12-13). For example, a CAD/CAM machine may be used to grind a drill template having a negative of the occlusal surfaces of the adjacent teeth. (*Id.* at 4:38-42). When seated in the patient’s mouth, the drill assistance device also provides the predetermined position and angle of the implant pilot hole as a guide for the dentist. (*Id.* at 4:51-67). Based on the correlated measured data records, “the visible proportions as well as the proportions that are not visible to the human eye, i.e., for example, the nerve paths, in the implant area become known and consequently allow the safe placement of a pilot[bore] hole in the jaw.” (*Id.* at 2:54-57).

D. The Prosecution History

U.S. Application Serial No. 09/699,363 was filed on October 31, 2000. Except for objections to form, the originally presented claims 1-10 were allowed

on a first action on the merits on July 31, 2001, less than one year from the application filing. (Ex. 1023 at p. 48). The Examiner stated in his reasons for allowance that “[t]he prior art does not disclose or fairly teach a method for producing a drill assistance device for a tooth implant including the step of correlating measured data records from an x-ray picture of the jaw and from a three-dimensional optical measuring of the visible surfaces of the jaw and determining the optimal bore hole for the implant and a pilot hole in a drill template.” (*Id.* at p. 60).

E. The German Nullity Proceedings

European Patent No. EP1101451, entitled “Method of Making a Drill Guide for a Dental Implant,” is a counterpart to the ‘006 patent in that EP 1101451 also claims priority to German application 199 52 962. (Ex. 1024 at p. 1). On April 8, 2014, the German Federal Patent Court issued its preliminary opinion with respect to the German Patent Right of EP 1101451, determining that its claims are not patentable. (Ex. 1012, trans. Ex. 1013).

In the decision, the German court found the claims unpatentable as lacking inventive step based on either Bannuscher (Ex. 1009; trans. Ex. 1010) or French Patent FR 2 705 027 A1 to Fortin (“Fortin Patent”) (Ex. 1004; trans. Ex. 1005), the latter of which appears to be based on the same work as the Fortin ‘95 reference. These claims are quite similar to the ‘006 patent claims, as shown in the

comparison of representative claim 1 of the '006 patent and the translation of claim 1 of EP1101451 provided below:

'006 Patent (Ex. 1001, cl. 1)	EP1101451 (Ex. 1024, p. 5-6)
1. Method for producing a drill assistance device for a tooth implant in a person's jaw, comprising the following process steps:	1. Method for creating a drill aid (16) for a tooth implant, with the following method steps:
taking an x-ray picture of the jaw and compiling a corresponding measured data record,	1.1 - the use of x-ray images (5) of the jaw (1) to generate a corresponding set of measurement data,
carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth and compiling a corresponding measured data record,	<u>Characterized by</u> 1.4 - the three-dimensional optical measurement of the visible surface of jaw (1) and teeth (2) and the generation of a corresponding set of measurement data,
correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,	1.5 - the correlation of the sets of measurement data from the x-ray image (5) and of the sets of measurement data from the three-dimensional optical measurement (10), and
determinating the optimal bore hole for the implant, based on the x-ray picture, and	1.2 - the possibility of determining an optimal drill hole for an implant, preferably based on the x-ray image,
determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.	1.3 - the possibility of determining a guide hole in a drill template (16), 1.6 - the possibility of determining a guide hole in a drilling template (16) relative to the surfaces of the neighbouring teeth based on x-ray images and optical measurement.

The German court determined that both Bannuscher and the Fortin Patent described all elements of claim 1 with the exception that measurement of the surfaces of the teeth and mouth structure are not necessarily taken with direct

optical methods. (Ex. 1012, trans. Ex. 1013 at p. 10, 13). As to this element, however, the German court concluded that such optical data acquisition was known to those skilled in the art because the specification lacked any detail as to how this step is performed. (*Id.* at p. 8). The patentee, instead, had claimed correlating the optical measuring of jaw and teeth surfaces with x-ray data to distinguish the claims from the prior art, but this was a concept previously disclosed by both Bannuscher and the Fortin Patent.

VI. HOW THE CHALLENGED CLAIMS ARE TO BE CONSTRUED

In an *Inter Partes* review, “[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b). The words of the claim are, therefore, given their plain meaning unless that meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). For the purpose of *inter partes* review only, the claim terms and phrases take on their broadest reasonable interpretation in view of the specification of the ‘006 patent. Because the standards of claim interpretation applied in litigation differ from PTO proceedings, any interpretation of claim terms in this IPR is not binding upon Petitioners or any real party in interest in any litigation related to the subject patent. *Id.*

A. “carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and teeth”

Claim 1 recites “carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth and compiling a measured data record.” Neither the claim nor the specification indicates whether the optical measuring of the visible surfaces of the jaw and teeth are to be taken directly on the patient, such as by inserting a measuring device inside the patient’s mouth, or whether they can also be taken indirectly, such as from an imprint or model of the patient’s jaw and teeth. (Ex. 1002, Benjamin Decl. at ¶ 44).

At the time of the effective filing date of the ‘006 patent claims, techniques for acquiring data concerning a patient’s oral situation included measuring models created from an imprint of the jaw and teeth (negative impression) or a model of the jaw and teeth (positive impression made from the imprint). (*See e.g.*, Ex. 1003, Fortin ‘95 at p. 53; 54). Where the imprint or model corresponds to actual jaw and/or teeth, measuring the imprint or model also constitutes measuring the jaw and teeth of the patient, albeit indirectly. (Ex. 1002 at ¶ 45).

The phrase “carrying out a . . . measuring of the visible surfaces of the jaw and of the teeth” should be construed according to its broadest reasonable construction, which includes both direct measuring of the actual jaw or teeth of the

patient and indirect measuring of such surfaces based on an imprint or a model of the jaw and teeth. (Ex. 1002 at ¶ 46).

B. “pseudo-x-ray”

Dependent claims 6 and 7 of the ‘006 patent refer to a “pseudo-x-ray picture” to which the measured data records compiled from the three-dimensional optical measuring are converted. The term “pseudo-x-ray picture” is not a term that has commonly understood meaning to persons skilled in the art. (Ex. 1002 at ¶ 45).

In dependent claim 6, the measured data records are converted to a pseudo-x-ray picture “assuming standard x-ray absorption values and the generation theory of the respective x-ray image.” (Ex. 1001 at 6:7-9). In dependent claim 7, the x-ray picture and the pseudo-x-ray picture are superimposed from several directions. (*Id.* at 6:11-12). The patent specification states that a pseudo-x-ray is “based on the surface data of the three-dimensional image.” (*Id.* at 4:5-6). The specification, however, does not indicate what type of three-dimensional optical image is to be taken, nor does it explain a mathematical model, algorithm or other process to convert a three-dimensional image to a pseudo-x-ray picture. (Ex. 1002 at ¶ 48).

According to its broadest reasonable construction, therefore, a “pseudo-x-ray picture” is any representation of measured data records of the three-dimensional optical measuring that can be superimposed on an x-ray image. (*Id.* at ¶ 49).

VII. DESCRIPTION OF THE PRIOR ART UPON WHICH THE CHALLENGE IS BASED

A. Fortin '95 (Ex. 1003)

Fortin '95 was not considered during prosecution of the '006 patent. Fortin '95 qualifies as prior art under 35 U.S.C. § 102(b) because it published in 1995, more than one year prior to the U.S. application filing date of the '006 patent (*i.e.*, October 31, 2000).

B. Mushabac (Ex. 1007)

Mushabac was not considered during prosecution of the '006 patent. Mushabac qualifies as prior art under 35 U.S.C. § 102(b) because it issued on October 8, 1996, more than one year prior to the U.S. application filing date (*i.e.*, October 31, 2000) of the '006 patent.

C. Truppe (Ex. 1008)

Truppe was not considered during prosecution of the '006 patent. Truppe qualifies as prior art under 35 U.S.C. § 102(b) because it issued on December 1, 1998, more than one year prior to the U.S. application filing date (*i.e.*, October 31, 2000) of the '006 patent.

D. Bannuscher (Ex. 1009, trans. Ex. 1010)

German Patent DE 195 10 294 A1 to Bannuscher (Ex. 1009) was not considered during prosecution of the '006 patent. Bannuscher qualifies as prior art under 35 U.S.C. § 102(b) because it published on October 2, 1996, more than one

year prior to the U.S. application filing date (*i.e.*, October 31, 2000) of the '006 patent. References to Bannuscher herein are to the translation, (Ex. 1010), which is certified pursuant to 37 C.F.R. § 42.63(b). (Ex. 1011).

VIII. DETAILED EXPLANATION OF GROUNDS FOR CHALLENGE

A. Ground 1: Claims 1-4 and 9-10 Are Anticipated By Fortin '95 (Ex. 1003)

Fortin '95 discloses a method for fitting a dental implant in an optimal position of the jawbone with use of a drill assistance device, which is referred to as a "splint." (Ex. 1003 at pp. 54, 56). A radiopaque pin and resin are applied to the splint, which is placed in the patient's mouth. Computed tomography (CT) scans (x-ray images) are acquired and the data is compiled by a computer. (*Id.* at p. 53, 54-55; FIG. 2). The splint "models the complexity of the teeth shape" to ensure its accurate placement in the patient's mouth, and it is a negative 3-D representation of the patient's teeth. (*Id.* at p. 54, 56; Ex. 1002 at ¶ 52).

After the CT images are acquired, modeling software displays two 2-dimensional images of the 3-D CT image dataset containing the radiopaque pin inserted into the splint. The software creates images to simulate a frontal view and a vertical plane perpendicular to the frontal view. The simulation process guides the clinician to determine an optimal implant position at the intersection of these two planes. (*Id.*; FIGS. 3a-b).

Fortin '95 also discloses a 3-D volume scanning process that uses a 3-D sensor with a video camera coupled with a moving laser plane to obtain the surface contour of the splint. (*Id.* at p. 55). Surface data of the visible surfaces of the jaw and teeth are therefore acquired from the 3-D volume scanning process, which are stored as data in the form of surface points. (*Id.* at pp. 55, 57; Ex. 1002, ¶ 54).

The CT image dataset is correlated with the surface data of the jaw and teeth obtained by the 3-D volume scanning process through a “rigid-body transformation.” (*Id.* at p. 55). The software correlates the 3-D/3-D registration between the surface contour data and the splint surface segmented on the CT images, to determine the optimal drill axis in the splint reference system. (*Id.* at p. 56; Ex. 1002 at ¶ 29, 52).

Fortin '95 also discloses planning or determining the bore hole for the “optimal position of the implant using computed tomography [CT] to accurately place the implant in the planned position using a guide drilled into a resin splint.” (Ex. 1003 at p. 53). The optimal bore hole axis is positioned according to the following considerations: (a) the optimal axis in the splint (which Fortin '95 refers to as the definitive axis) is positioned close to the actual axis (or prosthesis axis); (b) the implant trajectory is surrounded by the maximum amount of mineralized bone; and (c) the optimal axis is of the longest possible length. (*Id.* at p. 55).

Fortin '95 discloses that a clinician determines an optimal axis based on a balance

among these criteria. (*Id.*). This optimal axis, as defined in the CT coordinate system, is transferred to the splint coordinate system. Fortin '95, therefore, uses measured data records from x-ray data of the jaw to determine the optimal bore hole for the implant. (Ex. 1002 at ¶ 55).

A drilled cylindrical hole located coincident with the optimal axis in the splint forms a trajectory guide. (Ex. 1003 at p. 55). This guide drilled into the splint serves as a pilot hole for the dentist's drill in order to create the bore hole for the implant in the patient's jaw and is used to fasten the dental implant. A guiding system linked and calibrated with the 3-D scanning process is used to drill the trajectory guide into the splint to match the optimal axis used to define the optimum bore hole in the patient's jaw. (*Id.* at 55-57). The trajectory guide or pilot hole coincides with the optimal axis as defined in the CT coordinate system and transferred to the splint coordinate system. (*Id.* at 55-57).

The splint is a drill template with a pilot hole that was determined relative to the surfaces of the jaw and neighboring teeth. (Ex. 1002 at ¶ 56). The drill template is then positioned into the patient's mouth, and used by the dentist to guide the drilling process. Because an optimal axis was determined by a coordination of CT data and a 3-D scanning process, the procedure avoids adjacent anatomic structures. (Ex. 1003 at p. 57).

Accordingly, each of the limitations of claim 1 is present in Fortin '95, and claim 1 of the '006 patent is unpatentable as anticipated by Fortin '95.

Dependent claims 2-4 and 9-10 of the '006 patent recite various additional elements that are also present in Fortin '95. These claims are also unpatentable as anticipated by Fortin '95. For example, Fortin '95 discloses that CT image data is obtained of the jaw with the splint located in the patient's mouth. (Ex. 1003 at p. 53, 54; abstract; Ex. 1002 at ¶ 75). Fortin '95 therefore anticipates claim 2 of the '006 patent.

Fortin '95 discloses that the splint covers the teeth and the jawbone. (Ex. 1003 at p. 54; FIG. 2). Specifically, "[t]he complexity of each patient's tooth shapes is modeled in the splint, thus insuring that the placement of the splint is unique and accurate." (*Id.* at p. 56). The splint captures the visible surfaces of the jaw and teeth including occlusal surfaces of the neighboring teeth located in the jaw. (Ex. 1002 at ¶ 76). Fortin '95 therefore anticipates claim 3 of the '006 patent.

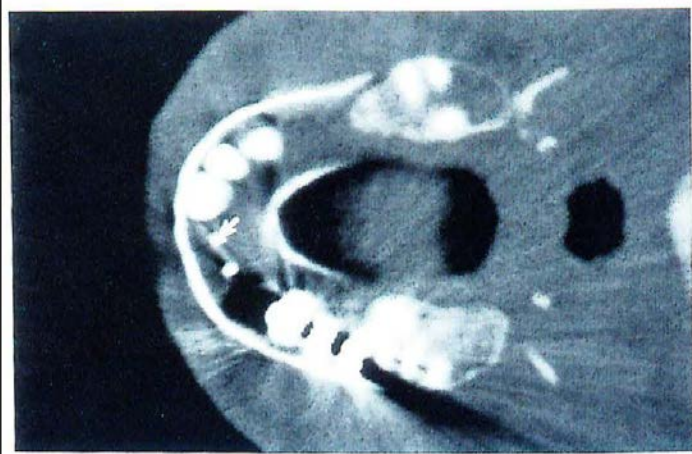
Fortin '95 also discloses that the splint is covered with a radiopaque resin and contains a radiopaque pin to make the splint visible in the CT (x-ray) image. The radiopaque resin and the pin serve as markers for the correlation between the x-ray image data and the surface data acquired by 3-D volume scanning process. (Ex. 1003 at p. 54, 56, FIG. 2, 8; Ex. 1002 at ¶ 54). Fortin '95 therefore anticipates claim 4 of the '006 patent.

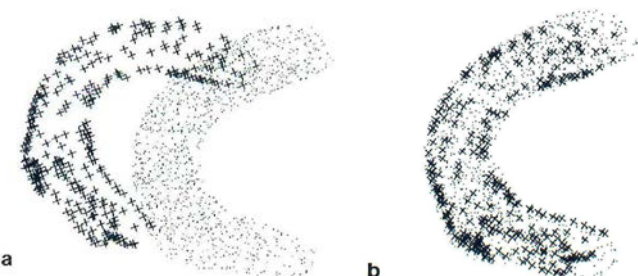
Dependent claim 9 is also anticipated by Fortin '95. According to Fortin '95, the splint is converted into a drill assistance device when the linear guide coincident to the optimal axis for the bore hole is ground out with a drill. (*Id.* at p. 55). In particular, the “complexity of each patient’s tooth shapes is modeled in the splint, thus insuring that the placement of the splint is unique and accurate.” (*Id.* at p. 56). The splint is made from a dimension-stable material, and covers the entire maxilla, while also providing a negative reproduction with respect to the implant position. (Ex. 1002 at ¶ 52, 64).

Fortin '95 discloses that the drill guide formed in the splint coincides with the optimal axis (*id.* at p. 55), and therefore serves as a bore hole position. The clinician, using the pilot hole in the splint as a bore hole position, then drills through pilot hole in the splint to form a bore hole for the implant in the patient’s jaw. (*Id.* at p. 55). Fortin '95 therefore anticipates claim 10 of the '006 patent.

The following claim charts show that Fortin '95 discloses all of the limitations of claims 1-4 and 9-10. Consequently, Fortin '95 (Ex. 1003) anticipates claims 1-4 and 9-10 of the '006 patent under 35 U.S.C. § 102(b).

Claims of '006 Patent	Exemplary Disclosure of Fortin '95 (Ex. 1003)
1. Method for producing a drill assistance device for a tooth implant in a person’s jaw, comprising the following process steps:	Fortin '95 discloses a method for fitting dental implants in an optimal position of the jawbone. (Ex. 1003 at p. 53, abstract).

Claims of '006 Patent	Exemplary Disclosure of Fortin '95 (Ex. 1003)
<p>taking an x-ray picture of the jaw and compiling a corresponding measured data record,</p>	<p>Fortin '95 discloses placing a splint/template in the patient's mouth, and taking CT scans (x-ray images). The data "are acquired and transferred into a workstation." (<i>Id.</i> at p. 53, 54-55; FIG. 2). The work station or a computer is used to compile the corresponding measured data. (Ex. 1002 at ¶52).</p> <div data-bbox="618 569 1305 1020" style="text-align: center;">  </div> <p>Fig. 2. Original CT slice. The arrow indicates the prosthesis axis (radiopaque pin). The splint surface is easily detected because of the radiopaque resin that covers the splint.</p>
<p>carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth and compiling a corresponding measured data record,</p>	<p>Fortin '95 discloses a splint that models the "complexity of each patient's tooth shape" to ensure that "the placement of the splint is unique and accurate." (Ex. 1003 at p. 56).</p> <p>A 3-D sensor with a video camera coupled with a moving laser plane is used to obtain surface points or surface contour of the splint. (<i>Id.</i> at p. 55). Surface data of the visible surfaces of the jaw and teeth are acquired from the 3-D volume scanning process, which are stored as data in the form of surface points. (<i>Id.</i> at pp. 55, 57; Ex. 1002 at ¶¶ 54-55).</p>

Claims of '006 Patent	Exemplary Disclosure of Fortin '95 (Ex. 1003)
<p>correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,</p>	<p>Fortin '95 discloses correlating the CT image dataset and the surface data acquired by the 3-D volume scanning process in a "rigid-body transformation between the surface segmented from the CT image dataset and the surface acquired with the 3-D sensor." (Ex. 1003 at p. 55, 56 FIGS. 7 and 8; Ex. 1002 at ¶ 54).</p>  <p>Fig. 8. Registration of the 3D points acquired by the pointer with the splint surface segmented on CT images. (a) Initial position. (b) Final position.</p>
<p>determinating the optimal bore hole for the implant, based on the x-ray picture, and</p>	<p>Fortin '95 discloses that the optimal axis for the implant bore hole is determined according to (CT) x-ray data. (Ex. 1003 at p. 55: "By using a coordinate system which includes both the prosthesis axis position and the CT densities in 3-D," the clinician can identify the optimal axis for the bore hole.)</p> <p>The axis position (bore hole) is determined based on "detecting regions of bone with high densities and avoiding all the adjacent anatomic structures." (<i>Id.</i> at p. 57; Ex. 1002 at ¶ 55).</p>
<p>determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.</p>	<p>Fortin '95 discloses determining a linear guide, which is a cylindrical hole (or pilot hole) coincident with the optimal axis, in the splint based on the correlated CT image data and 3-D surface data. (Ex. 1003 at p. 55: "a guiding system linked and calibrated with the 3-D sensor previously described performs the drilling of a linear guide into the splint that coincides with the</p>

Claims of '006 Patent	Exemplary Disclosure of Fortin '95 (Ex. 1003)
	<p>optimal axis.”) Because the splint “models the tooth shape” (<i>Id.</i> p. 56), the pilot hole is determined relative to the surfaces of neighboring teeth. (<i>Id.</i> at p. 53: “Our system provides a reference structure to directly correlate the computer developed axis with patient anatomy.”).</p> <p>The splint is used as a drill template by the clinician, who “drills the bone through the linear guide made in the splint.” (<i>Id.</i> at p. 57; see also, Ex. 1002 at ¶ 55).</p>
<p>2. The method according to claim 1, wherein the x-ray picture is one of a panoramic tomography image, a tomosynthetic image or a computer tomography image.</p>	<p>Fortin '95 discloses all the limitations of claim 1 as discussed above.</p> <p>Fortin '95 discloses the acquisition of computer tomography (CT) images. (Ex. 1003 at p. 53, 54; abstract; Ex. 1002 at ¶ 52, 54, 56).</p>
<p>3. The method according to claim 1, wherein the three-dimensional, measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw.</p>	<p>Fortin '95 discloses all the limitations of claim 1 as discussed above.</p> <p>Fortin '95 discloses obtaining surface data from 3-D measurements of a splint. The “complexity of each patient’s tooth shapes is modeled in the splint, thus insuring that the placement of the splint is unique and accurate.” (Ex. 1003 at p. 56; Ex. 1002 at ¶ 54).</p>
<p>4. The method according to claim 1, wherein the correlation of the measured data records from the x-ray picture and from the three-dimensional optical image is carried out by the provision of markers attached to the teeth.</p>	<p>Fortin '95 discloses all the limitations of claim 1 as discussed above.</p> <p>Fortin '95 also discloses placing a radiopaque pin in the splint and covering the splint with radiopaque resin as a part of the registration between the x-ray data and surface data acquired by 3-D measurements. (Ex. 1003 at p. 54, 56, FIGS. 2, 8).</p>

Claims of '006 Patent	Exemplary Disclosure of Fortin '95 (Ex. 1003)
	<p>The radiopaque resin the radiopaque pin serve as markers to make the splint and the pin clearly visible in the CT (x-ray) image. (<i>Id.</i>; Ex. 1002 at ¶ 54).</p>
<p>9. The method according to claim 1, wherein the drill assistance device is ground out from a dimension-stable material, and said material represents the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position.</p>	<p>Fortin '95 discloses all the limitations of claim 1 as discussed above.</p> <p>Fortin '95 discloses a splint that is converted into a drill assistance device when the linear guide is ground out with the use of a drill (Ex. 1003 at p. 55: “a guiding system linked and calibrated with the 3-D sensor previously described performs the drilling of a linear guide into the splint that coincides with the optimal axis.”). The “complexity of each patient’s tooth shapes is modeled in the splint, thus insuring that the placement of the splint is unique and accurate.” (<i>Id.</i> at p. 56).</p> <p>The splint is made from a dimension-stable material, and covers the entire maxilla. It also provides a negative reproduction with respect to the implant position. (Ex. 1002 at ¶ 52).</p>
<p>10. The method according to claim 9, wherein the drill assistance device contains a bore hole position that serves as a guide for the drill.</p>	<p>Fortin '95 discloses all the limitations of claim 9 as discussed above.</p> <p>The linear drill guide formed in the splint coincides with the optimal axis (Ex. 1003 at p. 55), and therefore serves as a bore hole position.</p> <p>The drill guide is used by the clinician to form a bore hole for the implant: “Finally, after repositioning the splint in the patient’s mouth, the dentist uses the guide made into the splint to perform a perfect fit of the implant on bone.” (<i>Id.</i> at p. 55; Ex. 1002 at ¶ 56).</p>

B. Ground 2: Claims 1-4 and 9-10 Are Anticipated By Mushabac (Ex. 1007)

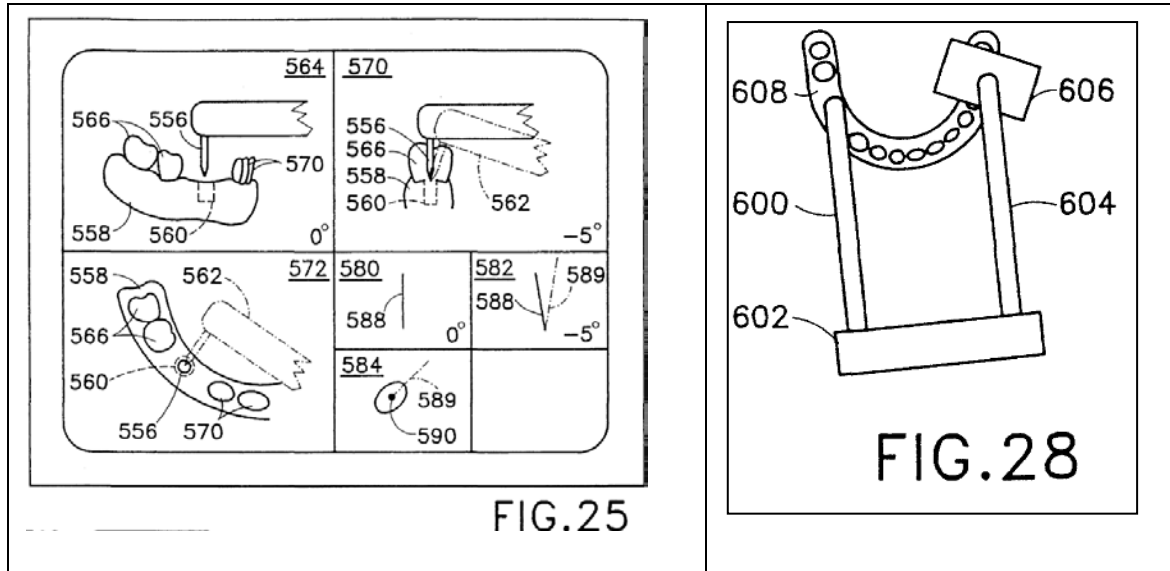
Mushabac discloses a system for dental diagnosis and treatment and fitting a dental implant in the jawbone. (Ex. 1007 at 3:35-37; 3:56-59). Mushabac uses a drill assistance device or a drill template to optimally position the dental implant. (*Id.* at 3:35-37; 3:56-59; 27:1-5). Both digitized three dimensional surface data and digitized x-ray data of the patient's mouth are acquired. (*Id.* at 4:3-10; 10:62-67).

To compile and display the three dimensional surfaces and contours of the tooth or teeth, Mushabac discloses three data generating devices 22, 26 and 28 that provide video signals to a computer having "commercially available stereophotogrammetric triangulation program." (*Id.* at 10:62-67). "X-ray data and the surface data are correlated [using the computer program] to produce a composite image showing both internal and external structures in the precise geometric relationships they have to each other in the patient's mouth." (*Id.* at 4:10-13). The practitioner can view the bone contours and surfaces, and therefore has "significant data to optimize the orientation and placement of a dental implant." (*Id.* at 7:38-39).

Mushabac discloses determining an optimal bore hole position and orientation for the dental implant, as shown by element 560 in FIG. 25. The bore hole placement is determined based on, among other things, the dimension and

shape of the jaw bone as well as the location of internal bone structures. (*Id.* at 24:66-67-25:1-10). The data for such internal structures is “obtained via X-ray data generating device or assembly 28 (FIG. 1).” (*Id.* at 25:14-16). Mushabac discloses creating an optimal bore hole by using a drill guide formed in an acrylic block 606 to provide a drill template. (*Id.* at 27:1-5; Ex. 1002 ¶ 64).

Mushabac also discloses forming a pilot hole in the drill template. (*Id.* at 27:1-5, FIG. 28; Ex. 1002 ¶ 64). To create the pilot hole, Mushabac discloses a virtual instrument 600 attached to a pantograph assembly 602, as shown in FIG. 28 reproduced below. Movement of the virtual instrument 600 is based upon the “coordination of the X-ray data as to internal structures [e.g., blood vessel canals of the jaw bone] and the data collected via optical data generating device” as to the visible three-dimensional surfaces of neighboring teeth. (*Id.* at 25:14-21). Such virtual instrument movement causes the movement of a drill 604 into the block 606 to form the pilot hole.



The pilot hole formed in the block 606 is used as a drill guide. (*Id.* at 27:8-10: “The hole in block 606 can then be used as a template to guide, limit or control the motions of an implant drill during an actual operation on the patient’s jaw bone 558.”). Claim 1 is therefore unpatentable as anticipated by Mushabac.

Dependent claims 2-4 and 9-10 of the ‘006 patent recite various additional elements that are also present in Mushabac. These claims are also unpatentable as anticipated by Mushabac.

Mushabac discloses digitized signals relating to internal structures of the tooth are received from a “data generating device or assembly 28,” which is an “X-ray device such as used in current extra-oral or intra-oral radiology or other methodologies.” (*Id.* at 10:51-53). Mushabac also discloses that “one or more cross-sectional views of tooth 550 may be provided.” (*Id.* at 24:2-3). At the time Mushabac was filed, x-ray computed tomography (CT) was a well known

methodology to obtain images of the internal human anatomy including oral structures such as cross sectional views of the teeth. (Ex. 1002 at ¶ 59). A person skilled in the art therefore would have understood Mushabac to disclose CT scanning as one of the radiological methodologies contemplated. (*Id.*). Claim 2 is therefore unpatentable as anticipated by Mushabac.

Mushabac discloses that the visible surfaces of neighboring teeth and related structure can be analyzed prior to preparation of the implant. (Ex. 1007 at 5:3-10). To do so, Mushabac discloses computer generation of “a plurality of views of the preexisting structure” based on the acquired data. (*Id.* at 5:29-30). Such contour data enables a computer display of “partial or complete graphic representations on monitor 34 of the subject tooth or teeth,” which may include the “visible three-dimensional surfaces of each such tooth, as well as invisible base line data.” (*Id.* at 16:7-11). In addition to the external surfaces of neighboring teeth, the visualization software shows the surfaces of the jaw. (*Id.* at 24:53-56; Ex. 1002 at ¶ 60). Claim 3 is therefore anticipated by Mushabac.

Mushabac also discloses the use of opaque reference elements on either the teeth or gums to enable registration of the x-ray data to the surface data: “[t]he position of the X-ray opaque reference element is then automatically recorded as part of the X-ray data and is additionally incorporated into the surface or contour data, whereby the two kinds of data (external and internal) may be correlated to

produce an integral composite image.” (Ex. 1007 at 6:27-31; *see also*, Ex. 1002 at ¶ 62). This meets the limitations of claim 4.

Mushabac discloses creating a drill guide from an acrylic block 606, which is a dimension-stable material. (Ex. 1007 at 27:1-5, FIG. 28; Ex. 1002 ¶ 64). Because the drill guide 606 is fastened to the patient’s jaw by conventional bonding techniques (*Id.* at 27:1-5), a person skilled in the art would have understood that the drill guide 606 is “form fit” to the contours of the teeth and the jaw. (Ex. 1002 at ¶ 64). That is, to “securely fasten” the drill guide to the jaw, the side of the drill guide facing the jaw would necessarily conform to the contours of the teeth and jaw. (Ex. 1007 at 27:1-5). This would also create on the acrylic block 606 the form of occlusal surfaces of neighboring teeth as a negative relative to the implant position. (Ex. 1002 at ¶ 64). This meets the limitations of claim 9.

Mushabac also discloses creating a pilot hole in drill template 606 that is used as a drill guide. (*Id.* at 27:8-10: “The hole in block 606 can then be used as a template to guide, limit or control the motions of an implant drill during an actual operation on the patient’s jaw bone 558.”). (Ex. 1002 at ¶ 64). Claim 10 is therefore unpatentable as anticipated by Mushabac.

The following claim charts show that Mushabac describes all of the limitations of claims 1-4, and 9-10. Accordingly, Mushabac anticipates claims 1-4 and 9-10 under 35 U.S.C. § 102(b).

Claims of '006 Patent	Exemplary Disclosure of Mushabac (Ex. 1007)
<p>1. Method for producing a drill assistance device for a tooth implant in a person's jaw, comprising the following process steps:</p>	<p>Mushabac discloses a method for fitting dental implants in the jawbone including the use of a drill template. (Ex. 1007 at 3:35-37; 3:56-59; 27:1-5; Ex. 1002 at ¶ 58).</p>
<p>taking an x-ray picture of the jaw and compiling a corresponding measured data record,</p>	<p>Mushabac discloses acquiring digitized x-ray data of the patient's jaw. (Ex. 1007 at 4:3-10; Ex. 1002 at ¶ 58).</p>
<p>carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth and compiling a corresponding measured data record,</p>	<p>Mushabac discloses the use of three data generating devices 22, 26 and 28 that provide video signals to a computer having "commercially available stereophotogrammetric triangulation program." (Ex. 1007 at 10:62-67).</p> <p>Such contour data enables computer display of "partial or complete graphic representations on monitor 34 of the subject tooth or teeth," which may include the "visible three-dimensional surfaces of each such tooth, as well as invisible base line data." (<i>Id.</i> at 16:7-11). In addition to the external surfaces of neighboring teeth, the visualization software shows the surfaces of the jaw. (<i>Id.</i> at 24:53-56; Ex. 1002 at ¶ 60).</p>
<p>correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,</p>	<p>The acquired "X-ray data and the surface data are correlated to produce a composite image showing both internal and external structures in the precise geometric relationships they have to each other in the patient's mouth." (Ex. 1007 at 4:10-13). The practitioner can view the bone contours and surfaces and has "significant data to optimize the orientation and placement of a dental implant." (<i>Id.</i> at 7:38-39; Ex. 1002 at ¶¶ 58, 62).</p>

Claims of '006 Patent	Exemplary Disclosure of Mushabac (Ex. 1007)
determinating the optimal bore hole for the implant, based on the x-ray picture, and	The placement of the bore hole is determined based on, among other things, the dimension and shape of the jaw bone as well as the location of internal bone structures. (Ex. 1007 at 24:66-67-25:1-10). The data for such internal structures is “obtained via X-ray data generating device or assembly 28 (FIG. 1).” (<i>Id.</i> at 25:14-16; Ex. 1002 at ¶ 63).
determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.	<p>A pilot hole in an acrylic block 606 is used as a drill template. (Ex. 1007 at 27:8-10: “The hole in block 606 can then be used as a template to guide, limit or control the motions of an implant drill during an actual operation on the patient’s jaw bone 558.”).</p> <p>The pilot hole determination utilizes virtual drill movement based upon the “coordination of the X-ray data as to internal structures [e.g., blood vessel canals of the jaw bone] and the data collected via optical data generating device” as to the visible three-dimensional surfaces of the teeth. (<i>Id.</i> at 25:14-21; Ex. 1002 at ¶ 64-65).</p>
2. The method according to claim 1, wherein the x-ray picture is one of a panoramic tomography image, a tomosynthetic image or a computer tomography image.	<p>Mushabac discloses all the limitations of claim 1 as discussed above.</p> <p>Mushabac discloses using x-ray equipment “such as used in current extra-oral or intra-oral radiology or other methodologies.” (Ex. 1007 at 10:51-53). Mushabac also discloses that “one or more cross-sectional views of tooth 550 may be provided.” (<i>Id.</i> 24:2-3). Computer tomography was a known radiological methodology to obtain images of the internal oral structures, particularly cross sectional views of the teeth. (Ex. 1002 at ¶ 22-24, 59).</p>
3. The method according to claim 1, wherein the three-dimensional,	<p>Mushabac discloses all the limitations of claim 1 as discussed above.</p> <p>The visual representations of the teeth and jaw are</p>

Claims of '006 Patent	Exemplary Disclosure of Mushabac (Ex. 1007)
measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw.	“partial or complete graphic representations on monitor 34 of the subject tooth or teeth,” which may include the “visible three-dimensional surfaces of each such tooth, as well as invisible base line data.” (Ex. 1007 at 16:7-11). The visualization software also shows the surfaces of the jaw. (<i>Id.</i> at 24:53-56; Ex. 1002 at ¶¶ 60-61).
4. The method according to claim 1, wherein the correlation of the measured data records from the x-ray picture and from the three-dimensional optical image is carried out by the provision of markers attached to the teeth.	Mushabac discloses all the limitations of claim 1 as discussed above. Mushabac also discloses the use of opaque reference elements to either the teeth or gums to enable registration of the x-ray data to the surface data. (Ex. 1007 at 6:23-26; Ex. 1002 at ¶ 62).
9. The method according to claim 1, wherein the drill assistance device is ground out from a dimension-stable material, and said material represents the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position.	Mushabac discloses all the limitations of claim 1 as discussed above. The drill template, which is a dimension-stable material, is fastened to the patient’s jaw by conventional bonding techniques. (Ex. 1007 at 27:1-5). The side of the drill template facing the patient’s anatomy was “form fit” to the contours of the teeth and the jaw, and thus is a negative representation of the implant position. Mushabac discloses grinding out of a pilot hole in an acrylic block 606 using a drill to form the drill assistance device. (<i>Id.</i> at 27:8-10; Ex. 1002 at ¶ 64).
10. The method according to claim 9, wherein the drill assistance device contains a bore hole position that serves as	Mushabac discloses all the limitations of claim 9 as discussed above. Mushabac discloses that the drill template has a hole that provides a bore hole position. (Ex. 1007 at 27:6-11; Ex. 1002 at ¶ 65).

Claims of '006 Patent	Exemplary Disclosure of Mushabac (Ex. 1007)
a guide for the drill.	

**C. Ground 3: Claims 1-10 Are Obvious Over Fortin '95 (Ex. 1003)
In View Of Truppe (Ex. 1008)**

Truppe (Ex. 1008) discloses a dental implant preparation method which includes “[t]aking at least one picture of the jaw of the person with an imaging process, such as X-ray . . . including the marking points in the picture, and storing the picture in memory as a data set.” (Ex. 1008 at 2:41-45). As illustrated in FIG. 1, a plastic positional device 3 embedded with lead beads 4 is disposed in the oral cavity 2. A 3-D sensor 5 is firmly connected to the device 3. (*Id.* at 5:54-62).

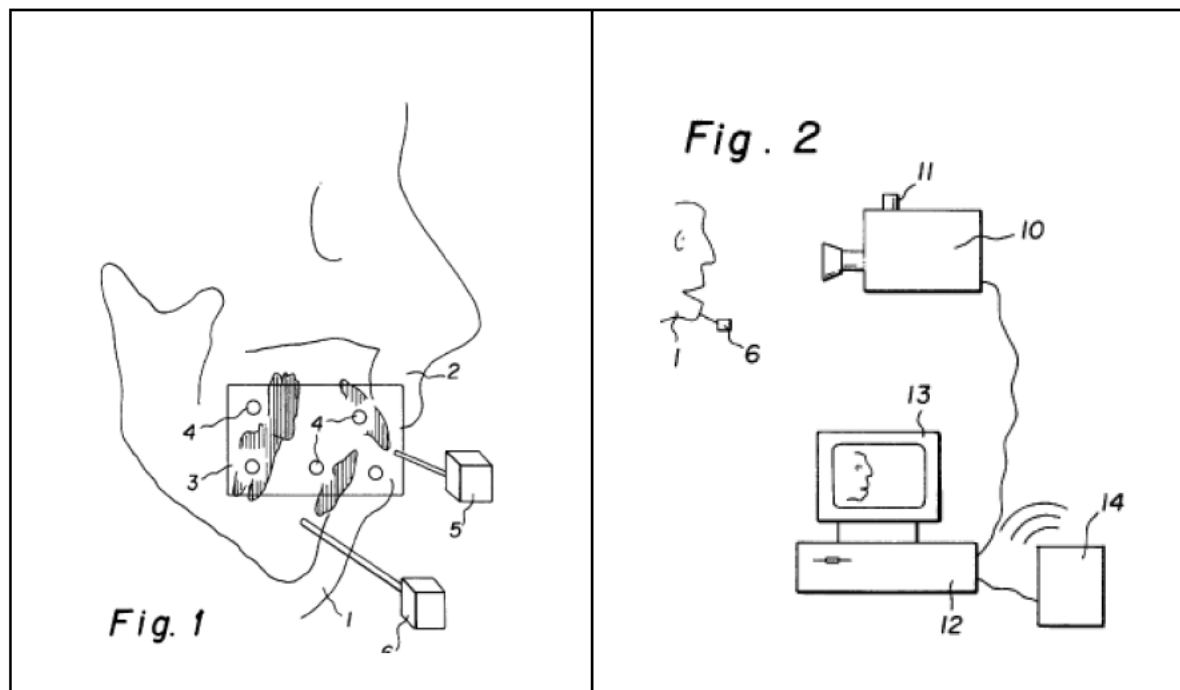
Truppe also discloses creating an optical 3-D model of the jaw, by inserting a 3-D sensor with a device for positional determination into the oral cavity and capturing the positions with respect to the markings in the oral cavity. (*Id.* at 2:65-3:11; 5:63-67). A camera 10 equipped with 3-D sensor 11 captures the optical image. (Ex. 1008 at FIG. 2.) The image “is stored in memory in the computer,” which “calculates a representation of the data set from the imaging process in real time and displays it on the screen.” (*Id.* 6:4-6). The optical representation can be acquired in different ways – either directly by obtaining an optical representation of the oral cavity or indirectly by obtaining an optical representation of a stereolithographic model of the jaw. (*Id.* at 3:48-55). Truppe considers such

representations to be interchangeable. (Ex. 1002 at ¶ 69; *see also id.* at 3:47-50: “In a second aspect of the present invention, the representation is not done with the applicable jaw itself, instead, a stereolithographic model of the jaw is made in a known manner.”). Truppe discloses that such optical representations may also be combined to represent “very vividly” the relationship between the actual jaw and the model. (*Id.* at 3:56-58).

The data set from the optical image of the jaw or the model is superimposed with a data set captured from an x-ray source. A sensor outside of the jaw locates the jaw’s current position. “By carrying out a number of coordinate transformations, it is possible to position the data set such that the structures of the data set always still match . . . the corresponding structures of the optical image.” (*Id.* at 3:19-27). When using a stereolithographic model of the jaw, by superimposing the optical image with the x-ray data set, the model can be represented with a “positionally correctly superimposed data set” to enable operation planning and simulation. (*Id.* at 3:53-55).

Claim 1 allows three-dimensional optical measuring to be carried out directly on the patient, such as by inserting a measuring device inside the patient’s mouth, or indirectly, such as from an imprint or model of the patient’s jaw and teeth. (Ex. 1002 at ¶ 69-72). Fortin ‘95 anticipates claim 1 because it discloses the indirect approach. Truppe supplements Fortin ‘95 because it discloses the direct

approach. Together, these two references disclose the full scope of claim 1. Fortin '95 and Truppe are directed to similar technologies, and a skilled artisan would have understood the benefits of combining these two references. (*Id.*).



Truppe discloses acquisition of optical image data of the actual jaw and teeth. A skilled artisan would have recognized that the method of preparing and fitting a dental implant in the optimal position of the jawbone disclosed by Fortin '95 would obtain the benefit of improved planning and simulation of the implant by utilizing optical image data of the actual jaw and teeth, as disclosed in Truppe. (*Id.* at ¶ 72). In particular, a skilled artisan would have used optical data corresponding to the actual jaw and teeth acquired according to Truppe in addition to (or substituted for) the data set from corresponding to optical measurements of

the splint as acquired in Fortin '95 to provide "vivid" representations for comparison. (*Id.*). A skilled artisan would have recognized the benefit of superimposing such data with CT scan data to aid in the computation of an optimal axis and for drilling a pilot hole in the drill template, as disclosed by Fortin '95. (*Id.*).

Truppe provides a motivation to obtain data for both an optical image of the actual jaw and teeth and of a model of the jaw and teeth. (*Id.* at ¶ 73). According to Truppe, these two methodologies (obtaining an optical representation of the actual jaw and of a model) "can be combined with one another, as a result of which the relationship of the actual jaw to the model can be represented very vividly." (*Id.* at 3:56-58). These approaches also can be used as alternatives. (Ex. 1008 at 3:47-55).

As explained in section VIII(A) above, Fortin '95 discloses all of the limitations of claim 1.¹ Because the combination of Fortin '95 and Truppe is merely the predictable use of interchangeable prior art elements according to their

¹ A claim chart showing how Fortin '95 satisfies the limitations of claims 1-4, 9 and 10 of the '006 Patent is set forth above in Section VIII(A) above and is not repeated here.

established functions, the full scope of claim 1 is unpatentable for obviousness based on Fortin '95 in view of Truppe. (Ex. 1002 at ¶ 73).

The dependent claims of the '006 patent recite various additional elements that can be also be found in the combination of Fortin '95 and Truppe. These claims are also unpatentable for obviousness based on Fortin '95 in view of Truppe.

Fortin '95 discloses that the x-ray scanner produces CT image data with a splint disposed in the patient's mouth. (Ex. 1003 at p. 53, 54; abstract; Ex. 1002 at ¶ 75). This meets the additional limitations of claim 2.

Fortin '95 discloses "a splint covered by a radiopaque resin" to cover the teeth and the jawbone. (*Id.* at p. 54; FIG. 2). "The complexity of each patient's tooth shapes is modeled in the splint, thus insuring that the placement of the splint is unique and accurate." (*Id.* at p. 56). Therefore, Fortin '95 discloses that the splint captures the complexity including occlusal surfaces of the neighboring teeth located in the jaw. (Ex. 1002 at ¶ 76). This meets the limitation of claim 3.

Truppe, in turn, discloses superimposing the x-ray data set upon the optical representation of the jaw region through use of marking points located on a positioning device inserted into the oral cavity and which comes in contact with the teeth. (Ex. 1008 at 2:25-27, 31-33; Ex. 1002 at ¶ 77). This meets the additional requirements of claim 4.

Truppe further discloses that the marking points may be lead beads. (Ex. 1008. at 2:33). This meets the additional requirements of claim 5.

A user can correlate a CT image with the three dimensional measurement in the Truppe system. The marking points of the device are made to be visible on the photographs and they can be made to coincide with the x-ray image on a monitor. (*Id.* at 4:60-67.). This depiction of the superimposed optical image on the x-ray image corresponds to the pseudo x-ray picture, which takes into account standard x-ray values and the generation theory of the respective x-ray image. (Ex. 1002 at ¶ 79). This meets the additional requirements of claim 6.

Truppe further discloses taking pictures of the jaw with x-ray, computed tomography (CT), or MRI. (Ex. 1008 at 2:40-46). It is known that CT scans take x-ray pictures from several directions and several planes. (*Id.* at 6:17-37; Ex. 1002 at ¶ 80). These pictures are also superimposed with the x-ray image on a monitor. Thus, Truppe discloses superimposing x-ray pictures on a pseudo-x-ray picture from several directions. (*Id.*). This meets the limitations of claim 8.

Fortin '95 discloses "a splint covered by a radiopaque resin" placed over the teeth and the jawbone. (Ex. 1003 at p. 54; FIG. 2). "The complexity of each patient's tooth shapes is modeled in the splint, thus insuring that the placement of the splint is unique and accurate." (*Id.* at p. 56). A splint can "cover[s] the entire maxilla and to serve as a radiographic template." (*Id.* at p. 53). This drill template

is made or “ground out” from a dimension-stable material. It is also the negative reproduction with respect to the implant position. (*Id.* at p. 56; Ex. 1002 at ¶ 81).

This meets the limitations of claim 9.

Fortin ‘95 discloses “an optimal axis position is interactively defined in the 3-D volume of CT data by detecting regions of bone with high densities and avoiding all the adjacent anatomic structures.” (Ex. 1003 at p. 57). “[A] guiding system linked and calibrated with the 3-D sensor is then used to pierce a linear guide in the splint, in the position of the optimal axis.” (*Id.* at p. 57). The linear guide in the splint serves as a drill guide for the dentist’s drill in order to create the bore hole that is used to fasten the dental implant. Again, several techniques can be used. “Finally, after repositioning the splint in the patient’s mouth, the dentist uses the guide made into the splint to perform a perfect fit of the implant on bone.” (*Id.* at 55; *see also*, Ex. 1002 at ¶ 82). The limitations of claim 10 are thus fully disclosed in the prior art.

As a result, each of claims 1-10 of the ‘006 patent are unpatentable for obviousness based on Fortin ‘95 in view of Truppe.

D. Ground 4: Claims 1-10 Are Obvious Over Bannuscher (Ex. 1009, trans. Ex. 1010) In View Of Truppe (Ex. 1008)

Bannuscher discloses a method of preparing an “operation template” or a drill template for fitting dental implants in the jaw. A “general medical and

implant-specific assessment of the patient's oral situation" is made by the dentist.

A dental impression is taken and a plaster model is prepared which extracts a three-dimensional relationship of a visual topography the patient's jaw and teeth. (Ex. 1010 at 8:23-29). An orthopantomogram – a panoramic x-ray – of the patient's jaw is taken at the same time. (*Id.* at 8:29-35; Ex. 1002 at ¶ 84).

Because the digitized three-dimensional model represents the jaw and teeth of the patient, Bannuscher discloses a visual representation of the actual physical proportions of the patient's jaw and teeth. Bannuscher explains that "[t]he plaster models obtained thus are transferred from the patient's head in a three-dimensional relationship into a skull-based simulator using a recording sheet." (Ex. 1010 at 8:29-35). The "three-dimensional plaster models and the X-ray image relating to the patient's skull are then input into a computer," indicating an acquisition of corresponding measured data records. (*Id.* at 8:36-39; Ex. 1002 at ¶ 85).

The regions which are intended for supporting zones of the implants are marked by static measuring points and the data are transferred into the x-ray image in a correlation step. (Ex. 1010 at 8:43- 9:10). A rendering of such data correlation enables a dentist to determine an optimum position of the implant and the available vertical bone supply. (Ex. 1002 at ¶ 86). Bannuscher teaches that after the positions have been coordinated, reference points are defined in the x-ray image. From this process, the dentist obtains, "[t]he information about the path of

nerve channels and anatomical data of the bone” in a “transparent and quantitative manner.” (Ex. 1010 at 9:12-16). These data identify supporting zones for the implant and “angles [of drilling] which are of primary importance for an implantation procedure.” (*Id.* at 9:25-30).

Truppe discloses that the optical image of the jaw can alternatively be captured indirectly by imaging a model of the jaw. (Ex. 1008 at 3:48-53; Ex. 1002 at ¶ 88; see also ¶ 69). From either the optical image of the actual jaw (direct method) or model thereof (indirect method), the optical representation of the jaw is acquired and superimposed with the x-ray data set to provide a “positionally correctly superimposed data set.” (*Id.* at 3:53-55).

A person of ordinary skill in the art would have recognized the benefit of utilizing the superimposed data sets disclosed by Truppe to assist in the planning for, and determination of the drill template disclosed by Bannuscher. (Ex. 1002 at ¶ 86-89). According to Truppe, the correlated data sets between the actual jaw and the model of the jaw are compared with each other so that their relationship “can be represented very vividly” in implant planning and simulation. (Ex. 1008 at 3:56-58). Truppe therefore provides a motivation to plan surgical implant procedures using correlated data sets including an optical image of the actual jaw, a model of the jaw, or both. (Ex. 1002 at ¶ 89).

Bannuscher and Truppe also include a step of planning or determining the optimal bore and pilot hole for the implant, “based on the x-ray picture” as claim 1 of the ‘006 patent requires. The pilot hole in the drill template serves as a drill guide for the dentist’s drill in order to create the bore hole that is used to fasten the dental implant. Bannuscher discloses that “the optimised implant positions established while taking into account all the necessary parameters, including the angles with the reference points required for this purpose are transferred to the operation template” (Ex. 1010 at 7:43 –8:4). Further, “[t]he definition of the implant position” and “operation planning can be optimised” (*id.* at 5:40-44) such that the drilling areas and drilling angles that position the drilling device in the implantological operation are “coordinated in respect of an optimised implant position and an available vertical bone supply, based on a three-dimensional model geometry of the mouth or jaw region and on an X-ray image thereof.” (*Id.* at 5:11-16). Thus, Bannuscher discloses using x-ray data to identify the optimum 3-D position of a pilot hole in the drill template, including the drill angle and the length of the hole in relation to the jaw bone. (Ex. 1002 at ¶¶ 90-91).

Truppe discloses superimposing the optical 3-D data with the x-ray data set to provide a “positionally correctly superimposed data set.” (Ex. 1008 at 3:53-55). Bannuscher discloses mounting the drill template on a swivel surface, which can be rotated so that “any angles determined by bringing together the three-

dimensional model geometry and the x-ray image of the mouth or jaw region of the patient can be produced on an operation template arranged on the three-dimensional model geometry.” (Ex. 1010 at 10:26-34). Based on the correlated x-ray image and 3-D measurement data, a pilot hole is drilled in the drill template. (*Id.* at 10:34-36). This procedure helps optimize the position of the implant teeth in relation to the available vertical bone supply and an angle at which to drill the pilot hole. (*Id.* 4:11-25; 5:6-16). The combination of Bannuscher and Truppe therefore disclose the steps of determining the optimal bore hole and the pilot hole in a drill template relative to neighboring teeth based on x-ray and optical measurements. (Ex. 1002 at ¶ 90-91).

Accordingly, to the extent that Bannuscher does not expressly disclose that three-dimensional measurement data is acquired from optical measuring, claim 1 of the ‘006 patent is unpatentable for obviousness based on Bannuscher in view of Truppe. (Ex. 1002 at ¶ 92). Truppe discloses the benefit of using optical image data of both the actual jaw and a model thereof to produce a “vivid” comparison. A person skilled in the art would have understood the benefits to using the optical image data disclosed by Truppe in the 3-D image creation of a drill template according to Bannuscher. (Ex. 1002 at ¶ 92; Ex. 1008 at 3:44-60). Bannuscher and Truppe, therefore, render claim 1 unpatentable for obviousness.

The dependent claims recite various additional elements relating to the method for producing a drill assistance device that can be found in the combination of Bannuscher and Truppe. Claims 2-10 of the '006 patent would also have been obvious based on Bannuscher in view of Truppe. (Ex. 1002 at ¶ 93).

Bannuscher discloses that the x-ray image can be in the form of an orthopantomogram, a type of panoramic tomography image. (Ex. 1010 at 8: 32-35; Ex. 1002 at ¶¶ 84, 94). This meets the limitations of claim 2.

Bannuscher discloses that the occlusion reliefs of the teeth can be marked on the computer and, therefore, these occlusal surfaces are included in the three-dimensional measurements discussed above. (Ex. 1010 at 8:36 –9:1). This meets the limitations of claim 3. (Ex. 1002 at ¶ 95).

Truppe discloses that the data set compiled from x-ray images and the optical representation of the jaw region are superimposed with the use of marking points located on a positioning device inserted into the oral cavity and which comes in contact with the teeth. (Ex. 1008 at 2:25-33). This meets the limitations of claim 4. (Ex. 1002 at ¶ 96).

Truppe discloses that the marking points may be lead beads. (Ex. 1008 at 2:33). Bannuscher similarly discloses that “[m]etal spheres of a defined diameter are bonded in the planned implant region.” (Ex. 1010 at 2:39-41). This meets the limitations of claim 5. (Ex. 1002 at ¶ 97).

Truppe discloses that a user can correlate a tomography image with the three dimensional measurement. The marking points of the device are made to be visible on the photographs and they can be made to coincide with the x-ray image on a monitor. (Ex. 1008 at 4:60-67). This depiction of the x-ray image corresponds to a pseudo x-ray picture, which takes into account standard x-ray values and the generation theory of the respective x-ray image. This meets the limitations of claim 6. (Ex. 1002 at ¶ 98).

Truppe discloses that the marking points of the device are made to be visible on the photographs obtained by optical scanning and they can be made to coincide or superimposed with the x-ray image on a monitor. (Ex. 1008 at 4:60-67).

Truppe discloses taking pictures of the jaw with x-ray, computed tomography (CT), or MRI equipment. (*Id.* at 2:40-46). CT equipment takes x-ray pictures from several directions and several planes. (*Id.* at 6:17-37). These optical pictures are also superimposed with the x-ray image on a monitor. Thus, Truppe discloses superimposing x-ray pictures and pseudo-x-ray picture from several directions as required by claim 7. (Ex. 1002 at ¶ 99).

Truppe discloses imaging of the jaw with x-ray, computed tomography (CT), or MRI. (Ex. 1008 at 2:40-46). It is known that CT scans take x-ray pictures from several directions and can be displayed as a panorama showing the transverse and longitudinal sections of the jaw. Bannuscher discloses producing “a

panoramic X-ray photograph”, which can be used to determine the “available vertical bone material or the bone height.” (Ex. 1010 at 2:38-45; 8:32-35). This meets the limitations of claim 8. (Ex. 1002 at ¶ 100).

Bannuscher explains that after a “general medical and implant-specific assessment of the patient’s oral situation” is made by the dentist. A dental impression is taken and a plaster model is prepared which extracts a three-dimensional relationship visual topography the patient’s jaws. (*Id.* at 8:20-35). This plaster model is ground from a dimension-stable material and is the negative impression with respect to the jaws and the implant position. Bannuscher further explains that “[t]he regions which are intended for the supporting zones to be replaced are marked by static measuring points or occlusion reliefs of the teeth.” (*Id.* at 8:43 –9:1). Thus, it meets the limitations of claim 9. (Ex. 1002 at ¶ 101).

The Bannuscher implant procedure also creates a drill guide in the drill template based upon the correlated the x-ray image data and three-dimensional measurement data. Bannuscher discloses optimizing the position of the implant teeth and the available vertical bone supply and an angle at which holes are to be drilled. (Ex. 1010 at 4:11-25; 5:6-16). Bannuscher therefore discloses a drill assistance device containing a pilot hole. When this drill template is placed in the patient’s mouth, it serves as a guide for the drill. Thus, it meets the limitations of claim 10. (Ex. 1002 at ¶ 102).

The following claim charts show that where all of the limitations of claims 1-10 are found in Bannuscher and Truppe. As further explained by Dr. Benjamin, claims 1-10 are unpatentable for obviousness over Bannuscher in view of Truppe. 35 U.S.C. § 103.

Claims of '006 Patent	Exemplary Disclosure of Bannuscher (Ex. 1009, trans. Ex. 1010) and Truppe (Ex. 1008)
1. Method for producing a drill assistance device for a tooth implant in a person's jaw, comprising the following process steps:	Bannuscher discloses a method for the production of an operation template or a drill template having a drill guide (pilot hole) to assist in positioning a drill during the placing of an implant in the jaw of a patient. (Ex. 1010 at 1:3-9; 5:6-16; 10:33-39; Ex. 1002 at ¶ 84).
taking an x-ray picture of the jaw and compiling a corresponding measured data record,	Bannuscher discloses that an x-ray image is taken of the patient's jaw and digitally input to a computer. (Ex. 1010 at 4:3-7; 8:35-39). This digital input includes compiling a data record corresponding to the measurements made by the x-ray in order for the disclosed data transfer to the computer. (Ex. 1002 at ¶¶ 84-85). Truppe discloses a dental implant preparation method which includes "[t]aking at least one picture of the jaw of the person with an imaging process, such as X-ray . . . including the marking points in the picture, and storing the picture in memory as a data set." (Ex. 1008 at 2:41-45; Ex. 1002 at ¶ 87).
carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth and compiling a corresponding measured data record,	Bannuscher discloses that a model of the patient's mouth, cast from an impression corresponding to the oral situation of the patient, is transferred in a three-dimensional relationship to a skull-based simulator and digitally input to a computer. (Ex. 1010 at 8:20-35). This digital input includes compiling a data record corresponding to three-dimensional

Claims of '006 Patent	Exemplary Disclosure of Bannuscher (Ex. 1009, trans. Ex. 1010) and Truppe (Ex. 1008)
	<p>measurements of the patient's jaw and teeth shown in the model. This information, including the marking of occlusion reliefs of the teeth, is transferred to the simulator or computer. (<i>Id.</i> at 8:39 – 9:1). Such three-dimensional measurements include measurements of the visible surfaces of the jaw and teeth since the model, and the impression from which the model is formed, correspond to the visible surfaces of the jaw and the teeth. (Ex. 1002 at ¶ 85).</p> <p>Truppe discloses a dental implant preparation method in which an optical image or images are acquired, either with respect to the patient's jaw or with respect to a model of the jaw. (Ex. 1008 at 3:48-53). Truppe also discloses that correlated data sets between the actual jaw and the model of the jaw may be compared with each other. (<i>Id.</i> at 3:56-58; Ex. 1002 at ¶¶ 87-89, 92).</p>
<p>correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,</p>	<p>Bannuscher discloses correlating the x-ray diagnostics and the model situation or oral situation of the patient using the computer (<i>i.e.</i>, using the measured data records which are transferred to the computer). (Ex. 1010 at 8:20-35). Bannuscher discloses, in one embodiment, marking measuring points at the occlusion reliefs of the teeth using data on the computer (<i>i.e.</i>, in the measured data records of the three-dimensional measuring of the teeth and jaw). These positions are transferred to and coordinated with the x-ray image (<i>i.e.</i>, correlated to the measured data records of the x-ray image). (Ex. 1010 at 8:39 –9:8; Ex. 1002 at ¶ 86).</p> <p>Truppe discloses that the captured optical representation of the jaw or of a model of the jaw is superimposed with the x-ray data set to</p>

Claims of '006 Patent	Exemplary Disclosure of Bannuscher (Ex. 1009, trans. Ex. 1010) and Truppe (Ex. 1008)
	provide a “positionally correctly superimposed data set” in the operation planning and simulation of an implant procedure. (Ex. 1008 at 3:53-55; Ex. 1002 at ¶ 88).
determinating the optimal bore hole for the implant, based on the x-ray picture, and	The pilot hole in the drill template serves as a drill guide to create the bore hole in the patient’s jaw and fasten the dental implant. Bannuscher discloses determining the optimum bore hole position for the implant with respect to the available bone supply in the jaw and 3-D model geometry of the mouth as shown in the x-ray data. (Ex. 1010 at 3:44 –4:25; 5:11-16; 9:2-8; Ex. 1002 at ¶ 90).
determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.	Bannuscher discloses that the positioning of the drill template with a pilot hole with respect to the implant position is coordinated based on the three-dimensional model geometry of the mouth or jaw region (corresponding to the optical measurement as discussed above) and on the x-ray image. (Ex. 1010 at 5:6-16; 10: 33-39). In addition, the implant position is compared with an available bone supply shown in the x-ray. (<i>Id.</i>). This pilot hole in the drill template is determined relative to the surfaces of the neighboring teeth because the drill template maintains its position with respect to the implant position. Therefore the position of the drill template does not change with respect to the neighboring teeth. (Ex. 1002 at ¶ 91).
2. The method according to claim 1, wherein the x-ray picture is one of a panoramic tomography image, a tomosynthetic image or a computer tomography image.	Bannuscher and Truppe disclose all the limitations of claim 1 as discussed above. Bannuscher discloses that the x-ray image can be in the form of an orthopantomogram, a type of panoramic tomography image. (Ex. 1010 at 8: 32-35; Ex. 1002 at ¶¶ 84, 94).
3. The method according	Bannuscher and Truppe disclose all the

Claims of '006 Patent	Exemplary Disclosure of Bannuscher (Ex. 1009, trans. Ex. 1010) and Truppe (Ex. 1008)
to claim 1, wherein the three-dimensional, measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw.	<p>limitations of claim 1 as discussed above.</p> <p>Bannuscher discloses that the occlusion reliefs of the teeth can be marked on the computer and, therefore, these occlusal surfaces are included in the three-dimensional measurements discussed above. (Ex. 1010 at 8:36 –9:1 Ex. 1002 at ¶ 95).</p>
4. The method according to claim 1, wherein the correlation of the measured data records from the x-ray picture and from the three-dimensional optical image is carried out by the provision of markers attached to the teeth.	<p>Bannuscher and Truppe disclose all the limitations of claim 1 as discussed above.</p> <p>Truppe discloses that the data set compiled from x-ray images and the optical representation of the jaw region are superimposed with the use of marking points located on a positioning device. (Ex. 1008 at 2:25-33; Ex. 1002 at ¶ 96).</p>
5. The method according to claim 4, wherein the marker comprises a ball shaped body.	<p>Bannuscher and Truppe disclose all the limitations of claim 4 as discussed above.</p> <p>Truppe discloses that the marking points may be lead beads. (Ex. 1008 at 2:33; Ex. 1002 at ¶ 97).</p>
6. The method according to claim 1, wherein the measured data records of the three-dimensional measurement are converted to a pseudo-x-ray picture, assuming standard x-ray absorption values and the generation theory of the respective x-ray image.	<p>Bannuscher and Truppe disclose all the limitations of claim 1 as discussed above.</p> <p>Truppe discloses that a user can correlate a tomography image with the three dimensional measurement. The marking points of the device are made to be visible on the photographs and they can be made to coincide with the x-ray image on a monitor. (Ex. 1008 at 4:60-67; Ex. 1002 at ¶ 98).</p>
7. The method according to claim 6, wherein the x-ray picture	<p>Bannuscher and Truppe disclose all the limitations of claim 6 as discussed above.</p>

Claims of '006 Patent	Exemplary Disclosure of Bannuscher (Ex. 1009, trans. Ex. 1010) and Truppe (Ex. 1008)
and the pseudo-x-ray picture are superimposed from several directions.	Truppe discloses that the marking points of the device are made to be visible on the photographs and they can be made to coincide or superimposed with the x-ray image on a monitor. (Ex. 1008 at 4:60-67). Truppe discloses taking pictures of the jaw with x-ray, computed tomography (CT), or MRI. (<i>Id.</i> at 2:40-46; Ex. 1002 at ¶ 99).
8. The method according to claim 7, wherein the x-ray picture comprises at least two individual panoramic images showing longitudinal and transverse sections of the jaw.	<p>Bannuscher and Truppe disclose all the limitations of claim 7 as discussed above.</p> <p>Truppe discloses taking pictures of the jaw with x-ray, computed tomography (CT), or MRI. (Ex. 1008 at 2:40-46; Ex. 1002 at ¶ 100).</p> <p>Bannuscher discloses producing “a panoramic X-ray photograph”, which can be used to determine the “available vertical bone material or the bone height.” (Ex. 1010 at 2:38-45; 8:32-35; Ex. 1002 at ¶ 100).</p>
9. The method according to claim 1, wherein the drill assistance device is ground out from a dimension-stable material, and said material represents the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position.	<p>Bannuscher and Truppe disclose all the limitations of claim 1 as discussed above.</p> <p>Bannuscher explains that after a “general medical and implant-specific assessment of the patient’s oral situation” is made by the dentist. A dental impression is taken and a plaster model is prepared which extracts a three-dimensional relationship visual topography the patient’s jaws. (Ex. 1010 at 8:20-35).</p> <p>Bannuscher further explains that “[t]he regions which are intended for the supporting zones to be replaced are marked by static measuring points or occlusion reliefs of the teeth.” (<i>Id.</i> at 8:39 – 9:1; Ex. 1002 at ¶ 101).</p>
10. The method	Bannuscher and Truppe disclose all the

Claims of '006 Patent	Exemplary Disclosure of Bannuscher (Ex. 1009, trans. Ex. 1010) and Truppe (Ex. 1008)
according to claim 9, wherein the drill assistance device contains a bore hole position that serves as a guide for the drill.	limitations of claim 9 as discussed above. The Bannuscher implant procedure also creates a drill guide in the drill template based upon the correlated the x-ray image data and three-dimensional measurement data. Bannuscher discloses optimizing the position of the implant teeth and the available vertical bone supply and an angle at which holes are to be drilled. (Ex. 1010 at 4:11-25; 5:6-16; Ex. 1002 at ¶ 102).

IX. CONCLUSION

Based on the foregoing, Petitioners respectfully request that a Trial be instituted and that claims 1-10 of the '006 patent be canceled as unpatentable.

Respectfully submitted,

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Date: May 11, 2015

CERTIFICATE OF SERVICE

I hereby certify that, on May 11, 2015, I caused a true and correct copy of this Petition for *Inter Partes* Review of U.S. Patent No. 6,319,006 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *Et Seq.*, including all exhibits thereto (Ex. 1001- Ex. 1024), was served in its entirety via Federal Express, upon the following attorney of record as listed on PAIR and the attorneys of record for Plaintiff in the concurrent litigation matter:

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