UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANATOMAGE, INC.

Petitioner

v.

SIRONA DENTAL SYSTEMS GMBH,

Patent Owner

CASE: Unassigned

Patent No. 6,319,006

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,319,006

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

EXHIBIT LIST

Ex. 1001	U.S. Patent No. 6,319,006 to Scherer *et al*.
Ex. 1002	Declaration of Dr. Richard A. Kraut, D.D.S., In Support of Petition for *Inter Partes* Review of U.S. Patent No. 6,319,006
Ex. 1003	U.S. Patent No. 5,562,448 to Mushabac
Ex. 1004	Fortin, Thomas *et al*., "Computer-Assisted Dental Implant Surgery Using Computed Tomography," Journal of Image Guided Surgery, 1:53-58, (1995)
Ex. 1005	German Patent Application Publication No. DE 195 10 294 to Bannuscher
Ex. 1006	U.S. Patent No. 5,372,502 to Massen *et al*.
Ex. 1007	Willer, Jurgen *et al*., "Computer-assisted milling of dental restorations using a new CAD/CAM data acquisition system," Journal of Prosthetic Dentistry, Vol. 80, No. 3, pp. 346-353 (September 1998)
Ex. 1008	U.S. Patent No. 5,725,376 to Poirier
Ex. 1009	Weese, Jurgen *et al*., "An approach to 2D/3D registration of a vertebra in 2D x-ray fluoroscopies with 3D CT images," CVR-Med-MRCAS'97, Lecture Notes in Computer Science, Vol. 1205, Springer, ISBN 978-3-540-62734-0 (1997)
Ex. 1010	Printout of purchase web page of Springer, publisher of CVR-Med-MRCAS'97, Lecture Notes in Computer Science, Vol. 1205, Springer, ISBN 978-3-540-62734-0 (1997)
Ex. 1011	Excerpts from Block, Michael S. and Kent, John N., ENDOSSEOUS IMPLANTS FOR MAXILLOFACIAL RECONSTRUCTION, W.B. Saunders Company, ISBN 0-7216-3958-5 (1995)
Ex. 1012	Affidavit Certifying English Language Translation of German Patent Application Publication No. DE 195 10 294

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, Anatomage, Inc. petitions for *Inter Partes* Review of Claims 1-10 of U.S. Patent No. 6,319,006 ("the '006 Patent," Ex. 1001), originally assigned to Sirona Dental Systems GmbH.

I. INTRODUCTION

The '006 Patent claims a method for producing a "drill assistance device" (also known as a "surgical guide" or "template" in the art) for placing a dental implant (on which a replacement tooth can be placed) into a patient's jaw. The disclosed drill assistance device includes a template that allows a dental surgeon to drill "bore holes" into a patient's jaw in the optimal locations, taking into consideration the external and internal structures of the jaw. As explained in the supporting Declaration of Dr. Richard A. Kraut, D.D.S., such surgical guides have been used for dental implant surgery for more than a decade preceding the November 1999 priority date of the '006 Patent. (*See* Ex. 1002 at ¶ 30.)

Not surprisingly, therefore, the '006 Patent describes that the production of an optimized drilling assistance device is accomplished using admittedly known imaging technologies—x-ray and three-dimensional optical imaging. The purportedly novel aspect claimed in the '006 Patent is the correlation of x-ray and three-dimensional data to produce a composite image showing the internal bone and nerve structures of the jaw (obtained from the x-ray image) and the external surfaces of the teeth surrounding the implant site (obtained from the optical image).

This correlation allegedly allows for the optimal placement of the drilling bore holes, so as to avoid damaging the patient's jaw or teeth.

However, this correlation was well known before the filing of the '006 Patent. The prior art cited in this Petition, which was not before the Patent Office during original prosecution, explicitly discloses the correlation of x-ray and three-dimensional data to produce an optimized drilling assistance device. As discussed in detail below, these references anticipate or render obvious every claim of the '006 Patent under 35 U.S.C. § 102 or § 103. Accordingly, there is a reasonable likelihood that Petitioner will prevail with respect to at least one of challenged Claims 1-10, and Petitioner respectfully requests that the Board institute a trial for *Inter Partes* Review and cancel all claims of the '006 Patent. As demonstrated by a preponderance of the evidence in this Petition, in compliance with 35 U.S.C. § 316(e), Claims 1-10 are not patentable under §§ 102 or 103, and must be cancelled.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(B)

A. REAL PARTY IN INTEREST

Petitioner is the sole real party in interest under 35 U.S.C. § 312(a)(3) and 37 C.F.R. § 42.8(b)(1).

B. RELATED MATTERS

The Patent Owner is asserting the '006 Patent against Petitioner in an action, *Sirona Dental Systems GmbH et al v. Anatomage, Inc.*, No. 1:14-cv-00540-LPS, filed in the U.S. District Court for the District of Delaware on April 24, 2014. Patent Owner filed a waiver of the service of summons on July 17, 2014.

C. NOTICE OF COUNSEL AND SERVICE INFORMATION

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner appoints David Pekarek Krohn as lead counsel and Christopher Kao and Brock S. Weber as back-up counsel:

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney executed by Petitioner for appointing the above-designated counsel is filed herewith.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW

This Petition complies with all statutory requirements under the AIA and requirements under 37 C.F.R. §§ 42.104, 42.105, and 42.15, and thus should be accorded a filing date as the date of filing of this Petition pursuant to 37 C.F.R. § 42.106.

A. GROUND FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Petitioner hereby certifies that the ’006 Patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging Claims 1-10 of the ’006 Patent on the grounds identified herein. Specifically, Petitioner has the standing, or meets all requirements, to file this Petition under 35 U.S.C. §§ 315(a)(1), 315(b), 315(e)(1) and 325(e)(1); and under 37 C.F.R. §§42.101 and 42.102.

B. IDENTIFICATION OF CHALLENGE

Pursuant to 37 C.F.R. §§ 42.104(b) and 42.22, Petitioner requests that the Patent Trial and Appeal Board invalidate the Claims 1-10 of the ’006 Patent.

1. Claims Challenged

Claims 1-10 of the ’006 Patent are challenged in this Petition.

2. The Prior Art

The prior art references relied upon are the following: (1) U.S. Patent No. 5,562,448 (“Mushabac”) (Ex. 1003); (2) Fortin, Thomas *et al.*, “Computer-Assisted Dental Implant Surgery Using Computed Tomography,” Journal of Image Guided Surgery, 1:53-58, 1995 (“Fortin”) (Ex. 1004); (3) German Patent Application Publication No. DE 195 10 294 (“Bannuscher”) (Ex. 1005); (4) U.S. Patent No. 5,372,502 (“Massen”) (Ex. 1006); (5) Willer, Jurgen *et al.*, “Computer-assisted milling of dental restorations using a new CAD/CAM data acquisition system,” Journal of Prosthetic Dentistry, Vol. 80, No. 3, pp. 346-353 (September

1998) ("Willer") (Ex. 1007); (6) U.S. Patent No. 5,725,376 ("Poirier") (Ex. 1008); and (7) Weese, Jurgen *et al*., "An approach to 2D/3D registration of a vertebra in 2D x-ray fluoroscopies with 3D CT images," CVR-Med-MRCAS'97, Lecture Notes in Computer Science, Vol. 1205, Springer, (1997) ("Weese") (Ex. 1009).

Notably, the German Federal Patent Court has already preliminarily rejected (court docket number 4 Ni 12/13 (EP)) the German counterpart to the '006 Patent (DE500 10 094 / EP1 101 451) based in part on the Bannuscher Patent (Ex. 1005) discussed herein.

3. Supporting Evidence Relied Upon For The Challenge

The Declaration of Dr. Richard A. Kraut, D.D.S., filed herewith (Ex. 1002), supports the challenge in this Petition that Claims 1-10 of the '006 Patent are invalid as anticipated and obvious.

4. Statutory Ground(s) Of Challenge And Legal Principles

This Petition challenges Claims 1-10 of the '006 Patent according to the versions of 35 U.S.C. §§ 102 and 103 that were in effect before March 16, 2013. Statutory provisions 35 U.S.C. §§ 311-319 that took effect on September 16, 2012 govern this *Inter Partes* Review.

5. Claim Construction

A claim in an unexpired patent subject to *Inter Partes* Review shall be given by the Patent Office "its broadest reasonable construction in light of the specification of the patent in which it appears" to one of ordinary skill in the art.

37 C.F.R. §§ 42.100(b) and 42.103(b)(3). Petitioner's proposed constructions of certain terms in the challenged claims pursuant to this standard are provided in Section IV.C below.

6. How Claims Are Unpatentable Under Statutory Grounds Pursuant to 37 C.F.R. § 42.104 (b)(2)

An explanation of how Claims 1-10 of the '006 Patent are invalid, including the identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section VI below.

IV. OVERVIEW OF THE '006 PATENT

The '006 Patent was filed on October 31, 2000 and claims priority to a foreign application filed on November 3, 1999. The '006 Patent was originally assigned to the Patent Owner, Sirona Dental Systems GmbH.

A. SUMMARY OF THE '006 PATENT

The '006 Patent relates to technology for dental implant surgery, and in particular, to providing a dentist with a drilling assistance device (also known as a surgical guide or template) for drilling bore holes into a patient's jaw in the appropriate location to anchor a dental implant, on which a prosthetic tooth can be placed. As the specification puts it, the '006 Patent "relates to a method for producing a drill assistance device in order to precisely place a pilot hole for a tooth implant, wherein the pilot hole for the tooth implant is aligned relative to the teeth." (Ex. 1001 at col. 1:7-10.) The pilot hole, according to the '006 Patent, "is necessary for fastening the implant in its optimal position, based on the location of neighboring teeth." (*Id*. at col. 2:36-37.)

The '006 Patent explains in the "Background of the Invention" section of its specification that methods for creating a surgical guide with optimal bore holes were known in the prior art. Specifically, the '006 Patent describes the use of 3-D imaging technology and x-ray imaging technology for creating optimized drill assistance devices. Regarding 3-D imaging technology, the '006 Patent describes that "a three-dimensional computer image is modeled using an image of the jaw" and "in this manner at least one bore hole is determined[.]" (*Id*. at col. 1:13-16.) Regarding x-ray imaging technology, the '006 Patent explains that "[t]he implant position in the jaw is predetermined with as much precision as possible . . . [using] information that is contained in the x-ray [picture.]" (*Id*. at col. 1:32-38.)

The alleged problem with these prior art methods, according to the '006 Patent, is that "the information that is contained in the x-ray cannot be exactly transferred to the optical images [*i.e.*, the 3-D image / model] which the physician sees while drilling [and therefore] the physician relies on experience, in particular with respect to the position and the path of the nerve tracts that run along the jaw bone." (*Id*. at col. 1:35-42.) In other words, the '006 Patent claims that the combination of 3-D imaging data and x-ray pictures is missing in the prior art.

The ’006 Patent addresses this alleged need in the art with a method wherein “the x-ray and the actual optical proportions inside the patient’s mouth are interconnected by linking the two images [*i.e.*, the x-ray image and the 3-D image] in such a way that a drill assistance device . . . can be made available which contains the pilot hole . . . in its optimal position[.]” (*Id*. at col. 2:33-39.) While the ’006 Patent does not provide any detail regarding what device could be used to capture the 3-D images of the patient’s mouth, it does explain that the 3-D images and x-ray pictures can be “linked” or “correlated” simply by superimposing them using “markers” that “are visible on the x-ray as well as on the three-dimensional optical image of the jaw.” (*Id*. at col. 2:59-65.) “By superimposing the markers the user can easily generate an interactive correlation of the x-ray picture and the three-dimensional optical image of the visible structures” of the teeth. (*Id.*) In this way, the alleged point of novelty could be accomplished, according to the ’006 Patent, even by the human action of superimposing the x-ray picture and the 3-D image.

Figure 5 of the ’006 Patent shows a drill assistance device produced according to this method, with the drill assistance device denoted as element 16 and the optimal pilot hole denoted as element 17.

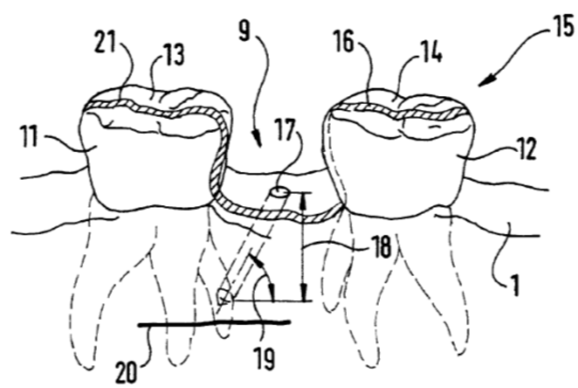

FIG. 5

(*See also id*. at col. 4:51-62 (describing Fig. 5).) As shown in Figure 5, the drill assistance device is attached to the "occlusal surfaces 13 and 14 [*i.e.*, the top] of the adjacent teeth 11 and 12, which form the limits to the implant position 9[.]" (*Id*. at col. 4:43-46.)

The '006 Patent includes a very sparse written description that only spans four columns. The written specification is insufficient to describe or enable the claims under 35 U.S.C. § 112, especially with respect to the "carrying out a three-dimensional optical measuring" and "compiling a corresponding measured data record" claim phrases. (*See* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 44-46.) Petitioner reserves the right to address the '006 Patent's failures under 35 U.S.C. § 112. Nevertheless, Petitioner proposes claim constructions as described below and as required to support this Petition that Claims 1-10 of the '006 Patent are invalid as anticipated and obvious.

B. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner believes that a person of ordinary skill in the art at the time of the alleged invention would hold a Doctor of Dental Surgery (D.D.S.) degree from an accredited university program and at least three years of residency training as an oral surgeon or two years of residency training as a periodontist or two years of residency training as a prosthodontist. (*See id.* at ¶¶ 19-24.)

Petitioner's expert, Dr. Richard A. Kraut, D.D.S., is qualified to testify about what a person of ordinary skill in the art would have understood at the time of the alleged invention of the '006 Patent. As detailed in his report, Dr. Kraut is a Professor in the Department of Dentistry and Chairman of the Department of Dentistry and Director of the Oral and Maxillofacial Surgery Residency Program, at the Montefiore Medical Center of the Albert Einstein College of Medicine in Bronx, New York. (*Id*. at ¶ 1.) He is a practicing oral surgeon and has directed the Oral and Maxillofacial Surgery Residency Program since 1989. (*Id*. at ¶ 9.) Dr. Kraut has also authored or co-authored a number of papers regarding the use of x-ray and three-dimensional imaging technologies in the planning of dental implants. (*Id*. at ¶ 10.)

C. PROPOSED CLAIM CONSTRUCTIONS

Petitioner proposes constructions of certain claim terms below pursuant to the broadest reasonable interpretation standard. The proposed claim constructions are offered only to comply with 37 C.F.R. §§ 42.100(b) and 42.104(b)(3) and for the sole purpose of this Petition, and thus do not necessarily reflect appropriate claim constructions to be used in litigation and other proceedings where a different claim construction standard applies.

Claim Term	**Broadest Reasonable Interpretation in View of the Specification**
"compiling a corresponding measured data record" (Claim 1)	"creating a digital representation of the image"

The '006 Patent does not expressly explain or define what it means to "compil[e] a corresponding measured data record" of the x-ray and 3-D images. However, from the context of the specification, this phrase must mean the creation of a digital representation of the image, such as in a computer file. For example, the '006 Patent explains that the x-ray image, which can be a "computer tomography" image (Ex. 1001at col. 2:46-48), and the 3-D image can be "automatically" correlated, including by converting the 3-D image to an x-ray image with the aid of a computer (*see id*. at col. 2:66 - col. 3:11). Thus, the correlation of the data records can be done with a computer, and therefore the "measured data records" must be "digital representations" of the x-ray and 3-D images.

Claim Term	**Broadest Reasonable Interpretation in View of the Specification**
"carrying out a three-dimensional optical measuring" (Claim 1)	"obtaining a visual representation of the actual physical proportions of"

Again, the '006 Patent does not describe how to obtain a "three dimensional optical measuring" of the patient's mouth, other than to refer to a prior art reference that discloses obtaining a "a three-dimensional computer image [] modeled using an image of the jaw." (*Id*. at col. 1:13-16.) From the context of the specification, however, the ’006 Patent shows that a “three-dimensional optical measuring,” to the extent it can be defined and according to the broadest reasonable interpretation standard, is a “visual representation of the actual physical proportions of.” It is a “visual representation” because the ’006 Patent explains that the 3-D image allows a dentist to see the “visible proportions” and “visible structures” in the patient’s mouth. (*See*, *e.g.*, *id*. at col. 2:51-60.) It is a representation of “the actual physical proportions of” because the ’006 Patent explains that the 3-D image provides the “actual optical proportions inside the patient’s mouth.” (*Id*. at col. 2:33-35.)

Claim Term	**Broadest Reasonable Interpretation in View of the Specification**
“panoramic tomography image” (Claim 2)	“radiographic images of upper and lower jaw comprising a wide-angle two-dimensional image”

The ’006 Patent does not prescribe a special meaning for this common term. Thus, the plain meaning of this term applies here. A “panoramic radiograph”(or “tomograph”) is one of the most commonly used radiographic techniques that takes multiple images of the upper and lower portion of a patient’s jaw to show a wide-angle two-dimensional image. (*See* Ex. 1011, Endosseous Implants for Maxillofacial Reconstruction, at 113-14; Ex. 1002, Declaration of Dr. Kraut, at ¶ 26.)

Claim Term	**Broadest Reasonable Interpretation in View of the Specification**
"tomosynthetic image" (Claim 2)	"an x-ray image that has been processed or generated with the aid of a computer"

The '006 Patent does not define this term. It also does not appear to be a standard term of art. (Ex. 1002 at ¶ 56.) However, as discussed above and recognized by the '006 Patent (Ex. 1001 at col. 3:47-49), a "tomographic image" is another term for an x-ray image. And to "synthesize" something in the context of radiographic imaging must mean to process or generate an image with the aid of a computer. For example, the '006 Patent discloses computer processing and modeling of 3-D images (*id*. at col. 1:11-15) and conversion of images (*id*. at col. 2:66 - col. 3:3). Thus, this term must mean "an x-ray image that has been processed or generated with the aid of a computer."

Claim Term	**Broadest Reasonable Interpretation in View of the Specification**
"computer tomography image" (Claim 2)	"computer-processed radiographic images or slices of specific areas of a scanned object"

The '006 Patent does not prescribe a special meaning for this common term. Thus, the plain meaning of this term applies here. A "computer tomography image" (or "CT") is a commonly used radiographic technique that takes multiple images or slices of specific areas of a scanned object, wherein such slices can then be used to generate a 3-D model of the object. (*See* Ex. 1011, Endosseous Implants for

Maxillofacial Reconstruction, at 115-19; Ex. 1002, Declaration of Dr. Kraut, at ¶ 29.)

V. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE ’006 PATENT IS INVALID

Claims 1-10 are each invalid under 35 U.S.C. §§ 102 or 103 for merely reciting known, predictable and/or obvious combinations of the prior art references.

A. IDENTIFICATION OF THE REFERENCES AS PRIOR ART

1. Mushabac is Prior Art Under 35 U.S.C. §§102(a), (b), and (e)

Mushabac is a U.S. Patent that was filed on August 9, 1991 and issued on October 8, 1996. (Ex. 1003.) Mushabac issued before the alleged date of invention of the ’006 Patent (November 3, 1999, based on the priority claim to the foreign filing date), and thus constitutes prior art under 35 U.S.C. § 102(a). Further, Mushabac issued more than one year before the November 3, 1999 foreign filing date of the ’006 Patent, and is therefore also prior art under 35 U.S.C. § 102(b). Lastly, Mushabac is also prior art under 35 U.S.C. § 102(e) because its application was filed before the presumptive invention date of the ’006 Patent (November 3, 1999).

2. Fortin is Prior Art Under 35 U.S.C. §§102(a) and (b)

Fortin is a publication that was available to the public in 1995. (Ex. 1004.) Fortin was published before the presumptive date of the alleged invention of the ’006 Patent (November 3, 1999), and is therefore prior art under 35 U.S.C.

§ 102(a). Fortin's publication date also predates the filing date of the '006 Patent by more than one year, and is therefore prior art under 35 U.S.C. § 102(b).

3. Bannuscher is Prior Art Under 35 U.S.C. §§102(a) and (b)

Bannuscher is a published German Patent Application. (Ex. 1005.) Bannuscher was published by the German Patent Office on October 2, 1996. This publication date is before the presumptive date of invention of the '006 Patent (November 3, 1999). Thus, Bannuscher is prior art under 35 U.S.C. § 102(a). In addition, Bannuscher was published more than one year before the filing date for the '006 Patent, and is also prior art to the '006 Patent under 35 U.S.C. § 102(b).

4. Massen is Prior Art Under 35 U.S.C. §§102(a), (b), and (e)

Massen is a U.S. Patent that was filed on November 7, 1991 and that issued on December 13, 1994. (Ex. 1006.) Thus, Massen is prior art under 35 U.S.C. § 102(a) because it was patented before the presumptive invention date of the '006 Patent (November 3, 1999). Massen is also prior art under 35 U.S.C. § 102(b) because it was patented more than one year prior to the filing date of the '006 Patent, and prior art under 35 U.S.C. § 102(e) because the application was filed before the presumptive invention date of the '006 Patent (November 3, 1999).

5. Willer is Prior Art Under 35 U.S.C. §§102(a) and (b)

Willer is an article that was published in September 1998. (Ex. 1007.) As such, Willer was published before the presumptive date of the alleged invention of the '006 Patent (November 3, 1999), and is prior art under 35 U.S.C. § 102(a).

Willer's publication date also predates the filing date of the '006 Patent by more than one year, and is prior art under 35 U.S.C. § 102(b).

6. Poirier is Prior Art Under 35 U.S.C. §§102(a), (b), and (e)

Poirier is a U.S. Patent filed February 26, 1997 and issued on March 10, 1998. (Ex. 1008.) Thus, Poirier is prior art under 35 U.S.C. § 102(b) because it was patented more than one year prior to the filing date of the '006 Patent. In addition, Poirier is prior art under 35 U.S.C. § 102(a) because it was patented before the presumptive invention date of the '006 Patent (November 3, 1999), and prior art under 35 U.S.C. § 102(e) because the application was filed before the presumptive invention date.

7. Weese is Prior Art Under 35 U.S.C. §§102(a) and (b)

Weese is an article that was presented at a conference in Grenoble, France in March 1997 and then published in 1997. (Ex. 1009 at 1; Ex. 1010 at 2-3.) As such, Weese was published before the presumptive date of the alleged invention (November 3, 1999), and is therefore prior art under 35 U.S.C. § 102(a). Weese's publication date also predates the filing date of the '006 Patent by more than one year, and is also prior art under 35 U.S.C. § 102(b).

B. SUMMARY OF INVALIDITY POSITIONS

The prior art presented in this Petition, which was not before the Patent Office during prosecution, discloses each and every element of the Claims 1-10 of the '006 Patent. Specifically, Claims 1-4 and 9-10 are anticipated by Mushabac and Fortin. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 68-108 and 109-140, respectively.) Claims 1-3 and 9-10 are also anticipated by Bannuscher. (*Id*. at ¶¶ 141-168.) To the extent that they are not anticipated by Fortin or Bannuscher, Claims 1-4 and 9-10 are rendered obvious by Fortin or Bannuscher in view of Mushabac, Massen, or Willer. (*Id*. at ¶¶ 169-188.) Claim 5 is rendered obvious by Mushabac or Fortin in view of Poirier. (*Id*. at ¶¶ 189-196.) Claims 4 and 5 are further rendered obvious by the combination of Bannuscher and Poirier. (*Id*. at ¶¶ 197-201.) Claims 6-7 are obvious over Mushabac, Fortin, or Bannuscher in view of Weese. (*Id*. at ¶¶ 202-216.) Lastly, Claim 8 is obvious over Fortin in view of Weese. (*Id*. at ¶¶ 217-220.)

VI. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY OF CLAIMS 1-10 OF THE ’006 PATENT

A. GROUND 1: CLAIMS 1-4 AND 9-10 ARE INVALID UNDER 35 U.S.C. § 102 AS ANTICIPATED BY MUSHABAC

1. Claim 1 is anticipated by Mushabac

Preamble: <u>Method for producing a drill assistance device for a tooth implant in a person’s jaw, comprising the following process steps:</u>

To the extent that the preamble is limiting, Mushabac discloses a method for “producing a drill assistance device for a tooth implant in a person’s jaw.” (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 70-71.) Specifically, Mushabac discloses that its method “is especially useful in boring through hard or soft tissues and preparing a site for anchoring a dental implant in a jaw of a patient” by determining “the optimal position and the optimal orientation of the drilling or material removal tool." (Ex. 1003 at col. 3:56-66.) This "optimal position and orientation" of the drill holes can be transferred to a "block of acrylic material," which can be used as a drilling template during an actual dental implant surgery:

> As illustrated in FIG. 28, a practice or trial run of an implant drilling operation may be performed with a practice or virtual instrument 600 mounted to a pantograph assembly 602 which holds a drill 604. . . . During motions of virtual instrument 600 towards jaw bone 558, as if an actual operation were being performed, drill 604 cuts a bore into a *block of acrylic material 606*. . . Upon the satisfactory completion of a practice operation, block 606 is provided with a hole (not shown) matching bore 560 [*i.e.*, the optimal bore hole] to be formed in the patient's jaw bone 608. 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."

(*Id*. at col. 26:62 - col. 27:11 (emphasis added).)

Element [a]: <u>taking an x-ray picture of the jaw and compiling a corresponding measured data record,</u>

Mushabac discloses "taking an x-ray picture of the jaw and compiling a corresponding measured data record," as set forth in Claim 1. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 72-75.) For example, one of the methods that Mushabac discloses is as follows:

> A method for use in forming a preparation in a patient's jaw compris[ing] . . . the steps of (a) *generating electrically encoded data specifying pre-existing dental*

> *structure for edentulous patients or those with at least one tooth, (b) transmitting the data to a computer*, (c) operating the computer to generate, on a monitor connected to the computer, a graphical representation of the pre-existing structure, (d) further operating the computer to determine an optimal position and an optimal orientation of a material removal tool [e.g., a drill] with respect to the pre-existing structure, and (e) additionally operating the computer to generate, on the monitor, a graphical representation of the tool in the optimal position and the optimal orientation relative to the pre-existing structure.

(Ex. 1003 at col. 3:42-55 (emphasis added).)

Mushabac explains that step (a) of "generating electrically encoded data specifying pre-existing dental structure" includes taking an x-ray picture of the jaw: "the step of generating electrically encoded data comprises a first step of generating digitized surface data [which corresponds with the "three-dimensional optical measuring" feature of the next claim limitation, as explained below] and a second step of *generating digitized X-ray data*." (*Id*. at col. 4:3-6 (emphasis added).) The "digitized X-ray data" is obtained through a common x-ray imaging device: "data generating device 28 may take the form of an X-ray device such as used in current extra-oral or intra-oral radiology or other methodologies and basically comprises a source 30 of X-ray radiation and a detector 32 for receiving the X-ray radiation after it passes through a tooth and converting the incident radiation into a digital stream fed to computer 24." (*Id*. at col. 10:49-56.)

Annotated Figure 1 from Mushabac shows the x-ray imaging device as element 28, the 3-D optical imaging device as element 26 and the combination (shown with arrows) of those two images at the computer, which is element 24:

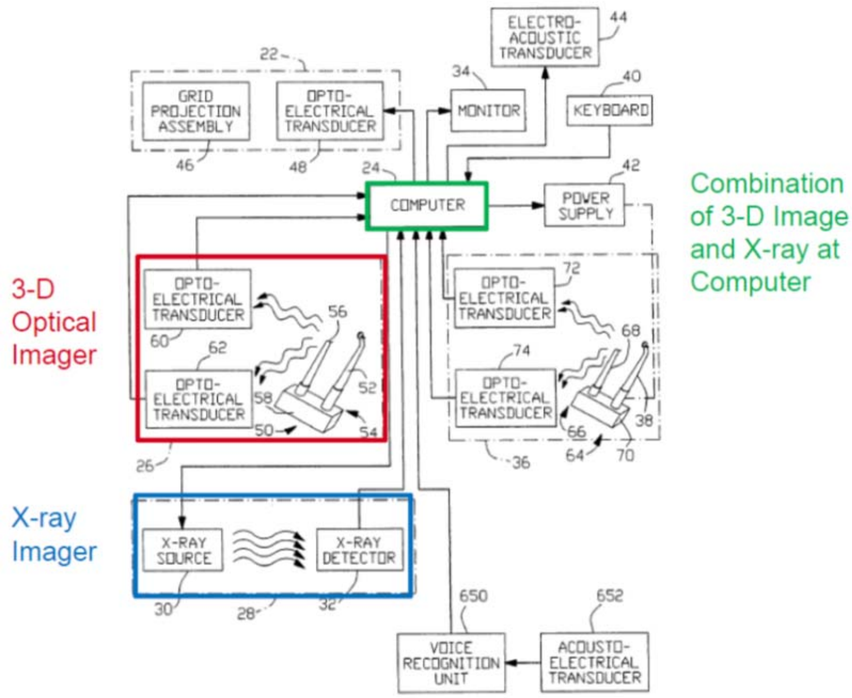

FIG. 1

Further, as quoted above, Mushabac discloses that the x-ray of a patient's jaw is "convert[ed] . . . into a *digital* stream fed to [a] *computer*." Thus, Mushabac discloses "compiling a corresponding measured data record" of the x-ray data in the form of a digital computer record, consistent with the claim construction for this term that includes "creating a *digital representation*."

Element [b]: <u>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>

As mentioned above, one of the steps disclosed in Mushabac for "generating electrically encoded data" relating to a patient's jaw and teeth is "generating digitized surface data." (Ex. 1003 at col. 4:3-6.) "The digitized surface data may include, for example, video surface data and/or contour data generated with the aid of a probe." (*Id*. at col. 4:8-10.)

Mushabac goes on to explain that the "video surface data" is a three-dimensional representation / image of a patient's jaw and teeth. For example, with reference to Figure 1 (shown above), Mushabac illustrates "a first data generating device or assembly 22 for providing a computer 24 with electrically encoded data, specifically, *digitized video signals representing a three-dimensional surface of an object such as a tooth*." (*Id*. at col. 10:38-42 (emphasis added).) Figure 1 shows the "data generating device" for generating 3-D images representing the surface of the jaw or teeth as element number 26, and the "stylus" or "probe" of the devices as element number 52.

Mushabac further describes that the 3-D "data generating device" can be an optical sensor: "data generating device 22 includes a grid projection assembly 46 for optically imposing a grid onto the surface of the patient's tooth. Data generating device 22 also includes an *opto-electrical transducer 48 such as a charge-coupled device for optically sensing or scanning the tooth surface*[.]" (*Id*. at col. 11:35-41 (emphasis added).) This allows for the representation and visualization of the physical dimensions of the jaw or teeth. As explained in Mushabac, the charge-coupled imaging device "generates and transmits to computer 24 a digitized video signal containing information used by computer 24 to calculate the *dimensions* of the subject tooth and to *display the tooth's structure in a three-dimensional graphic representation* on monitor 34." (*Id*. at col. 12:55-60 (emphasis added).)

After transmission of the 3-D optical data to the computer, the computer can display graphical representations of the teeth and jaw: "[t]he graphic representations include the visible three-dimensional surfaces of each such tooth, as well as invisible base line data fed to computer 24 by contour generating device 26." (*Id*. at col. 16:5-12.)

Figures 3 and 4 of Mushabac illustrate an example of the disclosed 3-D optical scanner, which includes "optical scanning element or elements . . . for providing computer 24 with a reference distance of dimension at the surface of a subject tooth being scanned" (*Id*. at col. 13:54-58). Mushabac makes clear that its 3-D optical scanner can be used to scan a patient's teeth, as well as the jaw. Mushabac labels the stylus / probe member of the 3-D optical imaging device as element number 52, and explains that it can be used to digitize the visible surfaces of the teeth and jaw: "The external surfaces of teeth 566 and 568 are measured or digitized as described above with reference to FIGS. 1-23. In addition, stylus or probe member 52 (FIG. 1) is used to digitize the surface of jaw bone 558." (*Id*. at col. 24:53-56.)

Because Mushabac discloses an optical sensor for obtaining a visual 3-D representation of a patient's teeth and jaw, including dimensional data of the scanned surfaces, Mushabac explicitly discloses "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth," which is construed herein as "obtaining a visual representation of the actual physical proportions of." (Ex. 1002, Declaration of Dr. Kraut, ¶¶ 76-82.) Further, as discussed above, Mushabac also explains that its 3-D optical imaging device "transmits to computer 24 a digitized video signal containing information used by computer 24 to calculate the dimensions of the subject tooth and to display the tooth's structure in a three-dimensional graphic representation on monitor 34." In this way, Mushabac discloses "compiling a corresponding measured data record" of the 3-D optical data in the form of a digital computer record, consistent with the claim construction for this term that includes "creating a *digital representation*." (*Id*. at ¶ 81.)

Element [c]: <u>correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,</u>

As discussed for the preceding two claim elements, Mushabac expressly teaches obtaining both x-ray and 3-D optical images and compiling corresponding data records. Mushabac then takes the next logical step (the alleged point of novelty claimed in the '006 Patent), and discloses "correlating" those two sets of data records:

> the step of generating electrically encoded data comprises a first step of generating digitized surface data and a second step of generating digitized X-ray data. Both kinds of data are necessary for using the method to implement a dental implant. The digitized surface data may include, for example, video surface data and/or contour data generated with the aid of a probe. *The 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. 1003 at col. 4:3-13 (emphasis added).)

Mushabac illustrates the "correlation" of data records, for example, in Figure 1. As can be seen from Figure 1 depicted above, the computer (element 24) takes data (represented by arrows) from the 3-D optical scanning device (element 26) and from the X-ray generating device (element 28) and forms a composite image from the correlation that can be displayed on the monitor (element 34).

In fact, this correlation of x-ray and 3-D data and display on the monitor is described as an object of Mushabac in its overview section: “An electronic chart which results from practicing the above-described method stores together and presents together different dental observations and measurements . . . the electronic chart combines X-ray data and [the 3-D] surface data into one storage medium and enables presentation of both kinds of data simultaneously. An electronic study chart implemented in accordance with the present inventions presents internal structural features and external structural features together, showing the geometrical and dimensional relationships among the various structures.” (*Id*. at col. 5:60 - col. 6:4.) Therefore, Mushabac discloses this claim limitation. (*See also* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 83-86.)

Element [d]: <u>determinating[sic] the optimal bore hole for the implant, based on the x-ray picture, and</u>

Mushabac explains that its disclosed invention “is especially useful in boring through hard or soft tissues and preparing a site for anchoring a dental implant in a jaw of a patient [and that the] optimal position and the optimal orientation of the drilling or material removal tool are adapted to produce a desired position and a desired orientation of the blade or anchor for the implant.” (Ex. 1003 at col. 3:57-66.) Mushabac discloses that it can “display on monitor 34 [] three views of an optimal position and orientation 556 of a drill (not separately enumerated) for cutting into a patient's mandible 558 (or any bone structure) *a bore 560* [*i.e.*, the "bore hole" in the language of the claim] for receiving an anchor or blade (not shown) of an implant." (*Id*. at col. 24:35-39 (emphasis added).) And Mushabac makes clear that the determination of the optimal bore hole is based on, among other things, the x-ray image. For example, Mushabac discloses that:

> The exact placement of bore 560 may be determined to a greater or lesser extent automatically by computer 24. Computer 24 makes this determination in accordance with (a) surface data as to molars 566 and front teeth 568, (b) surface data as to opposing teeth (bite information, obtained as described hereinafter particularly with reference to FIG. 31), (c) the dimensions and shape of jaw bone 558, and (d) *the location of internal bone structures, such as blood vessels such those which occupy inferior alveolar canals, or sinus structures*, which are to be scrupulously avoided during the drilling operation.

(*Id*. at col. 24:66 - col. 25:9 (emphasis added).)

This last criteria for the optimal bore hole—the location of internal structures—is obtained from the x-ray data: "Data as to internal structures (e.g., blood vessel canals) of jaw bone 558 may be *obtained via X-ray data generating device or assembly 28* (FIG. 1)." (*Id*. at col. 25:14-16 (emphasis added); *see also* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 87-90.)

Element [e]: <u>determinating[sic] a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.</u>

As explained above, Mushabac discloses a number of criteria for selecting an optical bore hole, including both "surface data" (*i.e.*, the 3-D optical image data) and data regarding internal structures in the jaw of the patient (*i.e.*, x-ray data):

> The exact placement of bore 560 may be determined to a greater or lesser extent automatically by computer 24. Computer 24 makes this determination in accordance with (a) *surface data* as to molars 566 and front teeth 568 [*i.e.*, the "neighboring teeth" in the language of the claim], (b) *surface data as to opposing teeth* [*i.e.*, also the "neighboring teeth" in the language of the claim] . . . , (c) the dimensions and shape of jaw bone 558, and (d) the *location of internal bone structures*, such as blood vessels such those which occupy inferior alveolar canals, or sinus structures, which are to be scrupulously avoided during the drilling operation.

(Ex. 1003 at col. 24:66 - col. 25:9 (emphasis added); see also Ex. 1002, Declaration of Dr. Kraut, ¶ 91 .)

This process of determining the optimal bore hole (element 560 in Mushabac) is depicted in Figure 25.

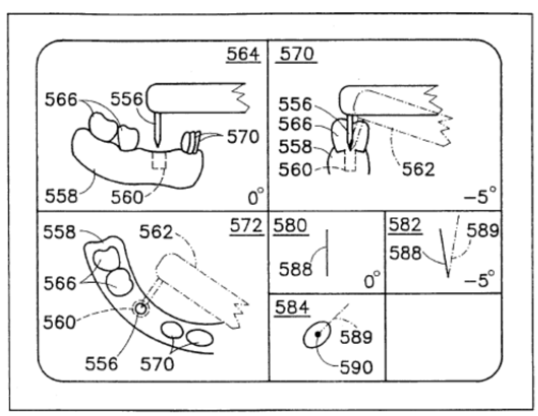

FIG.25

As explained above, the "surface data" for determining the optimal location of the bore hole is obtained from the 3-D optical scanner: "[d]ata generating device 22 [which] includes an opto-electrical transducer 48 such as a charge-coupled device for optically sensing or scanning the tooth surface[.]" (*Id*. at col. 11:35-41.) The location of "internal bone structures" is obtained from the x-ray data, as explained in the discussion of the immediately preceding claim limitation.

Finally, as discussed above with respect to the preamble, Mushabac describes that the optimal *bore* hole (element 560 in Mushabac) can be translated to a drilling assistance device or template, so that the *pilot* hole for the drilling assistance device can be determined. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 94-95.) Mushabac discloses that a practice procedure can be undertaken in order to create a drilling assistance device with an optimal pilot bore hole: "During motions of virtual instrument 600 towards jaw bone 558, as if an actual operation were being performed, drill 604 cuts a bore into a block of acrylic material 606 [*i.e*., the "drilling assistance device" in the language of the claim] . . . Upon the satisfactory completion of a practice operation, block 606 is provided with a hole [*i.e*., the "pilot hole" in the language of the claim] (not shown) matching the bore 560 [*i.e*., the "optimal bore hole" in the language of the claim] to be formed in the patient's jaw bone 608. 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." (*Id*. at col. 26:62 - col. 27:11.)

Figure 28 of Mushabac shows the "pilot hole" as the location where the drill (element 604) is contacting block 606 (the "drilling assistance device" depicted as element 606).

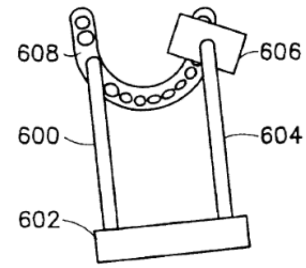

FIG.28

2. Claim 2 is anticipated by Mushabac

Claim 2: **<u>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.</u>**

Mushabac discloses that its x-ray picture is obtained from x-ray device that digitizes the data and feeds it to a computer: "data generating device 28 may take the form of an X-ray device such as used in current extra-oral or intra-oral radiology or other methodologies and basically comprises a source 30 of X-ray radiation and a detector 32 for receiving the X-ray radiation after it passes through a tooth and *converting the incident radiation into a digital stream fed to computer 24*." (Ex. 1003 at col. 10:49-56 (emphasis added).) This corresponds with the "tomosynthetic image" of Claim 2 because Mushabac discloses digitization and computer processing of the x-ray image, consistent with the claim construction of "tomosynthetic image as a "tomographic image, such as an x-ray image, that has been processed or generated with the aid of a computer." (*See* Ex. 1002, Declaration of Dr. Kraut, ¶ 96.)

Further, Mushabac describes x-ray data being fed to a computer that "may comprise two or more views of the same tooth from different angles." (Ex. 1003 at col. 27:65-67.) This allows the computer to "use a stereophotogrammetric triangulation program to determine the three-dimensional shapes and dimensions of structures internal to the subject tooth." (*Id*. at col. 28:1-3.). Thus, Mushabac's disclosure of taking multiple images of a tooth from multiple angles is the same as the claimed "computer tomography image," which means a "computer-processed radiographic images or slices of specific areas of a scanned object." (Ex. 1002, Declaration of Dr. Kraut, ¶ 97.)

3. Claim 3 is anticipated by Mushabac

Claim 3: <u>The method according to claim 1, wherein the three-dimensional, measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw.</u>

As discussed above for Claim 1, Mushabac discloses a 3-D optical scanner that "generates and transmits to computer 24 a digitized video signal containing information used by computer 24 to calculate the dimensions of the subject tooth and to display the tooth's structure in a three-dimensional graphic representation on monitor 34." (Ex. 1003 at col. 12:55-60.) After transmission of the 3-D optical data to the computer, the computer can display graphical representations of all visible surfaces of the teeth: "[t]he graphic representations include the visible three-dimensional surfaces of each such tooth, as well as invisible base line data fed to computer 24 by contour generating device 26." (*Id*. at col. 16:5-12.)

As explained in Dr. Kraut's Declaration, the "occlusal surface" of a tooth is simply the top or chewing surface. (Ex. 1002 at ¶ 27.) Because Mushabac discloses that the "visible three-dimensional surfaces of each [] tooth" are imaged, Mushabac necessarily discloses that the "occlusal surfaces" are captured, because the chewing surfaces are visible. (*Id*. at ¶¶ 98-99.)

4. Claim 4 is anticipated by Mushabac

Claim 4: <u>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.</u>

Mushabac explicitly discloses this limitation because it describes that the correlation of the x-ray and 3-D data (discussed above for Claim 1) can be accomplished with "T-shaped" radio-opaque "portions" (*i.e.*, "markers" in the language of the claim): "[i]n order to coordinate the data from optical generating device or assembly 22 and/or pantograph data generating device or assembly 26, on the one hand, with the data from X-ray data generating device or assembly 28, on the other hand, it is desirable to provide computer 24 with reference data to establish a common coordinate system . . . this common coordinate system may be established via . . . X-ray opaque or X-ray detectable portion 612 in the form of a cross-bar of a T shape[.]" (Ex. 1003 at col. 27:27-55; *see also* Ex. 1002, Declaration of Dr. Kraut, ¶ 100.)

5. Claim 9 is anticipated by Mushabac

Claim 9: <u>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.</u>

As explained above for Claim 1, Mushabac discloses a "drill assistance device" that is ground out from a "block of acrylic material." A block of acrylic material is clearly a "dimension-stable material," as acrylic is solid. Further, to act as a drill assistance device, the "block of acrylic material" in Mushabac would necessarily represent the occlusal surfaces (*i.e.*, the "chewing surfaces," as explained for Claim 4) of neighboring teeth as a negative with respect to an implant position, because for the "block of acrylic material" to be placed / installed in the mouth to aid in the dental implant surgery, it must necessarily include the form of the neighboring teeth for securing it in place. (*See* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 101-106.) Thus, Mushabac inherently discloses Claim 9.

6. Claim 10 is anticipated by Mushabac

Claim 10: <u>The method according to claim 9, wherein the drill assistance device contains a bore hole position that serves as a guide for the drill.</u>

Again, Mushabac discloses a "block of acrylic material" that acts as the surgical guide / drilling assistance device: "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. 1003 at col. 26:62 - col. 27:11 (emphasis added); *see also* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 107-108.)

B. GROUND 2: CLAIMS 1-4 AND 9-10 ARE INVALID UNDER 35 U.S.C. § 102 AS ANTICIPATED BY FORTIN

1. Claim 1 is anticipated by Fortin

Preamble: <u>Method for producing a drill assistance device for a tooth implant in a person's jaw, comprising the following process steps:</u>

To the extent that the preamble is limiting, Fortin discloses a method for producing a drill assistance device for a tooth implant in a person's jaw. (Ex. 1002, Declaration of Dr. Kraut, ¶ 112.) Specifically, Fortin discloses the production of a "drill splint," which is placed in a person's mouth and provides a guide for drilling into the bone of a patient's jaw for the purpose of inserting an implant. (Ex. 1004 at 4 ("By introducing the drill into the linear guide, the clinician can easily perform a perfect fit with the implant on the bone.").)

Element [a]: <u>taking an x-ray picture of the jaw and compiling a corresponding measured data record,</u>

Fortin discloses using "computed tomography (CT)," which is understood by one of ordinary skill in the art to be a form of x-ray photography. (Ex. 1004 at 1; *see also* Ex. 1001, '006 Patent, at col: 2:46-48; Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 29 and 114.) Specifically, Fortin discloses the use of a splint that covers "the maxilla" and serves as a "radiographic template." (Ex. 1004 at 1.) The "patient's tooth shapes are modeled in the splint" and the splint is covered with a "radiopaque resin"—*i.e.*, it is not penetrated by x-rays. (*Id.* at 3-4.) "With the template in the patient's mouth, CT scans are acquired with re-sliced frontal or sagittal images through the area of [a radiopaque] pin." (*Id.* at 1.)

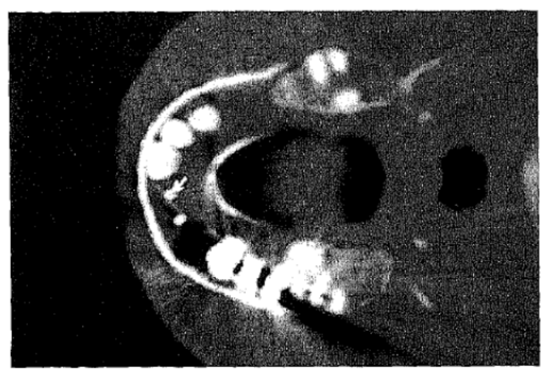

Fig. 2. Original CT slice. The arrow indicates the prosthesis axis (radiopaque pin). The splint surface is easily detected because of the radiopaque resin that covers the splint.

An example of such a CT image is included as Figure 2 of Fortin, to the right.

Fortin discloses creation of a data record corresponding to the CT images by creating a "three dimensional (3-D) CT image dataset[.]" (*Id.* at 2.) This dataset includes "a coordinate system which includes . . . the CT densities in 3-D[.]" (*Id.* at 3.) Therefore, Fortin discloses taking an x-ray picture and compiling a corresponding measured data record. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 113-122.)

Element [b]: <u>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>

Fortin discloses the optical scanning of the splint, which covers the "entire [] maxilla" and therefore necessarily replicates the visible surface of the upper jaw and teeth, which are part of the maxilla. (Ex. 1004 at 1; Ex. 1002, Declaration of Dr. Kraut, at ¶ 27.) Specifically, Fortin discloses that the "splint is used as a reference structure" and is optically measured using "a moving laser plane coupled with a video camera." (Ex. 1004 at 3.) Fortin also discloses measuring the splint using "an optical 3-D pointer." (*Id.* at 4.) The result of either of these optical measurements is a three-dimensional coordinate system that can be reconciled with the coordinate system created by the CT dataset. (*Id.* at 3.) Therefore, Fortin discloses three-dimensional optical measuring of the visible surfaces of the jaw and teeth and compilation of a corresponding measured data record. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 123-125.)

Element [c]: <u>correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,</u>

Fortin discloses correlating the CT dataset with the optically measured dataset via a "rigid-body transformation between the surface segmented from the CT image dataset and the surface acquired with the 3-D sensor[.]" (Ex. 1004 at 3.) Figure 8 of Fortin, reproduced to the right, shows the registration (*i.e.*, "correlation," in the language of the claim) between these two datasets.

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.

Therefore, Fortin discloses correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 126-128.)

Element [d]: <u>determinating[sic] the optimal bore hole for the implant, based on the x-ray picture, and</u>

Fortin discloses determining the "optimal implant axis"—*i.e.*, the size and placement of the implant by reviewing the two-dimensional CT images. (Ex. 1004 at 2.) The clinician switches between two CT images, each representing a different plane, until he or she finds "the optimum implant position at the intersection of these two planes." (*Id.*) "The width and height of the implant can also be determined at this stage." (*Id.*) Figure 3 of Fortin, reproduced below, show examples of these images.

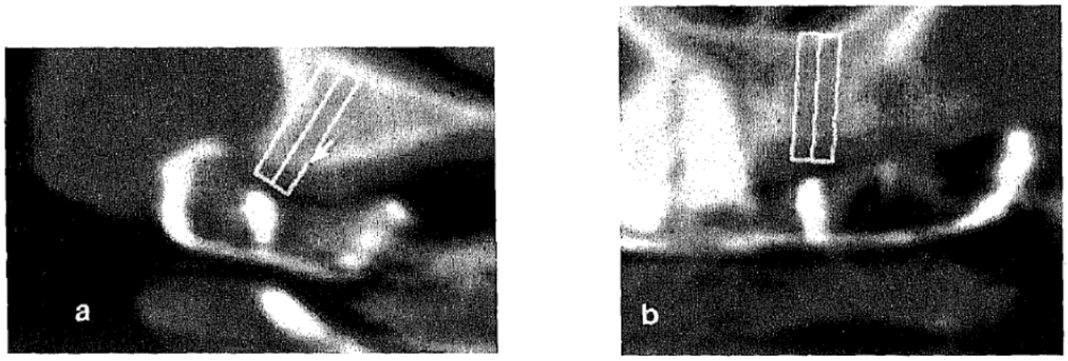

Fig. 3. Simulation of fixture axis. A custom software builds re-sliced sections passing by radiopaque pin inserted into the splint. There is no interpolation between acquisition slices, therefore the height of the structures seems to be smaller, but we have more information on the cancellous bone density using raw CT values instead of interpolated values. At that stage, the clinician can define the height and the width of the implant. Image **(a)** is the pseudo-frontal section, while **(b)** is the pseudo-sagittal section. Both pseudo-frontal and pseudo-sagittal planes are interactively modified until the optimal axis, which is the intersection of these two planes, is defined.

Therefore, Fortin discloses determining the optimal bore hole for the implant based on the x-ray picture. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 129-130.)

Element [e]: <u>determinating[sic] a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.</u>

Fortin discloses that "the optimal trajectory, previously defined in the CT [*i.e.*, x-ray] coordinate system, is transferred to the splint [*i.e*, optical measurement] coordinate system." (Ex. 1004 at 3.) Then "a guiding system linked and calibrated with the 3-D sensor . . . performs the drilling of a linear guide into the splint that coincides with the optimal axis." (*Id*.) Fortin also discloses that the "patient's tooth shapes [are] modeled in the splint." (*Id.* at 4.) The drilling of the pilot hole is shown in Figure 9 of Fortin, reproduced to the right.

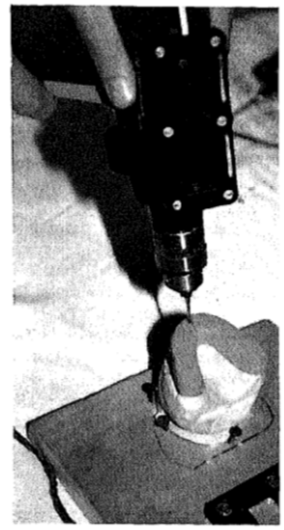

Fig. 9. A third rigid body is mounted on a calibrated drill. As soon as the drill position and orientation are superimposed with the definitive axis defined on the splint coordinate system, the operator pierces a linear guide in the splint.

Therefore, Fortin discloses determining a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 131-133.)

2. Claim 2 is anticipated by Fortin

Claim 2: **<u>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.</u>**

Fortin discloses that the x-ray picture is taken using "computed tomography," which is uploaded to a computer "workstation." (Ex. 1004 at 1-2.) Therefore, Fortin discloses an x-ray picture that is a computer tomography image. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶ 134.)

3. Claim 3 is anticipated by Fortin

Claim 3: <u>The method according to claim 1, wherein the three-dimensional, measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw.</u>

Fortin discloses that the splint that is optically measured covers "the maxilla" and the "patient's tooth shapes are modeled in the splint." (*Id.* at 1,4.) Therefore, Fortin discloses that the three-dimensional, measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw, for the same reasons as explained above for Claim 3 in view of Mushabac. (*See also* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 135-136.)

4. Claim 4 is anticipated by Fortin

Claim 4: <u>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.</u>

Fortin discloses that a "radiopaque pin is inserted into" the splint before the CT images are taken. (Ex. 1004 at 2.) This is shown in Figure 2 of Fortin, reproduced above regarding Element 1[i]. The radiopaque pin is therefore a marker attached to the teeth used to correlate the CT images with the optically measured images, meeting this limitation. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 137-138.)

5. Claim 9 is anticipated by Fortin

Claim 9: <u>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.</u>

Fortin discloses that the splint is made of an "autopolymerized clear acrylic resin" that models the "complexity of each patient's tooth shapes." (Ex. 1004 at 1 and 4.) Fortin also discloses that the linear guide is created by drilling through the splint. (*Id.* at 4-5.) Therefore, Fortin discloses grinding out the drill assistance device from a dimension-stable material, and that the material represents the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶ 139.)

6. Claim 10 is anticipated by Fortin

Claim 10: <u>The method according to claim 9, wherein the drill assistance device contains a bore hole position that serves as a guide for the drill.</u>

Fortin discloses that "the aim of our technique is to drill a linear guide into the splint to transfer the planned implant on the maxilla." (Ex. 1004 at 3.) To achieve this, "a cylindrical hole coincident with the optimal axis is made with a drill into the splint." (*Id.*) Fortin discloses that once the splint is placed in the patient's mouth "[b]y introducing the drill into the linear guide, the clinician can easily perform a perfect fit with the implant on bone." Therefore, Fortin discloses that the drill assistance device contains a bore hole position that serves as a guide for the drill. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶ 140.)

C. GROUND 3: CLAIMS 1-3 AND 9-10 ARE INVALID UNDER 35 U.S.C. § 102 AS ANTICIPATED BY BANNUSCHER

1. Claim 1 is anticipated by Bannuscher

Preamble: <u>Method for producing a drill assistance device for a tooth implant in a person's jaw, comprising the following process steps:</u>

To the extent that the preamble is limiting, Bannuscher expressly discloses a method "for producing a drill assistance device for a tooth implant in a person's jaw." (Ex. 1002, Declaration of Dr. Kraut, ¶ 144.) For example, Bannuscher teaches a "method for preparing a surgical template [*i.e.*, the "drill assistance device," in the language of the claim] for a dental implant surgery for installation of implants in the upper and/or lower jaw[.]". (Ex. 1005 at 1.)

Element [a]: <u>taking an x-ray picture of the jaw and compiling a corresponding measured data record,</u>

Bannuscher discloses that its "surgical template" (*i.e.*, the "drill assistance device," in the language of the claim) is produced by reference to three-dimensional and x-ray data, both of which are input into a computer: "a method for preparing a surgical template for a dental implant surgery for installation of implants in the upper and/or lower jaw, [that uses] a three-dimensional model geometry of the mouth and jaw area and an X-ray of the same are entered, digitally and relative to the patient's skull, into a computer." (Ex. 1005 at 1.) Therefore, Bannuscher explicitly discloses the taking of an x-ray picture of the jaw and inputting the same into a computer, which corresponds with "compiling a corresponding measured data record," as required by this claim limitation. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 145-146.)

Element [b]: <u>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>

As discussed above, Bannuscher discloses that its method for producing a surgical template includes obtaining "*a three-dimensional model geometry* of the mouth and jaw area and an X-ray image of the same are *entered*, digitally and relative to the patient's skull, *into a computer*." (Ex. 1005 at 1 (emphasis added).) In this way, the "basic statics [*i.e.*, dimensions] of both the upper and lower jaws are recorded [.]" (*Id*. at 3.) Thus, Bannuscher discloses obtaining a 3-D measuring of the physical characteristics of a patient's jaw and teeth, and inputting that data into a computer, which corresponds with, respectively, "obtaining a visual representation of the actual physical proportions of" the patient's jaw and teeth and "creating a *digital* representation" thereof, according to the proposed claim constructions for this claim limitation. Therefore, Bannuscher expressly discloses this claim limitation. (Ex. 1002, Declaration of Dr. Kraut, ¶¶ 147-149.)

Element [c]: <u>correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,</u>

Bannuscher discloses that the x-ray data and 3-D geometric data are both input into a computer, and that the surgical guide is fashioned from comparing both sets of data, thereby showing that the x-ray and 3-D data records are "correlated." (Ex. 1002, Declaration of Dr. Kraut, ¶¶ 150-153.) Specifically, Bannuscher discloses that, "[i]n a surgical template for dental implant surgery for installation of implants in the upper and/or lower jaw, to be able to attach a drilling device during the implant surgery, the drilling opening areas and bore angles are so arranged as to be aligned with the *optimized implant position* and the existing vertical bone *based on a three-dimensional model geometry of the mouth and jaw area and an X-ray image of the same*." (Ex. 1005 at 3-4 (emphasis added).) In fact, Bannuscher explains that the "core idea of the [its] invention is to *combine* the X-ray diagnostics and the model or oral situation of the patient." (*Id*. at 5 (emphasis added).)

Bannuscher confirms that this combination of x-ray and 3-D image data is used to create optimal bore holes in a drill assistance device: ". . . any angle, determined by the *combination of the three-dimensional model geometry and the X-ray of the mouth or jaw area of the patient*, can be made on a surgical template arranged on the three-dimensional geometric model. After the [bore] holes in the surgical template are made with regard to their areas and their bore hole opening angle, the surgical template is removed from the device illustrated in Figures 1 to 3, and may then be used in the operation in the mouth of the patient." (*Id*. at 6.)

Element [d]: <u>determinating[sic] the optimal bore hole for the implant, based on the x-ray picture, and</u>

Again, Bannuscher discloses that the basic structures of the patient's jaw are obtained, including internal bone structures, from the x-ray images. (Ex. 1005 at 1.) The optimal bore hole for the implant is based on the existing bone structures, as determined by the x-ray picture: "The basic structure of both the upper and the lower jaws is recorded. Regions intended to be replaced by supporting zones are labeled and transferred to the X-ray image. *An optimized implant position is compared with the existing vertical bone*." (*Id*. (emphasis added).)

Therefore, Bannuscher expressly describes " determinating[sic] the optimal bore hole for the implant, based on the x-ray picture." (Ex. 1002, Declaration of Dr. Kraut, ¶¶ 154-155.)

Element [e]: <u>determinating[sic] a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.</u>

Bannuscher discloses that the drilling locations and angles, such as the bore boles and pilot holes, are determined with reference to the x-ray picture and 3-D geometric data. (*Id*. at ¶¶ 156-158.) For example, Bannuscher teaches that, "the drilling opening areas and bore angles are so arranged as to be aligned with the *optimized implant position* and the existing vertical bone supply *based on a three-dimensional model geometry of the mouth and jaw area and an X-ray image of the same*." (Ex. 1005 at 3-4 (emphasis added).) And all drilling locations, including the mounting / pilot holes, are determined in this fashion in Bannuscher: "*any angle*, determined by the *combination of the three-dimensional model geometry and the X-ray of the mouth or jaw area of the patient*, can be *made on a surgical template* arranged on the three-dimensional geometric model. *After the [bore] holes in the surgical template are made* with regard to their areas and their bore hole opening angle, the surgical template is removed from the device illustrated in Figures 1 to 3, and may then be used in the operation in the mouth of the patient." (*Id*. at 6 (emphasis added).)

2. Claim 2 is anticipated by Bannuscher

Claim 2: <u>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.</u>

Bannuscher discloses that the known art includes the taking of "x-ray panoramic image[s]." (Ex. 1005 at 1-2.) Bannuscher explains that its disclosed invention uses this known technology for its x-ray imaging. (*See id*. (the "invention is, based on the above-described prior art, to provide a method of manufacturing a surgical template for a dental implant surgery[.]").) Further, Bannuscher discloses that "an x-ray image of the patient in the form of an orthopantomogram is made." (*Id*. at 6.) The term "orthopantomogram" is a commonly used term that denotes a panoramic x-ray of the upper and lower jaw.(Ex. 1002, Declaration of Dr. Kraut, at ¶ 160.) Thus, Bannuscher discloses that its x-ray picture is a "panoramic tomography image."

3. Claim 3 is anticipated by Bannuscher

Claim 3: <u>The method according to claim 1, wherein the three-dimensional, measured, visible surfaces are the occlusal surfaces of neighboring teeth located on the jaw.</u>

As discussed above, Bannuscher discloses that the 3-D geometric model of the patient's jaw and teeth includes the "basic structure of both the upper and the lower jaws[.]" (Ex. 1005 at 1.) For the same reasons as explained above for Claim 3 in view of Mushabac, the structure of upper and lower jaws will include the occlusal surfaces of the neighboring teeth. Further, Bannuscher expressly explains that, "[f]or the functional design of the implantological prosthetic planning, *the entire occlusion can be recorded* and all necessary parameters can possibly be connected to each other." (*Id*. at 4 (emphasis added).) Thus, Bannuscher discloses this Claim. (Ex. 1002, Declaration of Dr. Kraut, ¶¶ 161-162.)

4. Claim 9 is anticipated by Bannuscher

Claim 9: <u>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.</u>

As shown above, Bannuscher discloses that its surgical template (*i.e.*, the "drill assistance device," in the language of the claim) is planned "*based on a three-dimensional model geometry of the mouth and jaw area and an X-ray image of the same*." (Ex. 1005 at 4 (emphasis added).) The surgical guide is ground out from dimension stable material as explained on page 2 of Bannuscher (disclosing that surgical templates are "made of plastic material") and page 6 of Bannuscher (explaining that the surgical template can be used to guide a drill). And because the surgical template is a 3-D geometric model of the patient's upper and lower jaw, it includes the occlusal surfaces of neighboring teeth as a negative with respect to an implant position as a simple matter of human anatomy. (Ex. 1002, Declaration of Dr. Kraut, ¶ 163.) In fact, as explained above for Claim 9 in view of Mushabac, the drill assistance device must be fabricated this way in order to be placed in the patient's mouth and guide the drilling operation. Therefore, Bannuscher discloses Claim 9. (*See also id*. at ¶¶ 163-166.)

5. Claim 10 is anticipated by Bannuscher

Claim 10: <u>The method according to claim 9, wherein the drill assistance device contains a bore hole position that serves as a guide for the drill.</u>

As explained above, Bannuscher discloses that, "[a]fter the [bore] holes in the surgical template are made with regard to their areas and their bore hole opening angle, the surgical template is removed from the device illustrated in Figures 1 to 3, and *may then be used in the operation in the mouth of the patient*." (*Id*. at 6 (emphasis added).) Thus, Bannuscher discloses "wherein the drill assistance device contains a bore hole position that serves as a guide for the drill." (Ex. 1002, Declaration of Dr. Kraut, ¶¶ 167-168.)

D. GROUND 4: CLAIMS 1-4 AND 9-10 ARE RENDERED OBVIOUS BY FORTIN OR BANNUSCHER IN VIEW OF MUSHABAC, MASSEN, OR WILLER

Claim 1, element [b]: <u>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>

Fortin anticipates Claims 1-4 and 9-10 (*see* Section VI.B, above) and Bannuscher anticipates Claims 1-3 and 9-10 (*see* Section VI.C, above). As discussed in those sections, Fortin discloses that a patient's jaw is measured with "a moving laser plane coupled with a video camera" (Ex. 1004 at 3) or "an optical 3-D pointer" (*id.* at 4). Bannuscher discloses obtaining "a three-dimensional geometric model of the oral and mandibular area and an x-ray thereof [and] input[ting] [them] digitally into a computer with the patient's skull references." (Ex. 1005 at 1.) To the extent not anticipated, Petitioner maintains that the claims should alternatively be cancelled as being obvious under 35 U.S.C. § 103(a) over each of Fortin and Bannuscher in view of Mushabac, Massen, or Willer. (*See* Ex. 1002, Declaration of Dr. Kraut, ¶¶ 170-188.)

A person of ordinary skill in the art would have had a reason at the time of the alleged invention for making these combinations. For one, each of the references are directed to the same problem—*i.e.*, using imaging and/or modeling technology to aid in the planning of dental implant surgery. (*See*, *e.g.*, Ex. 1004, Fortin, at 1; Ex. 1005, Bannuscher, at 1; Ex. 1003, Mushabac, at Abstract; Ex. 1006, Massen, at col. 1:15-24; Ex. 1007, Willer, at 346; *see also* Ex. 1002, at ¶ 176.) Further, a person of ordinary skill would recognize that the finite ways of obtaining a three-dimensional image of a patient's jaw and teeth are interchangeable design choices, and that choosing the optical scanning methods disclosed in Mushabac, Massen, or Willer over those disclosed in Fortin and Bannuscher would be an simple substitution of one known element for another to obtain predictable results—*e.g.*, an actual 3-D image of a patient's jaw and teeth. (Ex. 1002 at ¶¶ 177-178.) A person of ordinary skill in the art would also be motivated to use the methods disclosed in Mushabac, Massen, or Willer for possibly providing greater realism or clarity regarding the patient's jaw and teeth, as compared to the methods disclosed in Fortin or Bannuscher. (*Id*. at ¶ 179.) Lastly, Fortin and Bannuscher disclose that their 3-D data is simply digitized into computer form for later combination with other image data (*see* Sections VI.B and C, above), and this is the same for Mushabac, Massen, and Willer, as discussed below. Thus, for at least that reason, it would be obvious for a person of ordinary skill to try, with a reasonable expectation of success, the methods in Mushabac, Massen, and Willer for obtaining a three-dimensional measuring of the jaw and teeth. (Ex. 1002 at ¶ 178.)

Each of Mushabac, Massen, and Willer explicitly disclose "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," as discussed below. Thus, the combination of Fortin with either Mushabac, Massen, or Willer renders obvious Claims 1-4 and 9-10, and the combination of those references with Bannuscher renders obvious Claims 1-3 and 9-10.

Mushabac. Mushabac expressly discloses this claim limitation as explained above in Section VI.A. For example, Mushabac discloses an "opto-electrical transducer 48 such as a charge-coupled device for optically sensing or scanning the tooth surface" (Ex. 1003 at col. 11:35-41) and digitizing this image data for input into a computer (*id*. at col. 12:55-60).

Massen. Massen discloses that "an optical three-dimensional measuring probe is utilized to generate a three-dimensional image of a single tooth or a group of teeth within the oral cavity of a patient." (Ex. 1006 at col. 4:14-17.) Massen further describes that its 3-D optical scanner can obtain an "image of the occlusal surface of the oppositely located tooth [from the implant site.]" (*Id*. at col. 6:58-62.) Massen explains that the optical 3-D image data is "projected into a form suitable for processing by [a] microprocessor." (*Id*. at col. 3:22-37.)

Willer. To obtain computer models of the patient's teeth and jaw for planning a dental implant, Willer provides that "surface and contact and occlusal surfaces of the adjacent and opposing teeth [in relation to the planned restoration site] . . . are digitized." (Ex. 1007 at 347.) This is accomplished with "an optical sensor" that "allows the generation of a 3-dimensional data record [in a computer] for each superstructure." (*Id*.) The optical sensor and an exemplary 3-D model of a tooth from the Willer computer-aided design (CAD) system is shown below:

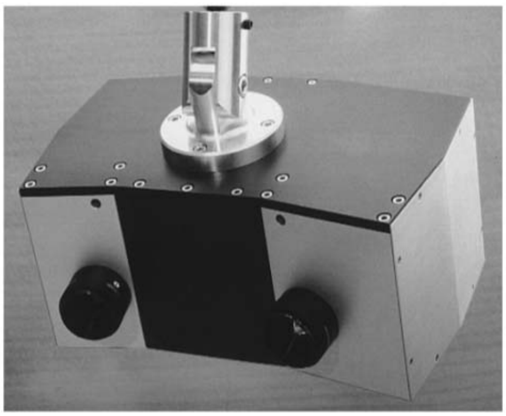

Fig. 1. Optical setup for data recording. Sensor consists of white light projector and CCD camera. Object to be measured is moved on rotatable table in front of sensor.

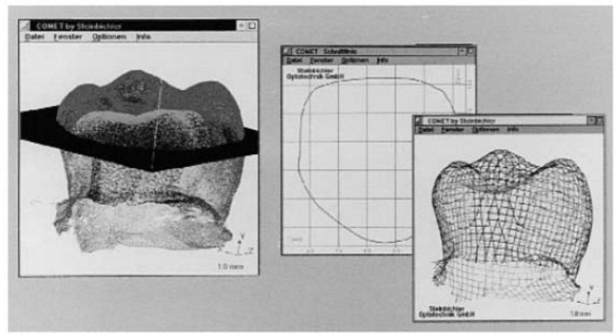

Fig. 4. Point cloud of COMET System.

E. GROUND 5: CLAIM 5 IS INVALID UNDER 35 U.S.C. § 103 OVER MUSHABAC IN COMBINATION WITH POIRIER

Claim 5: <u>The method according to claim 4, wherein the marker comprises a ball shaped body.</u>

As described above, Mushabac discloses each and every element of Claim 4 of the '006 Patent. Both Mushabac and Poirier disclose methods for dental implant surgery using a combination of radiographic and surface imaging. (Ex. 1003, Musabac, at col. 1:15-18, col. 4:3-10; Ex. 1008, Poirier, at col. 6:16-26.) Both Mushabac and Poirier use radiopaque markers for correlation. (Ex. 1003, Mushabac, at col. 27:57-64; Ex. 1008, Poirier, at col. 5:46-62.) While Mushabac discloses use of a "T-shaped" radiopaque element, it notes that "it is to be understood that numerous other shapes may be used." (Ex. 1003, Mushabac, at col. 27:58.) Thus, Mushabac clearly provides a reason for one of ordinary skill in the art to use other shaped markers, such as taught by Poirier, which discloses use of spherical—*i.e.*, ball-shaped—markers . (Ex. 1008, Poirier, at col. 5:46-62.) It would have been obvious to replace the T-shaped radiopaque element disclosed by Mushabac with the ball-shaped markers disclosed by Poirier. (*See also* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 189-196.)

F. GROUND 6: CLAIM 5 IS INVALID UNDER 35 U.S.C. § 103 OVER FORTIN IN COMBINATION WITH POIRIER

Claim 5: <u>The method according to claim 4, wherein the marker comprises a ball shaped body.</u>

As described above, Fortin discloses each and every element of Claim 4 of the '006 Patent. Both Fortin and Poirier disclose methods for producing a drill guide for dental implant surgery using a combination of radiographic and surface imaging. (Ex. 1004, Fortin, at 5; Ex. 1008, Poirier, at col. 6:16-26.) Both Fortin and Poirier disclose presenting two angles to the clinician to determine proper placement of the drill axis. (Ex. 1004, Fortin, at 2, Figure 3; Ex. 1008, Poirier, at col. 6:6-15.) And both Fortin and Poirier use radiopaque markers for correlating two different dental images, such as x-ray pictures and three-dimensional optical images. (Ex. 1004, Fortin, at 2, Figure 3; Ex. 1008, Poirier, at col. 5:46-62.)

While Fortin discloses use of a radiopaque pin, Poirier discloses use of radiopaque spheres—*i.e.*, ball-shaped bodies. (*Id*.) It would have been obvious to combine the methods disclosed by Fortin and Poirier by replacing the radiopaque pin disclosed by Fortin with the ball-shaped markers disclosed by Poirier. (*See also* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 189-196.)

G. GROUND 7: CLAIMS 4 AND 5 ARE INVALID UNDER 35 U.S.C. § 103 OVER BANNUSCHER IN COMBINATION WITH POIRIER

1. Claim 4 is obvious over Bannuscher combined with Poirier

Claim 4: <u>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.</u>

As described above, Bannuscher discloses each and every element of Claim 1 of the ’006 Patent. Both Bannuscher and Poirier disclose methods for producing a template for dental implant surgery using a combination of radiographic and surface imaging. (Ex. 1005, Bannuscher, at 2; Ex. 1008, Poirier, at col. 6:16-26.) Both Bannuscher and Poirier disclose use of a combination of x-ray imaging and three-dimensional surface modeling. (Ex. 1005, Bannuscher, at 3; Ex. 1008, Poirier, at col. 6:16-26.) Bannuscher discloses use of the patient's skull references and basic structure of the upper and lower jaw to correlate the x-ray picture and surface model. (Ex. 1005, Bannuscher, at 3.) As described above, Poirier discloses the use of markers attached to the teeth to correlate the x-ray picture and the surface model. (Ex. 1008, Poirier, at col. 5:46-62.)

Therefore, it would have been obvious to combine Bannuscher and Poirier, such that the correlation disclosed in Bannuscher used markers attached to the teeth as disclosed by Poirier. (*See also* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 197-201.)

2. Claim 5 is obvious over Bannuscher combined with Poirier

Claim 5: <u>The method according to claim 4, wherein the marker comprises a ball shaped body.</u>

As described above, Claim 4 of the '006 Patent is obvious over a combination of Bannuscher and Poirier. As described above, the combination of Bannuscher and Poirier uses the radiopaque markers disclosed by Poirier to correlate the x-ray picture and the surface model. As described above, Poirier discloses that these markers are spherical—*i.e.*, ball-shaped. It would have been obvious to combine Bannuscher and Poirier by using the ball-shaped markers disclosed by Poirier to correlate the x-ray picture and surface model disclosed in Bannuscher. (*See also* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 197-201.)

H. GROUND 8: CLAIMS 6 AND 7 ARE INVALID UNDER 35 U.S.C. § 103 OVER MUSHABAC, FORTIN, OR BANNUSCHER IN COMBINATION WITH WEESE

1. Claim 6 is obvious over Mushabac, Fortin, or Bannuscher combined with Weese

Claim 6: <u>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.</u>

Mushabac, Fortin, and Bannuscher anticipate Claim 1, as explained above. (Sections VI.A-C.) To the extent that these references do not disclose the "method according to claim 1, wherein the measured data records of the three-dimensional measurement are converted to a pseudo-x-ray picture," Weese explicitly teaches this subject matter, as discussed below.

Weese generally concerns the correlation of x-ray pictures with three-dimensional CT images in order to improve "the placement of pedicle screws in spine surgery." (Ex. 1009 at 1.) The screws "must accurately be drilled into the vertebra to avoid damage, especially to the spinal cord." (*Id*.) In this way, Weese is concerned with optimal drilling locations during surgery, just as is the '006 Patent and Mushabac, Fortin, and Bannuscher, as discussed above.

As opposed to the marker-based technique for correlating x-ray pictures and 3-D images, Weese discloses a method "based on the computation of pseudo projections from the [3-D] CT image which are correlated to the x-ray projection." (*Id*. at 2.) In this context, a person of ordinary skill in the art would understand that a "pseudo projection" is a "pseudo x-ray projection." (*Id*.; *see also*, Ex. 1002, Declaration of Dr. Kraut, ¶ 209.) Further, Weese teaches that the computation of the pseudo projections from the 3-D CT image (*i.e.*, "wherein the measured data records of the three-dimensional measurement are converted to a pseudo-x-ray picture," in the language of the claim) factors in standard x-ray absorption values: "[t]he absorption coefficients depend on the energy of the x-ray beam. . . . [so] the gray-values in the pseudo projection are scaled with a proper factor." (Ex. 1009 at 4.) Weese shows an exemplary pseudo x-ray picture converted from a 3-D CT image in Figure 3a.

Fig. 3a Pseudo projection of the CT image.

Accordingly, Weese discloses "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." While Weese deals with 3-D CT images and x-ray pictures of a patient's vertebra, the same techniques apply equally if those images were of a patient's jaw, as would be the case if Weese's conversion technique were used in the methods of Mushabac, Fortin, and Bannuscher, as discussed above.

A person of ordinary skill in the art would have had a reason at the time of the alleged invention for making these combinations. Each of the references are directed to similar problems—*i.e.*, combining two sets of imaging data to aid in the planning of surgical procedures. Further, a person of ordinary skill would recognize that the finite ways of correlating a three-dimensional image of a patient's jaw with an x-ray picture of the same are interchangeable design choices, and that choosing the conversion technique disclosed in Weese over the marker-based methods disclosed in Mushabac and Fortin (*see* the analysis for Claim 4 for Mushabac and Fortin, above, in Sections VI.A and B, respectively) would be an simple substitution of one known element for another to obtain predictable results—*e.g.*, a composite image of the patient's jaw. (Ex. 1002, Declaration of Dr. Kraut, ¶ 207.) A person of ordinary skill in the art would also find the use of pseudo x-ray imaging to correlate x-ray images to 3-D images, as disclosed by Weese, desirable because it would eliminate the need for the placement of markers in the patient's mouth to correlate the images for pre-operative planning. (*Id*.)

Therefore, Mushabac, Fortin, or Bannuscher in combination with Weese renders Claim 6 obvious. (*See id*. at ¶¶ 202-212.)

2. Claim 7 is obvious over Mushabac, Fortin, or Bannuscher combined with Weese

Claim 7: <u>The method according to claim 6, wherein the x-ray picture and the pseudo-x-ray picture are superimposed from several directions</u>.

As described above, Claim 6 of the '006 Patent is obvious over Mushabac, Fortin, or Bannuscher in view of Weese. Weese further discloses that the x-ray picture and pseudo-x-ray picture are correlated (*i.e.*, "superimposed," in the language of the claim) in several directions. Specifically, "the location and orientation of the CT image with respect to the x-ray device" is illustrated in Figure 1, which shows that the images are correlated in the x, y, and z directions.

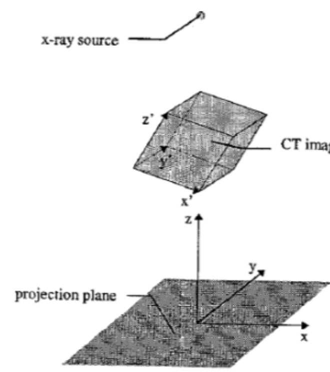

Fig. 1 Geometrical setup and coordinate systems.

Therefore, the combination of Mushabac, Fortin, or Bannuscher with Weese renders Claim 7 obvious. (*See* Ex. 1002, Declaration of Dr. Kraut, at ¶¶ 213-216.)

I. GROUND 9: CLAIM 8 IS INVALID UNDER 35 U.S.C. § 103 OVER FORTIN IN COMBINATION WITH WEESE

Claim 8: <u>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</u>.

As discussed above, the combination of Fortin and Weese renders Claim 7 obvious. Further, Fortin discloses that "computer tomography (CT)" scans are obtained of the patient's jaw (Ex. 1004 at 1.) As explained by Dr. Kraut, "one of ordinary skill in the art would understand that the medical grade CT scans of the patient's jaw disclosed in the Fortin Article would necessarily show the longitudinal and transverse sections of the jaw, because those sections are necessarily shown in three-dimensional images of the jaw. . . . this is a simple fact of three-dimensional CT images." (Ex. 1002 at ¶ 218.) Further, a person of ordinary skill in the art would understand that a CT scan could be used to show more than one panoramic view of the jaw because a CT scan is comprised of multiple x-ray slices of an object being imaged, such that more than one panoramic slice or image can be shown in a CT scan. (*Id*. at ¶ 219.)

Therefore, the combination of Fortin with Weese renders Claim 8 obvious. (*See id*. at ¶¶ 217-220.)

VII. CONCLUSION

In summary, there is a reasonable likelihood that Petitioner will prevail in its challenge of patentability for Claims 1-10 of the '006 Patent. Petitioner respectfully requests that a trial for *Inter Partes* Review of the '006 Patent be instituted and Claims 1-10 be rejected and canceled. Rejection and cancellation of Claims 1-10 would prevent Patent Owner from asserting the '006 Patent against technologies that were already well-known in the prior art.

Dated: April 15, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,319,006** and supporting materials (Exhibits 1001 - 1012 and Power of Attorney) have been served in its entirety this 15th of April, 2015, by Federal Express on Patent Owner at the correspondence address for the attorney of record for the 6,319,006 Patent shown in USPTO PAIR and the attorneys of record for Plaintiff in the concurrent litigation matter:

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