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Filed on behalf of: Sirona Dental Systems GmbH

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANATOMAGE, INC.,
Petitioner,
v.
SIRONA DENTAL SYSTEMS GMBH
Patent Owner.

Case IPR2015-01057
Patent 6,319,006

PATENT OWNER'S RESPONSE UNDER 37 C.F.R. § 42.120

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TABLE OF AUTHORITIES

Cases

Rules and Statutes

<u>**EXHIBIT LIST**</u>

Exhibit	Description
2001	Merriam-Webster’s Collegiate Dictionary, 10th Ed. Springfield, MA: Merriam-Webster, 1997
2002	Declaration of Dr. Douglas Erickson, D.D.S., M.S.
2003	Certified Translation of German Patent DE 195 10 294 A1 to Bannuscher
2004	Stedman’s Medical Dictionary 1077, 1095 (25th ed. 1990)
2005	[Reserved]
2006	U.S. Patent No. 5,939,211 to Mörmann
2007	[Reserved]
2008	U.S. Patent No. 943,113 to Greenfield
2009	U.S. Patent No. 5,888,065 to Sussman
2010	Dr. Doug Erickson, Guidance vs. Navigation in Dental Implant Planning and Placement, Presentation at the Design of Medical Devices Conference (Apr. 17, 2007)
2011	EP 0 834 292 A2 to Carlsson
2012	O. Schermeier et al., The precision of the RoboDent system – an in vitro study, CARS 2002, Proceedings of the 16th Int’l Congress and Exhibition, Paris, June 26-29, 2002, at 947-952
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2014	Robert L. Lee, *Jaw movements engraved in solid plastic for articulator, Controls. Part II. Transfer apparatus*, 22(5) J. Prosthetic Dentistry 513-527 (Nov. 1969)
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2025	R. Adell et al., *A 15-year study of osseointegrated implants in the treatment of the edentulous jaw*, 10 Int. J. Oral Surg. 387-416 (1981)
2026	Int'l Patent App. Pub. No. WO 95/28688 to Swaelens
2027	PDR Medical Dictionary, 1485-86, 1819-20, 1967 (1st ed. 1995)
2028	McGraw-Hill Dictionary of Scientific and Technical Terms 1640-41, 1779 (5th ed. 1994)
2029	Photographs of Physical Exhibit 1013 from the deposition of Dr. Richard A. Kraut
2030	U.S. Patent No. 5,598,454 to Truppe
2031	Prosecution History of U.S. Patent No. 6,319,006
2032	K. Verstreken et al., *Computer-Assisted Planning of Oral Implant Surgery, An Approach Using Virtual Reality*, Medicine Meets Virtual Reality, Health Care in the Information Age, Proceedings of Medicine Meets Virtual Reality 4, San Diego, Jan. 17-20, 1996, at 423-34

Sirona Dental Systems GmbH ("Patent Owner") submits this Response to the Petition of Anatomage, Inc. ("Petitioner") in the inter partes review ("IPR") of U.S. Patent No. 6,319,006 ("the '006 patent").

I. INTRODUCTION

The '006 patent is directed to a novel method for producing a drill assistance device of the type used in dental implant surgery. Such drill templates are placed in the mouth over the surgical site and contain a pilot hole which guides the path of a drill that bores a hole into a patient's jaw. That bore hole that is formed by the drilling can receive an implant. After the implant is placed, an abutment may be fixed on the implant, and a restoration (e.g., replacement tooth) may be secured on the abutment. In this way, the implant takes the place of the root of a natural tooth.

Determining the optimal path for a bore hole in a patient's jaw has been of great interest to dental clinicians. A preferred bore path engages quality bone while avoiding damage to other anatomical structures (e.g., veins, nerves, etc.). Further, it must secure precisely the replacement tooth in an aesthetically proper manner. '006 patent (Ex. 1001), 1:28-47.

Conventional systems/methods for planning and forming bore holes have generally been divided into two mutually exclusive groups – guidance systems and navigation systems. Guidance systems utilize drill templates, which are secured in the patient's mouth during surgery to control the path of the drill. Typically, clinicians formed drill templates by taking an impression of the patient's teeth and jaw, making a plaster cast from the impression, and using the plaster cast as a model on which the template could be molded to conform to the shape of the teeth. In this manner, the template would fit precisely into the patient's mouth during surgery. Clinicians often formed the pilot hole in the drill template freehand with reference to both the plaster model of the patient's teeth and an x-ray of the underlying anatomical structures. If the clinician was satisfied with the pilot hole, the thus formed template would restrict the path of the drill during surgery, to avoid misplacement. In this way, the clinician could judge a preferred drill path by visualizing the underlying anatomy from the x-ray (relative to the plaster model of the surface structure), while the template was mounted on the model. However, this process involved labor intensive casting and molding steps and required estimating the optimal pilot hole trajectory relative to the plaster model, using the clinician's best judgment.

Navigations systems eschewed drill templates (and the associated labor intensive casting) in favor of a real-time computer display of the underlying anatomical structure, sometimes superimposed with the surface structures. Ex. 2023, 87:1-16; 90:20-23. In some cases, the display could also include a virtual representation of the drill position relative to the anatomy. Ex. 2023, 156:22-25; 157:8-19. With that real time display, a surgeon would attempt to operate the drill in a freehand manner to engage quality bone shown on the display. However, this required that the clinician simultaneously monitor both the computer display showing a virtual representation of the drill relative to the underlying anatomical structures, and the actual surgical site in the patient's mouth where the real drill was inserted. Any error by the clinician during this process would result in a misplaced bore hole in the patient's jaw, which of course would be a very undesirable result.

Given the drawbacks of each method, dental clinicians searched for alternative processes to create an optimal bore hole. That search often resulted in increasingly complicated systems, as discussed in more detail below.

In view of these problems, the '006 patent introduced a simple and elegant solution in which a precise drill template could be formed based on computer modeling. In particular, the solution correlates x-ray data and data from a three-dimensional optical measurement of the surfaces of the teeth and jaw neighboring the surgical site, to provide a useful computer model of both the surface structures and underlying anatomy. From this data, not only can an optimal bore hole path be determined based on the x-ray of the bone, but a corresponding pilot hole position in a drill template can be determined relative to the optically measured surfaces of the neighboring teeth. With such a determination of the positioning of the pilot hole relative to the surfaces of the neighboring teeth, a precise drill template can be produced from the measured data.

The relative positioning can be replicated, for instance, using, in a preferred embodiment, a CAD/CAM system that forms a negative of the teeth and the pilot hole in a drill template. Ex. 2002, ¶¶ 56-58, 90. This approach can avoid the need for the time consuming casting and molding steps of the conventional guidance systems. *See* Ex. 2023, 92:21-93:22; 96:7-11; 113:5-12. Also, this approach can avoid the freehand drilling performed with navigation systems, inasmuch as a precise drill template guides the drill during the surgery.

In this regard, claim 1 of the ’006 patent recites a method of producing a drill assistance device that correlates data from both an x-ray and a three-dimensional optical measurement of the visible surfaces of the jaw and teeth, and then determines both (i) an optimal bore hole based on the x-ray and (ii) a pilot hole in the drill template relative to the surfaces of the neighboring teeth based on the x-ray *and the optical measurement*. Further, claim 9 recites that the device thus designed is ground out from a dimension-stable material, and that the dimension-stable material represents a negative of the surfaces of the neighboring teeth. This approach allows for the precise formation of a drill template in a manner that avoids drawbacks inherent in pre-existing guidance and navigation systems.

Mushabac does not describe a drill template at all, and instead describes a system in which a computer determines and displays a preferred bore hole path, and the surgeon tries to mimic the displayed path in a practice surgery, sometimes in association with a pantograph device. Mushabac's system does not describe any determination of a pilot hole relative to the surfaces of neighboring teeth based on a three-dimensional optical measurement. Instead, Mushabac's complicated mechanical pantograph device drills a hole in an acrylic block positioned away from the surgical site. That remote block is not a drill template because it is not positioned at the implant site and it does include a pilot hole to receive the drill that forms the bore hole during the surgical procedure. Petitioner's declarant, Dr. Kraut, agrees with Patent Owner's view of what a drill template is (Ex. 2023, 39:22-40:10; 36:16-37:6), but fundamentally misunderstands the operation of Mushabac.

Even leaving aside the fact that the remote block of Mushabac is not a drill template, Mushabac does not describe determining the hole in that block based on three-dimensional optical data, let alone three-dimensional optical data for neighboring teeth. Moreover, with respect to claim 9, Mushabac's acrylic block does not include a negative representation of surfaces of the neighboring teeth.

Accordingly, Petitioner has failed to demonstrate the unpatentability of any claim of the '006 patent. Nevertheless, out of an abundance of caution, Patent

Owner has submitted herewith a Contingent Motion to Amend, which presents an amended version of claim 1 (as substitute claim 19) that further defines over the prior art, as discussed in more detail below.

II. BACKGROUND

A. THE TECHNOLOGY OF THE ’006 PATENT

The ’006 patent describes a novel method for planning a drill assistance device, which can be used to assist in a surgical procedure to place an implant in a patient’s jaw. ’006 patent (Ex. 1001), 1:6-10. Dental implants typically screw into the patient’s jaw bone at the site of a missing tooth. Ex. 2002, ¶¶ 65-66; Ex. 2008, Figs. 1-5. Such an implant usually comprises a screw-like device positioned in a bore hole in the jaw and a crown or denture received thereon.

Placing dental implants is complicated, with the procedure requiring a dental clinician to first drill the bore hole, and then to secure a base of the implant in the bore hole. Typically, the dentist then secures an abutment and crown on top of the base. In planning the surgery and drilling the bore hole, the clinician must ensure that the bore hole engages quality bone to support the implant and avoids injuring nerves innervating the jaw. Ex. 2002, ¶ 67. A severed nerve could result in a loss of feeling in part of the patient’s face. Moreover, the bore hole and implant must be placed precisely so that the prosthesis can achieve proper aesthetics and function with respect to the other teeth in the patient's mouth (e.g., be properly aligned with the other teeth).

X-ray imaging helps dentists place implants. In particular, x-ray images provide subsurface information on, among other things, bone location, bone density, and nerve location. However, X-ray imaging cannot provide sufficiently precise information regarding the surface structure, because the dosage necessary to provide adequate resolution of surface structure using X-rays would be harmful to the patent. Ex. 2002, ¶ 68. During the actual surgery when viewing the implant site, the dentist sees only the surface of the jaw and teeth. Because the dentist cannot see the entire nerve and substructure during the procedure, he or she must rely on training, experience, and reference to the x-ray as to what lies below the visible jaw surfaces. Ex. 2002, ¶ 68.

Some practitioners performed implant surgery freehand, relying entirely on their training, experience and skill to form a proper bore hole in the patient's jaw. Ex. 2023, 92:4-7. With this approach, however, the quality of outcome was variable and depended largely on the individual practitioner's surgical skill. Two types of systems evolved to assist practitioners in planning and forming bore holes: guidance systems and navigation systems.

Guidance systems allowed the dentist to form a pilot hole in a drill template prior to surgery. While the drilling of the pilot hole in the template was often performed freehand with reference to both a model of the patient's jaw on which the template was mounted and an x-ray of the underlying anatomical structure, the dentist could make a sound determination concerning the drill path before actually drilling into the patient's jaw. Other methods used a fixed drill press, where the dentist manually adjusted the orientation of the drill template on an articulator relative to the fixed drill path. Ex. 2002, ¶¶ 70-72, 166-168; Ex. 2015, pp. 135-157. In either case, the drilling took place outside the confines of the patient's oral cavity. If satisfied with the template design, that template could then be placed in the patient's mouth to restrict the path of the drill along the pilot hole during surgery. However, this method required taking impressions of the patient's jaw, forming a cast of the impression to obtain a model of the jaw, and molding or otherwise forming a drill guide. Ex. 2023, 92:21-93:22. Further, the determination of the path of the pilot hole in the template still relied on the experience and judgment of the surgeon. Ex. 2023, 72:3-15. If a mistake was made in drilling the pilot hole, the surgical procedure would be compromised, and the surgeon would be unable to make any adjustments during the procedure.

To avoid this time consuming process, navigation systems provided a correlation of various sets of data to create a computer model of the anatomy of the patient's jaw and teeth, often with a virtual representation of the drill relative to the underlying anatomical structures. Ex. 2002, ¶¶ 73-74; Ex. 2010, 17-23; Ex. 2011, Abstract and Fig. 1; Ex. 2012, Abstract and Fig. 2. With this display of the position of the virtually represented drill relative to the underlying anatomical structures, the dentist could choose a bore hole path during surgery while simultaneously monitoring the display and the actual surgical site. Navigation systems offered an improvement over the unassisted freehand surgical approach, inasmuch as the practitioner would have access to more information about the underlying anatomical structures during the surgical procedure. However, monitoring both areas simultaneously proved difficult and the drill was still operated freehand, without any drill guide to limit the path. Ex. 2002, ¶ 76. Thus, the procedure allowed for human error.

The invention of the '006 patent provides a method that creates a precise drill guide using a correlation of x-ray data, for underlying anatomical structures, and three-dimensional optical data of the surfaces of the jaw and teeth. With this correlated data, the method determines both the optimal bore hole path for the implant and a pilot hole path in a drill template relative to the surfaces of the neighboring teeth. Ex. 2023, 114:3-4. With this second determination, the information needed to create a precise drill template is obtained without the need for the impression and casting steps of traditional guidance systems. Specifically, instead of taking a negative impression of the patient's teeth to obtain a representation of the occlusal surfaces, the optical measurement provides that information as a set of data. This allows for a determination of a pilot hole in a computer model relative to the optically measured surface structure. This calculation provides a precise indication of the position of the pilot hole relative to the surface structures of the teeth. With that determination, a precise drill template can be produced using that data to form, preferably, both the pilot hole and the negative representation of the patient's teeth in the proper alignment, and the need for the surgeon to operate a drill to try to place the pilot hole manually is avoided. At the same time, the system still results in a drill template that avoids the drawbacks of navigation systems (e.g., the requirement that the practitioner perform freehand drilling while simultaneously viewing and reacting to what they see on the display and at the surgical site during drilling).

While others in the field had attempted to improve on conventional of guidance and/or and navigation systems, the results often led to new complications. For example, Fortin (Ex. 1004) proposed a guidance system in which data concerning the drill template and underlying anatomical data were correlated in order to determine a pilot hole path in the template. Ex. 2002, ¶¶ 78-79. However, Fortin's system still relied on impressions of the patient's jaw to create the drill template and determine the pilot hole path. Ex. 1004, p. 53, col. 2, l. 2 – p. 54, col. 1, l. 4. Further, Fortin's system required that a CT scan be taken of the patient's underlying anatomical structure while the patient wore the molded drill template, which was covered in a radiopaque material. Ex. 1004, p. 53, col. 2, ll. 2-15. This allowed Fortin's system to correlate underlying anatomy and the radiopaque surface of the drill template with just a CT scan. Once a preferred pilot hole path was selected relative to that correlated data in a computer model, the actual pilot hole could be formed with reference to the known upper surface structure of the drill template obtained through the CT scan. However, not only did this method still rely on impressions of the patient's teeth, it further required the patient to undergo a CT scan while a mold created therefrom was held in his or her mouth. Ex. 2002, ¶¶ 78-80. Furthermore, to create the pilot hole, a drill with a 3D sensor had to be registered in space relative to reference points on the surface of the drill template, which had to be measured by a contact digitizer. Ex. 1004, Figs. 5, 7, 8, and 9. Thus, while a more precise pilot hole could be formed, the side effect was a more complicated and time consuming method. Ex. 2002, ¶ 79-80. Fortin's method did not use three-dimensional optical measurement of the visible surfaces of the patient's teeth at all, let alone in the efficient and precise manner claimed.

The '006 patent introduced a superior method for creating a surgical plan where others had failed. Specifically, the invention planned a pilot hole relative to surfaces of neighboring teeth obtained through a three-dimensional optical measurement. This allowed for creation of a precise drill template in a manner not previously known, in which the drill template limited the path of the drill during surgery to ensure proper bore hole placement.

B. THE ’006 PATENT CLAIMS

The challenged claims of the ’006 patent are directed to a method for producing a drill assistance device for use in placing an implant. Claim 1, the sole independent claim, reads as follows:

> 1. Method for producing a drill assistance device for a tooth implant in a person’s jaw, comprising the following process steps:
>
> taking an x-ray picture of the jaw and compiling a corresponding measured data record,
>
> 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,
>
> correlating the measured data records from the x-ray picture and from the measured data records of the three-dimensional optical measuring,
>
> determinating the optimal bore hole for the implant, based on the x-ray picture, and
>
> determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.

Thus, claim 1 requires correlating optical and x-ray images, planning a bore hole (*i.e.*, the hole to be drilled in a patient’s jaw) based on the x-ray, and planning a pilot hole (*i.e.*, the hole in the drill template through which the drill bit passes when drilling the bore hole into a patient's jaw) based on the correlated x-ray image and three-dimensional optical measurement.

Further, claim 9 recites that "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." In that manner, claim 9 provides a specific method of fabricating the drill assistance device through a grinding process, such as that used by CAD/CAM machines. '006 patent (Ex. 1001), 3:13-19. Such a procedure results in the formation of negatives of the occlusal surfaces of teeth neighboring the implant site, but is distinguished from a molding process. In particular, the drill assistance device may be milled by a machine with reference to the optical data of the measured occlusal surfaces.

Patent Owner has also submitted a Contingent Motion to Amend that proposes a substitute set of claims that further define novel aspects of the invention. The content of substitute independent claim 19 is discussed in that Motion, as well as below with respect to Mushabac.

III. PERSON OF ORDINARY SKILL IN THE ART

Petitioner assert that a person of ordinary skill in the art (POSA) would have held "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." Petition, 9:16-10:11. For purposes of this IPR proceeding, Patent Owner applies Petitioner's proposed definition of a POSA, as the Petitioner has failed to meet its burden even under its preferred definition. Ex. 2002, ¶¶ 17-21. Patent Owner reserves the right to challenge that definition in other proceedings. The relevant art is the field of dental implants. '006 patent (Ex. 1001), 1:5-2:10.

IV. CLAIM CONSTRUCTION

In an IPR, claims are given their "broadest reasonable construction in light of the specification of the patent in which [they] appear." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278-79 (Fed. Cir. 2015).

"Determinating a pilot hole in a drill template" – Petitioner did not construe this term. In the Decision on Institution, the Board construed the term to mean "defining a guide hole in a drill template for drilling a bore hole into the person's jaw." Decision (Paper No. 11), 8:21-9:2.

As described in the specification, pilot hole 17 is a hole in the drill guide through which the pilot drill actually passes while drilling bore hole 18 into a patient's jaw. '006 patent (Ex. 1001), 4:43-67; *see Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive;

it is the single best guide to the meaning of a disputed term.”). The pilot hole is positioned relative to the surfaces of the neighboring teeth so as to sit over the intended surgical site and actually receive the pilot drill bit during the drilling operation. ’006 patent (Ex. 1001), 1:28-46; Ex. 2031, 44 (Fig. 5). Moreover, a POSA would have understood a “pilot” hole in a drill template to be the hole that receives the “pilot” drill during drilling. Ex. 2002, ¶¶ 35-44.

By not construing the language, Petitioner has offered nothing to refute the evidence in this regard. Moreover, Petitioner’s own declarant agreed that a POSA would have understood a drill template to be an item positioned at an implant position, and the pilot hole to be a hole that receives the drill during formation of the bore hole in the jaw. Ex. 2023, 36:16-37:6; 39:22-41:9; 43:16-44:14 (“Q. [T]he drill template has to sit over the plan’s osteotomy site? A. Right. … [o]therwise, you’re not transferring the information from the model to the patient.”; “Q. So just to clarify for the record … the pilot hole that the drill passes through is over the planned osteotomy site --. A. Absolutely.”); 113:17-114:4.

Accordingly, the phrase “pilot hole in a drill template” should be construed to mean “a pilot hole in a drill template through which the pilot drill passes while drilling a bore hole into a patient’s jaw.” Ex. 2002, ¶¶ 35-44.

“Three-dimensional optical measuring of visible surfaces of the jaw and teeth” – The Board construed this phrase to mean “using light to measure the visible surfaces of the jaw and teeth in three dimensions." Decision (Paper No. 11), at 8. Patent Owner concurs with this construction and notes that it is supported by the Erickson Declaration and documents from the state of the art, which describe various methods for using light to make three-dimensional measurements of surface structures of teeth. Ex. 2002, ¶¶ 28-33; *see* Ex. 1006, 1:19-2:13 (describing techniques for making three-dimensional surface measurements using light); *see also* Ex. 2004, p. 1095 ("optics"); Ex. 2023, 116:14-117:5.

"Neighboring teeth" – Claim 1 recites using the measured surface structure data to determine "a pilot hole in a drill template relative to surfaces of *the neighboring teeth*." '006 patent (Ex. 1001), 5:16-17. In view of the language of the claim, which discusses the neighboring teeth relative to the pilot hole, and the content of the specification, a POSA would understand that "neighboring teeth" describes teeth adjacent the implant position (which corresponds to the pilot hole and bore hole). In particular, Fig. 5 illustrates "neighboring teeth" 11, 12, which neighbor implant position 9. '006 patent (Ex. 1001), 4:29-42. Further, surfaces 13, 14 of those neighboring teeth are the surfaces used to determine the relative position of the pilot hole. *Id.* Thus, "neighboring teeth" are "the teeth adjacent to the bore hole position." Ex. 2002, ¶¶ 46-52; Ex. 2023, 38:6-11 (acknowledging the meaning of "adjacent" teeth); 120:1-11; 212:6-9.

“Tomosynthetic image” (claim 2) – Petitioner alleges that a tomosynthetic image is not a term of art and that the term must simply refer to an x-ray generated with the aid of a computer. Petition, 13:1-9. Petitioner provides no independent evidence to support this position. However, patent literature established tomosynthesis was a known term in the dental arts referring to the use of multiple conventional x-ray shadows to mimic the three-dimensional, slice-by-slice images obtained by computer tomography. Ex. 2013, 1:10-2:35; 1:6-8 (“dental x-ray images”). Moreover, a digital x-ray is not the same as a tomograph, as alleged by Petitioner. Ex. 2027, pp. 1485 (“radiograph” and “digital r.”) and 1819 (“tomography” and “computed t.”). Thus, a POSA would have understood “tomosynthetic image” to refer to an image that mimics a tomograph using multiple x-ray shadows.

“Computer tomography image” (claim 2) – Petitioner acknowledges that a “computer tomography image” obtains “slices” of areas of a scanned image. Petition, 13:10-14. This type of image can be distinguished from conventional x-rays (also called shadowgraphs or conventional radiographs), which provide shadows of radiation passing through a body. Ex. 2023, 128:13-129:9; 124:7-128:12; Ex. 2028, p. 1640 (defining radiographs as “shadowgraphs”) and p. 1641 (radiography); Ex. 1011, 113, col.1, l. 16-p.116, col. 1, l. 24. *See id*. at Figs. 8-4 vs. Figs. 8-7. Computer tomography (CT) scans measure selected planes (or cross-sectional slices) of a volume that blur out images in other planes. Ex. 2027, p. 1819 (tomography). Thus, a POSA would have understood "computer tomography image" to mean an image obtained from one or more cross-sectional planes of the body. Ex. 2027, p. 1819 ("computed t. (CT)").

"Wherein the drill assistance device is ground out from a dimension-stable material …" (claim 9) – A POSA would have understood that a dimension stable material is a material that maintains its shape. Ex. 2002, ¶ 54. A POSA would have understood that the term "ground" refers to the act of grinding, which removes material by abrasive cutting to form a relief pattern, as acknowledged by Petitioner's declarant. Ex. 2023, 73:21-74:2 ("CAD/CAM machines have ways of removing material to create an object. That's grinding rather than drilling in my mind."); 75:6-18.

This process is also described in the specification with respect to the use of CAD/CAM machines that grind out patterns. '006 patent (Ex. 1001), 3:13-19 ("[u]sing the information that was obtained with respect to the surface structure, i.e., the occlusal surfaces of neighboring teeth, it is possible to *grind out* on a CAD/CAM unit an implant assistance device in the form of a drill template." (emphasis added)); *see also*, Ex. 2006, 1:44-49; 3:53-62; 5:66-6:6; Fig. 1; Ex. 1007, p. 346, col., 2, ll. 1-12.

A POSA would have understood that “said material” in claim 9 refers to the dimension-stable material that makes up the drill assistance device, and that the drill assistance device represents “the form of occlusal surfaces of neighboring teeth as a negative.” Ex. 2002, ¶¶ 53-60.

“Occlusal surfaces” (claim 9) – A POSA would understand “occlusal surfaces” of a tooth to refer to the top surfaces that come into contact with an opposing tooth in the opposing jaw. Ex. 2002, ¶¶ 61-63; *see* ’006 patent (Ex. 1001), Fig. 2 (occlusal surface 3); Fig. 5 (occlusal surfaces 13, 14). This term of art is also referred to as the “biting surface” or “top” surface of the tooth. Ex. 2002, ¶ 62.

V. LEGAL STANDARDS

A. ANTICIPATION

Unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot anticipate under 35 U.S.C. § 102 (pre-AIA). *Net MoneyIN, Inc., v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Inherent anticipation exists where the prior art reference does not expressly describe an element of the claim, but that element would be inherent in what is explicitly disclosed. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (emphasis added) (citations omitted).

B. OBVIOUSNESS

As stated in *KSR*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). "[I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 418-19. For this reason, "it can be important to identify a reason that would have prompted a [POSA] to combine the elements in the way the claimed new invention does." *Id.* at 418; *see also Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (citing *KSR*).

A petitioner must both "clearly point out the differences between the claimed invention and [the prior art]" and "explain why a person of ordinary skill in the art would have found the claimed subject matter obvious in spite of those differences." *Synopsys, Inc. v. Mentor Graphics Corp.*, IPR2012-00041, Paper No. 16, at 14 (P.T.A.B. Feb. 22, 2013). "[C]onclusory statements, without more detail, fail to satisfy any of the above-noted requirements." *Id.*; *see also Wowza Media*

Sys., LLC v. Adobe Sys. Inc., IPR2013-00054, Paper No. 12, at 15 (P.T.A.B. Apr. 8, 2013).

VI. ARGUMENTS

A. ALLEGED ANTICIPATION BY MUSHABAC

1. <u>Claim 1</u>

Mushabac does not anticipate claim 1 of the ’006 patent for multiple reasons. First, it does not disclose “determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the x-ray picture and optical measurement.” Claim 1 requires both a step of determinating an optimal bore hole for the implant (based on the x-ray picture) and a separate step of determinating the pilot hole in a drill template (based on the x-ray picture and the optical measurement). There is no description in Mushabac of using an optical measurement to make a determination of the position of a pilot hole in a drill template relative to the surfaces of neighboring teeth. Petitioner attempts to mask this deficiency by relying on Mushabac’s determination of a bore hole for both steps. However, Mushabac does not describe the second determination.

Second, Mushabac does not actually describe a pilot hole in a drill template. Mushabac’s acrylic block 606 is not positioned at the implant site during drilling, and it does not receive a pilot drill to form the bore hole at that site in the patient’s jaw. These features relate to the basic understanding of a drill template, as confirmed by Petitioner's own declarant. Thus, a POSA would not understand block 606 to be a drill template or any hole therein to be a pilot hole.

Third, Mushabac does not describe the optical measurement of the visible surfaces of the patient's jaw, only a patient's teeth, as discussed below.

a. <u>Mushabac Does Not Teach A Determination of a Pilot Hole as Claimed</u>

Claim 1 requires two determinations. The first determination relates to an optimal bore hole, which is the hole in a patient's jaw that receives an implant. The second determination relates to a pilot hole in a drill template, which determination is made relative to the surfaces of neighboring teeth based on optically measured three-dimensional data. Mushabac does not describe that second determination.

In Mushabac, the computer determines an optimal bore hole using a virtual model of the patient's anatomical structures. Ex. 1003, 24:66-25:13. Optimal bore hole 560 is depicted virtually on a computer display shown in Fig. 25 of Mushabac. The display also shows a preferred drill position 556 with respect to a phantom representation of the relative position of the actual drill in the real world (i.e., in the patient's mouth). Ex. 1003, 25:22-55.

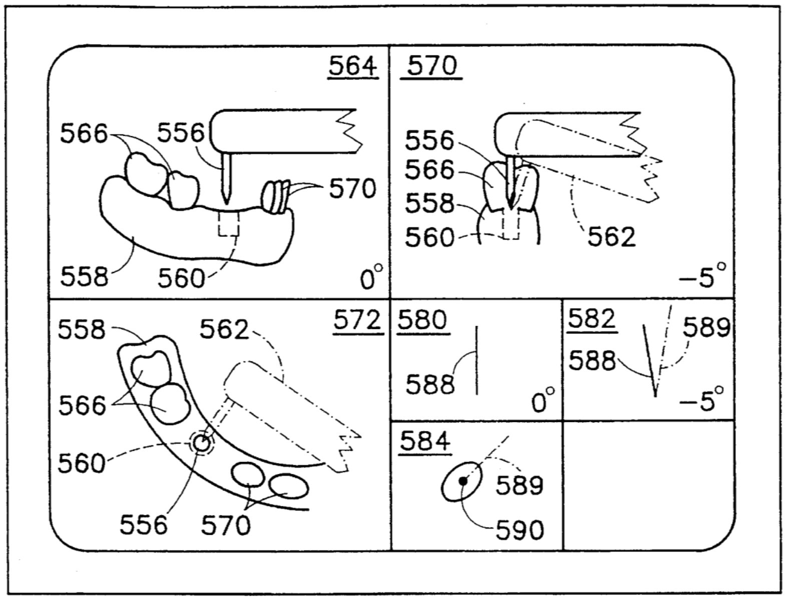

FIG.25

This allows the clinician to practice, freehand, the motion of the drill (or practice instrument) in a manner that attempts to mimic the optimal bore hole position shown on the display. Ex. 1003, 26:16-20. Once satisfied with the practice movements, the clinician then performs the actual drilling operation using the navigation system. The computer (or user), however, makes no determination of a pilot hole in a drill template, let alone with respect to neighboring teeth. In fact, no drill template is accounted for at all in the computer system depicted in Fig. 25. Furthermore, no drill template is ever placed at that implant site, so depicted position 556 does not correspond to a pilot hole position in a drill template.

In an alternative embodiment, the clinician can attach a pantograph device to replicate the movement of the practice instrument at a remote site. Ex. 1003, 26:62-27:14. The remote arm of the pantograph may include a drill that drills into block 606. Petitioner relies upon block 606 as being a drill guide, despite block 606 not being positioned at the implant site, not receiving a pilot drill that drills a bore hole, and not being accounted for at all in the computer model. Fig. 28 of Mushabac illustrates block 606 positioned away from the surgical site. The mechanical operation of the pantograph does not interact with the computer model. Instead, the movement of a practice instrument (e.g., instrument 562 in Fig. 25 and arm 600 in Fig. 28) is mimicked by the mechanical pantograph device to drill a hole in block 606.

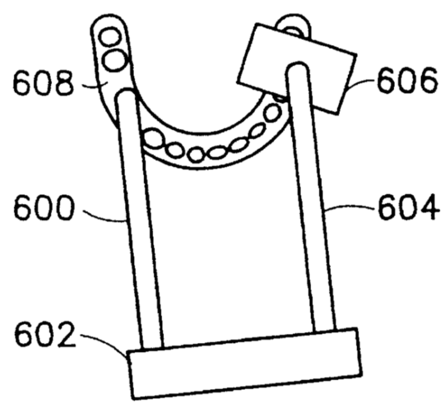

FIG.28

Not only is acrylic block 606 at a site positioned away from the neighboring teeth of the implant site, but it may be positioned outside the patient's mouth altogether. Ex. 1003, 26:62-27:14; 32:51-54 (positioning the block outside of the patient's mouth); Fig. 28. Petitioner does not address how the hole in block 606 would be made relative to the "neighboring teeth" based on an optical measurement. Block 606 is positioned nowhere near the teeth displayed in Fig. 25, nor does there appear to be any measurement of the teeth near block 606.

To mask the deficiency, Petitioner repeats the discussion of determining a bore hole in the section of the Petition relating to the determination of the pilot hole. Petition, 27:4-22; 28:5-8. Petitioner then concludes that the bore hole can be "translated" to the drill template using the practice operation with the pantograph. Petition, 28:5-19. Petitioner does not adequately explain how formation of the hole in block 606 relates to the manner of making the claimed determination. Specifically, Petitioner does not explain how the formation of the hole in block 606 involves a determination of a pilot hole in a drill template relative to surfaces of neighboring teeth. It does not. Nor does Petitioner explain whether it alleges that such a determination is made by the computer or the clinician.

At best, Mushabac describes that the clinician tries to match an actual freehand drill position (562) to a preferred drill position (556) in a computer model. *See* 1003, Fig. 25; 24:35-43. However, it is not clear how that would relate to the pilot hole determination recited in claim 1. Ex. 2002, ¶¶ 98-120; Ex. 2023, 143:24-144:13. It was the Petitioner's burden to establish in detail how Mushabac anticipated each and every step of claim 1. Yet, Petitioner failed to establish how Mushabac teaches a specific step of "determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth based on the … optical measurement." For at least these reasons, Petitioner has failed to establish that Mushabac anticipates claim 1.

b. Mushabac's Block 606 is not a Drill Template with a Pilot Hole

In the '006 patent, pilot hole 17 is a hole in the drill template through which a pilot drill passes to form bore hole 18 in a patient's jaw. '006 patent (Ex. 1001), 4:43-67. A pilot hole in a drill template serves to receive and guide a drill during the drilling operation, thus ensuring an optimal bore hole is formed in the patient's jaw. Ex. 2002, ¶¶ 34-44. The declarants for both sides agree on that definition, which excludes block 606 of Mushabac. Ex. 2023, 96:12-97:13; *see* Ex. 2019, p. 83, col. 1, ll. 14-42. Specifically, Dr. Kraut agreed that a drill template is placed at the implant site and receives the drill that creates the bore hole (osteotomy) in the patient's jaw. Ex. 2023, 36:16-37:6; 39:22-41:9; 43:16-44:14 ("Q. … the drill template has to sit over the plan's osteotomy site? A. Right. … otherwise you're not transferring the information from the model to the patient."; "Q. So just to clarify for the record … the pilot hole that the drill passes through is over the planned osteotomy site –. A. Absolutely.").

Mushabac does not teach the production or use of a drill template with any pilot hole. Rather, Mushabac teaches the use of a complicated pantograph device with a dual probe and drill assembly. In the method taught by Mushabac, a dentist first conducts a practice operation by (i) inserting a probe (with no drill bit) into the patient's mouth and (ii) practicing a freehand motion for drilling a bore hole in the jaw. In fact, the practice probe ("virtual instrument") has a telescoping tip 594 that allows it to replicate a drill path without penetrating the patient's jaw. Ex. 1003, 26:5-12; Fig. 26. During this practice operation, the pantograph assembly translates the probe movements to a drill that engages block 606 remote from the surgical site. *See* Ex. 1003, 26:62-27:5.

Specifically, Mushabac describes a pantograph assembly 602 that includes a drill 604 enslaved to a virtual instrument 600. Ex. 1003, 26:62-27:5. The surgeon moves the "virtual instrument 600 towards the jaw bone 558 as if an actual operation were being performed." Ex. 1003, 27:2-5. As virtual instrument 600 is moved at the actual implant site (shown in Fig. 25 with respect to the representation 562 of the manipulated instrument), drill 604 drills a hole in "material 606 which has been fastened to the patient's jaw." Ex. 1003, 27:2-5; 25:35-43.

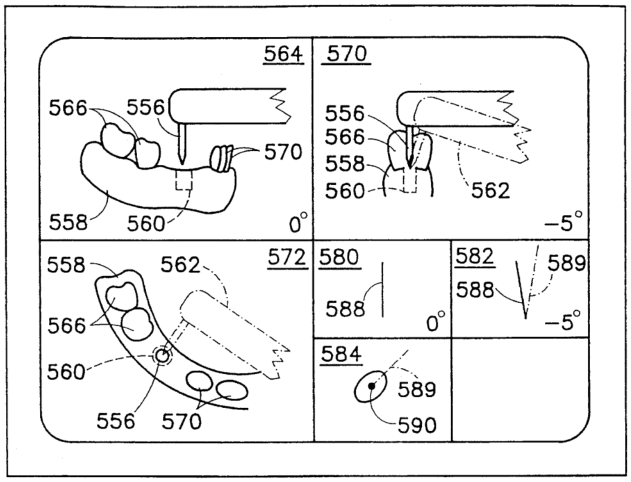

FIG.25

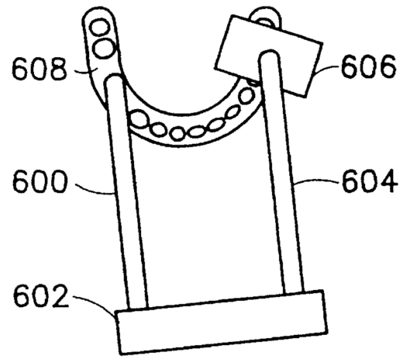

FIG.28

Thus, instrument 600 moves freely at the implant site of the patient's jaw as drill 604 drills into block 606 secured on the opposite side of the jaw. Consequently, Fig. 28 depicts the operation of the actual pantograph in the patient's actual mouth. In a variation, one arm of the pantograph may be in the patient's mouth while the block and second arm may be outside the mouth. Ex. 1003, 32:53-54 ("fixing a block of material relative to the patient's jaw so that said block is disposed *outside the patient's mouth*" (emphasis added)). This type of variation of the pantograph is depicted in Fig. 16.

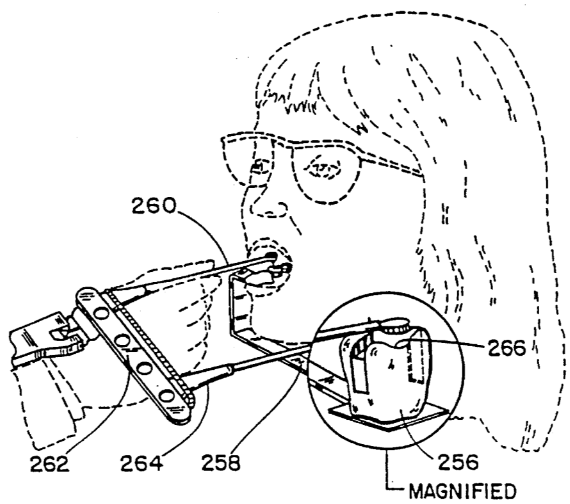

FIG. 16

In the embodiment shown in Fig. 28, once the hole in block 606 is formed during the practice surgery, the dentist switches virtual instrument 600 and drill 604 on the pantograph device and conducts the actual operation to drill the bore hole in the patient's jaw at the surgical site. Ex. 1003, 27:6-15. In that operation, the drill operates in free space and does not pass through a pilot hole in a drill template (or block 606). Specifically, Figs. 25 and 28 of Mushabac establish that no drill template is employed at the surgical site.

Therefore, Mushabac describes neither a drill template (i.e., a template at the implant site) nor a pilot hole that receives and guides the drill to the implant site. The drill does not pass through any hole during the drilling operation, as shown in Fig. 25.

Petitioner apparently contends that "a hole" formed during a practice operation in Mushabac's remotely stationed block 606 can be considered "a pilot hole in a drill template," as recited in claim 1 of the '006 patent. However, this evidence contradicts the understanding of a POSA at the time, as its own declarant agreed. Ex. 2002, ¶¶ 34-44; Ex. 2023, 39:22-40:10. First, the block 606 in Mushabac is not a drill template at all. A POSA would have understood a drill template to mean a template for the surgical site. Ex. 2002, ¶¶ 44; Ex. 2023, 36:7-37:6; 39:22-40:10. Second, a POSA would not have understood the hole in block 606 to be a pilot hole because a pilot hole in the dental arts receives a pilot drill. Ex. 2002, ¶¶ 98-109; Ex. 2023, 43:16-44:14 ("Q. So just to clarify for the record … the pilot hole that the drill passes through is over the planned osteotomy site –. A. Absolutely."). Specifically, a pilot hole in a drill template would guide a pilot drill that forms the initial drill path into the patient's jaw. Ex. 2023, 39:22-40:10; Ex. 2002, ¶¶ 34-44. Mushabac describes no such hole or operation. If Mushabac's drill entered the hole in block 606, it would miss the surgical site altogether.

While Dr. Kraut fully agreed with this understanding of a drill template and pilot hole during his deposition, he completely misunderstands how Mushabac works. Dr. Kraut believes that Fig. 28 of Mushabac does not show the use of a pantograph assembly on an actual patient's mouth. Rather, Dr. Kraut believes that Mushabac (and particularly Fig. 28) suggests the use of the pantograph on a *physical model* of the patient's jaw to create a drill template having two holes, with one hole being positioned relative to the implant site and the other being a practice hole on the opposite side of the jaw. Further, Dr. Kraut believes that block 606 in Mushabac would not have had the size or shape shown in Fig. 28 (i.e., covering only a few teeth), but would instead cover an entire arch of teeth in the jaw (i.e., the entire upper or lower arch). There is no support for this interpretation in Mushabac. In fact, Mushabac plainly states the pantograph assembly is used in the patient's mouth and flatly contradicts Dr. Kraut's interpretation.

Dr. Kraut appears to have arrived at this misunderstanding because he believes that the pantograph assembly as shown in Mushabac would never fit in the patient's mouth in the real world and that block 606 could never operate as a drill template unless it was expanded to cover the entire jaw. Patent Owner has its own doubts as to the viability of Mushabac's teachings. And, Patent Owner agrees that block 606 as described in Mushabac cannot be a drill template (although for different reasons). However, Dr. Kraut's skepticism of the operability of what is actually described in Mushabac does not give him license to essentially reimagine the actual disclosure of Mushabac. Dr. Kraut's stated understanding of Mushabac simply contradicts what Mushabac actually describes, as discussed in more detail below.

To understand how Dr. Kraut arrives at his conclusions concerning Mushabac, it is important to understand what Dr. Kraut believes is wrong with Mushabac. Dr. Kraut believes that the pantograph assembly depicted in Fig. 28 could not possibly fit in a patient's actual mouth and would not work if it did. Ex. 2023,161:19-162:4 ("Q. [I]f Mushabac required the pantagraph [*sic*] to go in the mouth, would Mushabac work? A. No."); 179:3-20. With that belief, Dr. Kraut asserts that Fig. 28 must show a model of a patient's jaw on which the pantograph functions. Ex. 2023, 52:8-53:4; 168:6-10. In this manner, Dr. Kraut assumes that that reference to a pantograph in Mushabac must mean a drill press used in the creation of a drill guide separate and apart from the actual surgery on the patient. Ex. 2023, 164:7-23 ("Q. So what would be the difference between a pantograph device and a drill press? A. Essentially the same."); 166:3-167:16; 168:6-10; 171:19-172:15; 173:12-175:21; 176:22-178:4; 179:3-20 ("We are very clear that the pantagraph [*sic*] does not go in the mouth."). Yet, as discussed above, Mushabac clearly describes that Fig. 28 shows an operation on an actual jaw. Ex. 1003, 27:2-5 ("virtual instrument 600 towards the jaw bone 558 as if an actual operation were being performed"); 27:2-5 ("material 606 which has been fastened to the patient's jaw"); *see also* Fig. 16. There is no evidence to support that Fig. 28 shows a model of a jaw.

In addition, Dr. Kraut believes that drill templates ("surgical guides") must cover the entire arch of the jaw; however, block 606 in Fig. 28 only spans a few teeth. Ex. 2023, 167:14-16 ("Q. If block 606 was that size, would it serve as a surgical guide? A. No."). Consequently, Dr. Kraut asserts without support that block 606 would have to span the entire arch, despite the fact that the actual depiction of that element contradicts that position. Ex. 2023, 166:22-167:16 (Q. "[T]he block 606 in figure 28 doesn't span the entire jaw … does it? A. In the diagram is doesn't, but in reality it does."); 160:23-161:18 (believing that 602 is part of a drill template). Thus, again, Dr. Kraut essentially rewrites Mushabac to suit his needs.

Furthermore, to account for the shape of the dual-armed pantograph assembly shown in Fig. 28 (which he thinks is a drill press), Dr. Kraut believes that two separate holes would be drilled into block 606, at positions corresponding to opposite sides of the jaw. First, Dr. Kraut imagines that a freehand drilling would be performed through the block 606 on one side of what he understands to be a jaw model (corresponding to the position of arm 600 in Fig. 28). Ex. 2023, 166:3-167:16; 168:6-10; 169:16-170:16; 187:16-189:1; 54:5-13; *see generally* Ex. 2029 (photos of Dr. Kraut's understanding of Mushabac). Second, Dr. Kraut imagines that the pantograph assembly would be used to replicate the angle of that first hole on a portion of block 606 the other side of the model (corresponding to the position of arm 604). Then, Dr. Kraut speculates that this template with two holes would be put in the patient's mouth, at which point "the pantagraph [*sic*] ceases to be part of the discussion." Ex. 2023, 172:1-15. Once in the patient's mouth, Dr. Kraut asserts that only one of the two drilled holes would be used. *Id.* None of this is even remotely suggested anywhere in Mushabac. Nowhere in Mushabac is there any suggestion that a plaster model of a patient's jaw is even created. Nowhere does Mushabac suggest using the pantograph assembly on a plaster model. And, nowhere does Mushabac describe drilling two holes in block 606. Further, with the size of block 606 as shown, drilling two holes in the block at the stated positions would be impossible (as block 606 does not span the entire jaw). Also, if block 606 did span the entire jaw, it would interfere with the change in orientation of the practice instrument shown in Fig. 25 with respect to element 562.

Even when it comes to placement of block 606, Dr. Kraut's understanding requires ignoring Mushabac's actual disclosure. Specifically, while Mushabac states that block 606 is bonded to the patient's jaw, Dr. Kraut does not believe that such conventional bonding would occur and, instead, believes that block 606 would be held in place by friction. Ex. 1003, 27:1-5; Ex. 2023, 174:15-175:21.

This total reimagining allows Dr. Kraut to believe that Mushabac describes a conventional process of forming a drill template on a model of the patient's jaw using a drill press. Ex. 2023, 57:18-24; 58:24-59:6. Of course, this has nothing to do with what is actually described in Mushabac. Ex. 2002, ¶¶ 98-109. For instance, as described above, block 606 is never positioned at an implant site. Ex. 2002, ¶¶ 96, 103-106. In fact, block 606 is used as a reference for the pantograph device and would have to remain at its remote position to help replicate the path from the practice surgery.

In view of the correct understanding of the operation of Mushabac, block 606 is not a "drill template" and does not have a "pilot hole," as understood by a POSA at the time. Thus, Mushabac cannot anticipate a determination of "a pilot hole in a drill template relative to surfaces of the neighboring teeth," as required by claim 1 of the '006 patent.

c. Mushabac Does Not Teach an Optical Measurement of the Jaw

Claim 1 requires a three-dimensional optical measurement of the visible surfaces of both the jaw and teeth. The sections of Mushabac cited by Petitioner describe that visible surfaces of the teeth are optically measured, but do not describe that the visible surfaces of the jaw are optically measured. Petition, 21:18-23:19; *see* Ex. 1003, 24:53-56. Specifically, Petitioner relies on transducer 48 and probe 52 as performing the optical measurement. Petition, 21:14-22:2. Transducer 48 performs an optical measurement of the teeth. However, probe 52 makes a mechanical measurement of underlying anatomy. Specifically, probe 52 has a sharp stylus 574 that penetrates the surface of the gum to measure the structure of the jaw *bone* by a contact measurement. Ex. 1003, 24:53-65 ("practitioner repeats the procedure of piercing the gum tissue in a region about the desired implantation site and taking point data until enough data has been collected … to map … the entire surface of bone"). That description does not suggest a measurement of visible surfaces of the jaw, but a measurement of the bone structure underneath the jaw's surface gum tissue. Moreover, the point-by-point contact measurement is not the same as the optical measurement performed on the teeth.

Petitioner asserts without explanation that the measurement performed with probe member 52 is an optical measurement, despite the clear statement in Mushabac to the contrary. Petition, 22:15-23:5. However, Petitioner's own declarant agreed that Mushabac described using contact, not optical, measurement of the jaw. Ex. 2023, 137:9-139:17 ("That's contact. He's optically doing the teeth, he's contacting in the jaw.").

For these reasons, Petitioner has not established the optical measurement of visible surfaces of the jaw.

2. Claim 2

Claim 2 recites that the x-ray picture of claim 1 "is one of a panoramic tomography image, a tomosynthetic image or a computer tomography image."

Mushabac, filed in 1991, simply describes the use of "an X-Ray device." Ex. 1003, 10:49-51. Petitioner alleges that one section of Mushabac describes a "tomosynthetic image" and another describes a "computer tomography image."

With respect to tomosynthetic images, Petitioner alleges that Mushabac teaches a tomosynthetic process merely because an x-ray is digitized. Petition, 29:9-20. However, this argument is premised on Petitioner's unsupported definition of tomosynthesis, which alleges that tomosynthesis was not a term of art. Yet, tomosynthesis is a known term referring to the use of multiple conventional x-ray shadows to mimic the three-dimensional, slice-by-slice images obtained by computer tomography. Ex. 2013, 1:10-2:35. Petitioner provides no explanation as to how simple "digitization" of a conventional x-ray would achieve a tomographic image. In fact, a digital radiograph is different than a computer tomograph. Ex. 2027, pp. 1485 ("radiograph" and "digital r.") and 1819 ("tomography" and "computed t."). Moreover, during his deposition, Dr. Kraut stated that the x-ray system shown in Fig. 1 of Mushabac was a conventional x-ray system that did not teach tomosynthesis (as defined in the prior art). Ex. 2023, 128:13-129:9; 212:17-213:23 ("I don't think he's referring to tomosynthesis"); 126:17-25; 130:4-131:13 ("Q. Do you understand the description of tomosynthesis here? A. No. Not at all." (referencing the discussion in Ex. 2013, 1:42-51)).

With respect to computer tomography (recited in claim 2), Petitioner argues that Mushabac teaches this feature because Mushabac uses a "stereophotogrammetric triangulation program" on different x-ray views of the same tooth. Petition, 30:1-9; Ex. 1003, 27:65-67. However, Mushabac simply describes conventional x-rays (also called shadowgraphs). Ex. 2023, 128:13-129:9; 124:7-128:12; Ex. 2028, p. 1640 (defining radiographs as "shadowgraphs"). Petitioner's own evidence establishes the difference between conventional radiographs (x-rays) and computer tomography (sectional radiographs). Ex. 1011, 113, col.1, l. 16-p.116, col. 1, l. 24; *see* Fig. 8-4 vs. Fig. 8-7; Ex. 2028, p. 1779 (sectional radiograph). Specifically, conventional x-rays are exposures showing a shadow of radiation passing through a structure. Ex. 2027, p. 1485 (radiograph); Ex. 2028, p. 1641 (radiography). CT scans measure selected planes (or slices) that blur out images in other planes. Ex. 2027, p. 1819 (tomography). Further, Dr. Kraut admitted that he did not really understand what was involved in a stereophotogrammetric triangulation program, which Petitioner alleges (without support) is a computer tomograph. Ex. 2023, 133:8-134:9; 232:16-233:8.

Thus, Petitioner has not met its burden of establishing that Mushabac *anticipates* claim 2.

3. **<u>Claim 9</u>**

As discussed above, claim 9 recites that "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*" (emphasis added). Petitioner offers that this claim would "inherently" have been met by Mushabac, despite no mention in the reference of (i) using a grinding process at all to form a drill template or (ii) forming negatives in a drill template (let alone of negatives of occlusal surfaces of neighboring teeth). Petition, 32:9-18.

Inherency cannot result from mere possibilities. In that regard, Dr. Kraut admitted that Mushabac may not use grinding at all, as discussed below. Thus, even if block 606 could be regarded as a drill assistance device as required by claim 1 (which it cannot), Mushabac still fails to disclose inherently a grinding process. Nor does Mushabac even suggest the formation of occlusal surfaces of neighboring teeth as a negative in block 606. And even if Petitioner could establish that Mushabac suggested the formation of negatives of teeth in a dimension-stable material, Petitioner has failed to establish how such negatives could be of teeth *neighboring the implant position*. In Mushabac, relied upon block 606 is plainly secured on the *opposite side* of the patient's mouth remote from the implant position.

a. Mushabac Does Not Describe a Drill Assistance Device That Is Ground Out

To begin, Petitioner asserts in a conclusory manner that Mushabac's block 606 is "ground out" with no citation to any support in Mushabac for that allegation. Petition, 32:9-18. In fact, Petitioner's discussion of claim 9 provides no citation at all to Mushabac. *Id.*

A POSA reading claim 9 (particularly in light of the specification) would have understood that claim to mean that the drill assistance device is ground out from a dimension-stable material to form a negative of the occlusal surfaces of neighboring teeth. Ex. 2002, ¶¶ 53-60. For instance, the specification describes that the grinding out may be performed by a CAD/CAM machine, which grinds away dimensionally stable material to form the negative of the occlusal surfaces of neighboring teeth in the material. '006 patent (Ex. 1001), 3:13-17 ("Using the information that was obtained with respect to the surface structure, i.e., the occlusal surfaces of neighboring teeth, it is possible to grind out on a CAD/CAM unit an implant assistance device in the form of a drill template."); 4:38-41.

While Petitioner relies upon acrylic block 606 in Mushabac as being a drill assistance device, Mushabac provides no description at all of grinding out block 606, let alone to result in a negative of the occlusal surfaces of neighboring teeth. While relying on an inherency argument for claim 9, neither Petitioner nor Dr. Kraut discusses whether or not there are other ways to form a drill template other than by grinding out a dimension stable material (e.g., through CAD/CAM). *See* Ex. 1002, ¶¶ 101-105. However, when asked about this during his deposition, Dr. Kraut freely admitted that the alleged negatives can be formed by molding instead of grinding and that Mushabac "doesn't tell you whether it is CAD/CAM or molded acrylic." Ex. 2023, 192:21-193:19; 191:3-19; 47:5-20; *see also id.*, 73:21-74:2 (distinguishing drilling from grinding); 75:6-18.

Thus, by Dr. Kraut's own admission, block 606 is not inherently ground out. Therefore, Mushabac cannot anticipate claim 9. Ex. 2002, ¶¶ 121-126.

b. <u>Mushabac Does Not Describe a Negative of Occlusal Surfaces of Neighboring Teeth in Block 606</u>

Mushabac also fails to describe explicitly or inherently that block 606 includes *any negative representations* of the surfaces of teeth (whether ground out or otherwise formed), let alone negatives of the specific occlusal surfaces of teeth neighboring an implant position.

Mushabac merely states that acrylic block 606 is "fastened to the patient's jaw by conventional bonding techniques." Ex. 1003, 27:1-5. Petitioner alleges that block 606 "would necessarily represent the occlusal surfaces … of neighboring teeth" in order to secure it in the patient's mouth. Petition, 32:9-18. Petitioner offers this assumption despite no support for the same in the figures or text of Mushabac.

Petitioner's argument fails for at least two reasons. First, Mushabac clearly shows that block 606 is not even positioned at the implant site. In Fig. 28, it is positioned on the opposite side of the mouth from the implant site. It would make no sense to form in block 606 the negative of occlusal surfaces of teeth neighboring the implant site, because such a negative could not engage properly with different teeth on the opposite side of the mouth where block 606 is positioned. Second, Mushabac, which is applied as an anticipatory reference, does not even suggest the formation of negatives of any teeth (whether at the implant site or otherwise) in block 606, inasmuch as the stated "conventional bonding techniques" do not suggest the formation of negatives. Ex. 2002, ¶¶ 127-139.

On the first point, claim 9 recites that the dimension stable material "represents the form of occlusal surfaces of *neighboring teeth* as a negative *with respect to an implant position*" (emphasis added). Thus, the claimed negative explicitly relates to the occlusal surfaces of teeth neighboring the implant position. This feature is illustrated in the '006 patent with respect to occlusal surfaces 13, 14 of neighboring teeth 11, 12. '006 patent (Ex. 1001), 4:42-46. These teeth neighbor implant position 9.

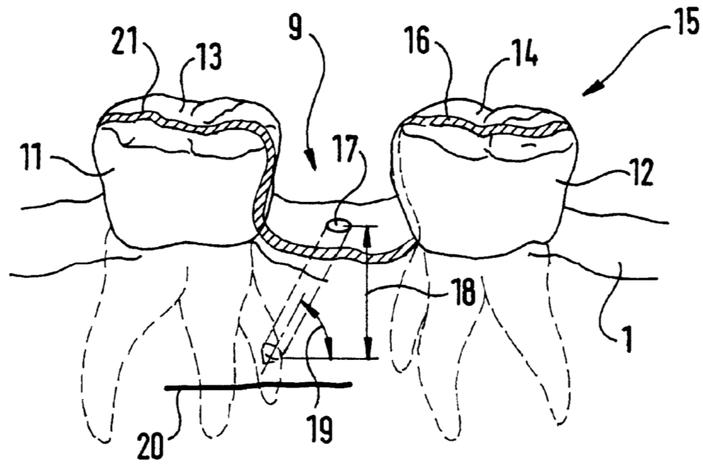

FIG. 5

As can be seen in Fig. 28, Mushabac's implant site is shown at the end of arm 600, while block 606 is positioned on the *opposite side* of the patient's mouth. Ex. 1003, 26:62-27:14; 25:22-44; Figs. 25 and 28. Thus, even if Petitioner could establish that "conventional bonding techniques" would necessarily result in negatives of the teeth below block 606, such negatives would not be of neighboring teeth "with respect to an implant position." Ex. 2002, ¶¶ 140-143. Instead, as can be seen from Fig. 28, at best, block 606 would be fastened near teeth that do not neighbor the implant site.

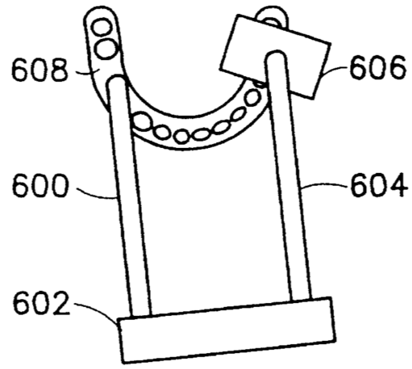

FIG.28

Petitioner has offered nothing to address this deficiency. Instead, Dr. Kraut insists that block 606 would have to be something entirely different than what is actually shown, and instead cover the full arch of the jaw, including the implant site. Ex. 2023, 166:22-167:16.

Second, there is nothing in Mushabac that establishes explicitly or inherently that any negative at all is formed in block 606. Ex. 2002, ¶¶ 128-138. Mushabac only states that block 606 is "fastened to the patient's *jaw* by conventional bonding techniques." Ex. 1003, 27:1-5 (emphasis added). Petitioner, again without explanation, assumes that fastening to the "jaw" would "necessarily" result in form fitting block 606 to the teeth. Petitioner offer no explanation as to why fastening the block to the "jaw" would have also included fastening the block to the "teeth," let alone occlusal surfaces of the teeth, as required by claim 9.

Mushabac establishes that fastening the block to the jaw does not even require positioning the block in the patient's mouth. Specifically, claim 32 of

Mushabac states that the block may be fixed relative to the jaw while being disposed outside of the patient's mouth. Ex. 1003, 32:53-54. Petitioner fails to explain why a block intended to be fastened relative to the jaw either inside or outside of the patient's mouth would "necessarily" have been form fit to the patient's teeth. In fact, the prior art explains that one conventional technique for securing a reference point to a "jaw" (even if outside the mouth) includes screwing the device directly into the patient's chin. Ex. 2030, 2:55-64; *see also id.*, Figs. 1 and 2 (showing sensor 6 attached to a patient's lower jaw).

Even for the embodiment of Mushabac in which block 606 is positioned near the patient's teeth (Fig. 28), Petitioner incorrectly assume that negatives of the teeth would be formed in block 606. Even assuming, *arguendo*, that acrylic block 606 would have been fastened to the "teeth," block 606 would still not necessarily be (i) fastened to occlusal surfaces of the teeth or (ii) formed with a negative of those surfaces in the acrylic material (dimension stable), as required by claim 9. Ex. 2002, ¶¶ 121-138. Instead, a POSA would have understood that conventional bonding to teeth would likely utilize an adhesive. Ex. 2002, ¶¶ 128-138. An adhesive could be used to affix the device to axial surfaces of the teeth, rather than occlusal surfaces.

Further, such adhesives would not require that *block 606* conform to the shape of the teeth. At most, a negative could potentially be formed in the adhesive itself (or associated composite material). Ex. 2002, ¶¶ 133-138. However, claim 9 requires that the negative be formed in the dimension stable material, which Petitioner state is the acrylic material of block 606.

The Petition did not even address this use of an adhesive in its *anticipation* argument. Instead, Dr. Kraut assumed that conventional bonding discussed in Mushabac would have meant a simple "friction" grip; yet, Dr. Kraut freely admitted that the term "bonding" is more properly understood to mean using some type of adhesive. Ex. 2023, 109:13-24; 110:24-112:7. Moreover, whether a negative would have occurred in the adhesive would have depended on, at least, the amount of adhesive used and its viscosity. Ex. 2002, ¶¶ 132-138. Nor would it be ground out.

Thus, nothing in Mushabac suggests the formation of negatives of occlusal surfaces in acrylic block 606 or a grinding process. Petitioner has failed to establish that Mushabac anticipates claim 9. Ex. 2002, ¶¶ 121-143.

B. ALLEGED OBVIOUSNESS GROUNDS

1. Claim 5 (Mushabac & Poirier)

Claim 5 is instituted for trial based on the combination of Mushabac and Poirier. Petitioner asserts that Poirier teaches the use of ball-shaped markers. Patent Owner submits that claim 5 remains patentable by virtue of its dependency from claim 1. Petitioner has not established that Poirier remedies any of the deficiencies in Mushabac discussed above. Ex. 2002, ¶¶ 145-148.

2. Claims 6 and 7 (Mushabac & Weese)

Claims 6 and 7 are instituted for trial based on the combination of Mushabac and Weese. Petitioner relies on Weese to teach pseudo-x-ray pictures. Patent Owner submits that claims 6 and 7 remain patentable by virtue of their dependency from claim 1. Petitioner has not established that Weese remedies any of the deficiencies of Mushabac discussed above. Ex. 2002, ¶¶ 149-150.

Further, Dr. Kraut admitted that a POSA would have had no reason to combine Weese with Mushabac because Weese is not directed to the dental arts. Ex. 2023, 230:18-25; Ex. 2002, ¶¶ 151-152. In addition, while claim 6 requires that a pseudo-x-ray picture be created from the optical three-dimensional measurement, Dr. Kraut also admitted that Weese does not describe an optical measurement. Ex. 2023, 83:9-84:14; 227:5-228:11; 229:4-9.

C. SUBSTITUTE CLAIMS 19-25

Accompanying this Response is a Contingent Motion to Amend, which proposes substitute claims 19-25. Those claims correspond to claims 1-7 of the original patent, respectively. Substitute independent claim 19 adds, in part:

> producing the drill template containing the pilot hole and negatives of the surfaces of the neighboring teeth, wherein the negatives of the surfaces of the neighboring teeth and the pilot hole are formed by a machine using data from the three-dimensional optical measuring

As discussed above with respect to claim 9, Mushabac does not even suggest the formation of negatives of any teeth surfaces in block 606, let alone the surfaces of teeth neighboring (adjacent) the implant site.

Furthermore, Mushabac does not describe or suggest producing in the drill template the negative representations based on measured data from the three-dimensional optical measurement, as recited in substitute claim 19. As discussed in the ’006 patent, the invention takes the data from the three-dimensional optical measurement and produces a drill template having negatives and the pilot hole formed therein using the measured three-dimensional data. ’006 patent (Ex. 1001), 3:12-24; 4:37-41. For instance, a CAD/CAM machine can mill the template from a dimension stable material to produce the negative representation of the surfaces using the optically measured data. Ex. 2002, ¶¶ 57-59, 90. This allows for creation of precise drill templates while avoiding the need for impressions and casts.

Not only does Mushabac fail to suggest that block 606 would have *any* negative representations of surfaces of teeth, but it fails to even hint at how such negatives could be formed. Moreover, the conventional methods of forming negatives of surfaces of teeth in drill templates involved (i) molding processes in which the template was molded on a plaster model of the patient's teeth, or (ii) molding the template directly from the patient's teeth. Ex. 2002, ¶¶ 71-72, 79-80, 122. Such methods were manual processes that did not rely on optically measured data. Neither Mushabac nor any other conventional system suggests producing in a drill template the pilot hole and negatives of teeth surfaces using a machine that uses measured data obtained from a three-dimensional optical measurement. Ex. 2002, ¶¶ 160-206.

Even Petitioner's own declarant admitted that he was not aware of any use of light-based measurements to form the negatives in such guides. Ex. 2023, 77:14-18 (stating CT data rather than optical data could have been used); 76:9-21. Moreover, claim 19 makes clear that the "neighboring" teeth are "adjacent an implant position." Accordingly, Mushabac does not describe or suggest the features of substitute claim 19. The accompanying Motion to Amend addresses the closest prior art other than Mushabac and the patentability of substitute claim 19 over the same.

VII. CONCLUSION

For the reasons set forth above, Patent Owner submits that the instituted grounds do not render unpatentable claims 1-7 or 9-10 of the '006 patent, or substitute claims 19-25. Accordingly, Patent Owner requests confirmation of the patentability of the claims.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4) and 42.105, the undersigned certifies that on this date, a true and correct copy of this Patent Owner Response and all supporting exhibits were served via email on the Petitioner at the following email addresses:

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