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Paper No. 34
Date: November 15, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INSTITUT STRAUMANN AG and DENTAL WINGS INC.,

Petitioner,

v.

SIRONA DENTAL SYSTEMS GMBH,

Patent Owner.

Case IPR2015-01190
Patent 6,319,006 B1

Before MICHELLE K. LEE, MEREDITH C. PETRAVICK and BRIAN P. MURPHY, *Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Institut Straumann AG and Dental Wings Inc. (together "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–10 (all claims) of U.S. Patent No. 6,319,006 B1 (Ex. 1001, "the '006 patent"). Paper 2 ("Petition" or "Pet."). Sirona Dental Systems GmbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp."). On November 16, 2015, we instituted an *inter partes* review of claims 1–10 of the '006 patent. Paper 11.

Petitioner supports its challenge with a Declaration of Dr. Lewis Benjamin, D.M.D., M.S. (Ex. 1002) and a Supplemental Declaration of Dr. Benjamin (Ex. 1028).

After institution, Patent Owner filed a Response (Paper 15, "PO Resp.") and a Contingent Motion to Amend claims 1–8 of the '006 patent (Paper 16, "MTA"). Patent Owner supports its Response and MTA with a Declaration of Dr. Douglas Erickson, D.D.S., M.S. (Ex. 2002) and a Supplemental Declaration of Dr. Erickson (Ex. 2024).

Petitioner filed a Reply (Paper 20, "Reply") and Opposition to Patent Owner's MTA (Paper 19, "MTA Opp."). Patent Owner filed a Reply to Petitioner's Opposition to Patent Owner's MTA. Paper 24 ("MTA Reply").

Petitioner filed Observations on Cross-Examination Testimony of Dr. Erickson. Paper 28 ("Observations"). Patent Owner filed a Response to Petitioner's Observations. Paper 31 ("Resp. Observations").

An oral hearing was held on August 9, 2016, and a transcript of the oral hearing is of record. Paper 33 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Decision is a final written decision under 35 U.S.C. § 318(a) as to the patentability of the

challenged claims. For the reasons that follow, based on our review of the complete trial record, we determine Petitioner has shown by a preponderance of the evidence that claims 1–8 of the '006 patent are unpatentable. We further determine Petitioner has not shown by a preponderance of the evidence that claims 9 and 10 of the '006 patent are unpatentable. We also determine that Patent Owner's Contingent Motion to Amend the claims, and enter proposed substitute claims 11–18, is *denied*.

A. Related Proceedings

The parties identify the following as related district court proceedings regarding the '006 patent: *Sirona Dental Systems GmbH v. Anatomage, Inc.*, No. 1:14-cv-00540-LPS (D. Del.), filed April 24, 2014; *Sirona Dental Systems GmbH v. Dental Wings Inc.*, No. 1:14-cv-00460-LPS (D. Del.), filed April 11, 2014; *Sirona Dental Systems GmbH v. Dentsply IH Inc*., No. 1:14-cv-00538-LPS (D. Del.), filed April 24, 2014; *Sirona Dental Systems GmbH v. OnDemand3D Technology Inc*., No. 1:14-cv-00539-LPS (D. Del.), filed April 24, 2014; *Sirona Dental Systems GmbH v. 3Shape*, No. 1:15-cv-00278-LPS (D. Del.), filed March 30, 2015. Pet. 3; Paper 7, 2–3.

We note that we instituted an *inter partes* review of claims 1–7, 9, and 10 of the '006 patent in IPR2015-01057. We further instituted an *inter partes* review of claims 1–10 in IPR2016-00481. A Final Written Decision in IPR2015-01057 was entered October 19, 2016 and determined the petitioner in that case did not prove by a preponderance of the evidence that claims 1–7, 9, and 10 of the '006 patent were unpatentable. We have not yet entered a Final Written Decision in IPR2016-00481.

B. Asserted Grounds of Unpatentability

We instituted an *inter partes* review of claims 1–10 on the following grounds of unpatentability under 35 U.S.C. §§ 102 and 103:

Reference[s]	Statutory Basis	Challenged Claims
Mushabac[1]	§ 102	1–4 and 9–10
Bannuscher[2] and Truppe[3]	§ 103	1–10

C. The '006 Patent

The '006 patent, titled "Method for Producing a Drill Assistance Device for a Tooth Implant," issued November 20, 2001, from an application filed October 31, 2000.[4] Ex. 1001, (45), (22). The '006 patent is directed to a method for producing a drill assistance device (also referred to as a drill template) for use in tooth implant surgery. *Id.* at Abstract. The object of the claimed method is "to precisely place a pilot hole" in the drill template, where the pilot hole is "aligned relative to the teeth that still remain in the jaw." *Id.* at 1:6–9; *see id.* at 2:6–10 ("a drill assistance device that will allow the exact drilling of a pilot hole for a tooth implant in relation to the teeth that still remain in the jaw").

[1] U.S. Patent No. 5,562,448 to Mushabac, filed August 9, 1991, issued October 8, 1996. Ex. 1007 ("Mushabac").
[2] Bannuscher, DE 19510294 A1, filed March 22, 1995, published October 2, 1996. Ex. 1009 (German language); Ex. 1010 (English translation) ("Bannuscher"). The English translation of Exhibit 1010 is certified by the translator pursuant to 37 C.F.R. § 42.63(b). Ex. 1011.
[3] Truppe, U.S. Patent No. 5,842,858, filed May 13, 1996, issued December 1, 1998. Ex. 1008 ("Truppe").
[4] The '006 Patent claims foreign application priority to a German patent application, DE 19952962, filed November 3, 1999. Ex. 1001, (30).

The method includes steps for determining i) the optimal bore hole to be drilled into a person's jaw based on an X-ray of the jaw, and ii) a pilot hole in the drill template. "[M]easured data records," derived from the X-ray and from a three-dimensional ("3-D") optical measuring of the visible surfaces of the person's jaw and teeth, are "correlated" to define the optimal location, angle and depth of the pilot hole. *Id.* at 2:16–28. The '006 patent generally describes use of a Computer-Aided Design/Computer-Aided Manufacturing ("CAD/CAM") machine to generate the measured data records and define a pilot hole in the drill template. *Id.* at 4:37–41. The location, angle, and orientation of the pilot hole in the drill template may be determined so as to correspond to the optimal bore hole to be drilled into the person's jaw. *Id.* at 3:19–22, 4:55–62.

Figure 5 of the '006 patent, is reproduced below.

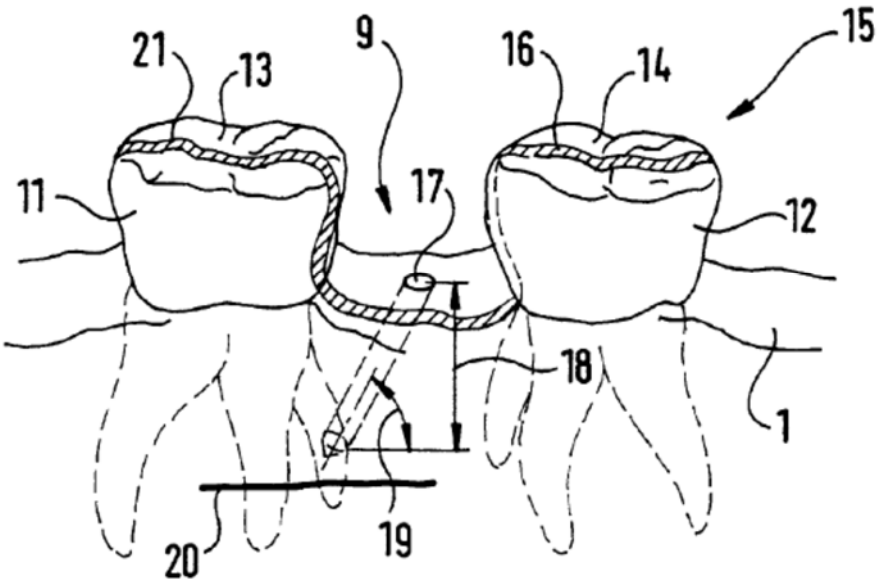


Figure 5, above, shows teeth 11 and 12 adjacent implant position 9. *Id.* at 4:23–31. In preparation for implant surgery, drill template 16 is attached to the surfaces of teeth 11 and 12 and includes pilot hole 17, which

is positioned over the implant position and set at angle 19. *Id.* at 4:51–58. Depth 18 corresponds to the desired depth of the bore hole, defined to avoid nerve 20. *Id.* at 2:39–45, 4:58–62. "The dentist determines the depth of the bore hole 18 based on the correlation of the measured data records from x-ray picture 5 . . . and transfers the depth to the drill template as a stop." *Id.* at 4:58–62.

Claims 1, 9, and 10 of the '006 patent are illustrative and reproduced below.

> 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.
>
> 9. The method according to claim 1, wherein the drill assistance device is ground out from a dimension-stable material, and said material represents the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position.
>
> 10. The method according to claim 9, wherein the drill assistance device contains a bore hole position that serves as a guide for the drill.

II. ANALYSIS

A. Claim Construction

We construe claim terms of an unexpired patent according to their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation standard, we assign claim terms their ordinary and customary meaning, as understood by one of ordinary skill in the art, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that the following claim terms require explicit construction for purposes of this Decision. *See, e.g.*, *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (internal citation omitted).

1. "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth"

Petitioner argues that the claim phrase "carrying out a three-dimensional optical measuring" should be construed such that the claim phrase "includes both direct measuring of the actual jaw or teeth of the patient and indirect measuring of such surfaces based on an imprint or a model of the jaw and teeth." Pet. 18–19 (citing Ex. 1002 ¶ 46). Petitioner argues that neither the claim language nor the specification of the '006 patent indicates whether the optical measuring is to be taken directly from

the patient's jaw and teeth or taken indirectly, such as from an imprint or model of the patient's jaw and teeth. *Id.* at 18 (citing Ex. 1002 ¶ 44). Petitioner further argues that, because techniques for acquiring three-dimensional data indirectly from an imprint or model of a patient's jaw and teeth were known at the time of the effective filing date of the '006 patent, such techniques should be included in the broadest reasonable interpretation of the claim phrase. *Id.* at 18–19 (citing Ex. 1002 ¶¶ 45–46).

Patent Owner responds that it concurs with our construction of the quoted phrase in the Decision to Institute. PO Resp. 17. In the Decision to Institute, we construed the quoted claim phrase as "using light to measure the visible surfaces of the jaw and teeth in three dimensions." Paper 11, 7. Petitioner does not comment on our construction or address the quoted claim phrase in its Reply. *See* Reply 2–8.

Claim 1 recites "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth." Ex. 1001, 5:7–8. The '006 patent describes 3-D optical measuring as generating an "optical image" of the "visible surfaces," "visible proportions," and "visible structures" of the teeth and jaw. Ex. 1001, 2:49–62. Figure 2 of the '006 patent depicts 3-D optical image 10 of the visible surfaces of a molar "measured using a three-dimensional system of coordinates." *Id.* at 3:50–56. The '006 patent does not further describe the details of carrying out the 3-D optical measuring step.

The claim language and written description are consistent with Petitioner's argument, to the extent that neither the claim language nor the specification excludes indirect 3-D optical measuring of the visible surfaces of the patient's jaw and teeth, such as by optically measuring an imprint or

physical model of the jaw and teeth. However, we do not view Petitioner as setting forth a formal construction based on the language of the claim phrase at issue, but rather as providing examples of techniques that fall within the scope of the phrase. In IPR2015-01057, we construed the phrase "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and teeth" as "using light to measure the visible surfaces of the jaw and teeth in three dimensions." *Anatomage, Inc. v. Sirona Dental Systems GmbH*, Case IPR2015-01057, slip op. at 7–9 (PTAB Oct. 19, 2016) (Paper 42). We adopt the same analysis and construction of the quoted claim phrase in this Decision.

Therefore, based on our review of the complete record, we maintain our construction of the phrase "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and teeth" from the Decision to Institute, as "using light to measure the visible surfaces of the jaw and teeth in three dimensions."

2. "determinating a pilot hole in a drill template"

Claim 1 of the '006 patent recites "determinating a pilot hole in a drill template relative to surfaces of the neighboring teeth." Ex. 1001, 5:16. Patent Owner construes a portion of that claim phrase – "a pilot hole in a drill template" – as referring to "a pilot hole in a drill template through which the pilot drill passes while drilling a bore hole into a patient's jaw." PO Resp. 17 (citing Ex. 2002 ¶¶ 33–44). Patent Owner argues that the '006 patent, particularly the embodiment of Figure 5, describes pilot hole 17 as a hole in the drill template "through which the pilot drill actually passes while drilling bore hole 18 into a patient's jaw." *Id.* at 16 (citing Ex. 1001, 1:42–46, 4:43–67). Patent Owner further relies on extrinsic evidence for the same

proposition. *Id.* at 16–17 (citing Ex. 2002 ¶¶ 37–43; Ex. 2023, 24:3–22, 25:18–27:2, 52:2–9).

Petitioner replies that we should retain the construction of the quoted claim phrase from our Decision to Institute, namely "defining a guide hole in a drill template for drilling a bore hole in a person's jaw." Reply 2–6. Petitioner argues that Patent Owner uses circular logic and introduces a new concept of a "pilot drill" to limit the quoted claim phrase, in order to avoid Mushabac's disclosure of a guide hole in a drill template. *Id.* at 2–3 (citing Ex. 1001, 3:21, 4:42; Ex. 1007, 27:9–11). Petitioner emphasizes the inconsistent use of the phrases "pilot hole" and "bore hole" in the '006 patent, and Dr. Erickson's effort to rationalize the inconsistencies by introducing the concept of a "pilot hole" that receives a "pilot drill" during a drilling operation. *Id.* at 3–5 (citing Ex. 1001, Abstract, 1:7–10, 2:7–10, 2:26–28, 3:19–22; Ex. 1029, 38:16–17, 39:19–21, 40:12–15, 54:20–25, 57:23–25; Ex. 2002 ¶ 35). Petitioner further notes that dependent claim 9 references the intended surgical site ("with respect to an implant position"), which means Patent Owner's proposed construction for the step of "determinating a pilot hole" in claim 1 is inconsistent, because claim 9 "expressly allows the drill template (and pilot hole) to be located at a position *relative* to the implant position, but not necessarily sitting over it." *Id.* at 5. Petitioner concludes with the observation that a "pilot hole" as described in the '006 patent includes a hole located in a drill template either at the implant position or elsewhere, "so long as it is guiding the implant drill." *Id.* at 6.

We agree with and adopt Petitioner's analysis. Patent Owner's proposed construction is not consistent with the broadest reasonable

interpretation of the language used in claim 1 and the additional limitations of dependent claims 9 and 10. Patent Owner's proposed construction also impermissibly reads limitations from the preferred embodiment of Figure 5 into claim 1. Patent Owner would limit the pilot hole location exclusively to a position directly over the implant position and require the drill bit to pass through the pilot hole while drilling a bore hole into the patient's jaw. The language recited in claim 1, in the context of the '006 specification, does not so-limit the "determinating a pilot hole" step.

First, Patent Owner fails to consider the present participle form "determinating"[5] at the beginning of the recited method step at issue. As a result, Patent Owner conflates the recited device production step with a specific process for drilling a bore hole into a patient's jaw during tooth implant surgery. PO Resp. 14–15. For example, Patent Owner relies on Dr. Erickson's Declaration testimony (and Dr. Benjamin's deposition testimony) for the proposition that "pilot hole" is a term of art referring to "an initial hole through which a pilot drill passes during an operation." Ex. 2002 ¶ 37 (cited at PO Resp. 16–17); *see also* PO Resp. 16–17 (citing Ex. 2023, 24:3–22, 25:18–27:2, 52:2–9). The '006 patent does not describe or reference any such "pilot drill" or "initial hole" being made during a tooth implant operation. Regardless, the claim limitation at issue is a step in a method of producing a drill template. It recites defining a pilot hole in a drill template with reference to the surfaces of neighboring teeth, nothing more. The function of actually passing a drill through a pilot hole in a drill template

[5] "Determinate" means "having defined limits." Merriam-Webster.com http://www.merriam-webster.com/dictionary/determinate (last visited November 14, 2016). Ex. 3001.

while drilling a bore hole into a patient's jaw is neither recited nor a necessary part of defining a pilot hole in a drill template under the broadest reasonable interpretation standard.[6]

Second, the language of dependent claims 9 and 10, in contrast to claim 1, limits the "determinating a pilot hole" step in a manner similar to that advocated by Patent Owner. Claim 10 depends from claim 9, which recites a drill template formed as a "negative" of "occlusal surfaces of neighboring teeth . . . with respect to an implant position." Ex. 1001, 6:17–21. Claim 10 further limits the drill template to one that "contains a bore hole position that serves as a guide for the drill." *Id.* at 6:23–24. Although the '006 patent is not always clear or consistent in the use of the phrases "pilot hole" and "bore hole," as Petitioner ably explains, we read claim 10 to limit the pilot hole in the drill template to "a bore hole position," directly above the surgical "implant position" (claim 9), to "serve[] as a guide for the drill" when drilling a bore hole into the patient's jaw as depicted in Figure 5. *Id.* at 3:19–22 ("The drill assistance device contains a bore hole which serves as a drill guide for the dentist's drill in order to create the bore hole that is used to fasten the implant."); 4:63–67 ("[P]ilot hole 17 is positioned on the top side of the drill assistance device 16 [so] the dentist can carry out the drilling operation in the jaw 1 secure in the knowledge of having chosen the optimal pilot hole position for fastening the implant between the adjacent teeth 11 and 12."). In short, dependent claims 9 and 10 recite specific

[6] Although the pilot hole is determined "relative to surfaces of the neighboring teeth," that limitation does not recite or require locating the pilot hole in the drill template such that it will be positioned directly over the implant position where the bore hole will be drilled into the patient's jaw. Tr. 34:6–12.

limitations from the disclosed embodiment regarding the location of the pilot hole; claim 1 does not. Under the circumstances, the doctrine of claim differentiation weighs against Patent Owner's proposed construction. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (The "doctrine of claim differentiation is at its strongest" where "the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim.") (internal citations omitted).

Third, Petitioner is correct that the '006 patent includes a pilot hole located in a drill template either at the implant position or elsewhere, "so long as it is guiding the implant drill." Reply 6. The '006 patent describes a conventional preferred embodiment for locating a pilot hole in a drill template that will be positioned directly over the implant (bore hole) position for drilling a bore hole into a patient's jaw, as depicted in Figure 5. Ex. 1001, 1:28–46; 3:19–22, 4:51–67. The broadest reasonable interpretation of claim 1, however, does not limit the "determinating a pilot hole" step to the preferred embodiment. The '006 patent, although not entirely clear, describes using measured data from the X-ray and 3-D optical measuring steps in a CAD/CAM machine "to produce the bore hole template including . . . a guide path for the drill." *Id.* at 4:38–41. That description evokes a guide path for the drill but does not limit the guide path (pilot hole) exclusively to a location directly over the implant (bore hole) position. Therefore, we do not agree with Patent Owner that the cited description, when read in the context of the language used in claims 1, 9, and 10, requires limiting claim 1 in the manner urged by Patent Owner. PO Resp. 16–17 (citing Ex. 2002 ¶ 35 (citing Ex. 1001, 4:37–41)).

Therefore, we maintain our claim construction of the phrase "determinating a pilot hole in a drill template" as "defining a guide hole in a drill template for drilling a bore hole into the person's jaw."[7]

3. "neighboring teeth"

Patent Owner contends that "neighboring teeth" should be construed to mean "teeth adjacent the implant position" or "teeth adjacent to the bore hole position." PO Resp. 17–18 (citing Ex. 1001, 4:29–42, Fig. 5; Ex. 2002 ¶¶ 45–51; Ex. 2023, 54:2–15). Petitioner contends that "neighboring teeth" should be construed to mean "teeth in the jaw branch where the drill assistance device will be located." Reply 6–8 (citing Ex. 1001, 3:13–17, 3:50–55, 4:51–55; Ex. 2023, 53:9–23; 56:19–24; 239:7–19). We determine that the '006 patent consistently refers to "neighboring teeth" and "adjacent teeth" interchangeably as "teeth adjacent the implant position."

Petitioner cites a section of the Summary of the Invention in the '006 patent that references "neighboring teeth" in the context of grinding out a form of drill template, which includes negatives of the occlusal surfaces of "the still remaining adjacent teeth" to which the drill template will be attached. Ex. 1001, 3:13–19; Ex. 2002 ¶ 47. The Detailed Description section cited by Petitioner (Ex. 1001, 3:50–55) describes the option of generating a 3-D optical image of an entire jaw branch, but it does not reference "neighboring teeth." Other sections of the Detailed Description not cited by Petitioner provide specific and consistent contextual references to "neighboring teeth" as teeth adjacent the implant position.

[7] Antecedent basis for "the person's jaw" is provided in the preamble. Ex. 1001, 5:2–3.

For example, Figure 5 of the ’006 patent depicts “two neighboring teeth,” 11 and 12, adjacent implant position 9, as shown below. *Id.* at 3:37–39, Fig. 5; Ex. 2002 ¶ 48.

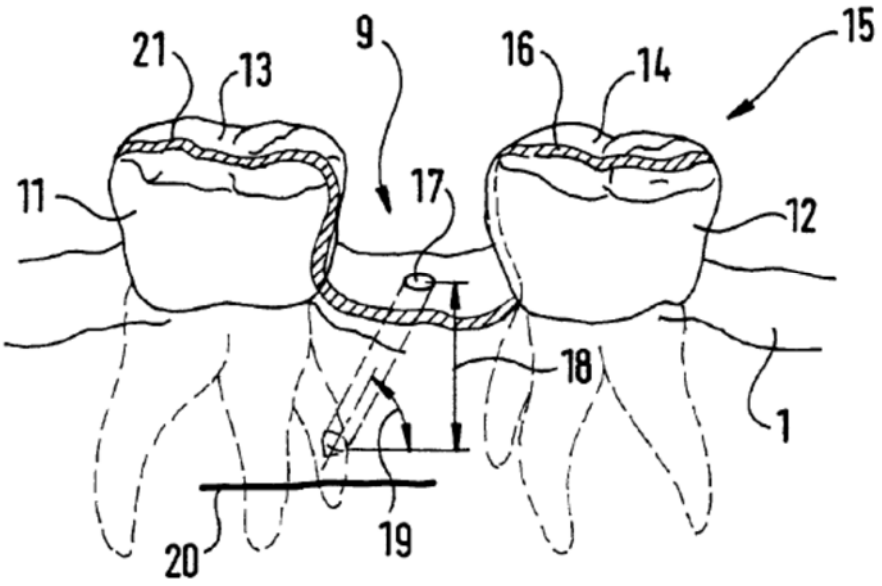


Figure 5, above, more particularly depicts “neighboring teeth 11 and 12” as “arranged adjacent to the implant position 9.” *Id.* at 4:23–31. The ’006 patent then repeatedly refers, interchangeably, to “adjacent teeth 11 and 12” and “neighboring teeth 11 and 12” in the context of determining the position of the pilot hole in the drill template. *Id.* at 4:29–36, 4:42–45, 4:63–67; *see also* Ex. 2002 ¶ 49 (The “term ‘neighboring’ connotes a distance relationship that a POSA [person of ordinary skill in the art][8] would have

[8] The parties agree that, for purposes of this proceeding, a person of ordinary skill in the art of dental implants (“POSA”) would have either a doctorate degree in dentistry from an accredited institution, or a degree in biomedical, electrical, or computer engineering or a related field and several years of experience in planning and placing dental implants and related structures and/or would have familiarity with computer-aided design processes and systems. Pet. 9 (citing Ex. 1002 ¶ 18); PO Resp. 15 (citing Ex. 2002 ¶¶ 17–

understood to relate to the intended pilot hole/osteotomy location described in the patent."). When a patent "repeatedly and consistently" characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization. *See, e.g.*, *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1318 (Fed. Cir. 2014); *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374–75 (Fed. Cir. 2009). We apply the doctrine here to construe "neighboring teeth" as referring to teeth adjacent the implant position.

Petitioner argues that "neighboring teeth" are used to stabilize the drill template, and that the '006 patent uses "neighboring teeth" and "adjacent teeth" to indicate different things. Reply 7. Stabilizing the drill template while positioning it in a patient's mouth during tooth implant surgery is not a method step recited in claim 1. Moreover, with reference to Figure 5, the '006 patent does describe attaching drill template 16 "on the occlusal surfaces 13, 14 of the neighboring teeth 11 and 12," Petitioner's argument to the contrary notwithstanding. Ex. 1001, 4:53–55; Reply 7 (citing Ex. 1001, 4:51–55). Therefore, we find the '006 patent does not describe or define "neighboring teeth" as including the jaw branch where a drill template may be positioned during tooth implant surgery.

In sum, "neighboring teeth" are repeatedly referenced and depicted in the '006 patent as teeth adjacent the implant position. Neighboring teeth are a subset of additional teeth in a jaw branch. Those additional teeth may be used to align the pilot hole and stabilize the drill template when positioned in

21). We adopt and apply this definition of a POSA to our analysis in this Decision.

a patient's mouth during tooth implant surgery, but they are not part of the "neighboring teeth" recited in claim 1 and described in the '006 patent.

For the reasons given above, we construe "neighboring teeth" as "teeth adjacent the implant position."

4. "pseudo-x-ray picture"

Claim 6 depends from claim 1 and recites "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." Ex. 1001, 6:5–9. Claim 7 depends from claim 6 and further recites "the x-ray picture and the pseudo-x-ray picture are superimposed from several directions." *Id.* at 6:10–12. The '006 patent describes a pseudo-x-ray picture as "based on the surface data of the three-dimensional image," and states that the pseudo-x-ray picture can "overlap" the "actual x-ray." *Id.* at 2:66–3:7, 4:3–9. The '006 patent references "pseudo-x-ray B´, 8," that overlaps with "x-ray 5" as shown in Figure 4, but Figure 4 provides little additional information beyond the descriptive text. *Id.* at 4:3–9, Fig. 4. The '006 patent does not provide a detailed description of what type of 3-D optical image is to be taken or how "measured data records" are converted to a "pseudo-x-ray picture," other than by referencing the recited "standard" X-ray absorption values and "the generation theory" of the X-ray image. *Id.*; Pet. 19 (citing Ex. 1002 ¶ 48).

Petitioner argues that the term "pseudo-x-ray picture" is not a term that has a commonly understood meaning to a POSA. Pet. 19 (citing Ex. 1002 ¶ 45 [47]). Patent Owner does not comment on the construction of "pseudo-x-ray picture." PO Resp. 15–19. Having reviewed the complete record, we adopt Petitioner's argument and evidence in support of

Petitioner's proposed broadest reasonable interpretation of "pseudo-x-ray picture."

Therefore, we adopt Petitioner's proposed broadest reasonable interpretation of "pseudo-x-ray picture" as "any representation of measured data records of the three-dimensional optical measuring that can be superimposed on an x-ray image." Pet. 19 (citing Ex. 1002 ¶ 49).

B. Asserted Anticipation of Claims 1–4 and 9–10 by Mushabac

Petitioner argues that Mushabac (Ex. 1007) discloses every limitation of claims 1–4 and 9–10 of the '006 patent and, therefore, anticipates the claims pursuant to 35 U.S.C. § 102. Pet. 20, 30–38. Mushabac issued more than one year before the U.S. application date of the '006 patent and is prior art under 35 U.S.C. § 102(b) (pre-AIA). Petitioner supports its argument with citations to Mushabac, asserted to correspond to each limitation of the claims, and with Dr. Benjamin's Declaration. *Id.* at 30–38 (citing Ex. 1002 ¶¶ 22–24, 58–65; Ex. 1007). Patent Owner opposes. PO Resp. 21–40. We address the parties' arguments below.

1. Mushabac

Mushabac Figure 25, reproduced below, depicts a computer monitor used to aid a dental surgeon. Ex. 1007, Fig. 25.

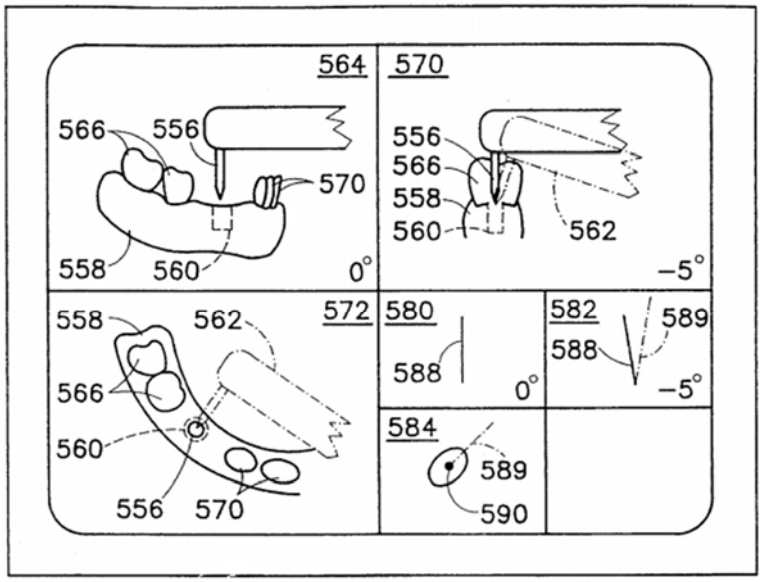


FIG.25

The two left-hand quadrants of Mushabac Figure 25, above, depict an implant position between molars 566 and front teeth 568 (labelled 570[9]). *Id.* at 24:43–49. Area 560 is the bore hole to be drilled into jaw bone 558 for receiving an anchor or an implant. *Id.* at 24:35–39.

2. Analysis of Claim 1 – "visible surfaces of the jaw"

Claim 1 of the '006 patent recites "carrying out a three-dimensional optical measuring of the *visible surfaces of the jaw* and of the teeth." (Emphasis added). The Petition cites to sections in Mushabac that expressly disclose 3-D optical measuring of the visible surfaces of a patient's "tooth" or "teeth" but not the jaw. Pet. 30–31, 35; PO Resp. 30–31. Petitioner recognizes that Mushabac discloses data generating devices for the display of "the three dimensional surfaces and contours of the tooth or teeth." Pet.

[9] Mushabac repeatedly describes "molars 566" and "front teeth 568." Ex. 1007, 24:44–46, 24:49, 25:2.

30 (citing Ex. 1007, 10:62–67). Petitioner further recognizes that Mushabac's disclosure of determining the exact placement of a bore hole (560, Fig. 25) and a pilot hole (block 606, Fig. 28) is based on the dimensions and shape of "the jaw bone," "internal bone structures," and surface data for the teeth. *Id.* at 30–31 (citing Ex. 1007, 24:66–25:10, 25:14–21, Figs. 25, 28). Petitioner's claim chart for claim 1 cites Mushabac's disclosure regarding the use of optically imaged surface data to display the "visible three-dimensional surfaces of each such tooth." *Id.* at 35 (quoting Ex. 1007, 16:7–11).

Petitioner argues that Mushabac discloses visualization software that "shows the surfaces of the jaw," but Petitioner's supporting citation to Mushabac does not disclose an *optical* (light-based) measurement of the *visible* surfaces of a patient's jaw. Pet. 35 (citing Ex. 1007, 24:53–56); PO Resp. 30. The cited section of Mushabac discloses the use of a sharp stylus to pierce the patient's gum and contact the jaw bone (contact digitization), as shown in the computer display of Figure 25 (jaw bone 558). Pet. 35; Ex. 1007, 24:53–65. Petitioner also cites a conclusory one-line statement of Dr. Benjamin that "the visualization software shows the surfaces of the jaw." Pet. 35 (citing Ex. 1002 ¶ 60).

Patent Owner correctly explains that Mushabac discloses the use of a grid-based projection method in data generating device 22, which "focus[es] the grid light on the surface of a subject tooth." Ex. 1007, 12:50–51; PO Resp. 30 (citing Ex. 1007, 12:45–60, Figs. 2–3). "CCD 48 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 [Fig. 25]." Ex. 1007, 12:55–60. Mushabac's disclosure is very specific regarding optical measurement of a tooth or teeth, without mentioning, suggesting, or implying optical measurement of the visible surfaces of the jaw.[10]

With respect to the jaw, Patent Owner correctly explains that a sharp stylus is used to penetrate the surface of the gum repeatedly to measure the structure of the jaw *bone* displayed in Figure 25. PO Resp. 30–31 (citing Ex. 1007, 24:53–65 ("[S]tylus member 52 is provided with a sharp stylus 574 (FIG. 1) having a length sufficient[ly] long to penetrate gum tissue and contact the bone surface. . . . [P]ractitioner 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 558 [Fig. 25] about the implantation site.")). We agree with Patent Owner and find that the use of a sharp stylus to pierce the gum and take multiple data points via contact digitization of the jaw bone beneath the skin surface is not a 3-D optical measuring of the visible surfaces of a patient's jaw.

[10] At oral argument, Patent Owner's counsel cited the prior art Massen reference as an example of a 3-D optical measuring system that uses laser light to measure a single tooth in a patient's mouth. Tr. 38:21–39:12 (citing U.S. Patent No. 5,372,502 to Massen et al., filed November 7, 1991, issued December 13, 1994. Ex. 2005 ("Massen")). Massen discloses an optical 3-D measuring probe "utilized to generate a three-dimensional image of a single tooth or a group of teeth . . . . The measuring probe projects a particular pattern onto the single tooth or group of teeth . . . to be surveyed." Ex. 2005, 4:14–19. Massen, therefore, provides an explicit example of a precise optical measuring technique known to a POSA to be capable of optically measuring an individual tooth without necessarily measuring the gum or other visible surfaces of a patient's jaw.

Patent Owner further emphasizes that Mushabac Figure 25, the discussion of which is relied upon for support in the Petition, depicts only jaw bone 558, not the visible surfaces of the jaw. Tr. 37:14–18. We agree. The display of jaw bone and teeth in Mushabac Figure 25 is consistent with Mushabac's description of using contact digitization to measure the jaw bone and 3-D optical imaging to measure the visible surfaces of the teeth.

Petitioner's Reply makes an entirely new argument, that "[i]t is *difficult to conceive* how Mushabac's disclosed system would operate by capturing three-dimensional optical measurements of the teeth without obtaining measurements of the jaw as well." Reply 13 (citing Ex. 1007, 28:16–19, 28:30, Fig. 31) (emphasis added). Petitioner's Reply is inconsistent with the Petition, which relies on Mushabac's disclosure of non-optical contact digitization of the jaw bone, as depicted in Figure 25, and a conclusory, unexplained assertion that visualization software shows the surfaces of the jaw. Pet. 35 (citing Ex. 1007, 24:53–56; Ex. 1002 ¶ 60). We view Petitioner's Reply argument as a new assertion that Mushabac inherently discloses 3-D optical measuring of the visible surfaces of the jaw.

Petitioner's Reply cites to a disclosure regarding Mushabac's Figure 31 that was not cited or discussed in the Petition. Reply 13 (citing Ex. 1007, 28:16–19, 28:30, Fig. 31). Mushabac Figure 31 is reproduced below.

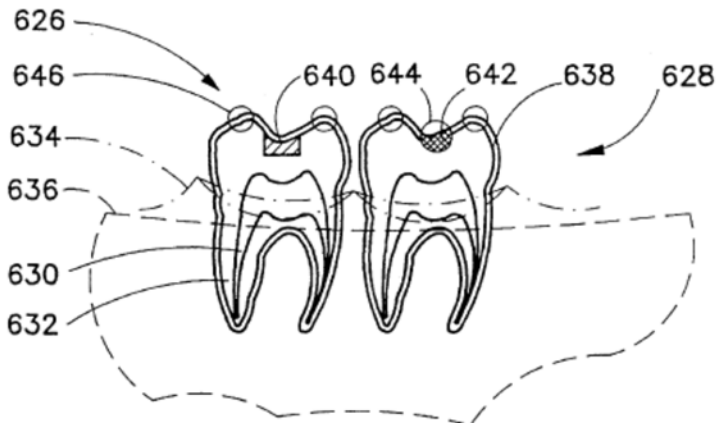


Figure 31, above, depicts a display of "different structures of molars 626 and 628, such as the root 630, the pulp 632, the gum 634, the bone 636, and the enamel 638." Ex. 1007, 28:29–31. Petitioner relies exclusively on Mushabac's statement – that Figure 31 is generated by a computer analysis of "external surface data from optical data generating device or assembly 22 and/or pantograph data generating device or assembly 26 and internal structure data from X-ray data generating device or assembly 28 to determine three-dimensional dentitious structures" – in support of its argument. Reply 13 (citing Ex. 1007, 28:16–20). Notably, Petitioner's Reply does not cite to any testimony of Dr. Benjamin or Dr. Erickson, or any other documentary evidence, to support Petitioner's argument. *Id.* Dr. Erickson testified as follows with respect to Mushabac Figure 31:

> Q. In other words, if the dentist put the radio -- put the optical scanner above the gum, it would image the gum, correct, Doctor?
>
> A. In nowhere does he mention – it's quite possible it could, but in nowhere in Mushabac does he say that, nowhere. He, again – it's very, very clear that Mushabac gets the gum contours either by measuring it in the x-ray data, using the grid in figure 30, or that other instance where he talks about putting a radiopaque device on top

> of the gingival tissues to help measure there. Those are the ways he does it.

Ex. 1032, 30:15–31:8. We credit Dr. Erickson's testimony regarding Mushabac's disclosure of Figure 31.

The statement in Mushabac relied upon by Petitioner references optical data, pantograph data, "and/or" X-ray data generating techniques, but there is no express disclosure that the gum surface in Figure 31 was measured using a 3-D optical measuring technique, as opposed to some other technique. The possible use of Mushabac's 3-D optical scanner to measure the visible surfaces of a patient's jaw (e.g., gum 634 in Fig. 31) while optically measuring the patient's teeth, does not satisfy the "necessarily present" standard for inherent anticipation. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) ("To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'"); *id.* at 1269 ("'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.'" (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981))). Therefore, we are not persuaded Mushabac's disclosure regarding Figure 31 supports Petitioner's argument.

Patent Owner's counsel effectively articulated the problem with Petitioner's argument at oral argument:

> [W]here the Petitioner directs your attention and highlights gum 634 [in Figure 31], it indicates other structures that can be shown: the root of the tooth, the pulp of the tooth, and the gums. Root and pulp are not surface structures. They cannot be optically measured. Because gum 634 is categorized with other things here that cannot optically be measured, how can we say that Mushabac necessarily describes that gum 634 is being optically

> measured, when it describes other contact digitation -- digitization as a method of measuring surface contours? . . .
>
> Furthermore, there's also no explanation as to why you would actually take that gum surface 634 in Figure 31 and use it in Figure 25. Figure 25 doesn't show the gums at all. So, the question is, well, why do we combine those two different embodiments, particularly where it was never discussed in the original petition?

Tr. 41:7–42:8. We agree with Patent Owner. The cited disclosure in Mushabac does not support Petitioner's argument for the reasons given by Patent Owner, which we adopt as our own.

For the reasons given above, we determine that Petitioner has not satisfied its burden of proving that Mushabac anticipates claim 1 of the '006 patent by a preponderance of the evidence.

3. Dependent Claims 2–4 and 9–10

Dependent claims 2–4 and 9–10 all depend directly or indirectly (claim 10) from claim 1. Because Petitioner has not satisfied its burden of proving that Mushabac anticipates claim 1, Petitioner's assertion of anticipation necessarily fails for dependent claims 2–4 and 9–10.

C. Asserted Obviousness of Claims 1–10 Over Bannuscher and Truppe

Petitioner argues that the subject matter of claims 1–10 would have been obvious over Bannuscher and Truppe. Pet. 44–57 (citing Ex. 1008; Ex. 1010; Ex. 1002 ¶¶ 84–102). Patent Owner opposes. Prelim Resp. 31–35 (citing Ex. 1008; Ex. 1010). Obviousness under 35 U.S.C. § 103 requires an assessment of (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior

art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long-felt but unsolved needs, failure of others, etc."[11] *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). A party who petitions the Board for a determination of obviousness must show that "'a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007)).

The Supreme Court has made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To reach this conclusion, however, requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined the prior art elements in the normal course of their work to yield the claimed invention. *Id.*

[11] Patent Owner has not offered secondary consideration evidence in this proceeding. PO Resp. 42–58.

We address the parties' arguments and evidence according to the standards articulated above.

1. Bannuscher

Bannuscher discloses a method of preparing a surgical template for dental implant surgery. Ex. 1010, Abstract (57), 5:1–3.[12] First, a plaster model is cast from an impression taken of a patient's mouth or jaw area. *Id.* at 2:22–28, 8:23–29. An X-ray image also is taken to determine the "available vertical bone material" for drilling a bore hole into the patient's jaw. *Id.* at 2:41–45, 8:32–35. The 3-D geometry of the plaster model and the X-ray image are both "input digitally, relative to the patient's skull, into a computer." *Id.* at 3:44–4:7; *see also id.* at Abstract (57), 8:36–39 ("The three-dimensional plaster models and the X-ray image relating to the patient's skull are then input into a computer by digital transfer."). Markers are used to correlate the data for determining the optimum positioning of the implant, including the vertical dimension of available jaw bone and the drilling angles, "which are of primary importance for an implantation procedure." *Id.* at 8:43–9:30; *see also id.* at 4:3–21. Bannuscher discloses that the data or "real values" representing the drilling angles for an optimized implant position are "transferred to the operation template." *Id.* at 4:20–25, 7:43–8:4, 9:26–33.

To produce a dental implant operation template, Bannuscher mounts a plaster model of the patient's mouth or jaw area on a base frame having two "swivel platforms." *Id.* at 9:34–10:15, Figs. 1–3; Ex. 2002 ¶ 144. The

[12] Bannuscher published on October 2, 1996, more than one year before the October 31, 2000 U.S. application filing date of the '006 patent, and Bannuscher qualifies as prior art under 35 U.S.C. § 102(b). Pet. 20–21.

plaster model can be swiveled and rotated so as to assume any angular position. Ex. 1010, 10:22–27. An operation template is "arranged on the three-dimensional" plaster model. *Id.* at 10:31–33. A drill is used to drill a pilot hole in the operation template at "any angle[] determined by bringing together the three-dimensional model geometry and the X-ray image of the mouth or jaw region of the patient." *Id.* at 10:16–33; Ex. 2002 ¶ 144. The pilot hole in the operation template acts as a drill guide "during the operation in the patient's mouth region." Ex. 1010, 10:33–39; *see also id.* at 5:6–16 ("In an operation template . . . drilling opening areas and drilling angles . . . are provided to position a drilling device in the implantological operation."), 12:12–23 (claim 3); Ex. 2002 ¶ 144.

2. Truppe

Truppe discloses a multi-step method of imaging a person's jaw in preparation for a dental implant operation. Ex. 1008, Abstract, 1:7–11. Truppe's method begins with the insertion of a "positional determination device" having marking points, such as lead beads, into a person's mouth. *Id.* at 2:25–33. The device and marking points are inserted at a "precisely reproducible position in the oral cavity" to allow for removal and re-insertion at precisely the same position. *Id.* at 2:25–29, 2:65–67. Positional determination device 3 and marking points 4 are depicted in Truppe Figure 1, reproduced below.

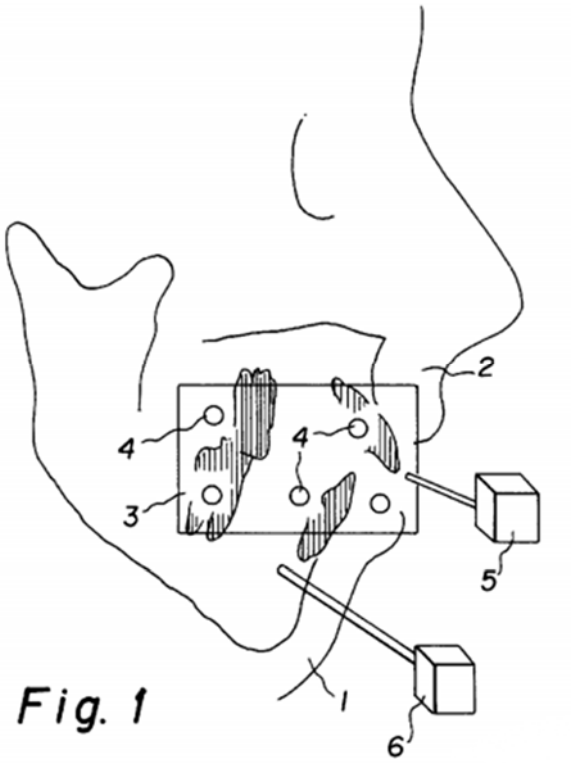


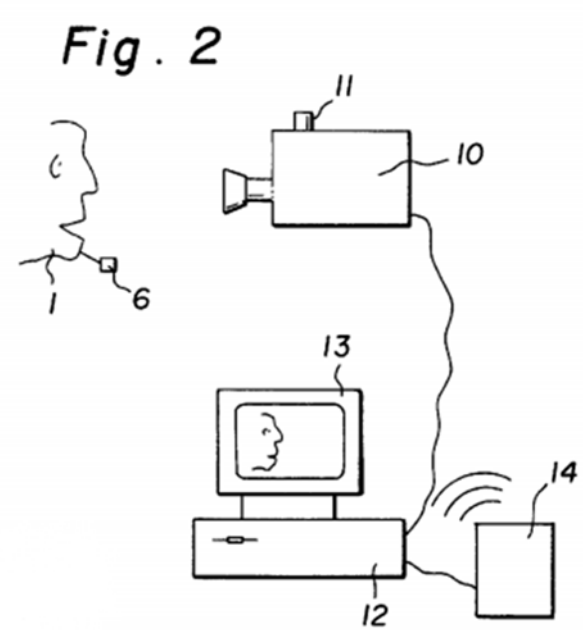
Fig. 1

With reference to Truppe Figure 1, above, marking points 4 are selected and positioned so as to be clearly seen. *Id.* at 5:58–60. An X-ray image of a patient's jaw is taken and stored "in memory as a data set." *Id.* at 2:41–46. Truppe uses phrasing such as "imaging process" or "imaging method" to refer to "[t]aking at least one picture of the jaw of the person with an imaging process" such as "X-ray, computed tomography (CT), MRI or the like." *Id.*; *see also id.* at Abstract ("at least one picture of the jaw of the person is taken with an imaging process, such as X-ray, CT, MRI or the like"), 4:3 ("from the picture of the imaging process"), 4:64–67 ("the data set from the imaging method"), 5:66–67 ("[a] picture taken by the imaging process"), 6:4–6 ("the data set from the imaging process"). The X-ray imaged marking points are identified on a computer and "the coordinates of

the marking points are fixed in the coordinate system of the [X-ray] picture." *Id.* at 2:47–52.

Next, 3-D magnetic sensor 5 is connected to positional determination device 3, and 3-D magnetic sensor 6 is screwed to the outside of the patient's jaw.[13] *Id.* at 2:59–3:1, 5:60–62. The positional relationship between 3-D sensors 5 and 6 is determined, and device 3 (with 3-D sensor 5) is removed from the patient's mouth to "establish[] free access to the oral cavity." *Id.* at 3:12–18. By referring to the obtained information, and monitoring the 3D sensor secured to the outside of the jaw, "the current position of the jaw is always known." *Id.* at 3:19–22.

The next steps are depicted in the embodiment of Figure 2, reproduced below.



[13] 3-D sensor 6 allows for correction of any movement of the patient's jaw during the imaging process. Ex. 1008, 5:2–7.

Truppe Figure 2, above, depicts camera 10, on which 3-D magnetic sensor 11 is mounted. *Id.* at 5:63–64. Camera 10 is connected to a computer, with monitor 13, which is connected to magnetic field emitter 14 used for locating the 3-D magnetic sensors. *Id.* at 3:61–65, 5:64–6:1. The camera generates an optical representation of the jaw (and any visible teeth) by "making photographs or video recordings," which are also stored in computer memory with the X-ray image for display on the computer monitor. *Id.* at 3:58–65, 5:63–67. Given the configuration depicted in Figure 2, because "the three-dimensional location of the camera and that of the [jaw] is known, a representation of the data set that corresponds to the same angle of view and the same scale can be calculated." *Id.* at 3:65–4:1; *see also id.* at 3:12–16, 6:2–4. As a result, "the corresponding structures of the optical representation [from the camera] and from the picture of the [X-ray] imaging process thus coincide and can be represented in their correct position simultaneously or alternatively." *Id.* at 4:1–5; *see also id.* at 3:19–27 ("By carrying out a number of coordinate transformations, it is possible to position the [X-ray] data set such that the structures of the [X-ray] data set always still match . . . the corresponding structures of the optical image, even if the jaw should move three-dimensionally."); Ex. 1002 ¶ 70.

Truppe discloses that the aforementioned method steps also may be performed on a physical model of a patient's jaw. *Id.* at 3:48–55. Ex. 1002 ¶ 70.

3. Claim 1 – Analysis of Bannuscher and Truppe

With regard to claim 1 of the '006 patent, Bannuscher discloses a method of producing a drill template for use in a dental implant procedure. Pet. 44, 52 (citing Ex. 1010, 1:3–9; 5:6–16; 10:33–39; Ex. 1002 ¶ 84); Ex.

2002 ¶ 136. Bannuscher discloses the step of "taking an X-ray picture of the jaw" and generating a "measured data record" that is stored in a computer. Pet. 45, 52 (citing Ex. 1002 ¶¶ 84, 85; Ex. 1008, 2:41–45; Ex. 1010, 4:3–7, 8:23–39); Ex. 2002 ¶ 142. Bannuscher discloses the step of "correlating" the X-ray data with 3-D data from the plaster model, and the digitized 3-D computer model represents the visual topography of the patient's jaw and teeth, which would include the teeth adjacent the implant position. Ex. 1010, 8:23–39; Ex. 1002 ¶¶ 84–85.

As stated above, Bannuscher discloses that the 3-D geometry of the plaster model and the X-ray image are both "input digitally, relative to the patient's skull, into a computer." Ex. 1002 ¶ 85; Ex. 1010, 3:44–4:7; *see also* Ex. 1010, Abstract (57), 8:36–39. Markers are used to correlate the data and determine the optimum positioning of the bore hole and the drilling angles for a pilot hole. Ex. 1002 ¶ 86; Ex. 1010, 4:3–21, 8:43–9:30. Patent Owner does not challenge this evidence. PO Resp. 42–46, 50–55; Ex. 1029, 174:6–176:19. Therefore, Patent Owner's argument regarding Bannuscher's use of a "recording bow" to record articulation movements of a patient's jaw is not relevant to our analysis. PO Resp. 44–46. We find that Bannuscher discloses digitally inputting the X-ray image and 3-D model geometry of a patient's jaw and teeth into a computer for "correlating" the data sets.

Bannuscher includes a step of planning or determining the optimal bore hole and corresponding pilot hole for the implant based on the X-ray picture and the 3-D surface topography of the jaw and teeth from the plaster model. Bannuscher discloses that "[t]he optimised implant positions established while taking into account all the necessary parameters, including the angles with the reference points required for this purpose are transferred

to the operation template . . . ." Ex. 1010, 7:43–8:4. Bannuscher further discloses that "[t]he definition of the implant position" and "operation planning can be optimised" (*id.* at 5:40–44) such that the drilling areas and drilling angles are "coordinated in respect of an optimised implant position and an available vertical bone supply, based on a three-dimensional model geometry of the mouth or jaw region and on an X-ray image thereof" (*id.* at 5:8–16). Thus, Bannuscher discloses using digitized 3-D X-ray data and 3-D geometry data of the jaw and teeth to determine the optimum 3-D position of a bore hole and corresponding pilot hole in the drill template. Ex. 1002 ¶¶ 90, 91.

Bannuscher discloses mounting the drill template on swivel platforms that can be rotated so that "any angles determined by bringing together the three-dimensional model geometry and the X-ray image of the mouth or jaw region of the patient can be produced on an operation template arranged on the three-dimensional model geometry." Ex. 1010, 10:26–34. Based on the correlated X-ray image and 3-D measurement data, a pilot hole is drilled in the drill template at an optimized angle. *Id.* at 4:11–25, 5:6–16, 10:34–36. Bannuscher, however, does not disclose carrying out a 3-D "optical measuring" of the visible surfaces of a patient's jaw and teeth in accordance with our claim construction. Pet. 52–53 (citing Ex. 1010; Ex. 1002 ¶¶ 84–89, 92); PO Resp. 42–43, 46 (citing Ex. 2023, 157:3–22 ("Q. And because Bannuscher doesn't describe measurements using light, you rely on Truppe, correct? A. Yes."); 158:3–5). Petitioner, therefore, relies on Truppe's disclosure of optically measuring a patient's jaw, or model of the jaw, and "superimposing the optical 3-D data with the x-ray data set to provide a

'positionally correctly superimposed data set,'" to fill the gap in Bannuscher. Pet. 46–47 (citing Ex. 1008, 3:48–55; Ex. 1002 ¶¶ 69, 88).

a. "carrying out a three-dimensional optical measuring"

Patent Owner argues that Truppe does not disclose the "carrying out a three-dimensional optical measuring" step recited in claim 1, because Truppe's system "merely describes determining a *position of a camera* in three dimensions" but the camera itself "does not three-dimensionally measure any surface structures." PO Resp. 43 (citing Ex. 1008, 5:67–6:4; Ex. 2002 ¶¶ 163–69). Patent Owner argues, in particular, that Truppe's use of magnetic 3-D sensors to measure a camera position is "neither an optical measurement nor a measurement of the three-dimensional surfaces of the jaw or teeth." *Id.* at 49 (citing Ex. 2002 ¶¶ 163–69; Ex. 2023, 45:8–12). In other words, "[j]ust because you have taken multiple images from multiple angles won't necessarily create a three-dimensional image. You have to do more." Tr. 59:3–5. We find that the "more" is adequately disclosed in Truppe.

Contrary to the implication of Patent Owner's argument, our claim construction – "using light to measure the visible surfaces of the jaw and teeth in three dimensions" – does not require the camera itself to measure the surface structures of the jaw and teeth directly in three dimensions. As Petitioner correctly notes, the '006 patent generally describes optical imaging of the jaw and teeth as "measured using a three-dimensional system of coordinates." Reply 18–19 (citing Ex. 1001, 3:52–53,[14] Fig. 2). The '006 patent does not further describe or otherwise limit the manner in which the

[14] Petitioner cites incorrect line numbers 3:32–33.

3-D coordinate system is provided or used for making the optical measurement. Truppe optically measures the visible surfaces of a patient's jaw and teeth using light from a conventional video camera, with reference to a three-dimensional coordinate system provided by the relative positions of the magnetic sensors.

We agree with Petitioner that Truppe uses a 3-D coordinate system to re-position (e.g., rescale) dental structures in three dimensions "based on relative position or movement of the teeth and jaw to a camera to match the optical image with CT [X-ray] scanning images." Reply 19 (citing Ex. 1008, 3:22–28, 3:65–4:5; Ex. 1002 ¶¶ 70, 87–88). With regard to the X-ray image, Truppe explains it is "especially preferred . . . that three-dimensional structures are inserted by the user into the data set of the [X-ray] picture, and that the picture is represented in the positionally correct association with the optical image." Ex. 1008, 4:33–37. The insertion of 3-D structures into the X-ray image is accomplished based on the positions of the marking points in Truppe's positional determination device, which are identified on a computer, and the coordinates fixed in a 3-D coordinate system, such as shown in Figure 4. *Id.* at 2:47–52, 6:18–22, Fig. 4.

With regard to the optical image, Truppe makes clear that because the three-dimensional location of the camera and the jaw is known, "a representation of the data set that corresponds to the same angle of view and the same scale can be calculated." *Id.* at 3:65–4:1; *see also id.* at 3:12–16, 6:2–4. Truppe refers to the calculations as "coordinate transformations." *Id.* at 3:22–28, 4:60–64.[15] We agree with Petitioner that the calculated optical

[15] Truppe also explains that photographs may be taken with the positional determination device and marking points in place, and then they are

representation of the structures is located in a 3-D coordinate space (based on the relative positions of the sensors) to align it in a different 3-D coordinate space (based on the marking points) with X-ray (CT) image data. Pet. 19–20 (citing Ex. 1002 ¶¶ 69–70). Thus, Truppe's goal – improving implant surgical planning by superimposing X-ray image and optical image data sets in a "positionally correct" (Ex. 1008, 2:15, 3:19–20) and "vivid way" (*id.* at 2:7–11) – is accomplished using coordinate transformations in 3-D coordinate systems based on the relative positions of the marking points and magnetic sensors.

Truppe further explains the goal is to superimpose data sets from the X-ray image and the optical image "such that the *structures* of the [X-ray] data set always still match, i.e., remain in agreement with, the corresponding *structures* of the optical image, even if the jaw should move *three-dimensionally*." Reply 19 (quoting Ex. 1008, 3:22–28 (emphasis added)); Ex. 1002 ¶ 70. The reference to "structures" and 3-D movement is consistent with Truppe's use of three-dimensional coordinate systems to superimpose data sets of the X-ray image and optical image that represent the structures of the jaw and teeth. We agree with Petitioner that Truppe optically measures the visible surfaces of the jaw and teeth with reference to a 3-D coordinate system based on the relative positions of the 3-D sensors. Reply 19. Otherwise, the dental structures in the optical image could not be matched in a "positionally correct" way with the 3-D X-ray image data,

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removed from the patient's jaw (or model of the jaw). Ex. 1008, 4:47–60. "Since the marking points of the device are also visible on the photographs, they can be made to coincide with the X-ray image or the like on a monitor." *Id.* at 4:60–63.

particularly when the jaw moves relative to the camera in three-dimensional space. *Id.* As Truppe states, "[t]he *corresponding structures* of the optical representation and from the picture of the [X-ray] imaging process thus *coincide* and can be represented in their correct position simultaneously or alternatively." Ex. 1008, 4:1–5 (emphasis added).[16]

For the reasons given above, we find Petitioner has established by a preponderance of the evidence that Truppe discloses the step of "carrying out a three-dimensional optical measuring of the visible surfaces of the jaw and of the teeth," as recited in claim 1 of the '006 patent.[17]

b. Motivation to combine Bannuscher and Truppe

Petitioner argues that a POSA would have been motivated to combine Bannuscher and Truppe, because a POSA would have recognized the benefit of utilizing Truppe's superimposed optical imaging and X-ray data sets in Bannuscher's method of planning for implant surgery and producing a tooth implant drill template. Pet. 46 (citing Ex. 1002 ¶¶ 86–89). Petitioner emphasizes the motivation provided by Truppe's capability of representing superimposed data sets of a patient's actual jaw and a model of the jaw "very vividly" during implant planning. *Id.* at 46, 48 (citing Ex. 1008, 3:56–58; Ex. 1002 ¶¶ 89–92). Dr. Benjamin explains that Bannuscher uses position markers to correlate X-ray and 3-D model geometry data, in a manner similar to that described in Truppe, from which Bannuscher

[16] We also agree with Petitioner that Patent Owner's criticism of Dr. Benjamin's testimony loses sight of the purpose of Truppe's 3-D sensors. *Compare* Reply 20, *with* PO Resp. 49.

[17] With respect to the remaining limitations of claim 1, Patent Owner does not challenge Petitioner's arguments and evidence in support of Bannuscher and Truppe's disclosure of those limitations. PO Resp. 42–55.

determines the optimal bore hole and corresponding pilot hole drilling angles in a drill template. Ex. 1002 ¶¶ 86–90. Dr. Benjamin explains, in particular, that Bannuscher's drill template is arranged on a model of the jaw and mounted on a swivel platform to create the pilot holes based on the correlated data sets. *Id.* ¶ 91. Petitioner argues that Truppe, therefore, would have provided the motivation for one of ordinary skill to plan dental implant surgery using correlated "positionally correct" data sets from a 3-D optically imaged jaw, model of the jaw, or both, in Bannuscher's drill template production method. Pet. 46–48 (citing Ex. 1002 ¶¶ 89–92; Ex. 1008, 3:44–60; Ex. 1010, 4:11–25, 5:6–16, 5:40–44, 7:43–8:4, 10:26–36).

Patent Owner first argues there is a "fundamental conflict" between Bannuscher and Truppe, because Bannuscher's method produces a drill template for use during implant surgery while Truppe's method is used in a "navigation system" of implant surgery that does not utilize a drill template. PO Resp. 50–53. We agree with Petitioner that the distinction Patent Owner attempts to make is unpersuasive. Reply 22–23. Patent Owner again conflates the claimed method of producing a drill template with a method of performing implant surgery. Moreover, as Petitioner points out, navigation systems and drill template systems are alternative ways to accomplish the same thing, namely transfer preplanned implant positions to the jaw. *Id.* at 22 (citing Ex. 2012, 947). Both systems require planning and modeling of the patient's jaw and teeth prior to the actual surgical implant procedure.[18]

[18] We are not persuaded by Patent Owner's citation to Dr. Benjamin's testimony on this point. PO Resp. 51–52 (citing Ex. 2023, 159:3–20, 167:11–169:7, 180:14–185:8). As Petitioner indicates, Bannuscher and Truppe both rely on simulation planning software; Dr. Benjamin was

Patent Owner next argues that Truppe's disclosed capability of superimposing images of an actual jaw and model of the jaw to provide a more "vivid" image in real-time during surgery "has nothing to do with the creation of drill templates." PO Resp. 52 (citing Ex. 2002 ¶¶ 175–76). Patent Owner further argues that Petitioner has not provided sufficient evidence to explain how the proposed combination would work, presuming that Petitioner was proposing to use Truppe's camera in place of Bannuscher's recording bow. *Id.* at 53–55 (citing Ex. 1002 ¶ 178, Ex. 1008, 3:56–60, Ex. 1010, 8:29–32, 10:6–39; Ex. 2023, 140:16–141:5, 145:19–152:23, 190:20–194:8).[19] Petitioner persuasively addresses Patent Owner's arguments, as we discuss below. Reply 21–23.

With regard to Patent Owner's reference to Bannuscher's recording bow, we have previously rejected such reference to the recording bow as irrelevant. *See* Section II.C.3 n.14. Likewise, Petitioner's argument regarding Truppe does not propose substituting Truppe's camera in place of Bannuscher's recording bow as postulated by Patent Owner. Reply 21–22. Furthermore, we agree with Petitioner's argument that, because both Bannuscher and Truppe are directed to dental implant planning, a POSA

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commenting on "on the fly" surgical changes during implant surgery. Reply 23 (citing Ex. 2023, 183:3–184:13).

[19] It is well established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements. *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc) ("Etter's assertions that Azure cannot be incorporated in Ambrosio are basically irrelevant, the criterion being not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole."); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983); *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

would have been motivated to combine their teachings with respect to correlating X-ray imaging data of the jaw and 3-D surface data of the jaw and teeth. Reply 22–23 (citing Ex. 1002 ¶¶ 89, 92; Ex. 1008, 1:10–11 ("precise planning of the surgical operation is necessary"); Ex. 1010, 5:19–25 ("it is possible to carry out the entire implantological, treatment and operation planning on a scientific basis . . . to implement holistic planning results in a precisely clinical manner")).

More particularly, Bannuscher discloses the desire to obtain "all the necessary [clinical] parameters" relevant to pre-surgical implant planning, which can be "combined together" ("correlated" in the language of claim 1) using planning simulation software, for transfer to a drill template. Ex. 1010, 5:44–6:13, 6:24–40, 7:38–8:4. As Dr. Erickson testified, it would have been desirable for a POSA to have as much diagnostic information as possible when planning for dental implant surgery. Ex. 1029, 31:12–21. Truppe discloses the advantage of correlating three-dimensional X-ray imaging data of the jaw and *optical* imaging data of the jaw and teeth, using simulation software, to obtain a "vivid" representation. Ex. 1008, 2:7–16, 3:19–28, 3:56–58; 4:1–5. Truppe, therefore, discloses a similar process to that disclosed in Bannuscher with respect to correlating 3-D X-ray imaging data and 3-D optical data representing the surfaces of the jaw and teeth, to generate the best possible representation of the patient's jaw and teeth. Ex. 1002 ¶¶ 89–92.

A POSA would have been motivated to use Truppe's optical measurement system to generate 3-D surface data of the jaw and teeth for use in Bannuscher's planning simulation software, in order to produce an enhanced image for determining the optimal bore hole and pilot hole in the

drill template. *Id.*; Ex. 2023, 186:8–187:13 ("the optical imaging [of Truppe] would basically just enhance the diagnostic data [of Bannuscher]"). For example, a POSA would have optically measured the plaster model of the jaw and teeth referenced in Bannuscher and the patient's actual jaw and teeth, as in Truppe, to produce a "vivid" image for correlation with the X-ray imaging data. Ex. 1002 ¶¶ 89, 92.[20] Bannuscher's determination of the optimized bore hole and corresponding pilot hole in the drill template would be based on the enhanced imagery generated from the correlated 3-D data sets. In short, we are persuaded that a POSA would have had reason to incorporate the teaching of Truppe's enhanced 3-D optical measurement technique into Bannuscher's method for correlating 3–D X-ray image and model geometry data sets, to determine an optimal bore hole and corresponding pilot hole in the drill template.

For the reasons given above, we are persuaded that Petitioner has established a sufficient motivation for a POSA to combine the relevant teachings of Bannuscher and Truppe, with a reasonable expectation of success, by a preponderance of the evidence.

[20] Patent Owner characterizes Dr. Benjamin's deposition testimony, regarding "how substituting camera images for the plaster model would allow for execution of the later steps that use [the] plaster model," as not "coherent." PO Resp. 54 (citing Ex. 1010, 10:6–39; Ex. 2023, 140:16–141:5, 145:19–152:23, 190:20–194:8). Patent Owner's argument is based on an incorrect premise. Dr. Benjamin did not propose "substituting" camera images for Bannuscher's plaster model. He testified that a POSA would use Truppe's optical imaging technique "in addition to" Bannuscher's X-ray imaging and plaster model geometry techniques to "enhance the diagnostic information" available in Bannuscher's method for determining the bore hole and corresponding pilot hole in the drill template. Ex. 2023, 191:9–194:5. Having read the cited testimony, we do not find it incoherent.

c. Conclusion

To the extent not addressed explicitly above, we adopt Petitioner's arguments and evidence in support of its assertion that the subject matter of claim 1 would have been obvious to a POSA over Bannuscher and Truppe. Pet. 44–54; Reply 17–23. We determine Petitioner has established that the subject matter of claim 1 of the '006 patent is unpatentable as obvious over Bannuscher and Truppe by a preponderance of the evidence.

4. Dependent Claims 2–8

Petitioner argues that Bannuscher and/or Truppe disclose the limitations of dependent claims 2–8 of the '006 patent and render the subject matter of those claims obvious. Pet. 49–51, 54–56 (citing Ex. 1002 ¶¶ 84, 93–100). Apart from the arguments regarding claim 1, discussed above, Patent Owner does not separately challenge Petitioner's argument and evidence in support of the asserted obviousness of dependent claims 2–8. PO Resp. 42–55. Based on our review of the complete record, we adopt Petitioner's arguments and evidence in support of our determination that Bannuscher and/or Truppe disclose the limitations recited in claims 2–8 and render the subject matter of those claims obvious.

5. Dependent Claims 9 and 10

Claim 9 depends from claim 1 and recites "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." Claim 10 depends from claim 9 and recites "wherein the drill assistance device contains a bore hole position that serves as a guide for the drill." In comparison to claim 1, claims 9 and 10 recite an additional step for producing a drill template in a particular form –

"ground out . . . [in] the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position." Given our construction of "neighboring teeth" in Section II.A.3., above, the drill template must form negatives of occlusal surfaces of the teeth adjacent the implant position.

Petitioner first asserts that Bannuscher's *plaster model* of a patient's jaw and teeth is ground out from a dimension-stable material. Pet. 51, 56. Petitioner further asserts, without explanation, that because Bannuscher discloses the use of markers in the form of "static measuring points or occlusion reliefs of the teeth," it satisfies the limitations of claim 9. *Id.* We agree with Patent Owner that Petitioner's assertions are unpersuasive on several levels. PO Resp. 55–58.

Petitioner's reference to Bannuscher's plaster model as satisfying the "drill assistance device" limitation in claim 9 is incorrect. The "drill assistance device" limitation finds antecedent basis in claim 1. Regarding claim 1, Petitioner asserts that Bannuscher's "operation template" is the recited "drill assistance device." Petition 52 (claim chart citing Ex. 1010, 1:3–9, 5:6–16, 10:33–39; Ex. 1002 ¶ 84). Bannuscher discloses an operation template "arranged on" a plaster model of the patient's jaw (the "three-dimensional geometry") (Ex. 1010, 10:31–33), but the *plaster model* is not the recited drill assistance device that must be ground out from a dimension-stable material in accordance with claim 9. The plaster model, moreover, is cast from plaster, not ground out, and it is a positive representation of the teeth, not a negative representation. Petitioner acknowledges the point. Tr. 74:3–7.

The Petition and Reply also do not explain the Petition's reference and citation to Bannuscher's disclosure regarding the use of occlusion reliefs

to mark supporting zones. Pet. 51 (citing Ex. 1002 ¶ 101); Reply 24–25. As Patent Owner notes, Petitioner's supporting declaration merely repeats the language from the Petition. PO Resp. 57; Ex. 1002 ¶ 101. Petitioner's Reply does not mention the occlusion reliefs at all. Reply 24–25. Accordingly, we give no weight to that argument.

Petitioner's Reply raises a new argument that a POSA "would have understood the operation template [of Bannuscher] to be milled by a CNC milling apparatus." *Id.* at 24 (citing Ex. 2023,[21] 113:10–114:12). Dr. Benjamin testified that Bannuscher's operation template was "probably" or "most likely" CNC milled. Ex. 2023, 113:21–114:4.[22] Patent Owner responds with Dr. Erickson's testimony that such an operation template typically would be molded on the surface of the plaster model, not ground out or milled. PO Resp. 58 (citing Ex. 2002 ¶ 187; Ex. 2018, 6:63–7:11). Petitioner further argues that because Bannuscher's drilling device 8 (Fig. 1) drills a guide hole in the operation template, the operation template is "ground out" as recited in claim 1. *Id.* at 25.

It is Petitioner's burden to establish the unpatentability of the challenged claims. Regardless of whether a POSA would have understood that Bannuscher's drill template could have been "ground out from a dimension-stable material," Petitioner has not provided a sufficient analysis of why or how Bannuscher would have taught a POSA to grind out a drill assistance device that "represents the form of occlusal surfaces of neighboring teeth as a negative with respect to an implant position." *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)

[21] Petitioner's Reply cites Exhibit 2013 rather than Exhibit 2023.
[22] CNC stands for Computer Numerical Control milling. Ex. 1020, 7:38–46.

("[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention."). Bannuscher does not disclose how the operation template is made, e.g., by molding or grinding, although these were known techniques. More importantly, Petitioner does not cite supporting evidence or explain why a POSA would have understood Bannuscher to form the drill template to include negatives of the occlusal surfaces of neighboring teeth adjacent the implant position. Truppe does not disclose a drill template. Petitioner, therefore, does not offer sufficient evidence or analysis directed to the production and form of Bannuscher's operation template or explain persuasively why it would have satisfied the quoted limitation in claim 9.

Given the inconsistency in positions taken in the Petition and Reply, and the lack of a technical analysis directed to the production and form of Bannuscher's operation template, we find Petitioner's arguments and evidence to be unpersuasive. In short, Petitioner has not satisfied its burden of persuasion. Therefore, for the reasons given above, we determine Petitioner has not established by a preponderance of the evidence that the subject matter of dependent claims 9 and 10 would have been obvious to a POSA based on the teachings of Bannuscher and Truppe.

III. PATENT OWNER'S CONTINGENT MOTION TO AMEND

We have concluded that claims 1–8 of the '006 patent are unpatentable. Therefore, we address Patent Owner's contingent motion to enter proposed substitute claims 11–18. MTA 1. Patent Owner states that

substitute claim 11 includes all of the features of original claim 1 of the '006 patent, as well as additional recitations. *Id.* at 2. Substitute claims 12–18 depend, directly or indirectly, from substitute claim 11, and they are substantively identical to original claims 2–8. *Id.* at 1. Patent Owner's proposed claims 11–18, therefore, represent a one-for-one substitution for original claims 1–8 in compliance with our rules. 37 C.F.R. § 42.121(a)(3).

As the moving party, Patent Owner bears the burden of proving that it is entitled to the relief requested. *See* 37 C.F.R. § 42.20(c); *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1307 (Fed. Cir. 2015) ("The Board has reasonably interpreted these provisions as requiring the patentee to show that its substitute claims are patentable over the prior art of record."). Entry of proposed amendments is not automatic, but occurs only upon the patent owner having met the requirements of 37 C.F.R. § 42.121 and demonstrating, by a preponderance of the evidence, the patentability of the proposed substitute claims. *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1334 (Fed. Cir. 2016) ("[T]he Board did not err by placing the burden on [Patent Owner] to establish patentability over the prior art of [Patent Owner]'s proposed substitute claims."); *see Idle Free Sys., Inc. v. Bergstrom, Inc.*, Case IPR2012-00027, slip op. at 7–8 (PTAB June 11, 2013) (Paper 26, "*Idle Free*") (informative). For the reasons explained below, we conclude that Patent Owner has not met its burden with respect to the proposed substitute claims.

A. *Proposed Substitute Independent Claim 11*

Proposed substitute claim 11 is reproduced below, with added text underlined and a single strike-through deletion. MTA App. i–ii.

> 11. Method for producing a drill assistance device for a tooth implant in a person's jaw, the tooth implant to be positioned between neighboring teeth, 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 surfaces of the neighboring 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 the surfaces of the neighboring teeth, based on the x-ray picture and optical measurement, and
>
> 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 are formed by a machine based on the measured data record obtained from the three-dimensional optical measuring in the carrying out step.

Substitute claim 11 specifies that the visible surfaces of the teeth, measured in the step of "carrying out a three-dimensional optical measuring," are the surfaces of teeth that neighbor (i.e., are adjacent) the position of the tooth implant. *Id.* at 2. Patent Owner also emphasizes the newly added clause that further recites producing a drill template containing negative representations of the "surfaces of the neighboring teeth," wherein the negatives are formed by a "machine-based" production step based on the measured data record obtained from the three-dimensional optical measuring step. *Id.* at 2–3, 11–12. We address the issue of the obviousness of substitute claims 11–18 below.

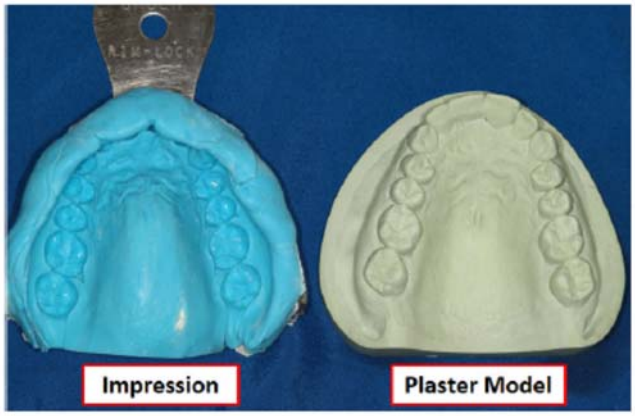
B. *Obviousness of Substitute Claims 11–18 over Bannuscher and Truppe in view of Klein and Poirier*

In Section II.C., above, we explain our reasoning and cite the evidence supporting our determination that the subject matter of claim 1 would have been obvious to a POSA over Bannuscher and Truppe, including the motivation for a POSA to have combined the teachings of Bannuscher and Truppe with a reasonable expectation of success.

1. "producing the drill template containing the pilot hole and negatives of the surfaces of the neighboring teeth"

With regard to the step of "producing the drill template containing the pilot hole and negatives of the surfaces of the neighboring teeth" in substitute claim 11, Bannuscher discloses producing a conventional drill template containing a "pilot hole" at an optimized hole position and angle, based on the correlated 3-D X-ray image data and physical model geometry data. Ex. 1010, 4:11–25, 5:6–16, 10:34–36; Ex. 1002 ¶¶ 90–91. Please see our analysis in Section II.C., above.

The drill template is "arranged on" a 3-D plaster model of the patient's jaw and teeth. Ex. 1010, 10:25–33. A POSA would have understood the plaster model of the patient's jaw and teeth is formed from a negative impression of "the patient's oral situation." Ex. 1010, 8:20–39. The plaster model represents the actual 3-D physical proportions of the patient's jaw and teeth. Ex. 1002 ¶¶ 84, 101; Ex. 2002 ¶¶ 137, 186. Dr. Erickson provides a useful image of the type of negative impression and corresponding plaster model described in Bannuscher, albeit without showing an "implant position" where a tooth would be missing, which is reproduced below.



Ex. 2002 ¶ 176. A POSA would have understood that Bannuscher's drill template, arranged on the plaster model, would be formed as a negative of surfaces of the patient's jaw and teeth, in a similar way as shown in the negative impression mold above. *Id.* ¶ 187 ("[A] POSA would have understood that such a surgical guide could be formed by molding a material to the surface of the plaster cast and allowing it to set such that it forms to the shape of the patient's jaw and teeth (as represented in the plaster model)."); Tr. 83:22–84:5 ("JUDGE PETRAVICK: [W]hen you make a drill template in the classic way on a plaster mold, right, it forms to the surfaces of the teeth, the occlusal or the axial surfaces of the teeth, correct? MR. OLIVER: Correct. JUDGE PETRAVICK: So it has that in the impression. MR. OLIVER: Correct."). Thus, Bannuscher's drill template, arranged on the plaster model, would have included negatives of surfaces of the neighboring teeth adjacent the "optimized implant position." Ex. 1010, 3:44–4:25, 5:6–16, 7:43–8:4.

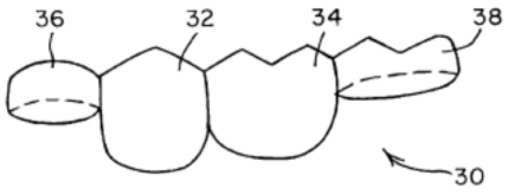
An example of such a conventional implant drill template is disclosed in Klein. Ex. 1028 ¶ 16 (citing Ex. 1020, 7:34–37, 9:4–20, Figs. 2, 3, 22, 23, and 27). Klein discloses a dental implant surgical template (the recited "drill assistance device") made from a plastic material. Ex. 1020, 1:44–57. Klein

Figure 2, reproduced below, depicts a side elevational view of a patient's jaw 20 with teeth 22 and 24 adjacent the implant position. *Id.* at 5:56–57, 7:30–32.

FIG. 2

Klein Figure 2, above, depicts the implant position space between adjacent teeth 22 and 24. Klein Figure 3, reproduced below, depicts a "plastic replica" for use as a dental implant drill template in cooperation with adjacent teeth 22 and 24. *Id.* at 5:58–60, 7:32–37.

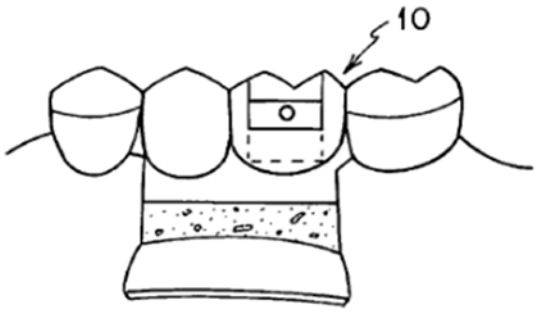
FIG. 3



Klein Figure 3, above, depicts plastic teeth 32 and 34 with anchors 36 and 38 "for attaching plastic replica 30 to the patient's teeth 22 and 24 (FIG. 2) bordering the space." *Id.* at 7:35–37. Anchors 36 and 38 are depicted as formed for placement over the axial surfaces of teeth 22 and 24 adjacent the implant position. Ex. 1028 ¶ 16.

Klein Figure 23, reproduced below, depicts the surgical template attached to the patient's teeth with anchors 36 and 38 positioned over the axial surfaces of teeth 22 and 24. Ex. 1020, 6:38–40, 9:64–10:4.

FIG. 23



As depicted in Klein Figure 23, above, anchors 36 and 38 are formed as "negatives" of the axial surfaces of "neighboring teeth" 22 and 24 adjacent the implant position. *Id.*; Ex. 1028 ¶ 16 ("As shown in Figs. 2, 3, 22, 23 and 27, the anchors match the teeth 22, 24, including negatives of surfaces of neighboring teeth."). Dr. Erickson also acknowledged that "it could quite possibly be" that Klein discloses a drill template with negative surfaces of neighboring teeth. Ex. 1032, 72:9–16.

Bannuscher discloses forming a drill template that would have included negatives of surfaces of the neighboring teeth adjacent the implant position. Klein depicts precisely the same type of conventional drill template disclosed in Bannuscher, where anchor bands are formed as negatives of the axial surfaces of the teeth adjacent the implant position. A POSA would have understood that, because Bannuscher discloses a partially endentulous case where a patient needs a tooth implant but not a full denture (i.e. fully endentulous), the surgical template would have been in the form disclosed in Klein. Ex. 1028 ¶ 20 ("For a partially edentulous case, such a surgical template would have been in the form disclosed by Klein."). We find, therefore, that Klein teaches a conventional drill template, of the same

type referenced in Bannuscher, "containing . . . negatives of the surfaces of the neighboring teeth" as recited in substitute claim 11.

> 2. *wherein the negatives of the surfaces of the neighboring teeth are formed by a machine based on the measured data record obtained from the three-dimensional optical measuring in the carrying out step*

Poirier discloses that a CNC (Computer Numerical Control) milling machine was a machine known for use in producing dental implant drill templates. Ex. 1028 ¶ 12 ("Poirier discloses that a CNC device can be used to form the entire drill template body."); Ex. 2018, 3:48–56 ("While it would be possible to prepare the drill template body and provide it with the drill guide sockets using the CNC device, the drill template body is preferably molded");[23] *see also* Ex. 2007, 346, 350–51 ("Milling of dental restorations from a block of base material, such as metal, ceramic or resin, is proposed as an alternative for fabricating restorations. . . . [D]igitization of the prepared tooth surface and converting the data into control signals for computer-assisted milling is [described]."); Ex. 1028 ¶ 14 ("Willer discloses a method for using CAD/CAM [Computer-Aided Design/Computer-Aided Manufacturing] technology to fabricate dental restorations . . . using a CAD/CAM milling machine that 'is especially developed for dental applications.' Willer (Ex. 2007), at 350"); Ex. 2002 ¶ 58 ("Willer [Ex. 2007] states that this CAD/CAM method is preferable to alternative methods using traditional casting techniques"). Based on our review of the trial

[23] We credit Dr. Benjamin's testimony, and a plain reading of the cited section of Poirier, Patent Owner's argument to the contrary notwithstanding. *Compare* MTA Reply, 7 (citing Ex. 2024 ¶¶ 18–20; Ex. 2026, 107:11–111:23, 131:4–8), *with* Observations (#5) (citing Ex. 1032, 162:6–164:21; Ex. 2018, 3:48–56).

record, we find that the evidence establishes CNC milling (also referred to as a CAD/CAM milling) was known in the art as a computer-controlled machine process that uses digitized input data for various dental applications, such as producing a dental implant drill template.

When we consider the combination of Bannuscher and Truppe, as explained in Section II.C.3., above, the computer graphics model of Bannuscher would have included the "measured data record obtained from the three-dimensional optical measuring in the carrying out step" recited in substitute claim 11, because it would have been based on a correlation of 3-D X-ray image data and optical image data of the jaw and teeth modeled in Bannuscher (and disclosed in Truppe), for use in producing a dental implant drill template. Ex. 1002 ¶¶ 69–70; Ex. 1008, 3:12–27, 3:47–4:5, 5:63–6:4.[24] Poirier (and Willer) are evidence that a POSA would have understood that CNC milling was nothing more than the predictable use of a prior art production method according to its established function for producing the drill template disclosed in Bannuscher and Klein, which contains negatives of surfaces of the neighboring teeth. Ex. 1008, 3:47–49; Ex. 1028 ¶¶ 12–13 (In Poirier, "[t]he computer graphics model, based on a correlation of x-ray image data and surface image data, is used to manufacture a dental implant drill guide or drill template," and "a CNC

[24] The parties dispute whether Poirier discloses the use of correlated 3-D X-ray imaging data and optical imaging data of the gum surface to produce the drill template. *Compare* MTA Opp. 11; Observations (#4), *with* MTA Reply 7; Resp. Observations (#4). We need not resolve this dispute, because we rely on the combination of Bannuscher and Truppe for disclosure of "the measured data record obtained from the three-dimensional optical measuring in the carrying out step," recited in substitute claim 11, as explained in Section II.C.3., above.

device can be used to form the entire drill template body."); *see also KSR*, 550 U.S. at 417, 421. Therefore, a POSA would have been motivated by Poirier to use the enhanced imagery generated by a computer model, such as Bannuscher and Truppe's correlated 3-D data sets (Section II.C.3.b., above), to form the dental implant drill template disclosed in Bannuscher and Klein using CNC milling. Ex. 1028 ¶ 23 ("From the teachings of Poirier, a [POSA] would have been motivated to use a CNC machine for milling a complete surgical template, such as the surgical template in Klein.").

Patent Owner argues that a POSA would have understood Bannuscher's drill template to have been formed by molding, in the same way that Poirier discloses a preference for molding a drill template and using CNC milling only for "precision drilling" of the pilot holes. PO Resp. 58–59 (citing Ex. 1010, 8:20–29, 10:25–39; Ex. 2002 ¶¶ 187, 205; Ex. 2018, 6:63–7:11). Petitioner responds that Bannuscher's drill template would have been formed by CNC milling. Reply 24 (citing Ex. 2023, 113:21–114:21 ("It's most likely CNC modeled on there . . . based upon the diagnostic information . . . that he [Bannuscher] digitizes the 3-D [plaster] model and the digitization of the X-ray.")). Having considered the evidence of record, we determine that Patent Owner has not satisfied its burden to demonstrate the patentability of the proposed substitute claims.

Patent Owner's burden includes demonstrating both that the proposed substitute claims are not anticipated by the prior art of record *and* that the subject matter of the proposed substitute claims would not have been obvious over the prior art. Patent Owner's argument and supporting evidence, that a POSA would have understood Bannuscher's drill template to have been formed by molding rather than CNC milling, does not address

the question of why CNC milling would not have been obvious to a POSA based on the prior art of record. As stated above and explained by Dr. Benjamin, CNC milling was a known production technique within a POSA's knowledge and skill level for producing a dental implant drill template from a 3-D computer model, such as the 3-D computer model described in Bannuscher and Truppe. Therefore, CNC milling was nothing more than the predictable use of a prior art production method according to its established function for producing the drill template disclosed in Bannuscher and Klein. *See KSR*, 550 U.S. at 417, 421.

3. Conclusions

For the reasons given above, we determine that the combination of Bannuscher and Truppe in view of Klein and Poirier would have rendered the subject matter of substitute claim 11 obvious to a POSA at the time of the invention claimed in the '006 patent.

Substitute claims 12–18 are substantively identical to original claims 2–8. For the reasons given in Section II.C.4. and III.B., above, we further determine that the combination of Bannuscher and Truppe in view of Klein and Poirier would have rendered the subject matter of substitute claims 12–18 obvious to a POSA at the time of the invention claimed in the '006 patent.

IV. CONCLUSION

For the reasons given above, we are persuaded Petitioner has shown by a preponderance of the evidence that claims 1–8 of the '006 patent are unpatentable. We further determine Petitioner has not shown by a

preponderance of the evidence that claims 9 and 10 of the ’006 patent are unpatentable. We also determine that Patent Owner’s Contingent Motion to Amend the claims with proposed substitute claims 11–18 is *denied*.

This is a Final Written Decision under 35 U.S.C. § 318(a). Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

V. ORDER

It is

ORDERED that claims 1–8 of the ’006 patent have been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that claims 9 and 10 of the ’006 patent have not been shown by a preponderance of the evidence to be unpatentable; and

FURTHER ORDERED that Patent Owner’s Contingent Motion to Amend the claims with substitute claims 11–18 is denied.

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