

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Patent Owner.

Case IPR2016-00270
Patent 6,699,037 B2

Before MICHAEL P. TIERNEY, JOSIAH C. COCKS, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

MAYBERRY, *Administrative Patent Judge*.

DECISION

Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, ClearCorrect Operating, LLC (“ClearCorrect”), filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1, 2, 9, and 10 of U.S. Patent No. 6,699,037 B2 (“the ’037 patent”). Patent Owner, Align Technology, Inc. (“Align”), timely filed a Preliminary Response (Paper 8, “Prelim. Resp.”) to the Petition. We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons set forth below upon considering the Petition and the Preliminary Response, we conclude that the information presented in the Petition establishes a reasonable likelihood that ClearCorrect will prevail in challenging claims 1, 2, 9, and 10 of the ’037 patent. Pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to those claims.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Matters

According to the Petition, the ’037 patent is the subject of litigation in the District Court for the Northern District of California, *Align Technology, Inc. v. SmileCareClub, LLC*, N.D.Cal., Case No. 5-15-cv-04864. Pet. 2–3.

Further, U.S. Patent Nos. 6,217,325 and 5,975,893, which are related to the '037 patent, are currently undergoing *ex parte* reexamination, Control Nos. 90/013,457 and 90/013,581, respectively. *Id.* at 4.¹

Patent Owner additionally identifies that U.S. Patent No. 6,398,548, which is related to the '037 patent, is undergoing *ex parte* reexamination, Control No. 90/013,606. Paper 5, 3. Patent Owner further identifies the following pending litigation and other proceedings that involve patents related to the '037 patent:

- *Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same*, Investigation No. 337-TA-833, before the U.S. International Trade Commission (“USITC”); and
- *Align Technology, Inc. v. ClearCorrect, Inc.*, No. 4:11-cv-00695-VDG (S.D. Tex.).

B. The '037 Patent

The '037 patent, titled “Method and System for Incrementally Moving Teeth,” issued March 2, 2004 with 21 claims, including independent claims 1, 9, and 17. ClearCorrect challenges claims 1, 2, 9, and 10 only. Pet. 2. The '037 patent “is related to a method and system for incrementally moving teeth from an initial tooth arrangement to a final tooth arrangement.” Ex. 1001, 1:18–21. Specifically, the challenged claims are directed to a method that includes the steps of providing, at the outset of treatment, a plurality of digital data sets representing successive tooth arrangements and controlling a

¹ The parties are reminded of their continuing obligation to update their mandatory notices within 21 days of any change of the information listed in 37 C.F.R. § 42.8(b) stated in an earlier paper, including, *inter alia*, changes in related matters. 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

fabrication machine based on the digital data sets to produce a plurality of incremental position adjustment appliances. *Id.* at 15:28–42, 16:1–15.

The method of the '037 patent begins by obtaining a digital data set representing the initial tooth arrangement of a patient. Ex. 1001, 9:20–25. The '037 patent indicates that methods for obtaining the digital data set were well known in the art at the time of the invention. *Id.* at 9:25–33. One such method takes a cast of the patient's teeth and the casting is digitally scanned. *Id.* at 9:33–40.

Next, the digital data set representing the initial tooth arrangement is manipulated using a computer system to incrementally move each tooth to arrive at a digital data set representing the final tooth arrangement. Ex. 1001, 10:36–48. From the initial and final tooth arrangement digital data sets, intermediate digital data sets corresponding to successive tooth arrangements from the initial arrangement to the final arrangement are generated. *Id.* at 10:50–55. In the disclosed embodiment, these intermediate data sets reflect a mapping of the movement of individual teeth. *Id.* at 12:39–44. “[T]he successive digital data sets are produced by determining positional differences between selected individual teeth in the initial data set and in the final data set and interpolating said differences.” *Id.* at 6:30–33.

The intermediate and final data sets are used to fabricate dental incremental position adjustment appliances. Ex. 1001, 14:44–47.

C. Illustrative Claims

Claim 1 of the '037 patent is representative of the claimed subject matter and is reproduced below.

1. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:
providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient; and
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances for the individual patient.

Ex. 1001, 15:28–42.

D. The Prior Art

ClearCorrect's asserted grounds of unpatentability for the challenged claims of the '037 patent rely on the following references:

Snow	US 6,068,482	May 30, 2000	Ex. 1003
Hultgren	US 6,217,334 B1	Apr. 17, 2001	Ex. 1004
Kesling	US 2,467,432	Apr. 19, 1949	Ex. 1005
Lemchen	US 5,011,405	Apr. 30, 1991	Ex. 1006

E. Asserted Grounds of Unpatentability

ClearCorrect asserts the follow grounds of unpatentability for the challenged claims of the '037 patent.

References	Basis	Claims Challenged
Snow, Hultgren, and Kesling	35 U.S.C. § 103(a)	1, 2, 9, and 10
Snow, Lemchen, and Kesling	35 U.S.C. § 103(a)	1, 2, 9, and 10
Snow, Admitted Prior Art (APA), and Kesling	35 U.S.C. § 103(a)	1, 2, 9, and 10

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (“[L]imitations are not to be read into the claims from the specification.”) (citation omitted).

1. “at the outset of treatment”

Independent claims 1 and 9 each recite, in relevant part, “providing *at the outset of treatment* a plurality of digital data sets representing a plurality of successive tooth arrangements.” *See* Ex. 1001, 15:31–33, 16:4–6. ClearCorrect contends that we should construe the phrase “at the outset of treatment” to mean “a point in time when a patient begins/starts to wear/use a dental incremental position adjustment appliance.” Pet. 16. ClearCorrect asserts that claim terms should be given their ordinary and customary meaning and bases this proffered construction on definitions of the terms “outset,” meaning “the beginning or start,” and “treatment,” meaning “the

application of medicines, surgery, psychotherapy, etc., to a patient or to a disease or symptom.” *Id.* at 15.²

Align disputes ClearCorrect’s construction, although Align also contends that the term “at the outset of treatment” should be given its plain and ordinary meaning. Prelim. Resp. 25–27. Align contends that we should construe the term “at the outset of treatment” to mean “a time prior to when a patient begins wearing the dental incremental position adjustment appliances fabricated according to the claims.” *Id.* at 26.

Based on the record before us at this stage of the proceeding, we agree with Align. “Properly viewed, the ‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc). “[H]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification,” including the claims. *Id.* Although the Specification does not specifically define the term “at the outset of treatment,” the appropriate definition of this term can be ascertained from the Specification, including the claims themselves. *See id.* at 1322–23.

Claims 1 and 9 recite that the plurality of digital data files are provided at the outset of treatment and that these digital data sets are used to fabricate the dental incremental position adjustment appliances. *See* Ex. 1001, 15:31–38, 16:4–11. Because the claims require these data files to be

² ClearCorrect does not provide a citation to these definitions. We note that Dr. Martz, one of ClearCorrect’s expert declarants, indicates that these definitions come from www.dictionary.com. *See* Ex. 1007 ¶ 41.

used in fabricating the appliances, the “outset of treatment” is a time prior to a patient using the first fabricated appliance. This timing is also consistent with the Specification of the ’037 patent, which provides that “the plurality of appliances which comprise the system of the present invention are preferably supplied to the treating professional all at one time.” *Id.* at 15:9–11. That is, in this preferred embodiment, first, digital data sets are generated, then those data sets are used in fabricating the appliances, which are then provided to a patient to begin treatment. Although we are careful not to read limitations from the Specification into the claims, the meaning of claim terms cannot be divorced from the Specification.

Accordingly, for the purposes of this Decision, we construe the term “at the outset of treatment” to mean “a time prior to when a patient begins wearing a dental incremental position adjustment appliance fabricated according to the claims.”

B. Asserted Grounds of Unpatentability

ClearCorrect proposes three grounds of unpatentability for claims 1, 2, 9, and 10 of the ’037 patent: 1) claims 1, 2, 9, and 10 are unpatentable under 35 U.S.C. § 103(a) over Snow, Hultgren, and Kesling; 2) claims 1, 2, 9, and 10 are unpatentable under 35 U.S.C. § 103(a) over Snow, Lemchen, and Kesling; and 3) claims 1, 2, 9, and 10 are unpatentable under 35 U.S.C. § 103(a) over Snow, Admitted Prior Art (APA), and Kesling. ClearCorrect presents a limitation-by-limitation analysis of the identified claims against the identified references, an analysis supported by Dr. Martz’s declaration

and Dr. Mah's³ declaration. *See* Pet. 17–29; Exs. 1007 and 1008. Align's Preliminary Response presents detailed arguments countering positions taken in the Petition. *See* Prelim. Resp. 8–28.

Align provides two declarations prepared in support of the *ex parte* reexamination of U.S. Patent No. 6,217,325 (Control No. 90/013,457)—the Declarations of Dr. Cheang and Dr. Valley. If a genuine issue of material fact is created by this testimonial evidence, the issue will be resolved in favor of ClearCorrect solely for institution purposes. *See* 37 C.F.R. § 42.108(c). ClearCorrect and Align will have an opportunity to cross-examine declarants during the trial.

1. Claims 1, 2, 9, and 10 over Snow, Hultgren, and Kesling

a. Overview of Snow

Snow, titled “Method for Creation and Utilization of Individualized 3-Dimensional Teeth Models,” relates “to storing and [utilizing] 3D computer graphic structures representative of a patient's individual tooth and jaw structure.” Ex. 1003, 1:13–16.

Snow discloses that a three-dimensional individualized model of a patient's teeth is created using a standard three-dimensional model and two-dimensional datasets that represent the patient's teeth. Ex. 1003, 2:47–50. A two-dimensional plaster cast model of a patient's teeth is digitally

³ Align contends that Dr. Mah's declaration should be given no probative weight, as he is ClearCorrect's Chief Technical Officer and, as such, his testimony is self-interested. Prelim. Resp. 27. Although we recognize that Dr. Mah may have an interest in the outcome of this proceeding given his position with Petitioner, Align will have an opportunity to explore any bias at deposition during a trial.

scanned, such as by using a flatbed scanner, to produce two-dimensional images of the patient's upper and lower jaw. *Id.* at 2:59–63. Also, x-rays or other side medical images are scanned to create digital renderings. *Id.* at 2:63–65.

The three-dimensional standard model is a computer graphical representation of a standard male or female patient's teeth. Ex. 1003, 2:66–3:2. Snow discloses that the structure of an individual's teeth with respect to the size and shape of the teeth have low variance across a population but a high variance as to the positioning of the teeth. *Id.* at 3:2–7. The digitized two-dimensional cast, digitized side medical images, and the three-dimensional standard model are used to generate a three-dimensional individualized model for a specific patient from the standard model. Ex. 1003, 3:28–35. The digital representation of individual teeth of the standard model are rotated, translated, and scaled, based on the digitized two-dimensional cast and digitized side medical images, to arrive at an orientation for each tooth in the individualized model. *Id.* at 3:40–56. This individualized model can be used for treatment planning and record keeping. *Id.* at 3:34–35.

With respect to treatment planning, Snow discloses that the three-dimensional individualized model serves as a starting point, that is, it represents the initial orientation of a patient's teeth. Ex. 1003, 4:7–16. Then, the position of each tooth in the three-dimensional individualized model is mapped to the corresponding position in the three-dimensional standard model, which serves as the final positioning of the teeth after treatment, through a series of interpolation steps. *Id.* at 4:16–22. The computer system can then animate the movement of the teeth from their

position in the individualized model to the final position in the standard model for viewing by a specialist or patient. *Id.* at 4:23–27.

b. Overview of Hultgren

Hultgren, titled “Dental Scanning Method and Apparatus,” relates to “a system of dental modeling and imaging . . . for uses relating to creating dental appliances.” Ex. 1004, 1:5–12. Hultgren discloses taking a dental impression of a patient’s teeth and surrounding soft tissue using impression trays for the upper and lower teeth. *Id.* at 4:61–5:2. The impressions are then mounted in a fixture and scanned using a laser device to generate a digital data file corresponding to the impressions in the impression trays. *Id.* at 5:6–28.

The digital data, which represents a negative image of the patient’s teeth and soft tissue, is processed, such as by converting the data to a form that may be used by a device to fabricate a cast. Ex. 1004, 5:29–36. The fabrication device takes the digital data and creates a three-dimensional object from the data, such as a study cast of the patient’s teeth and soft tissue. *Id.* at 7:28–39, 7:61–66.

c. Overview of Kesling

Kesling, titled “Method of Making Orthodontic Appliances and of Positioning Teeth,” relates to tooth positioning appliances. Ex. 1005, 1:1–2. Kesling’s method begins with a plaster cast of the patient’s teeth, representing the initial teeth positioning. *Id.* at 2:43–49. The individual teeth of the plaster cast are then sawed off of the cast and repositioned into an ideal position. *Id.* at 3:30–56. The teeth are secured into place and a plaster cast of the positioning is taken. *Id.* at 3:57–64. Although Kesling discloses a single operation of moving each tooth from an initial to a final

position, Kesling's method contemplates multiple iterations. Kesling discloses that multiple appliances may be used to incrementally move a patient's teeth from an initial position to a final position through a series of incremental positioning appliances. *Id.* at 2:50–3:1; *see also* 5:22–32 (“[I]t will also be evident that this appliance and technique may be employed in a plurality of steps for moving the teeth step by step from any extreme position to the desired and final position.”).

Next, an impression tray is used to capture an impression of the cast of the teeth in the desired position, where the tray serves as a pattern for making a tooth positioning appliance. Ex. 1005, 4:8–51. A mold is made from the impression and filled with a suitable material for fabricating the appliance. *Id.* at 4:52–58.

d. Independent Claims 1 and 9

ClearCorrect contends that “Snow generally discloses a method for creating and utilizing an individualized, digital three-dimensional (‘3D’) teeth model for simulating the movement of a patient's teeth during orthodontic treatment from an initial position to an ‘[idealized] second position.’” Pet. 17 (referencing Ex. 1003, 1:45–48, 4:7–23). ClearCorrect contends that Snow's disclosure of a computer-generated model that produces a sequence of images that maps the movement of teeth from a current position to the idealized second position corresponds to the step of providing, at the outset of treatment, a plurality of digital data sets. *Id.* at 17, 24–25. ClearCorrect further contends that these digital data sets represent successive tooth arrangements, including initial, final, and intermediate tooth arrangements. *Id.* at 17, 25–26. ClearCorrect explains that Snow discloses that its digital data sets can be used to fabricate dental appliances that

correspond to the digital data. *See id.* at 17 (referencing Ex. 1003, 5:49–56; Ex. 1007 ¶ 42; Ex. 1008 ¶ 95).

ClearCorrect contends that Hultgren discloses controlling a fabrication machine to produce a positive model of a patient's teeth from the data based on negative image scan data. Pet. 18–19 (referencing Ex. 1004, 7:28–39); *see also id.* at 26–27 (referencing Ex. 1004, 7:57–65, as corresponding to the step of controlling a fabrication machine based on digital data). ClearCorrect also contends that Kesling discloses a manual process for fabricating dental incremental position adjustment appliances from positive dental models, such as those produced by Hultgren. *Id.* at 20, 27–28.

In summary, ClearCorrect contends that Snow teaches producing digital data sets at the outset of treatment representing successive tooth arrangements from an initial to a final arrangement for the purpose of developing a dental treatment plan. Pet. 24. Hultgren teaches converting digital data sets representing negative image scan data of a patient's teeth into positive image data and controlling a fabrication machine to produce positive models. *Id.* Modifying Snow with the teachings of Hultgren results in a set of incremental, positive models representing repositioned tooth arrangements, fabricated with digital data as taught in Snow. *Id.* This combined teaching is further modified by the teachings of Kesling of creating dental appliances as negatives of the positive models, resulting in fabricating dental incremental position adjustment appliances. *Id.*

ClearCorrect reasons that a person of ordinary skill in the art at the time of the invention of the '037 patent would have combined the teachings of Snow, Hultgren, and Kesling to arrive at the invention of claims 1 and 9.

Pet. 22. As ClearCorrect explains, Snow, Hultgren, and Kesling are all in the field of dentistry and are concerned with creating or manipulating three-dimensional models of a patient's teeth. *Id.* ClearCorrect contends that the combination would result in more precise dental appliances as digital data represents more precise tooth arrangements. *Id.* at 22–23. Also, machine fabrication of positive models would save manufacturing costs as it replaces Kesling's labor-intensive process. *Id.* at 23. As ClearCorrect further explains, the combination represents merely automating a known manual process. *Id.* Finally, ClearCorrect explains that the predictability in the art would have suggested to the artisan of ordinary skill that there was a reasonable likelihood of success. *Id.*

Align argues that Snow fails to disclose the subject matter of the “providing step” of claim 1. Prelim. Resp. 11–18. First, Align contends that Snow fails to disclose the recited digital data sets representing successive tooth arrangements. *Id.* at 12–14. Align argues that Snow's three-dimensional individualized model does not represent an initial tooth arrangement, because the model includes generic representations of teeth rather than representations of actual teeth of an individual patient. *Id.* at 9–10, 15. Align argues that Snow's three-dimensional individualized model does not reflect the actual size and shape of a patient's teeth but, instead, relies on the size and shape of the teeth contained within the standard model. *Id.* Align similarly argues that Snow's standard three-dimensional model fails to correspond to the recited final tooth arrangement, because this standard model includes a generic arrangement of generically-shaped teeth and, as such, is not for an individual patient as required by the challenged claims. *Id.* at 14, 16–17.

Align's arguments do not persuade us of a deficiency in ClearCorrect's position at this time. Initially, we note that claims 1 and 9 merely recite "tooth arrangements" and the individualized orientation of a generic representation of a tooth would constitute a tooth arrangement. *See* Pet. 17; Ex. 1007 ¶ 42. As such, Align's argument is based on subject matter not recited in claims 1 and 9.

Further,

analysis [of whether the subject matter of a claim would have been obvious] need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007). Here, Snow teaches producing digital data representing the tooth arrangements of a specific, individual patient. Snow further teaches that "[i]t is well known in the field of dentistry that the structure of individual's teeth in respect of their size and shapes is substantially of low variance across a general population." Ex. 1001, 3:2–5. A person of ordinary skill in the art, such as a practicing orthodontist or individual with expertise in digital modeling and analysis and substantive knowledge of orthodontics (*see* Ex. 1007 ¶ 23; Ex. 2002 ¶ 15; Ex. 2010 ¶ 17), would have applied her creativity to ensure that the variance in the size and shape of the teeth was acceptable or would modify the data accordingly. *See, e.g.*, Ex. 1007 ¶ 33 (describing the state of the art, which includes the knowledge of digitizing the shapes of individual teeth); Ex. 1006, 2:50–68 (disclosing that it was known in the art to generate digital information that defines the shape of a tooth); Ex. 1001, 9:30–33 ("Methods for digitizing such conventional images to produce data sets useful in the

present invention are well known and described in the patent and medical literature.”).

Next, Align argues that Snow’s animation steps do not represent the recited successive tooth arrangements. Prelim. Resp. 13. Align contends that, because Snow’s progressive images represent a treatment-agnostic linear progression from the individualized model to the standard model, the digital data sets do not “have any relationship to orthodontic treatment stages for an individual patient.” *Id.* at 13–14.

Based on the record before us, Align’s argument does not persuade us of a deficiency in ClearCorrect’s position. Snow expressly discloses that the computer-generated animation is for treatment planning purposes, to show a specialist movement of individual teeth from the position associated with the individualized three-dimensional model to a final position represented by the standard model. Ex. 1003, 4:7–27. Snow discloses that the depictions in the animation represent a series of steps determined by interpolation. *Id.* at 4:16–22. As such, the depiction of each step would be generated from a digital data set. Further, Snow’s use of linear interpolation is the same as a process disclosed in the ’037 patent for moving from the initial to final tooth arrangements. The ’037 patent states:

The plurality of successive digital data sets are then produced based on the initial digital data set and the final digital data set. Usually, the successive digital data sets are produced by determining positional differences between selected individual teeth in the initial data set and in the final data set and interpolating said differences. Such interpolation may be performed over as many discrete stages as may be desired, usually at least three, often at least four, more often at least ten, sometimes at least twenty-five, and occasionally forty or more.

Many times, the interpolation will be linear interpolation for some or all of the positional differences.

Ex. 1001, 6:27–38. Here, Align fails to persuade us why Snow’s interpolative steps from the initial to final positions do not represent treatment stages given this disclosure in the ’037 patent describing that linear interpolative steps are used to define the treatment stages.

Next, Align argues that Snow fails to disclose that the animation stages are used to develop brackets or braces for treating the patient. Prelim. Resp. 14. This argument does not persuade us of a deficiency in ClearCorrect’s position, as ClearCorrect relies on Kesling for the teaching of preparing progressive dental appliances based on successive tooth arrangements. *See* Pet. 27. ClearCorrect relies on Snow for teaching a plurality of digital data sets that represent a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient—data sets generated at the outset of treatment. Based on the current record, we find that Snow’s computer-generated animation teaches this claimed subject matter of the “providing step.”

Align further argues that ClearCorrect’s reasons to combine Snow, Hultgren, and Kesling are unsupported. First, Align contends that an artisan or ordinary skill would not have looked to Snow to create Kesling’s appliances, as Snow’s models use generic teeth size and shape and Kesling’s appliance requires the size and shape of a patient’s actual teeth. Prelim. Resp. 19–20. This argument does not persuade us of a deficiency in ClearCorrect’s position. The test for obviousness is not whether the features of one reference may be bodily incorporated into the features of another reference—instead, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). ClearCorrect's position is that Snow teaches digital data sets that represent progressive tooth arrangements as claimed in claims 1 and 9 and that digital data sets can be used to fabricate positive models as taught by Hultgren, which can then be used to fabricate a dental appliance, as taught by Kesling. *See* Pet. 24; *see also* Ex. 1007 ¶ 55 ("The combination of Snow, Hultgren, and Kesling represent the natural progression of using digital technology to assist in the fabrication of dental appliances.").

Align further argues that a person of ordinary skill would not combine the teachings of these references because, as it has already argued, Snow's animation steps do not represent target treatment positions. Prelim. Resp. 21. As discussed above, this argument fails to persuasively explain why Snow's interpolative steps from the initial to final positions do not represent treatment stages given the disclosure in the '037 patent describing that linear interpolative steps are used to define treatment stages.

Align further argues that "Snow provides no indication the data underlying its animation steps is even in a format that could be used to fabricate appliances." Prelim. Resp. 21. This argument does not persuade us of a deficiency in ClearCorrect's position, as it is based on improperly incorporating the features of Snow into the system of Hultgren. ClearCorrect's position is that Snow's teachings would have suggested to one of ordinary skill in the art to use digital data sets representing successive tooth arrangements to fabricate successive positive models as taught by Hultgren.

Align also argues that a person of ordinary skill in the art would not have used Snow's digital data for Hultgren's fabrication device, as Snow's data does not include representations of soft tissue. Prelim. Resp. 21. Again, this argument does not persuade of a deficiency in ClearCorrect's position, as it is based on bodily incorporating the features of Snow into the system of Hultgren.

Next, Align contends that the benefits of the combination proffered by ClearCorrect are contrary to the cited references. Prelim. Resp. 22. First, Align contends that Snow's use of generic teeth and procedure for generating the idealized model provides a less precise model of a patient's teeth than an actual cast. Based on the current record, we do not find this argument persuasive of a deficiency in ClearCorrect's position. ClearCorrect contends that the successive data files provide a more precise representation of the successive tooth arrangements. *See* Pet. 22–23. That is, the discrete movements represented by each successive data set represents more precise tooth arrangements, presumably as compared to the manual arrangements provided by Kesling's approach. As discussed above, even though Snow uses generic teeth shapes and sizes, it does not follow that the tooth arrangements, or orientations, are not represented adequately.

Align further argues that the proposed combination would not result in any cost savings, as the produced appliances, based on generic teeth shapes and sizes, would be unusable. Prelim. Resp. 23. This argument does not persuade us of a deficiency in ClearCorrect's position, as it is based on bodily incorporating the features of the three references. As discussed above, an artisan of ordinary skill would use her creativity to ensure that the digital data is of sufficient detail for the appropriate dental appliance. “[A]

person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int’l Co.*, 550 U.S. at 421.

Next, Align argues that “[r]eplacing any of these manual techniques would simply recreate the one-step-at-a-time process,” as none of the references teach a proactive manual technique. Prelim. Resp. 24. This argument does not persuade us of a deficiency in ClearCorrect’s position, as it is not commensurate with ClearCorrect’s position. ClearCorrect contends that Snow teaches proactively generating a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient as a component of treatment planning—that is, at the outset of treatment. Pet. 24; *see* Ex. 1003, 4:7–27. ClearCorrect’s position is that these data sets would then be used to automate the process for generating the positive models that are used to ultimately produce the appliances.

Finally, Align argues that “tooth movements using the orthodontic treatments contemplated by the references were notably *unpredictable*.” Prelim. Resp. 24. This argument does not persuade of a deficiency in ClearCorrect’s position. “The obviousness inquiry entails consideration of whether a person of ordinary skill in the art ‘would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and . . . would have had a reasonable expectation of success in doing so.’” *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015); *see also In re Longi*, 759 F.2d 887, 897 (Fed. Cir. 1985) (“Only a reasonable expectation of success, not absolute predictability, is necessary for a conclusion of obviousness.”). Here, the inquiry is whether an artisan of ordinary skill would have a reasonable expectation of success in fabricating

dental appliances as taught by Kesling from Hultgren's positive models when provided a plurality of digital data sets developed at the outset of treatment. That is, the predictability inquiry goes to the predictability in combining the teachings of the references, not the predictability in adjusting a patient's teeth. As Dr. Martz declares, this technology—using digital data to control a fabrication machine to ultimately produce a dental appliance—is predictable, such that one of ordinary skill in the art would have a reasonable expectation of success. Ex. 1007 ¶ 55; see Pet. 23.

On the record before us, we are persuaded that ClearCorrect has shown a reasonable likelihood of prevailing in its assertion that independent claims 1 and 9 are unpatentable over Snow, Hultgren, and Kesling.

e. Claims 2 and 10

ClearCorrect contends that Snow, Hultgren, and Kesling renders obvious the subject matter of dependent claims 2 and 10. Align does not address the subject matter of these dependent claims at this time. After review of the record before us, we are persuaded that ClearCorrect has shown a reasonable likelihood of prevailing in its assertion that claims 2 and 10 are unpatentable over Snow, Hultgren, and Kesling. See Pet. 28–29; see *also supra* (discussing Snow's digital data sets representing successive tooth arrangements).

2. Claims 1, 2, 9, and 10 over Snow, Lemchen, and Kesling

a. Overview of Lemchen

Lemchen, titled "Method for Determining Orthodontic Bracket Placement," relates to a method for correcting a maloccluded tooth—that is, a tooth that is not perfectly positioned when the jaw is closed. See Ex. 1006,

Abstract. Lemchen's method includes the step of generating digital information defining the shape and location of the maloccluded tooth with respect to the patient's jaw. *Id.* at 2:56–60. Next, Lemchen's method generates a mathematical model that uses the digital information, such as through a computer-aided design tool. *Id.* at 3:1–9. Next, the method calculates a final position for the tooth. *Id.* at 3:20–29. This final positioning is preferably customized for a particular patient. *Id.* at 3:56–61.

Lemchen further discloses manufacturing customized brackets. Ex. 1006, 4:39–5:15. Lemchen teaches that “customized brackets may be provided to the practitioner by a dental laboratory, where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion.” *Id.* at 5:31–35.

b. Claims 1, 2, 9, and 10

ClearCorrect contends that Lemchen “discloses transmitting the digitized information to known fabrication devices that utilize such data to create customized brackets.” Pet. 36 (referencing Ex. 1006, 5:31–35).

Based on our review of the current record, we conclude that the information presented in the Petition fails to establish a reasonable likelihood that ClearCorrect will prevail in challenging claims 1, 2, 9, and 10 of the '037 patent as unpatentable over Snow, Lemchen, and Kesling. ClearCorrect has failed to explain adequately how Lemchen discloses the step of controlling a fabrication machine based on individual ones of the digital data sets as required by the challenged claims. Although the disclosure in Lemchen relied on by ClearCorrect states “the digitized information is utilized in the process of providing the practitioner with the

required dental appliances,” ClearCorrect fails to demonstrate that the data sets are “utilized in the process” to control a fabrication machine. Similarly, ClearCorrect’s experts fail to explain adequately that Lemchen’s digital data sets are used to control a fabrication machine. *See* Ex. 1007 ¶¶ 51, 59; Ex. 1008 ¶ 112.

3. *Claims 1, 2, 9, and 10 over Snow, APA, and Kesling*

a. Overview of Admitted Prior Art

ClearCorrect asserts that the ’037 patent includes admitted prior art (APA) that “evidences that it is known in the art to transform three-dimensional image data into a three-dimensional physical model.” Pet. 47. ClearCorrect contends that this APA demonstrates “that the machines and methods for producing and fabricating positive models and aligners formed therefrom are known and conventional [and that] it is conventional to use digital data sets to control fabrication machines.” *Id.* Specifically, ClearCorrect cites the ’037 patent at column 6, line 64 to column 7, line 10 and at column 14, lines 46 to 63 as providing the alleged APA.

b. Claims 1, 2, 9, and 10

ClearCorrect contends that the “APA specifically discloses controlling a fabrication machine based on the digital data sets to produce a three-dimensional physical, positive model.” Pet. 57–58 (referencing Ex. 1001, 6:64–7:10, 14:46–63, 14:63–15:8).

Based on our review of the current record, we conclude that the information presented in the Petition fails to establish a reasonable likelihood that ClearCorrect will prevail in challenging claims 1, 2, 9, and 10 of the ’037 patent as unpatentable over Snow, APA, and Kesling.

ClearCorrect has failed to explain adequately how the APA discloses the step of controlling a fabrication machine based on individual ones of the digital data sets as required by the challenged claims.

Although the disclosures in the APA relied on by ClearCorrect demonstrate the existence of computer-driven fabrication machines, ClearCorrect recognizes that this disclosure fails to serve as an admission of controlling a fabrication machine with digital data sets representing a plurality of successive tooth arrangements. *See* Pet. 49 (“Such admission, however, does not encompass a digital data set which represents a positive model of a modified tooth arrangement.”). ClearCorrect further contends, however, that statements in the ’037 patent equating the computer-fabrication process of the invention with a manual process, such as that disclosed in Kesling, constitutes an admission that using digital data sets representing a plurality of successive tooth arrangements in controlling a fabrication machine was in the prior art. *Id.* at 49–50 (referencing Ex. 1001, 10:19–35).

We conclude that ClearCorrect has failed to explain adequately how the ’037 patent’s disclosure that non-computer-aided methods may be employed without departing from the disclosed invention amounts to an admission that using digital data sets representing a plurality of successive tooth arrangements to control a known fabrication machine is prior art.

Similarly, ClearCorrect’s experts fail to explain adequately how the mere existence of computer-aided fabrication and the equivalence of computer-aided and manual fabrication amounts to an admission that digital data sets representing a plurality of successive tooth arrangements were

known to control a fabrication machine. See Ex. 1007 ¶¶ 64–65; Ex. 1008 ¶¶ 127, 128.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that ClearCorrect would prevail in showing that claims 1, 2, 9, and 10 of the '037 patent are unpatentable. We have not made a final determination with respect to the patentability of those claims or the construction of any claim term.

IV. ORDER

After due consideration of the record before us, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1, 2, 9, and 10 of the '037 patent on the ground that claims 1, 2, 9, and 10 are unpatentable under 35 U.S.C. § 103(a) over Snow, Hultgren, and Kesling.

FURTHER ORDERED that no other ground of unpatentability other than that specified above is authorized for *inter partes* review; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this decision.

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