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Paper No. 43
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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, *Vice Chief Administrative Patent Judge*, and JOSIAH C. COCKS and JAMES J. MAYBERRY, *Administrative Patent Judges*.

MAYBERRY, *Administrative Patent Judge*.

DECISION

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

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"), filed a Preliminary Response (Paper 8, "Prelim. Resp.") to the Petition. We instituted trial on all challenged claims. Paper 10, 25 ("Dec. on Inst.").[1]

After institution of trial, Align filed a Patent Owner Response ("PO Resp.") to the Petition. Paper 21.[2] ClearCorrect filed a Reply ("Reply") to the Patent Owner Response. Paper 29.[3] Oral hearing was conducted on February 1, 2017. The record contains a transcript of the hearing. Paper 41 ("Tr."). ClearCorrect relies on the Declaration testimony of Dr. Martin Martz (Ex. 1007) and Dr. James Mah (Ex. 1008) in support of its Petition. Align relies on the Declaration testimony of Dr. Maureen A. Valley (Ex. 2011) and Ms. Ka Man Cheang (Ex. 2013) in support of its Patent Owner Response.

The Board has jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. ClearCorrect has shown by a preponderance of the evidence that claims 1, 2,

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[1] The Petition asserts three grounds of unpatentability for the challenged claims. *See* Pet. 7. We instituted trial on the first ground only. *See* Dec. on Inst. 25.

[2] Paper 21 is a redacted version of Align's confidential Patent Owner Response, filed as Paper 20. We granted Align's motion to seal Paper 20. *See* Paper 19; 25, 2.

[3] Paper 29 is a redacted version of ClearCorrects's confidential Reply, filed as Paper 32. We granted ClearCorrect's motion to seal Paper 32. *See* Paper 31; 35, 2.

9, and 10 of the ’037 patent are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,068,482 (Ex. 1003, “Snow”), U.S. Patent No. 6,217,334 B1 (Ex. 1004, “Hultgren”), and U.S. Patent No. 2,467,432 (Ex. 1005, “Kesling”).

A. Related Maters

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; Paper 5, 5. Further, the following U.S patents related to the ’037 patent are undergoing *ex parte* reexamination:

Patent	Control Number
U.S. Patent No. 5,975,893	Control No. 90/013,581
U.S. Patent No. 6,217,325	Control No. 90/013,457
U.S. Patent No. 6,398,548	Control No. 90/013,606
U.S. Patent No. 6,626,666	Control No. 90/013,506
U.S. Patent No. 6,722,880	Control No. 90/013,491
U.S. Patent No. 7,125,248	Control No. 90/013,607

Pet. 4; Paper 5, 3–4; *see also* Paper 42, 1–2 (providing the status of certain of these proceedings and identifying additional relevant *ex parte* reexamination proceedings).

Align 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.).

Paper 5, 5–6.

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 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 to obtain the digital data set. *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 '037 patent's method contemplates tooth movement such as "translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ('root angulation' and 'torque') as well as rotation about the centerline." *Id.* at 8:7–12.

The intermediate and final data sets are used to fabricate dental incremental position adjustment appliances. Ex. 1001, 14:44–47. "In a broadest sense, the methods of the [the '037 patent] can employ any of the known positioners, retainers, or other removable appliances [that] are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment." *Id.* at 8:50–54.

C. Illustrative Claims

Claims 1 and 9 of the '037 patent, the two independent claims under review in this proceeding, are representative of the claimed subject matter and are 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, 15:28–38.

> 9. 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; and
>
> controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances.

Id. at 16:1–11.

D. The Prior Art and Ground of Unpatentability

We instituted *inter partes* review on a single ground of unpatentability for claims 1, 2, 9, and 10 of the '037 patent that 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

The instituted ground of unpatentability is that claims 1, 2, 9, and 10 of the '037 patent are unpatentable under 35 U.S.C. § 103(a) over Snow, Hultgren, and Kesling. *See* Dec. on Inst. 25.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

ClearCorrect's expert, Dr. Martz, declares that the level of ordinary skill in the art of the '037 patent is "a doctorate in dental science and three to five years of training and practical experience in orthodontics." Ex. 1007 ¶ 23; *see also* Ex. 1008 (Decl. of James Mah) ¶ 26 (providing the same level of ordinary skill). Dr. Valley declares that the level of ordinary skill in the

art of the ’037 patent is that of a practicing orthodontist *or* a person “with expertise in digital modeling and analysis and substantive knowledge of orthodontics.” Ex. 2011 ¶ 18; *see also* Ex. 2013 (Decl. of Ka Man Cheang) ¶ 12 (providing the same level of ordinary skill).

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros*.). We find that the prior art of record is primarily directed to computer modeling an individual patient’s teeth and orthodontics. For example, Snow is primarily focused on creating a three-dimensional computerized dental record for an individual patient. Ex. 1003, Abstract. Hultgren is related to generating electronic data by scanning dental and soft tissue of a specific patient. Ex. 1004, Abstract. The ’037 patent’s “Description of the Background Art” describes tooth positioners for orthodontic treatment and digital imaging for designing orthodontic appliances and orthodontic treatment. *See* Ex. 1001, 2:21–63; *see also id.* at 9:44–47 (“General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Pat. No. 5,605,459.”).

Align contends “that digital modeling was in its very early stages in the relevant timeframe and that practitioners were still in the process of determining how best to measure 3D tooth models.” PO Resp. 35 (citing to Dr. Mah’s deposition testimony). This contention contradicts the ’037

patent, which discloses that generating three-dimensional digital data representing the shape and position of a patient's tooth was known in the prior art. *See, e.g.*, Ex. 1001, 9:44–48 (incorporating by reference into the '037 patent U.S. Patent No. 5,605,459, which discloses generating three-dimensional electronic data representing a patient's teeth); *id.* at 2:50–52 (identifying as background art U.S. Patent No. 5,011,405, which discloses a number of ways to generate accurate digital information defining the shape and location of a patient's tooth).[4] As ClearCorrect contends, the record is replete with evidence that the level of ordinary skill of a practicing orthodontist encompasses knowledge of making three-dimensional representations of the shape and location of an individual patient's teeth. *See* Reply 14–15.

Accordingly, based on our underlying factual findings discussed above, we determine that the level of ordinary skill in the art is a practicing orthodontist, including a person having a doctorate in dental science and three to five years of training and practical experience in orthodontics or a person with expertise in digital modeling and analysis and substantive knowledge of orthodontics.

B. 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 generally given their ordinary and customary meaning, as would be understood by one of ordinary

[4] U.S. Patent No. 5,605,459 is provided in the record as Exhibit 1054 and U.S. Patent No. 5,011,405 is provided in the record as Exhibit 1006.

skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

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 (emphasis added). In our Decision on Institution, we construed 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," which was Align's proposed construction. Dec. on Inst. 6–8. Neither party disputed our construction. *See, e.g.*, PO Resp. 15 n.4 ("Patent Owner agrees with the Board's construction of 'at the outset of treatment.'"); Reply 6–13 (failing to address the construction of "at the outset of treatment").

After considering anew the underlying bases for the above construction in light of the complete trial record, we discern no reason to alter our construction of this term.

2. the "providing" steps

As presented above, claim 1 recites the step of "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." Ex. 1001, 15:31–35. Claim 9 more broadly recites the step of "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." *Id.* at 16:4–7. That is, claim 9 does not include the recitation "for an individual patient."

Align contends that the "providing" steps "require patient-specific digital data sets representative of a patient's actual teeth in actual treatment positions." PO Resp. 16. Align further contends that "the digital data sets must be actual [three-dimensional] representations of a patient's actual teeth." *Id.* Align argues that an interpretation of the "providing" steps that encompasses digital data representing generic teeth positioned in a generic final position would not be useful to an individual patient, as any appliance based on these data would not fit the patient. *Id.* Align further argues that references cited by ClearCorrect's experts use plaster casts or digital scans of a patient's actual teeth to create elastomeric appliances. *Id.* at 17. Align asserts, in summary, that

> the challenged claims require that the "plurality of digital data sets representing a plurality of successive tooth arrangements" be representative of a patient's actual teeth (not generic teeth) at actual successive treatment positions (not generically-calculated positions) and be usable to create actual successive appliances that fit that patient and apply forces that predictably move the teeth into calculated positions.

Id. As we understand Align's position, the "providing" steps of claims 1 and 9 require the digital data sets to be three-dimensional representations of a patient's actual teeth, which characterizes the position and actual shape of each tooth. *See, e.g.*, Tr. 23:11–13. ("It's our view that the digital data sets that -- this claim requires the digital data sets to be 3D representations of patients' actual teeth.").

In reply, ClearCorrect disputes Align's contention, arguing that neither the claim language nor the Specification of the '037 patent requires

three-dimensional digital data of a patient's actual teeth. Reply 6. As we explain in greater detail below, we agree with ClearCorrect.

Claim construction begins with the language of the claims. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014). We discern no language in the "providing" steps themselves that require that the digital data be three-dimensional representation of a patient's actual teeth. The express phrase "plurality of digital data sets" is not further limited to the underlying source of the digital data, whether it be two-dimensional or three-dimensional data. Further, the claim language characterizes a plurality of digital data sets as representing a progression from an initial tooth arrangement, through at least one successive tooth arrangement, to a final tooth arrangement. Align fails to adequately explain how this language requires the initial and successive tooth arrangements to include the actual *shape* of individual teeth. As we discuss in greater detail below, claims 1 and 9 recite that the digital data sets representing these successive tooth arrangements serve as the basis for fabricating incremental position adjustment appliances, but the claim language does not otherwise limit these appliances to appliances requiring to fit precisely the actual shape of the patient's tooth. *See, e.g.*, Ex. 1001, 8:50–54 (defining appliances broadly to include, for example, retainers, which would not necessarily include tooth-receiving cavities that must be precisely fit to a patient's actual tooth).

Unlike claim 9, the providing step of claim 1 does include the phrase "for an individual patient." Although this language associates a specific patient with the plurality of digital data sets, we discern nothing from this phrase that requires the digital data sets to be based on three-dimensional

representations of that individual's actual teeth (including the actual shape of the teeth) and Align fails to explain adequately how this phrase would so limit the claim. Further, Align does not distinguish claim 1 from claim 9, which does not recite "for an individual patient," suggesting that this claim language is not the basis for Align's proffered narrow construction. [5]

We also discern no language in the remainder of claims 1 and 9 that would necessitate us construing the "providing" steps to require the digital data sets to be three-dimensional representations of actual teeth. The "controlling" steps of claims 1 and 9 require controlling a fabrication machines with each data file of the digital data sets to produce a plurality of appliances, with claim 1 further limiting the step to appliances "for the individual patient." Align's argument seems to at least suggest that fabricating incremental position adjustment appliances for a patient necessitates the digital data sets to be based on three-dimensional representations of a patient's actual teeth or otherwise the appliance would not fit. *See* PO Resp. 16. This argument seems to require the recited appliances to conform with the *shape* of at least some of the patient's teeth. *See*, *e.g.*, Tr. 26:7–25 (arguing that the claimed appliances are "precision appliances" and that, without data representing the actual shape of each individual tooth, the appliances would not fit). We discern nothing from the language of claims 1 and 9 that would limit the claim to such an appliance. *Cf.* Ex. 3001, 15:18–18:22 (providing the claims of a related patent further

[5] At oral hearing, Align's counsel made clear that the claim language at issue is "digital data sets representing a plurality of successive tooth arrangements." Tr. 23:18–23. That is, Align did not consider the phrase "for an individual patient" as affecting its proposed construction of the "providing" steps.

limiting the recited appliance to having cavities shaped to receive teeth); *id.* at 26–28 (providing reexamination certificate with claims including similar limitations). Further, Align does not direct us to any language in any other claim of the '037 patent that supports Align's proposed construction.

As we stated above, claims must be read in the context of the entire Specification, not just the claims. Align contends that the Specification supports its narrow construction of the "providing" steps of claims 1 and 9. PO Resp. 17. First, Align reminds us that the '037 patent is directed to "patient-specific [tooth] arrangements, not generic ones." *Id.* at 18. Next, Align contends that the phrase "tooth arrangement" in the "providing" steps, as that phrase is used in the Specification, dictates the claims' "patient-specific natures." *Id.* at 19. Align fails, however, to explain adequately why this "patient-specific nature" requires the digital data sets to be three-dimensional representations of actual patient's teeth. For example, Align fails to explain adequately why we should construe the providing steps to preclude tooth arrangements that are two-dimensional representations of a specific patient's teeth, such that the representations show the orientation and location of a tooth, but not the actual shape of the tooth. That is, Align fails to explain why a tooth arrangement would not encompass simply the rotation of the tooth relative to its vertical centerline or the cant of a tooth relative to the tooth's vertical centerline.

Align further argues that the Specification confirms that the phrase "digital data sets" "represent an actual patient's teeth." PO Resp. 19. To support this position, Align argues that, in describing Figure 2 of the '037 patent, the first step in the described process is obtaining a digital data set representing an initial tooth arrangement and that this initial digital data set

is a "full [three-dimensional] representation of a 'patient's teeth." *Id.* Align continues that the final digital data set represents a final position of the teeth for a patient and that, based on these initial and final digital data sets, a plurality of intermediate data sets are generated and, from these data sets, appliances are fabricated. *Id.* at 19–20. We find, however, that the Specification does not support Align's characterization of the process of Figure 2 as requiring three-dimensional data. The Specification expressly states that

> the patient's teeth may be scanned or imaged using well known technology, *such as X-rays*, three-dimensional X-rays, computer-aided tomographic images or data sets, magnetic resonance images, etc. 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.

Ex. 1001, 9:26–33 (emphasis added). We agree with ClearCorrect that this disclosure informs a person having ordinary skill in the art that the digital data sets may be based on *two-dimensional* x-rays. *See* Reply 7–8. As ClearCorrect further contends, the '037 patent Specification also states that "the initial digital data set may be provided by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the like. Preferably, the images will be three-dimensional images and digitization may be accomplished using conventional technology." Ex. 1001, 5:39–46; Reply 7. As ClearCorrect emphasizes, the Specification states that using three-dimensional images is a preference, not a requirement and further that the Specification expressly identifies two-dimensional data sources. Reply 7. Align fails to address these disclosures in the Specification or explain adequately why a person having

ordinary skill in the art would understand the "providing" steps to require three-dimensional digital data to the exclusion of two-dimensional data despite the express disclosure of two-dimensional data sources in the '037 patent Specification.

We find that other information in the Specification belies Align's position. As ClearCorrect indicates, the Specification provides that its disclosed methods can be employed by a broad range of appliances, including positioners and retainers. Reply 9–10 (citing Ex. 1001, 8:50–54 ("In a broadest sense, the methods of the present invention can employ any of the known positioners, retainers, or other removable appliances which are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment.")). As ClearCorrect explains, the '037 patent references, for example, U.S. Patent No. 4,755,139 (provided as Exhibit 1057), which discloses a positioner that requires merely a general fit, rather than a precise fit, over teeth to be corrected. Align fails to explain adequately why each and every appliance contemplated by the '037 patent, such as a retainer or other positioners requires the actual tooth shape to fit the appliance to the patient (or how the language of claims 1 and 9 excludes certain types of appliances expressly disclosed in the '037 patent). For example, the '037 patent provides that the tooth movement contemplated by the disclosed method includes "translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ('root angulation' and 'torque') as well as rotation about the centerline." Ex. 1001, 8:7–12. Align fails to explain why the actual tooth shape of a patient is *required* for *all* of the contemplated appliances to accomplish at least one of these types of movement. We note

that the "providing" steps of claims 1 and 9 do not require any specific type of movement, such that any *one* of the movements contemplated in the '037 patent would fall within the scope of the steps. As ClearCorrect asserts, Align's claim construction position appears to limit the type of appliance recited in claims 1 and 9 to a type of aligner corresponding to Align's commercial products, rather than encompassing the broader types of appliances. *See* Reply 9–10 ("It should also be noted that Patent Owner bases much of its 'must fit all teeth' argument on some uses of 'aligner' appliances today, as opposed to other types of dental positioning appliances . . . [that] the [S]pecification specifically contemplates."); *see e.g.*, PO Resp. 11 (quoting a section of the '037 patent disclosure a specific type of appliance that receives the teeth in a cavity); *id.* at 12–13 (stating that the inventive system requires tooth movements of less than 0.5 mm);[6] (Ex. 2011 ¶¶ 46–55 (discussing the '037 patent in terms of "aligners").

Align also references the prosecution history to support its narrow construction of the "providing" steps of claims 1 and 9. Specifically, Align points to a June 3, 2002 claim amendment to support its position. PO Resp. 18–19. In that amendment, Align added the phrase "for an individual patient" to the "providing" and "controlling" steps of claim 1. Ex. 1002, 59. Align then argued that none of the art at issue in the prosecution disclosed fabricating or forming a plurality of appliances for an individual patient (or

[6] We note that none of the challenged claims recites any limitation of the degree of tooth movement nor does the '037 patent require any amount of tooth movement as part of its disclosed method. *See* Ex. 1001, 3:1–15 (indicating that *typically*, movement is less than 2 mm but not specifying any limit to tooth movement), 13:24–25 ("Treatment planning is extremely flexible in defining the movement of teeth and other components.").

the same patient). *Id.* at 57; *see* PO Resp. 18–19. Align fails, however, to explain adequately why this claim amendment supports its position that the digital data sets include the representation of the shape of an individual patient. Further, Align fails to explain why claim 9 should be entitled to the same limited construction, as it does not recite "for an individual patient."

Further, Align discusses the *ex parte* reexamination of U.S. Patent No. 6,629,840 ("the '840 patent"), Control No. 90/011,199. Align argues that, in response to a rejection of claim 7, which recites similar subject matter as claims 1 and 9 of the '037 patent, Align amended claim 7 to recite "a plurality of successive tooth arrangements of the patient's teeth." PO Resp. 23. Align further amended claim 7 by adding the following wherein clause: "wherein the providing digital data representing the plurality of successive tooth arrangements of the patient's teeth is accomplished before any of the plurality of dental appliances are used by the patient to reposition the teeth of the patient." *Id.* Align argues that the examiner, in an interview summary, stated that "Snow is limited to generic shaped teeth and [is] not useful for fa[b]ricating aligners custom shaped to a patient's teeth." *Id.* at 22 (corrections in original).

We do not find Align's reliance on this *ex parte* reexamination persuasive. As ClearCorrect points out, the examiner distinguishes claim 7 over Snow based on the timing requirement of the added wherein clause, not the generic nature of Snow's teeth. Reply 10–11; *see also* Ex. 2047, 14 (providing the examiner's reasons for allowance). Further, the examiner's statement regarding Snow stated that Snow's generically shaped teeth would not be useful in fabricating *aligners custom shaped to a patient's teeth*. As we stated above, Align fails to explain persuasively why the appliances of

claims 1 and 9 are limited to those appliances that are custom shaped to a patient's teeth in exclusion of other appliances contemplated by the '037 patent.

Finally, Align asks us to consider construing the claims of the '037 patent under the district court claim construction rubric of *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), given that the '037 patent will expire before any ruling on appeal to the Federal Circuit. PO Resp. 15–16 n.6. Our rules expressly state that "[a] claim in an unexpired patent *that will not expire before a final written decision* is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R 42.100(b) (emphasis added). Although our rules do allow a party to request a district court-type claim construction approach, such a request must include a certification that the involved patent will expire within 18 months from the entry of the Notice of Filing Date Accorded to the Petition. *See id.* Align has not argued, nor does the record reflect, that the '037 patent will expire within that window nor did Align file a motion to request such a claim construction approach. Accordingly, we afford the claims of the '037 patent their broadest reasonable interpretation.

Even if we construe the claims of the '037 patent under the district court claim construction rubric of *Phillips*, we are not persuaded that the resulting construction of the "providing" steps would limit the digital data sets recited in the steps to three-dimensional images of a patient's teeth, such that the data includes the actual shape of the patient's teeth, as proffered by Align. Align fails to provide any credible and persuasive evidence or argument that would support a construction under the *Phillips* rubric that is narrower than the broadest reasonable interpretation. *See* PO Resp. 15–16

n.6. Further, as we discussed above, we discern nothing in the plain language of the claims, the Specification, or the prosecution history that would require Align's narrow construction, even under *Phillips*. As we determined, the ordinary and customary meaning of the "providing" steps, when read in light of the Specification by an artisan of ordinary skill, is not limited to three-dimensional images of a patient's teeth, such that the data includes the actual shape of the patient's teeth. *See Phillips*, 415 F.3d at 1312–13 ("We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning[,]'. . . the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.").

For the foregoing reasons, we are not persuaded that we should depart from the ordinary and customary meaning of the "providing" steps of claims 1 and 9.[7] *See Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016) (providing that claim terms are given their ordinary and customary meaning unless the patentee acted as its own lexicographer or disavowed certain claim scope, which are determined applying an exacting standard). Accordingly, we construe the "providing" steps of claims 1 and 9 to encompass digital data sets that are *not* limited to three-dimensional images of a patient's teeth, such that the data includes the actual shape of the patient's teeth.

[7] ClearCorrect asserts that Align's proffered construction in this proceeding is in conflict with a construction of the same claim limitation before the U.S. International Trade Commission, where Align argued that the claim term should be afforded its ordinary and customary meaning. Reply 12.

B. Overview of the Prior Art

We instituted trial on a ground of unpatentability that relied on Snow, Hultgren, and Kesling. *See* Dec. on Inst. 25. We summarize these three references below.

1. Overview of Snow

Snow, titled "Method for Creation and Utilization of Individualized 3-Dimensional Teeth Models," relates "to storing and [utilizing] [three-dimensional] 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. 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. That is, the standard model is a representation of generic male or female teeth with respect to the teeth's size and shape.

To generate two-dimensional data sets for an individual patent, a two-dimensional plaster cast model of the patient's teeth is digitally scanned, such as by using a flatbed scanner, to produce two-dimensional images of the patient's upper and lower jaw. Ex. 1003, 2:59–63. Also, x-rays or other side medical images are scanned to create digital renderings. *Id.* at 2:63–65.

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. That is, the two-dimensional data sources are used to modify Snow's standard model to generate a three-dimensional individualized digital model, where the digital data is a three-dimensional representation of the individualized model. 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. That is, the treatment goal is represented by the orientation, or arrangement, of teeth as represented in the standard model. 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.

2. 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, 7:61–65.

3. 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.

C. Ground of Unpatentability

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

We instituted trial on a single ground: claims 1, 2, 9, and 10 are unpatentable under 35 U.S.C. § 103(a) over Snow, Hultgren, and Kesling. Dec. on Inst. 25.

> Section 103(a) [of 35 U.S.C.] forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007).

The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We analyze these factual determinations, along with the reasons for

combining Snow, Hultgren, and Kesling, below.[8] In making our factual findings underlying our obviousness conclusions, we consider the entire trial record.[9]

1. Independent Claims 1 and 9

a. The subject matter of 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). 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 a plurality of

[8] We analyze the level of ordinary skill in the art in Section II.A.1, *supra*.
[9] In weighing the record evidence, we recognize that declarants Dr. Mah and Ms. Cheang are interested parties—Dr. Mah is ClearCorrect's Chief Technical Officer (Ex. 1008 ¶ 7) and Ms. Cheang has a financial interest in Align (Reply 4–5). We have considered their testimony with that in mind.

dental incremental position adjustment appliances. *Id.* We address ClearCorrect's specific contentions and Align's counter positions, below.

With respect to the "providing" steps of claims 1 and 9, ClearCorrect contends that Snow's disclosure of a computer-generated model that produces a sequence of images that maps the movement of teeth from an initial position to an idealized second position corresponds to the step of providing, at the outset of treatment, a plurality of digital data sets. Pet. 17, 24–25. ClearCorrect further contends that these digital data sets (the digital data underlying each depicted movement of the patient's teeth) represent successive tooth arrangements, including initial, final, and intermediate tooth arrangements for each individual patient. *Id.* at 17, 25–26; *see also* Ex. 1007 ¶ 42 ("[B]ecause the movements are mapped from the current state of the patient's teeth, the plurality of digital data sets necessarily represent successive tooth arrangements that have been customized and created for each individual patient.").

ClearCorrect also 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 does not allege that any of the digital data of Snow are used to control a fabrication machine to fabricate the dental appliances disclosed in Snow.

Align disputes that Snow discloses the "providing" steps of claims 1 and 9. PO Resp. 32–33. First, Align argues that the "initial tooth arrangement" and "digital data set" representing the initial tooth arrangement recited in the "providing" steps "must be a 3D representation of an actual tooth arrangement of an actual patient." *Id.* at 33. As discussed

above in our claim construction analysis, the "providing" steps encompass two dimensional representations of an individual patient's teeth. Further, the "providing" steps encompass digital data sets that include the representation, with respect to size and shape, of a generic tooth—that is, not the patient's actual tooth. As Snow discloses, its three-dimensional individualized model is a digital representation of a patient's actual teeth, with respect to the teeth's location, rotation, and, through scaling, size (but not shape). *See* Ex. 1003, 4:12–16; *see also id.* at 3:44–46 ("The individual teeth [of the standard model] are then adjusted by means of translation, scaling and rotation so as to match the X-ray image [of a patient]."), *id.* at 3:66–4:1 (indicating that the individualized model includes teeth positions corresponding to an individual patient).

In Reply, ClearCorrect contends that, even if Align's claim construction position was employed, such that the "providing" steps of claims 1 and 9 required three-dimensional digital representations of a patient's actual teeth, the proposed combination renders claims 1 and 9 obvious. Reply 13; *see also id.* at 3 ("A [person having ordinary skill in the art] would have applied her creativity to ensure that any variance in the size and shape of the teeth was acceptable, using actual 3D scans to the extent necessary." (citing *Randall Mfg. v. Rea*, 733 F.3d 1355, 1363 (Fed. Cir. 2013))).

ClearCorrect argues that a person having ordinary skill in the art would know that three-dimensional scans of a patient's teeth could be used such that Snow's individualized model would be a representation of a patient's actual teeth, including the teeth's shape. *Id.* at 14; *see also* Dec. on Inst. 15 ("A person of ordinary skill in the art . . . 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."). To support this position, ClearCorrect points to record evidence that indicates that digitizing the shape of individual teeth was known in the prior art. *See* Reply 14. ClearCorrect continues that the '037 patent itself recognizes that this knowledge was in the prior art, as the patent incorporates by reference a prior art patent—U.S. Patent No. 5,605,459 (Ex. 1054)—that teaches creating digital data sets by scanning a patient's actual teeth. *Id.* at 14–15.

Align contends that the record provides no evidence that a person having ordinary skill in the art "could have used their creativity to modify the generic representation of teeth to make sure the variance in the size and shape of the teeth was acceptable." PO Resp. 35. Align argues that, to the contrary, ClearCorrect's experts testified that "practitioners were still in the process of determining how best to measure [three-dimensional] tooth models." *Id.*

Further in Reply, ClearCorrect contends that Align's argument treats the artisan of ordinary skill as an automaton. Reply 15. ClearCorrect argues that the artisan of ordinary skill would not have ignored the well-known alternative of using digital data representative of three-dimensional actual teeth, including the teeth's size and shape, to the extent such data was needed. *Id.* at 15–16. ClearCorrect concludes that "[j]ust as in *Randall Mfg.*, it would have been obvious for a [person having ordinary skill in the art] to make use of this prevalent teaching of the prior art." *Id.* at 16.

We agree with ClearCorrect and find that the knowledge of a person having ordinary skill in the art would include techniques for acquiring an initial digital data set representative of actual patient's teeth. In making this

finding, we weight the record evidence in prior art references against the cross-examination testimony that Align elicited from ClearCorrect's experts in favor of the prior art disclosures. The prior art of record is replete with such knowledge. *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). We further recognize that the '037 patent itself relies on this knowledge for its disclosed method. *See* Ex. 1001, 2:41–44 (identifying a prior art method for producing digital data of a patient's teeth using laser scanning), 2:50–59 (identifying prior art patents that disclose digitizing actual teeth), 9:25–48 (describing known ways to capture and digitize three-dimensional images). Given that we construe the "providing" steps to not require digital data sets representing three-dimensional scans of a patient's actual teeth, including teeth shape, however, we need not reach this alternative obviousness theory.

Align next contends that Snow fails to disclose providing a digital data set representative of a final tooth arrangement for an individual patient and, as such, Snow is directed to a clinically inappropriate outcome. PO Resp. 38. Align apparently argues that, because Snow's final tooth arrangement is based on a standardized model that is independent of any individual, it is not a final tooth arrangement for an individual patient. *See* Tr. 27:22–32:15.

Align's argument does not demonstrate that ClearCorrect's position with respect to Snow and the "providing" steps of claims 1 and 9 is deficient. Align fails to adequately explain how Snow's idealized final tooth arrangement is a clinically inappropriate outcome. To the extent that

Align's position is that the fabricated appliances would not function, we find this argument inapposite, as it appears to be limited to a specific type of appliance—Align's commercial aligner. Align fails to explain adequately why another appliance contemplated by the '037 patent would not function. Further, Align fails to explain why Snow's idealized standard model would not be representative of a final tooth arrangement for an individual patient—that is, why the position and rotation of the teeth represented in the standard model would not be a treatment goal for an individual patient, even if that standard model also would be a treatment goal for other patients.[10]

Next Align contends that "*Snow's* use of 'linear interpolation' of its generic teeth from a starting position to a generic final position does not somehow transform its underlying deficient data to that which would be orthodontically relevant." PO Resp. 38 (citing Ex. 2011 ¶¶ 134–135). Dr. Valley declares that

> *Snow's* linear interpolations for example, do not take into account a number of factors, including but not limited to: (i) tooth collisions; (ii) the speed at which you can move teeth; (iii) or the sequence (e.g., the order in which teeth should be moved), which are all factors that must be taken into account in treatment planning.

Ex. 2011 ¶ 135.

[10] We also credit Dr. Martz's testimony that a person having ordinary skill in the art would understand that, with Snow's modeling, a treatment goal could be represented by any of the intermediate digital representations of the tooth arrangements generated between the initial and final arrangements. *See* Pet. 17; Ex. 1007 ¶ 42. In that way, the "final tooth arrangement" would not be the standardized model, but an individualized arrangement, including being scaled for teeth size.

Align's argument does not demonstrate that ClearCorrect's position with respect to Snow and the "providing" steps of claims 1 and 9 is deficient. Snow expressly discloses that its process of generating subsequent digital images through interpolation is used for treatment planning. *See* Ex. 1003, 4:7–9. Snow further discloses that its model can be enhanced with data related to the patient's upper and lower jaw to give an orthodontist "the ability to accurately view a patient's likely jaw movement *for each corresponding movement in individual tooth arrangements* thereby locating likely problems in a patient's treatment program." *Id.* at 4:29–44 (emphasis added). Further, neither Dr. Valley nor Align adequately explains how Snow's linear interpolation as part of its treatment planning differs from that disclosed in the '037 patent. The '037 patent provides that "if only a final position is defined for a particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a quaternion) closer to the final position." Ex. 1001, 13:41–45; *see also id.* at 6:37–38 ("Many times, the interpolation will be linear interpolation for some or all of the positional differences."). That is, the method for providing intermediate digital data sets as described in the '037 patent is seemingly identical to the linear interpolation described in Snow.

Align further contends that Snow's treatment planning is in the context of braces, which is a reactive treatment process. PO Resp. 38. Align argues that Snow does not contemplate using the intermediate digital data sets to fabricate subsequent braces for a patient. Align's argument does not demonstrate that ClearCorrect's position with respect to Snow and the "providing" steps of claims 1 and 9 is deficient. ClearCorrect relies on

Hultgren and Kesling for the fabrication step. To the extent that Align argues that Snow being directed to braces and a reactive treatment process cuts against any reason to combine Snow with Hultgren and Kesling, we address that contention below.

On the complete record before us, we conclude that ClearCorrect has demonstrated, by a preponderance of the evidence, that Snow discloses the "providing" steps of claims 1 and 9.[11] In addition to our express findings above, we have reviewed ClearCorrect's positions and the underlying evidence cited in support of those positions and are persuaded ClearCorrect sufficiently establishes that Snow discloses the providing steps of claims 1 and 9 and we adopt those positions as our own findings. *See* Pet. 17–21, 24–29. Included in these findings is that Snow's disclosure of using its three-dimensional model for treatment planning demonstrates that Snow's process provides, 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. S*ee* Ex. 1003, 4:7–44 (describing using Snow's individualized model for treatment planning); Ex. 1007 ¶¶ 42–43, 53 (explaining the teachings of Snow).

Claim 1 further recites the step of "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, 15:36–38. Claim 9 recites

[11] Align further argues that Hultgren fails to disclose a digital data set representative of an initial tooth arrangement as recited in the providing steps of claims 1 and 9. As we find that Snow discloses the "providing" steps of claims 1 and 9, we need not address this argument.

a similar step, except it omits the phrase "for an individual patient." *See id.* at 16:9–11. 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; *see also* Tr. 58:17–20 ("We have cited Kesling for a simple proposition that it's been known since the 1940s to make a set of appliances to incrementally move teeth. . . . No timing aspect of Kesling [that is, reactive compared to proscriptive] is cited"). Align does not address ClearCorrect's contentions.

Upon review of the complete record, we find that Hultgren and Kesling disclose the "controlling" steps of claims 1 and 9. *See, e.g.*, Ex. 1004, 7:28–39 (discussing fabrication device 507); Ex. 1005, 2:50–3:1 (describing producing a plurality of appliances based on intermediate tooth positioning), 4:39–58 (describing forming appliances from a mold made from an impression of articulated teeth). In additional to our express findings above, we have reviewed ClearCorrect's positions and the underlying evidence cited in support of those positions and are persuaded ClearCorrect sufficiently establishes that Hultgren and Kesling disclose the subject matter of the "controlling" steps and we adopt as our own findings ClearCorrect's positions. *See* Pet. 17–21, 24–29; Ex. 1007 ¶¶ 25–28, 44–49, 54 (explaining the relevant disclosures of Hultgren and Kesling).

b. Reasons to combine Snow, Hultgren, and Kesling

"'The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.'" *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (quoting *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)). 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 to provide more precise dental appliances and save manufacturing costs. Pet. 22. ClearCorrect explains that

> a skilled artisan would have been motivated to create a plurality of digital data sets and digitally reposition the teeth, as taught by Snow, and to use the digital data sets representing the repositioned teeth to control a fabrication machine to produce a plurality of positive casts of the successive tooth arrangements, as described by Hultgren. The positive casts would then be used for producing the plurality of dental incremental position adjustment appliances well known in the art, as negatives of the positive casts taught by Kesling.

Id. (citing Ex. 1007 ¶¶ 54-55; Ex. 1008 ¶¶ 101-102).

ClearCorrect further explains that 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. Pet. 22. ClearCorrect contends that the combination would result in more precise dental appliances as Snow's digital data represents more precise tooth arrangements as compared to Kesling's manual process. *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.* (citing Ex. 1007 ¶ 55 and Ex. 1008 ¶ 105).

Align contends that "the Petition fails to set forth a reasoned basis to combine the cited references in the manner alleged." PO Resp. 40. Specifically, Align asserts that: (1) a person having ordinary skill in the art "would have recognized that the references would not have been combined – particularly in the manner asserted in the Petition;" and (2) "the purported benefits of the alleged combination identified by Petitioner are contrary to the teachings of the cited references." *Id.* We address these assertions in turn.

With respect to its first assertion, Align contends that a person having ordinary skill in the art "would not have looked to Snow to create *Kesling's* appliances" or any appliance. PO Resp. 41. Align argues that Kesling teaches using actual teeth from a patient and Snow's model is based on generic teeth that do not reflect the actual shape of the patient's teeth. *Id.* at 41–42. Align continues that if one employed Snow's models to fabricate Kesling's appliances, the generic-based positions would not fit the patient's

teeth, making the appliances unsuitable for orthodontic treatment. *Id.* at 42.[12]

We rejected a similar argument in our Decision on Institution, providing that the measure of obviousness is not whether the model of Snow can be bodily incorporated into Kesling's process. *See* Dec. on Inst. 17–18. As we stated in that Decision,

> 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.").

Dec. on Inst. 18. Align, in renewing its argument, contends that its argument is not one of bodily incorporation but, rather, is that a person having ordinary skill in the art would not have used Snow's digital models, based on generic teeth, to make any form of appliance. PO Resp. 42. Align argues that no artisan of ordinary skill "would have reviewed *Snow* and thought to create appliances based on its disclosure because its data has no relevance to an actual patient." *Id.*

[12] At oral hearing, Align's counsel argued that Dr. Martz's testimony supports this point and further, contrary to ClearCorrect's position, when Dr. Martz referred to "aligners" in his testimony, he was using the term generically to mean the recited appliances. Tr. 39:1–40:8. Our review of the record indicates that Dr. Martz testified that the term "aligner" has become a generic term for appliance. Ex. 2015, 29:9–13. However, we find the record unclear as to whether Dr. Martz was referring to all of the types of appliances that fell within the scope of claims 1 and 9 and do not credit this testimony to support Align's position as to the recited "appliances."

Align's argument does not demonstrate a deficiency in ClearCorrect's obviousness position. Align fails to explain adequately why Snow *has no relevance to an actual patient*. Snow expressly, and repeatedly, discloses that its model is an "individualized model." *See, e.g.*, Ex. 1003, 3:34; 3:66; 4:7; 4:25; 5:32–33. This model includes the position and rotation of each of a specific patient's teeth. We do not discern how Snow has no relevance to an actual patient when its model is patent-specific. Further, Align fails to explain adequately why Snow's individualized model, with its representation of generically-shaped teeth having the location and rotation of a specific patient is not relevant to appliances contemplated by the '037 patent, such as a positioner or a retainer, which need not fit precisely over the actual shaped tooth, particularly considering that the shape of the teeth in Snow's model approximates an average for a man or woman.

Further, Align repeats its argument that Snow's animation steps do not represent target treatment positions. PO Resp. 43. Align argues that "the animations simply depict steps of a linear transition from an imprecise approximation of a patient's tooth arrangements using generically shaped teeth to an idealized arrangement of generic teeth." *Id.* As we discussed above in connection with this same argument, Align's position is contrary to the express teachings in Snow and in the '037 patent—both of which disclose that linear interpolation of tooth movement represents treatment positions.

With respect to its second assertion, Align contends that the benefits of the combination of Snow, Hultgren, and Kesling alleged by ClearCorrect are contrary to the express teachings of the references. PO Resp. 44. First, Align addresses ClearCorrect's allegation that Snow's digital data sets

would provide more precise tooth arrangements for Hultgren's fabrication. Align argues that Snow's use of generic teeth is less accurate than Kesling's use of actual teeth for a patient. *Id.* Align continues that "[u]sing the generic teeth and generic positioning of Snow would be a step backward because the tooth shapes would not match the patient's teeth." *Id.* (citing Ex. 2011 ¶ 161).

Align also argues that "[t]here is no indication that Snow's 'discrete movements' are more precise than other movements." PO Resp. 45. In particular, Align argues that the Snow's teachings would result in less precision than taught in Kesling alone, such that no cost savings would be realized. *Id.* (citing Ex. 2011 ¶ 166).

Align's argument does not demonstrate a deficiency in ClearCorrect's obviousness position as it is not commensurate with that position. ClearCorrect's position is that the interpolated, intermediate, positions resulting from Snow's model represent more precise movement of teeth from an initial to a final arrangement than the manual process disclosed in Kesling, such that the successive appliances would reflect this more precise movement. *See* Pet. 22–23 ("[T]he digital data sets from Snow[] represent[] more precise tooth arrangements."). Instead, Align's argument seems to be limited to one type of appliance—appliances that must fit precisely over teeth. In that regard, we do not attribute much weight to Dr. Valley's testimony in response to ClearCorrect's reasoning. Her position is based on the underlying assumption that the claims of the '037 patent require digital data sets based on three-dimensional models of actual teeth, including teeth shape. *See* Reply 9; Ex. 1056, 28:6–11); *see also* Ex. 2011 ¶ 69 (emphasizing that the third limitation that the "digital data sets" be used "to

produce the plurality of appliances for the individual patient" requires the "digital data sets" to be ***actual 3D representations of a patient's actual teeth in planned treatment positions***, as the produced appliances must fit the recited "individual patient").

Similarly, we give little weight to Dr. Valley's opinion that the combination of Snow, Hultgren, and Kesling would not result in a cost savings. Dr. Valley's opinion assumes that the fabricated appliances are aligners that must fit precisely over the patient's teeth and aligners fabricated based on generic teeth would not fit. *See* Ex. 2011 ¶ 166 ("[T]here are no cost savings by manufacturing aligners using *Snow*'s data."). Instead, we credit Dr. Martz's testimony, that the combination of Snow, Hultgren, and Kesling "would [ ] provide cost savings by avoiding the need for labor intensive efforts to make the modified tooth arrangements on physical casts. Indeed, using automation to replace manual efforts is commonly sought to achieve cost savings and improve efficiency." Ex. 1007 ¶ 56; Ex. 2015, 80:14–20.

Accordingly, we find that a person having ordinary skill in the art would have had a reason to combine the teachings of Snow, Hultgren, and Kesling to replace Kesling's labor-intensive process with a computerized process, resulting in labor cost savings and resulting in modeling of more precise teeth movement. *See* Pet. 21–24; *see also* Ex. 1007 ¶¶ 52–56 (describing the combination of Snow, Hultgren, and Kesling and how the resulting combination "provide[s] cost savings by avoiding the need for labor intensive efforts to make the modified tooth arrangements on physical casts"); Ex. 1008 ¶ 103 ("[T]he combination [of Snow, Hultgren, and Kesling] would result in the fabrication of . . . more precise dental position

adjustment appliances, as the digital data sets from Snow, representing more precise tooth arrangements, would be used to control the fabrication machine in Hultgren."); Ex. 1005, 3:30–60 (describing Kesling's labor-intensive process for successively positioning teeth using its plaster cast model).

c. Secondary Considerations

Align contends that extensive evidence of non-obviousness, in the form of secondary considerations, supports the patentability of claims 1, 2, 9 and 10.[13] PO Resp. 45. First, Align alleges that the methods of claims 1, 2, 9, and 10 are practiced with respect to a number of Align products, including Invisalign Full, Invisalign Teen, Invisalign Lite, Invisalign Express 10, and Invisalign Express 5. *Id.*; *see also id.* at 46–47 (providing a claim chart mapping the elements of claims 1 and 2 to commercial embodiments from Align), *id.* at 45 n.8 (indicating that the claim chart for claims 1 and 2 is applicable to claims 9 and 10 as well).

Align contends that the listed products (1) "have enjoyed significant commercial success;" (2) satisfy a long-felt, yet unsolved need; (3) were met with initial skepticism and disbelief; (4) "have received significant industry praise;" and (5) have been copied. PO Resp. 47, 58. We address each of these secondary considerations in turn.

i. Commercial success

Align asserts that their commercial products have experienced significant commercial success, including a significant increase in sales from

[13] Although this section of our Decision addresses claims 1 and 9 only, we address secondary considerations for claims 2 and 10 here as well, as both parties address these secondary indicia for all four of the challenged claims together.

1999 to 2015, both in dollar amount and volume. PO Resp. 48. Align further asserts that the number of orthodontists using the subject products has increased. *Id.* Align contends that this success is directly attributable to claims 1, 2, 9, and 10. *Id.*

Specifically, Align alleges that generating successive digital data sets from an initial to a final tooth arrangement allows Align to fabricate unique, highly-specific aligners, which led to the commercial success. PO Resp. 49. Align continues that the steps of claims 1, 2, 9, and 10 allow for "the efficient and accurate creation of successive dental appliances that were capable of performing significant tooth movement over multiple treatment stages and were directly responsible for the commercial success of the Invisalign products." *Id.* at 50. To support this assertion, Align relies on declaration testimony of Dr. Valley (Ex. 2011) and a 2002 article in the *American Journal of Orthodontics and Dentofacial Orthopedics* (Ex. 2035). *Id.* Align contends that the article "emphasized the criticality of the computer-based technology in the success of Invisalign." *Id.* Further, in rebutting assertions in the Petition regarding secondary considerations and commercial success, Align references the decision in *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312–13 (Fed. Circ. 2006), quoting the Federal Circuit that "it is undisputed that Align's Invisalign product is commercially successful" and tying the success to "the aesthetic appeal and improved comfort of transparent devices without brackets and wire, and ***the computerized design and manufacture of the appliances***." *Id.* at 52. Align asserts that the Federal Circuit's decision supports a finding of commercial success. *See id.*

In reply, ClearCorrect contends that Align fails to demonstrate a nexus between the alleged commercial success and claims 1, 2, 9, and 10. Reply 18. Specifically, ClearCorrect argues that Align fails to demonstrate that the Align products are co-extensive with the invention of claims 1, 2, 9, and 10. *Id.* at 18–19. ClearCorrect also argues that Align fails to demonstrate that the alleged commercial success is not due to aspects of the claimed invention not in the prior art. *Id.* at 19–20.

ClearCorrect further argues that the record evidence demonstrates that any alleged success is attributed to factors unrelated to claims 1, 2, 9, and 10. ClearCorrect asserts that any success was attributed, in part, to marketing. Reply 20. ClearCorrect also argues that the decision in *Ormco Co.* supports a finding that any success is attributable to unclaimed features of Align's products, such as aesthetic appeal and convenience. *Id.* at 21.

"For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). "[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (internal citation omitted); *see also PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 734, 747 (Fed. Cir. 2016) ("Because the evidence shows that the SignalTight connectors are 'the invention disclosed and claimed in the patent,' we presume that any commercial success of these products is due to the patented invention . . . . This is true even when the product has additional, unclaimed features.") (internal citations omitted).

"The presumption of nexus is rebuttable: a patent challenger may respond by presenting evidence that shows the proffered objective evidence was 'due to extraneous factors other than the patented invention.' Such extraneous factors include additional unclaimed features and external factors, such as improvements in marketing." *WBIP, LLC*, 829 F.3d at 1329 (internal citation omitted).

We find that Align is entitled to the presumption of a nexus. Align offers evidence that its method claimed in claims 1, 2, 9, and 10 is used in producing it products. *See* PO. Resp. 45–47. As discussed in greater detail below, we further find, however, that the record evidence rebuts this presumption. Accordingly, we afford little weight to Align's commercial success evidence.

We find that the record evidence demonstrates that the commercial success is attributable, in greater part, to the aesthetic appeal and convenience of products in addition to any computer implementation and fabrication reflected in the challenged claims. For example, Align's 10-K for 2000 states that its products "significantly reduces the aesthetic and other limitations associated with braces." Ex. 2018, 5.[14] Align states that benefits of its products include excellent aesthetics, comfort, improved oral hygiene, reduced treatment time, reduced root absorption, and reduced emergency situations as broken aligners can be replaced. *Id.* at 8. Align fails to explain how these benefits are attributed to claimed features of the challenged claims. *See also* Ex. 2019, 7–8 (providing a 10-K for 2003 that provides benefits to dental professionals and patients, with only one benefit—

[14] In referencing Align's 10-K exhibits, we cite to the exhibit page number, not the 10-K page number.

"[a]bility to visualize treatment and likely outcomes"—attributable to claimed features of the challenged claims); Ex. 2020, 7–8 (providing the 10-K for 2006 stating the same benefits); Ex. 2021, 10–11 (providing 10-K for 2008 stating same benefits); Ex. 2022, 12 (providing 10-K for 2011 stating favorability with respect to key competitive factors are "effectiveness of treatment; price; software features; aesthetic appeal of the treatment method; customer support; customer online interface; brand awareness; innovation; distribution network; comfort associated with the treatment method; oral hygiene; ease of use; and dental professionals' chair time"); Ex. 2023, 13 (providing 10-K for 2014 with same statement as in 2011 regarding favorability with respect to key competitive factors); Ex. 2024, 12 (providing 10-K for 2015 with same statement as in 2011 regarding favorability with respect to key competitive factors).

Other record evidence also supports a finding that any commercial success of Align's products is attributable, at least in part, to unclaimed features. For example, Exhibit 2025 indicates that features such as the invisible nature of the aligners and comfort attribute to the products' success. *See* Ex. 2025, *A Stealth Substitute for Braces, Designed Only for Adults*, col. 2. The article also notes Align's $38 million advertising campaign. *Id.* at col. 3; *see also* Ex. 2012, 2 (explaining that Align initiated "the first effort by an orthodontics products company to appeal directly to consumers through television"). Further, the article quotes Dr. Jerrold, program director of postgraduate orthodontics at New York University's School of Medicine, as saying "[t]he only reason that this is a better mousetrap is that it's invisible." *Id.* at col. 4. Further, as ClearCorrect argues, Dr. Valley testified that Align's product success was attributable to

factors that includes aligners that are less noticeable than braces, more comfortable than braces, and allows for better oral hygiene than braces. *See* Reply 21; Ex. 1056, 34:8–35:5.

Still further, a finding that any commercial success of Align's products is attributable, at least in part, to unclaimed features is consistent with the ruling by the Federal Circuit in *Oromco Corp*. In *Oromco Corp.*, the Federal Circuit confirmed that in addition to the computerized design and manufacture of the appliances, the aesthetic appeal and improved comfort of transparent devices without brackets and wire attributed to the commercial success of Align's Invisalign products. *See Ormco Corp.*, 463 F.3d at 1312.

For the reasons above, we attribute little weight to Align's commercial success evidence.

ii. Long-felt but unsolved need

Evidence of a long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would have not persisted had the solution been obvious—however, "[a]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness." *See Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). In asserting that the challenged claims address a long-felt, yet unsolved need, Align identifies the need as a "market for aesthetic, removable appliances that (a) could serve as an alternative to traditional fixed appliances and (b) were also capable of treating moderate to severe malocclusions over multiple treatment stages." PO Resp. 53. Align contends that "[t]he [claimed] digital data sets are [ ] used to efficiently fabricate a series of

dental appliances such as polymeric shells[and] [a]s a consequence, the patented inventions were able to meet this long-felt industry need." *Id.* at 55.

In reply, ClearCorrect contends that Align "has failed to submit 'probative evidence that claimed and novel features met a long-felt but unresolved need.'" Reply 21–22 (quoting *Ormco Corp.*, 463 F.3d at 1313). We agree. Even if we assume, for the purposes of our Decision, that Align's statement of a long-felt need is correct, Align fails to explain persuasively how the claimed features of claims 1, 2, 9, and 10 resolved that need. For example, Align fails to explain how providing digital data sets *at the outset of treatment* served to meet the long-felt need identified by Align.

Further, the record evidence supports a finding that other appliances met the alleged long-felt need prior to the '037 patent. *See, e.g.*, Ex. 2027, 10 (providing Table 10, which shows removable and functional appliances used routinely prior to 1997); Ex. 2036, 40–42 (indicating that the use of thin, clear overlay appliances for staged treatment was not new); Ex. 2045, 10 ("The concept of moving teeth with clear overlay appliances has been around since 1926."). Align does contend that prior removable appliances had to be made by hand, but Align fails to explain adequately how the use of automation to fabricate appliances was a key to meeting its stated need of an alternative to traditional fixed appliances that could treat moderate to severe malocclusions over multiple treatment stages. *See* PO Resp. 54–55.

Accordingly, we give very little weight to this secondary consideration.

iii. Skepticism and disbelief

"Evidence of industry skepticism weighs in favor of non-obviousness. If industry participants or skilled artisans are skeptical about whether or how a problem could be solved or the workability of the claimed solution, it favors non-obviousness." *WBIP, LLC*, 829 F.3d at 1335. Align contends that industry treated with skepticism "whether Invisalign would work in 'more complex cases' and [was] hesitan[t] 'to adopt this new type of treatment approach quickly.'" PO Resp. 55–56 (quoting Ex. 2011 ¶ 205). Align further contends that "[n]umerous orthodontists opined that Invisalign could not facilitate major tooth movements over multiple treatment stages." *Id.* at 56.

Align contends that this skepticism is tied to the claimed features of claims 1, 2, 9, and 10. Align argues that the claimed features "provide for major tooth movements over multiple treatment stages, which was the very target of the industry's initial skepticism." PO Resp. 56. In reply, ClearCorrect argues that this alleged skepticism is irrelevant "because it is directed to the efficacy of treatment—not the ability to manufacture devices according to the methods claimed in the '037 patent, let alone any novel, claimed aspect of these methods." Reply 22.

We agree with ClearCorrect that the alleged skepticism is directed to the effectiveness of treatment with Align's commercial products, not skepticism that the claimed method could be implemented to fabricate a plurality of aligners based on digital data sets provided at the outset of treatment. Accordingly, we assign very little weight to this evidence.

iv. Industry praise

Evidence that the industry praised a claimed invention or a product which embodies the patent claims weighs against an assertion that the same claim would have been obvious. *WBIP, LLC*, 829 F.3d at 1334. Align contends that it "has won several awards relating to the Invisalign products' use of the patented technology," including the Canon Communications LLC Medical Design Excellence Award in 2002 and the Frost and Sullivan Technology Leadership of the Year Award in 2004. PO Resp. 57. Align further identifies certain publications that "have acknowledged Invisalign as one of the most innovative advancements in orthodontics since its introduction in 1999." *Id.* at 58.

In reply, ClearCorrect again argues that the asserted evidence is not tied to any novel aspect of claims 1, 2, 9, and 10. Reply 22. Although we do not agree with ClearCorrect, we do not assign a significant amount of weight to Align's evidence. Some evidence suggests that "cost-effectiveness in manufacturing" was a factor in the praise, which may be tied to the claimed invention. *See* Ex. 2038, 1; Ex. 2039, 2. However, even this praise fails to support a finding that the awards were based, even in part, on providing, *at the outset of treatment*, digital data files that could be used to fabricate the aligners. The praise also focuses on end benefits of the patient—benefits not reflected in the claims. *See* Ex. 2038, 1; Ex. 2039, 2; *see also* Ex. 2042, 6 ("The easy process provides adults (and now teens) with the means of straightening their teeth without the hindrance of unaesthetic metal braces"); Ex. 2043, 1 (stating that Invisalign provides a viable alternative to fixed braces but fails to support a finding that the praise

is attributable to fabricating aligners using digital data sets provided at the outset of treatment).

v. Copying

The fact that a competitor copied technology suggests it would not have been obvious. *See Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1000 (Fed. Cir. 1986) ("[C]opying the claimed invention, rather than one within the public domain, is indicative of non-obviousness.").

> Our [reviewing court's] case law holds that copying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product.

Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010). Align contends that "there is considerable evidence that [ClearCorrect] copied the Invisalign products." PO Resp. 59. Align further contends that "International Trade Commission has found that [ClearCorrect]'s products infringed many of Align's patents, including the parent of the '037 Patent." *Id.*

We find that this evidence is entitled to no weight. Align never contends that ClearCorrect or any other party copied the methods of claims 1, 2, 9, and 10 or ever has been found to infringe these claims. Even if merely infringing a patent claim was considered copying, evidence supporting the allegation of infringing claims other than the subject claims is irrelevant to this secondary consideration.

vi. Conclusion with respect to secondary considerations

In weighing the totality of the secondary considerations evidence proffered by Align, we attribute little weight to the evidence for the reasons described above.

d. Conclusion with respect to claims 1 and 9

On the complete record before us and weighing underlying factual determinations in an obviousness analysis, we conclude that ClearCorrect has shown, by a preponderance of the evidence, that independent claims 1 and 9 are unpatentable over Snow, Hultgren, and Kesling.

2. Claims 2 and 10

Claim 2 depends from claim 1 and further recites "wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements." Ex. 1001, 15:39–42. Claim 10 depends from claim 9 and recites identical subject matter. *Id.* at 16:12–15. ClearCorrect contends that the combination of Snow, Hultgren, and Kesling renders obvious the subject matter of dependent claims 2 and 10. Pet. 17. Specifically, ClearCorrect contends that Snow discloses that "'[T]he computer graphic model . . . has the ability to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position.'" Pet. 28 (emphasis in original Petition). That is, Snow discloses multiple images and, therefore, multiple digital data sets, and each image represents a successive tooth arrangement. *See* Ex. 1007 ¶¶ 42, 53. We agree with ClearCorrect as to its assessment of the disclosure of Snow, and adopt that assessment as our own findings. *See* Pet. 28–29.

Align does not address the subject matter of these dependent claims at trial. *See* PO Resp. 32–45. After review of the complete trial record before us and weighing underlying factual determinations in an obviousness analysis (including our secondary considerations analysis discussed above in connection with our analysis of claims 1 and 9), we conclude that ClearCorrect has shown, by a preponderance of the evidence, that claims 2 and 10 are unpatentable over Snow, Hultgren, and Kesling.

III. CONCLUSION

For the foregoing reasons, ClearCorrect has demonstrated by a preponderance of the evidence that claims 1, 2, 9, and 10 of the '037 patent are unpatentable.

IV. ORDER

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

ORDERED that claims 1, 2, 9, and 10 of the '037 patent are held *unpatentable* under 35 U.S.C. § 103(a) over Snow, Hultgren, and Kesling; and

FURTHER ORDERED that, because this is a Final Written Decision, 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.

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