NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ALIGN TECHNOLOGY, INC.,

Appellant

 \mathbf{v} .

CLEARCORRECT OPERATING, LLC,

Appellee ____

2017-2106

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-00270.

Decided: August 22, 2018

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for appellant. Also represented by DAVID ZIMMER, Boston, MA.

SCOTT ANTHONY MCKEOWN, Ropes & Gray LLP, Washington, DC, argued for appellee. Also represented by DOUGLAS HALLWARD-DRIEMEIER.

Before PROST, Chief Judge, TARANTO and CHEN, Circuit Judges.

TARANTO, Circuit Judge.

Technology, Inc., owns U.S. Patent No. 6,699,037. In an inter partes review requested by ClearCorrect Operating, LLC, the Patent Trial and Appeal Board determined that claims 1, 2, 9, and 10 are unpatentable. The Board's determination rested on its findings regarding the key prior art, U.S. Patent No. 6,068,482 (Snow), as teaching certain claim elements and the motivation of a skilled artisan to combine that reference with others. Neither the Board's decision nor ClearCorrect's brief on appeal reveals substantial evidence in support of those findings. We vacate the Board's final written decision and remand the matter for further proceedings consistent with this opinion. We affirm the Board on the one issue of claim construction presented to us.

Ι

The '037 patent, with a 1997 priority date, addresses realignment of teeth. The patent describes braces as "conventionally" used for such orthodontic treatment. '037 patent, col. 1, lines 22-26. Treatment with braces was "tedious and time consuming" as well as "expensive," id., col. 1, lines 26–30; id., col. 2, lines 3–5; and braces were "unsightly, uncomfortable," carried the risk of infection, and made it difficult for the patient to brush and floss teeth, id., col. 2, lines 5–9. The patent identifies methods and systems to reposition teeth that, it says, (1) reduce the amount of time required for the orthodontist to create a treatment plan for each patient and oversee each patient during treatment, (2) use less visible and more comfortable appliances, (3) reduce the risk of infection, and (4) make brushing and flossing easier. *Id.*, col. 2, lines 10–20.

The patent describes producing, before treatment even starts, a sequence of digital data representations of a patient's teeth—from an initial tooth arrangement to a final tooth arrangement. Id., col. 5, lines 31–48. initial tooth arrangement may be created using both twodimensional and three-dimensional images. Id., col. 5, lines 39-46 ("Conveniently, the initial digital data set may be provided by conventional techniques, including digitizing X-ray images, images produced by computeraided 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."). The initial data set can then be "manipulated" using "a suitable computer system equipped with computer-aided design software." Id., col. 5, lines 55–58. After the teeth have been repositioned in the computer representation, "a final digital data set representing the desired final tooth arrangement will be generated and stored." Id., col. 6, lines 3–6. A plurality of digital data sets is produced "representing a series of discrete tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement," id., col. 6, lines 20–22, using techniques such as interpolating in small increments, for an individual tooth, from its initial position to its final position, id., col. 6, lines 22–33. Interpolation may be linear or non-linear. *Id.*, col. 6, lines 37–39.

A plurality of appliances is then fabricated based on the "plurality of successive digital data sets" that "represent[] the target successive tooth arrangements." *Id.*, col. 6, lines 56–64. The set of appliances may be fabricated at the start of treatment and provided to the patient "as a single package or system." *Id.*, col. 3, lines 52–56. The time spent with the orthodontist is thereby reduced. *Id.*, col. 3, line 60 through col. 4, line 2.

Independent claims 1 and 9 describe the method for fabricating appliances that incrementally reposition teeth based on digital data sets representing the arrangement of teeth from an initial position to a final position. Claim 1 is representative:

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.

Id., col. 15, lines 28–38. While the Board addressed both the providing and the controlling steps of claims 1 and 9,¹ only the providing step is at issue in this appeal. Dependent claims 2 and 10 elaborate in ways that do not alter the analysis on appeal. E.g., id., col. 15, lines 39–42 (claim 2: "A method as in claim 1, wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements."). The '037 patent expired in October 2017. See id., col. 1, lines 7–13.

ClearCorrect filed a petition for an inter partes review of the '037 patent under 35 U.S.C. §§ 311–19 challenging claims 1, 2, 9, and 10 as unpatentable for obviousness

¹ The Board noted in its decision that Align did not address ClearCorrect's arguments regarding the "controlling" step. Final Written Decision at 32, *ClearCorrect Operating*, *LLC v. Align Tech.*, *Inc.*, No. IPR2016-00270 (P.T.A.B. Mar. 24, 2017), Paper No. 43 (*Board Decision*).

under 35 U.S.C. § 103. The Board instituted a review for obviousness based on the combination of U.S. Patent No. 6,068,482 (Snow), U.S. Patent No. 6,217,334 (Hultgren), and U.S. Patent No. 2,467,432 (Kesling).

The Board issued a final written decision on March 24, 2017, concluding that all of the challenged claims are unpatentable for obviousness based on the Snow, Hultgren, and Kesling combination. The Board construed the "providing" step in 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." Board Decision at 19. The Board found that Snow teaches the "providing" step in claims 1 and 9. *Id.* at 31. It also found the "controlling" step in claims 1 and 9 to be disclosed in Hultgren (application filed in January 1997), which addresses scanning of teeth for creation of a digital representation, and Kesling (issued in 1949), which describes tooth adjustments based on a physical model of teeth that has been cut up so that individual teeth in the model can be repositioned. *Id.* at 32. The Board found that a skilled artisan would have been motivated to combine 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." Id. at 38. Finally, the Board gave little weight to Align's evidence on secondary considerations. Id. at 42–48. The Board therefore determined that all challenged claims are unpatentable for obviousness based on the Snow, Hultgren, and Kesling combination. *Id.* at 50.

Align timely appealed that decision. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

Align's challenges on appeal focus on claim 1, to which we limit our attention because neither party has provided any sound reason why our conclusion as to claim 1 does not apply equally to claims 2, 9, and 10. Align principally asserts that the Board erred in its finding as to what Snow discloses and, relatedly, as to a skilled artisan's motivation to combine Snow with the other references. It also challenges the Board's discounting of secondary considerations of non-obviousness. And it challenges the Board's claim construction.²

We review the Board's determination of obviousness de novo and its underlying factual findings for substantial evidence support. South Ala. Med. Sci. Found. v. Gnosis S.P.A., 808 F.3d 823, 826 (Fed. Cir. 2015). Whether ClearCorrect has demonstrated a motivation to combine the identified prior art references is an underlying question of fact that we review for substantial evidence support. See Redline Detection, LLC v. Star Envirotech, Inc., 811 F.3d 435, 449 (Fed. Cir. 2015). "Substantial evidence review asks 'whether a reasonable fact finder could have arrived at the agency's decision' and requires examination of the 'record as a whole, taking into account evidence that both justifies and detracts from an agency's decision." Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1366 (Fed. Cir. 2016).

Α

The Board found that Snow teaches the "final tooth arrangement for an individual patient" required by

² Align preserved a challenge to the constitutionality of inter partes review, Appellant Br. 61–62, which we reject based on *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1370 (2018). We reject as well Align's contention that the Board shifted the burden of persuasion in the proceedings. Appellant Br. 30–31. The Board found ClearCorrect's contentions persuasive and that Align had not shown deficiencies in those positions. *See, e.g., Board Decision* at 28–29.

claim 1. Board Decision at 28–31. Align challenges that finding, arguing that any final tooth arrangement shown in Snow is generic, i.e., not for an actual individual patient. The Board's opinion and ClearCorrect's brief on appeal do not point to substantial evidence to support the Board's finding. That finding, and hence the Board's final written decision resting on it, cannot stand; we therefore vacate and remand. See, e.g., Personal Web Techs., LLC v. Apple, Inc., 848 F.3d 987, 992–94 (Fed. Cir. 2017). We do not foreclose the Board from addressing this factual issue again on remand, but leave to the Board, acting within applicable statutory and regulatory constraints, the determination of whether and (if so) how to do so. See id. at 994; Ariosa Diagnostics v. Verinata Health, Inc., 805 F.3d 1359, 1367 (Fed. Cir. 2015).

Snow relates to "storing and utilising 3D computer graphic structures representative of a patient's individual tooth and jaw structure." Snow, col. 1, lines 13-16. Snow describes starting with a 3D "standard model" (on a computer) of either of two generic tooth arrangements (either male or female), id., col. 2, line 59 through col. 3, line 2, and then manipulating that generic model—by using patient-specific images or other information, and "by means of translation, scaling and rotation" of individual teeth, id., col. 3, lines 45-46—to create a 3D "individualised model" of an individual patient's teeth in their "current position," id., col. 1, line 41. See id., col. 1, lines 38–44; *id.*, col. 3, lines 14–65. That "individualised 3D model" of a patient's pre-correction mouth can be used "for treatment planning and record keeping." Id., col. 3, lines 33–34; see id., col. 4, lines 7–9. In particular, it can be used to show "a sequence of images mapping movements of teeth from a first position corresponding to the patient's current state to an idealised second position." Id., col. 1, lines 46–48. The only description in Snow of an idealized second position as an endpoint of a step-by-step transition is the generic standard model (male or female) out of which the individualized model of correction-required teeth was created: Snow describes interpolating from the individualized model back to the standard model. *Id.*, col. 4, lines 23–27.

Align argues that Snow does not teach a final tooth arrangement for an individual patient. Align points to the fact that the standard model endpoint is generic, not individualized, and that no other endpoint of tooth movements is identified in Snow. Align points also to testimony by ClearCorrect's expert, Dr. Martz, seemingly indicating that the final arrangement in Snow, the standard model, would not be a final arrangement for an individual patient. J.A. 6912–14, 6971–73. Align stresses that individual patients have varying jaws and tooth sizes and, in particular, would not actually have their teeth resized in tooth-repositioning treatment—yet Snow, having initially "scaled" particular teeth from the standard model to arrive at the individualized pre-correction model, describes the later interpolation process as returning to the standard model, seemingly requiring the re-sizing of the individual's teeth.

Neither the Board's decision nor ClearCorrect's brief identifies how, contrary to Align's arguments, Snow teaches an individualized final tooth arrangement. They do not provide answers to Align's key contentions as to Snow's failure to teach the standard model (or some modified version of the standard model) as a final tooth arrangement for an individual patient. And they do not show support for understanding Snow to teach that one of the intermediate stages in Snow is a final tooth arrangement for an individual patient.

As to the latter point, the Board, in footnote 10 of its decision, referred to ClearCorrect's expert Dr. Martz and stated that it "credit[ed] Dr. Martz's testimony that a person of ordinary skill in the art would understand that, with Snow's modeling, a treatment goal could be repre-

sented by any of the intermediate digital representations of the tooth arrangements generated between the initial and final arrangements." Board Decision at 29 n.10 (citing ClearCorrect's Petition at 17 and Dr. Martz's declaration at \P 42). But the cited paragraph of Dr. Martz's declaration states only that "[s]ince the plurality of digital data sets map the movements from the initial or current position of a patient's teeth to the idealized second position, it would be understood that the plurality of digital data sets can be generated at any point in time during treatment including at the outset or later in treatment. . . . [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." J.A. 1755–56. That simply does not say or imply that any intermediate position on the way toward to the standardized model endpoint in Snow would itself be a *final* tooth arrangement for a patient. Nor does it say how even the intermediate Snow steps could be a tooth arrangement for an individual patient which Align suggests is not taught because actual patients do not have their teeth re-sized and, according to Align's reading of Snow, in returning to the standard model, Snow discloses re-scaling by interpolation, so that re-sizing occurs at each intermediate step. The Board did not address the accuracy of this reading of Snow.

The Board's footnote also cites ClearCorrect's Petition at 17, which asserts that "the plurality of digital data sets representing the successive tooth arrangements are customized and created for each individual patient, with each set representing one of the successive tooth arrangements." J.A. 135. That conclusory assertion, which is not evidence, does not even say that a pre-final member of the Snow sequence would be a final tooth arrangement for an individual patient. And the Petition at 17 cites only two bits of evidence: Dr. Martz's declaration at

Paragraph 42; and Paragraphs 93 and 94 of the declaration of Dr. Mah, a ClearCorrect employee. already indicated why Paragraph 42 of Dr. Martz's declaration does not support the point at issue. As for Paragraphs 93 and 94 of Dr. Mah's declaration, we note: the Board said in its footnote only that it was crediting Dr. Martz, not Dr. Mah; and the only relevant portion of the Mah paragraphs are a passing clause in Paragraph 93— "the 'idealised second position', which could correspond to any point in time during the treatment (such as an intermediate or final tooth arrangement)"—in a sentence that makes a different point, i.e., that for any given nonstarting position, a sequence of images intermediate between the starting position and that position can be generated. J.A. 1828. We can hardly rely on this clause itself distinguishing "intermediate" from "final"—as supporting the Board's finding on the point at issue, especially when the Board did not say that it was reading the Mah clause to make this point or crediting it or examining whether Snow actually supports such a reading in light of Align's arguments.³

The Board may consider on remand what alternative arguments as to the *final* tooth arrangement limitation were timely made by ClearCorrect and are supported by the evidence. Without suggesting an answer to those questions, we note the Board's statement that ClearCorrect argues that "Snow's individualized model would be a representation of a patient's actual teeth" and the Board's "see also" citation to its institution decision's statement that a skilled artisan "would have applied her creativity to ensure that the variance in size and shape of the teeth was acceptable or would modify the data accordingly" based on knowledge in the art regarding more accurate ways to digitize the shape of individual teeth. *Board Decision* at 26–27 (quoting J.A. 240). We note, too, Snow's

In these circumstances, we must set aside the Board's finding about Snow as to the claim element "final tooth arrangement for an individual patient." The deficiency in this finding, we note, is independent of the issue of claim construction discussed *infra*. Because this finding was a premise of the Board's obviousness determination—the Board did not find the "providing" claim limitation taught in any source outside Snow—the obviousness determination itself must be set aside.

В

The Board determined that Snow teaches the "providing" step and Hultgren and Kesling teach the "controlling" step in claims 1 and 9. Hultgren teaches "a system of dental modeling and imaging which creates digital images of teeth topography; and more particularly relates to scanning a dental impression wherein a set of negative image electronic data of the patient's teeth and surrounding soft tissue is created which can be electronically manipulated, displayed, stored and transmitted for uses relating to creating dental appliances and diagnosis, among others." Hultgren, col. 1, lines 5–12. discloses physical model building as a step in "the provision of improved [tooth positioning] appliances which are adapted to be used to maintain or bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic

statement that "the structure of individual's teeth in respect of their size and shapes is substantially of low variance across a general population," Snow, col. 3, lines 2–5, and the Board's quotation of ClearCorrect's reply as stating that a skilled artisan "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." *Board Decision* at 26 (quoting J.A. 510).

bands, wires, or any of the other appliances of the prior art." Kesling, col. 1, lines 3–8.

The Board determined 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." Board Decision at 38. The Board further determined that the appliance created by the prior art combination did not need to "precisely" fit over the patient's teeth and that the '037 patent was not limited to appliances having a precise fit over the teeth. Id. at 37–38. On appeal Align raises two main challenges regarding the Board's finding of a motivation to combine—that the prior art combination would not allow for the creation of a functional dental appliance and that a skilled artisan would not be motivated to create "an imprecise dental appliance." Appellant Br. 37, 43.

We are not persuaded by Align's argument that any appliance created based on the teachings of Snow, Hultgren, and Kesling would be non-functional. The argument appears to rest on the premise that the only functional appliances created as a set from pre-treatment data must be ones that closely fit the contours of teeth. We simply do not see in anything that Align has identified to us why the Board had to accept this seemingly broad non-functionality assertion. Nothing in Align's own claim language specifies degrees of fitness beyond functionality, and the specification of Align's patent indicates that a precise fit is not required for the appliances contemplated. '037 patent, col. 8, lines 50–64. And to the extent that this position implicitly rests on the contention that the asserted claims of the '037 patent are limited to appliances that closely fit the contours (shape) of teeth, that is a claim construction we reject *infra*.

Align's other challenge to the motivation finding of the Board has more merit—though we do not definitively rule on it, but instead require that it be reconsidered on the remand required for the reasons already set out. The Board focused on a motivation to secure "precise teeth movement" by making the posited combination, including with Snow. But as we have discussed, Snow appears not to produce a final arrangement having precision for the individual patient. More broadly, the Board has not explained adequately what "precise teeth movement" means and how the combination of the prior art references would allow for such "precise teeth movement." Without elaboration from the Board, we cannot discern whether there was substantial evidence to support the Board's finding. See Personal Web Techs., 848 F.3d at 993-94 (vacating and remanding where inadequate explanation of how a combination worked or, therefore, why there was a motivation to make it).

 \mathbf{C}

The Board gave little weight to Align's evidence of secondary considerations of non-obviousness. *Board Decision* at 42–48. On appeal, Align briefly challenges the Board's determination in that respect, focusing particularly on commercial success, industry praise, and skepticism. Appellant Br. 58–61.

To the extent that Align challenges certain Board findings as unsupported by substantial evidence, we see no merit in the challenges. To the extent that Align argues that an obviousness determination should take account of commercial success (or industry praise) that is partly but not fully attributable to the merits of the invention, we agree, but also conclude that the Board did such an accounting here. Board Decision at 39–44; id. at 44 (citing Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1312 (Fed. Cir. 2006)); see Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1273 (Fed. Cir. 1991) ("It

is not necessary . . . that the patented invention be solely responsible for the commercial success, in order for this factor to be given weight appropriate to the evidence, along with other pertinent factors."); Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392–94 (Fed. Cir. 1988). Rather than rejecting that legal proposition, we read the Board's decision as giving the evidence of secondary considerations little weight in its overall obviousness determination. When the Board reassesses the issues of Snow's disclosure and motivation to combine on remand, it need not reconsider its factual findings on secondary considerations, but it should, as always, give those findings "weight appropriate to the evidence" in the overall obviousness determination. Continental Can, 948 F.2d at 1273.

D

Align challenges the Board's construction of the "providing" step because the Board did not require that the digital data sets consist of three-dimensional images that include the actual shape of the patient's teeth. Board Decision at 18–19. We review the Board's claim construction, which was based on intrinsic sources only, de novo. See Teva Pharms., USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015). We also apply the judicial construction standard of Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc), not the broadest reasonable interpretation standard. The patent has expired, the parties agree that we should apply Phillips, and the Board adopted its claim construction under both standards. Board Decision at 18.

We see no error in the Board's construction. The language of the claims says nothing to require that the "appliances" conform to the contours of a patient's teeth. The language requiring that the data sets "represent[]" tooth "arrangements" readily covers representations of position and orientation, not necessarily each tooth's

shape. In particular, "arrangement" and "representation" do not require something akin to a replica. Nothing in the specification is to the contrary. Indeed, the specification provides that any known positioners, removable appliances, and retainers can be used to employ the claimed methods and that "preferably, but not necessarily," the appliance will fit over all of the teeth. '037 patent, col. 8, And the specification suggests that the lines 50–64. initial data set can be based only on two-dimensional images (though three-dimensional images are preferred), without describing use of such images to create a representation of a tooth's full shape. *Id.*, col. 5, lines 31–54; id., col. 9, lines 20–48. We therefore agree with the Board that the claim element at issue should not be construed to contain an actual-shape requirement.

III

The Board's decision is affirmed in part and vacated in part, and the matter is remanded for further proceedings consistent with this opinion. Besides the matters discussed here, the Board may address in the remand any properly preserved contentions it found unnecessary to address in the final written decision currently before us.

Costs awarded to Align.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED