Filed on behalf of Petitioners
By: Todd R. Walters, Esq.
Roger H. Lee, Esq.
Adam R. Banes, Esq.
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Main Telephone (703) 836-6620
Main Facsimile (703) 836-2021
todd.walters@bipc.com
roger.lee@bipc.com
adam.banes@bipc.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3SHAPE A/S and 3SHAPE INC.
Petitioners

v.

ALIGN TECHNOLOGY, INC.
Patent Owner

Case No. IPR2020-00223
Patent 7,156,661

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,156,661 B2 UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

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I. INTRODUCTION

3Shape A/S and 3Shape Inc. ("3Shape" or "Petitioners") respectfully request *inter partes* review for claims 1-4, 6, 19-22, and 26 of U.S. Patent No. 7,156,661, issued on January 2, 2007 to Woncheol Choi et al. ("the '661 Patent") (Ex.1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

II. MANDATORY NOTICES PURSUANT TO 37 C.F.R. § 42.8(A)(1)

A. Real Party-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioners certify that 3Shape A/S, 3Shape Inc., 3Shape Holding A/S, 3Shape Trios A/S, and 3Shape Poland sp. z.o.o. are real parties-in-interest. Out of an abundance of caution, 3Shape Medical A/S, 3Shape Germany GmbH, 3Shape France SAS, 3Shape Italy SRL, 3Shape S.A.S., 3Shape (Shanghai) Co., Ltd., 3Shape Do Brasil Soluções Tecnologicas Para Saude Ltda, 3Shape Australia Pty Ltd., 3Shape Trios Sociedad Limitade, 3Shape Japan GK, 3Shape Ukraine Ltd., 3Shape (UK branch), SC Investment Company, LLC, Drop Dental LLC, Shenzhen Full Contour Design Company Ltd., Bosques Humedos Del sur Sociedad De Responsabilidad Limitada, Full Contour SRL, Full Contour LLC, 3Shape Medical Equipment Manufacture Shanghai Ltd., 3Shape Korea Ltd., 3Shape Manufacturing US LLC, Clausen Engineering APS, Tais Clausen, Deichmann Media APS, Nikolaj Hoffmann Deichmann, and the individuals listed in Appendix B are also identified as real parties-in-interest, for purposes of compliance with 35 U.S.C. § 312(a)(2).

B. Identification of Related Matters Under 37 C.F.R. § 42.8(b)(2)

The following is a list of any judicial or administrative matters that would affect, or be affected by, a decision in this proceeding:

Align Technology, Inc. v. 3Shape A/S, Civil Action No. 1:18-cv-01950 (D. Del.) (Complaint filed December 11, 2018) ("Delaware litigation");

In the Matter of Certain Dental and Orthodontic Scanners and Software, Inv. No. 337-TA-1144 (U.S. International Trade Commission) (Complaint filed December 10, 2018) ("ITC Investigation");

3Shape A/S and 3Shape Inc. v. Align Technology, Inc., Petition for *Inter Partes* Review of U.S. Patent No. 7,156,661, IPR2020-00222 (to be filed);

U.S. Patent Application No. 10/640,439, filed on August 12, 2003, which issued as U.S. Patent No. 7,156,661 on January 2, 2006; and

U.S. Patent Application No. 10/225,889, filed on August 22, 2002, which issued as U.S. Patent No. 7,077,647 on July 18, 2006.

C. Lead and Backup Counsel

Pursuant to 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioners hereby identify their lead and backup counsel as follows:

Lead Counsel:
Todd R. Walters, Esq.
Registration No. 34,040
Buchanan Ingersoll & Rooney PC
1737 King Street, Suite 500
Alexandria, VA 22314
Main Telephone (703) 836-6620
Direct Telephone (703) 838-6556
Main Facsimile (703) 836-2021
todd.walters@bipc.com

Backup Counsel:
Roger H. Lee, Esq.
Registration No. 46,317
Buchanan Ingersoll & Rooney PC
1737 King Street, Suite 500
Alexandria, VA 22314
Main Telephone (703) 836-6620
Direct Telephone (703) 838-6545
Main Facsimile (703) 836-2021
roger.lee@bipc.com

Backup Counsel:
Adam Banes, Esq.
Registration No. 60,177
Buchanan Ingersoll & Rooney PC
1737 King Street, Suite 500
Alexandria, VA 22314
Main Telephone (703) 836-6620
Main Facsimile (703) 836-2021
Direct Telephone (703) 299-6878
adam.banes@bipc.com

Powers of Attorney are being filed concurrently herewith in accordance with 37 C.F.R. § 42.10(b).

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Petitioners consent to e-mail service at the addresses listed above.

III. PAYMENT OF FEES

The undersigned authorizes the Office to charge Deposit Account No. 02-4800 for the fees required by 37 C.F.R. § 42.15(a).

IV. REQUIREMENTS UNDER 37 C.F.R. § 42.104

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioners hereby certify that the ’661 Patent is available for *inter partes* review in accordance with 37 C.F.R. § 42.102(a)(2), and that Petitioners are not barred or estopped from requesting *inter partes* review challenging the claims of the ’661 Patent on the grounds identified in this Petition.

This Petition is filed within one year from the date on which Petitioner 3Shape A/S was served a Complaint by Patent Owner in the related litigation, *Align Technology, Inc. v. 3Shape A/S*, Civil Action No. 1:18-cv-01950 (D. Del.), which asserted infringement of the ’661 Patent.

Neither Petitioners nor any privies of Petitioners have received a final written decision under 35 U.S.C. § 318(a) with respect to any claim of the ’661 Patent on any ground that was raised or could have been raised by Petitioners or privies of Petitioners in any *inter partes* review, post grant review, or covered business method patent review.

B. Identification of Challenges and Precise Relief Requested

Pursuant to 37 C.F.R. § 42.104(b), Petitioners challenge claims 1-4, 6, 19-22, and 26 of the ’661 Patent (“the challenged claims”) based on the following Ground:

Ground	References	Basis	Claims Challenged
1	Ashmore (Ex.1009) in view of Jovanovski (Ex.1010)	35 U.S.C. § 103	1-4, 6, 19-22, and 26

Petitioners rely upon the evidence listed in the Exhibit List including the Declaration and *Curriculum Vitae* of Dr. Eli Saber. (Exs.1005, 1006).

C. Prior Art Qualification of Asserted References

The ’661 Patent issued from Application No. 10/640,439 filed on August 12, 2003, which is a continuation-in-part of Application No. 10/225,889 filed on August 22, 2002. Exs.1001, 1003-1004. The asserted references identified below constitutes prior art under § 102(b) or § 102(a) with respect to the earliest possible effective filing date of the ’661 Patent.[1]

Ashmore published in January of 2002, and thus is prior art at least under 35 U.S.C. § 102(a). Jovanovski published in 2001, and thus is prior art at least under 35 U.S.C. § 102(b). Petitioners submit the Declaration and Curriculum Vitae of Dr. Sylvia D. Hall-Ellis (Exs.1007, 1008), an expert in the field of library cataloging and classification. The testimony of Dr. Hall-Ellis demonstrates that Ashmore was published and accessible to the public on January 30, 2002. Ex.1007. *See id.*, ¶¶40-

[1] Petitioners do not concede that any challenged claim is entitled to an effective filing date of August 22, 2002.

46, 73. The testimony of Dr. Hall-Ellis demonstrates that Jovanovski was published and accessible to the public on June 28, 2001. Ex.1007. *See id.*, ¶¶47-52, 73. Thus, Ashmore and Jovanovski are prior art under § 102(a) and/or § 102(b).

V. BACKGROUND

A. The ’661 Patent and Technical Background

1. Use of computer models to measure teeth movement was well known

The ’661 Patent describes techniques for treatment analysis by teeth matching utilizing computer models. Ex.1001, title, 2:15-19, 9:14-23, 9:32-53. The ’661 Patent discloses “taking two digital models, one before treatment and one after treatment, superimposing them in the virtual space, and calculating the movement of each tooth.” *Id.*, 2:15-18. The ’661 Patent discloses that the use of digital dental models allows for precise measurements and accurate teeth matching. *Id.*, 2:9-11. However, the use of digital dental models to accurately assess changes to teeth over time was well known at the time of the purported invention. Exs.1009, 1010, 1011. Ex.1005, ¶27.

2. Use of reference points on a stable region to match computer dental models was well known

The ’661 Patent discloses using reference points on a stable region such as the palatal rugae to obtain good matching of computer dental models. Ex.1001, 2:41-44, 11:2-5. However, using reference points on a stable anatomical region (such as palatal rugae) to match computer dental models was well known at the time of the purported invention. Ex.1009, 21 (using "palatal rugae points as the registration landmarks"), 22 ("palatal rugae are stable landmarks"); Ex.1010, 102-103 (using "stable regions" to match models); Ex.1016, title, abstract ("The medial rugae appear to be suitable anatomical points"). Ex.1005, ¶28.

3. Registration and superposition, which result in matching according to the '661 Patent, were well known

The '661 Patent describes that "registration" of the initial and subsequent models achieves matching of the models:

> The ***registration*** process is accomplished by determining a transformation T that minimizes the discrepancy between D1 and D2…. An iterative optimization method is employed to refine the solution until ***a best fit match*** is found.

Ex.1001, 5:36-42 (emphases added). The '661 Patent discloses that superimposing two models by minimizing distances between teeth is a "matching process":

> The search algorithm finds the relative position of the teeth by minimizing the distance between two ***superimposed*** teeth. ***The matching process*** is completed throughout the entire teeth of a jaw. After ***matching*** the teeth…

Id., 8:52-59 (emphases added). *See also id.*, 10:62-11:5, 10:62-64 ("The system thus provides a 3-dimensional superimposition tool that measures dental changes based on an algorithm of best fit"). However, the concept of registering and superimposing initial and subsequent computer models (which the '661 Patent discloses results in matching), and minimizing distance between superimposed models to attain a best fit match, were well known. Ex.1009, 21 ("best-fit superimposition"); Ex.1010; Ex.1017; Ex.1031. Ex.1005, ¶29.

4. The embodiment using rugae of the '661 Patent has two matching steps that match the models as a whole

The Fig. 10A embodiment of the '661 Patent matches models based on palatal rugae. Ex.1001, 11:2-4, 3:22-23 ("FIG. 10A shows an exemplary embodiment for matching shapes based on rugae."), 9:14-53.[2] Fig. 10A is reproduced below:

[2] Fig. 10A and its description do not appear in the parent '647 Patent, and were first presented in the continuation-in-part application which issued as the '661 Patent.

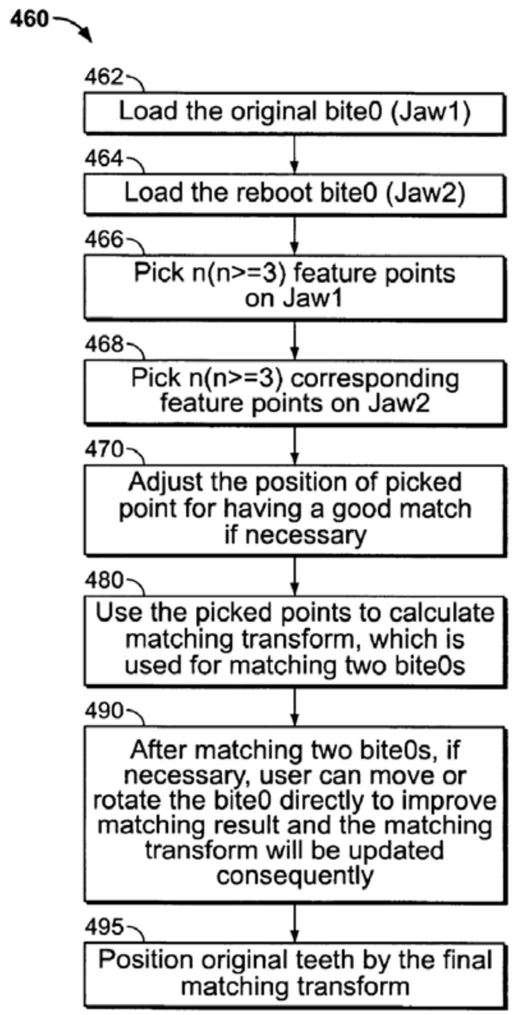

FIG. 10A

Fig. 10A of the ’661 Patent

Ex.1005, ¶30.

In Fig. 10A, the original impression of the teeth (“Jaw1”) which is the first model is loaded, and the subsequent impression (“Jaw2”) which is the second model is also loaded (462, 464). Ex.1001, 9:32-34. The process selects a plurality of points on Jaw1 and corresponding points on Jaw2 (466, 468). *Id.*, 9:35-37. All points on the region or a minimum of 3 points may be used. *Id.*, Fig. 10A (“n>=3”), 9:35-36. The picked points are used to calculate a matching transform, which is used for matching "two scanned jaw models" (480). *Id.*, 9:46-48. *See also id.*, Fig. 10A ("matching two bite0s" in 480, where the "two bite0s" refer to "Jaw1" and "Jaw2"). After this initial matching (480), the user can move or rotate the jaw model directly to improve the matching result and the matching transform will be updated consequently (490). *Id.*, 9:48-51. The second matching step is conducted to improve the accuracy of the match, and uses the initial match obtained from the first matching step (480) as a starting point for the second step (490). *Id.* Ex.1005, ¶31.

B. Prosecution History

During prosecution, the Examiner rejected the original claims based on U.S. Patent No. 6,250,918 (Sachdeva) alone and in combination U.S. Patent No. 6,068,482 (Snow). Ex.1002, 73-75. Patent Owner obtained allowance by arguing that Sachdeva does not disclose that the reference point is on a region comprising a portion of the jaw other than the teeth (*e.g.*, rugae on a palate of the jaw). *Id.*, 63-65 (Patent Owner's argument), 45 (examiner's reasons for allowance states Sachdeva "does not teach the [point] exterior [to the tooth] is a region of the model.").

However, the use of reference points on palatal rugae as a stable region for comparing dental models was well known. *See, e.g.*, Ex.1009, 21, 22; Ex.1016, title, abstract.

The Examiner also stated "Sachdeva does not teach matching the jaw models as a whole in addition to calculating the differences between individual teeth."

Ex.1002, 45. However, it was well known to conduct a second matching step of matching models as a whole in order to refine an initial, approximate matching. *See, e.g.*, Ex.1010, 98-105.

C. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. With respect to the '661 Patent, one of ordinary skill in this art would have at least: (1) a bachelor's degree in electrical and/or computer engineering, or computer science (or equivalent course work) with two to three years of work experience in computer modelling of physical structures or (2) a master's degree in electrical and/or computer engineering, or computer science (or equivalent course work) with a focus in computer modelling of physical structures.[3] Ex.1005, ¶25.

D. Overview of the Prior Art

Ashmore

Ashmore discloses a method "for superimposing 3-dimensional data obtained from selected landmarks" on dental casts to assess tooth "movement during headgear

[3] Petitioners and Patent Owner agree that a POSITA need not have any dental experience. Ex.1014, 8-10. The challenged claims are unpatentable under either description.

treatment" of a patient. Ex.1009, abstract. Ashmore discloses using "serial maxillary models" (jaw models) which include an "initial" model and "subsequent" models obtained at different times over the course of patient treatment. *Id.*, 19-20. Ashmore seeks to compare the models of casts taken at different times in order to "evaluate how the molar positions changed over time." *Id.*, 21. Ex.1005, ¶32.

Ashmore discloses using points on a palatal rugae as landmarks for matching the initial model of a patient's teeth obtained before headgear treatment with subsequent models obtained after headgear treatment. Ex.1009, abstract, 21 ("palatal rugae points as the registration landmarks"). Ashmore discloses calculating (*e.g.*, "measuring") the movement of teeth caused by the headgear treatment. *Id.* *See also id.*, 19 ("describe the bimonthly molar movement for each patient during headgear treatment"). Ex.1005, ¶33.

Ashmore discloses using palatal rugae as a reference region for superimposing serial models and uses same in its study of teeth movement. Ex.1009, 19 (citing Ex.1016). Ashmore discloses that "specific parts … of the palatal rugae may be sufficiently stable to serve as an anatomic reference for superimposing serial maxillary models, despite intervening headgear … treatment." *Id.*, 19 ("Palatal rugae retain their shape and pattern throughout a person's lifetime"). Ashmore discloses that the use of palatal rugae as a stable region for matching provides accurate results. *Id.*, 28 ("The method … allowed accurate measurement of maxillary first-molar translational movement in 3 dimensions"). Ex.1005, ¶34.

Ashmore also acknowledges that the accuracy of its method may be improved and suggests doing so "[i]n future research." Ex.1009, 27-28 (*e.g.*, "[G]reater statistical emphasis can be placed on rugae points known to be the least susceptible to treatment-induced changes"). A POSITA would have recognized that it would have been obvious to modify Ashmore's matching in view of Jovanovski, discussed below. Ex.1005, ¶35.

Jovanovski

Jovanovski relates to techniques for superimposing a series of dental models taken at different times into a common reference frame. Ex.1010, abstract, 75. Jovanovski's techniques are broadly applicable to measuring changes in models of "tooth surfaces" and "oral structures." *Id.*, abstract, 105. Jovanovski discloses constructing computer models of the study surface and matching (*e.g.*, superposing) the models. Ex.1010, 75 (flowchart). Superimposing initial (*e.g.*, "baseline") and subsequent (*e.g.*, "follow-up") models allows "changes in the shapes of oral structures to be quantified accurately." *Id.* *See also id.*, 98, 103-105. Like Ashmore, Jovanovski improves accuracy by using stable anatomical regions as a reference in its matching process. *Id.*, 102-103 ("in most cases there exists a region which remains relatively stable throughout…. [R]egistration … is achieved by restricting the selection of representative points to such stable regions.”), Fig. 18. Ex.1005, ¶36.

Jovanovski discloses a two-step matching process where the first “point-to-point fit” matching step (*e.g.*, “landmark-based method”) provides an “initial approximation” and the second step (*e.g.*, “shape-based method”, “main processing phase”) provides a more accurate, “refined” match. Ex.1010, 93-105. Indeed, the very purpose of Jovanovski’s second matching step is to “refine” the “approximation” obtained from the initial point-to-point fit matching. *Id. See also id.*, 99 (first matching step “is capable of quickly providing an initial approximation which can further be refined by other methods, described next.”), 103 (“First, an initial approximation of the transformation parameters is obtained….”). Ex.1005, ¶37.

Jovanovski recognizes the desirability of obtaining an accurate matching of initial and subsequent models to obtain accurate model comparisons. Ex.1010, 98 (seeking to improve accuracy of landmark-based method), 99 (“this method is capable of quickly providing an initial approximation which can further be refined by other methods, described next.”), 105 (“tooth surfaces can generally be superposed to within 6-9 µm RMS/point.”). Jovanovski discloses that the matching technique described therein can be used in a wide variety of clinical applications, such as measurements pertaining to restorations. *Id.*, 114-119. *See also id.*, 74, 126

(Jovanovski is relevant to "simulation and planning of orthodontic treatments"). Ex.1005, ¶38.

VI. HOW THE CHALLENGED CLAIMS ARE TO BE CONSTRUED

Claim terms are interpreted according to *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and its progeny. Some of the claim terms of the '661 Patent are disputed in the ITC investigation. Exs.1014, 1020-1023. Any claim terms not addressed should be interpreted consistent with the *Phillips* standard.

A. "reference point"

In the ITC investigation, Petitioners construed "reference point" as "a point on a stable anatomical structure." Ex.1014, App. A, 7-11. Patent Owner asserted that no construction is necessary but if the ALJ determines that a construction is necessary, the proper construction of "reference point" is the plain and ordinary meaning which is "points used to determine the position of a computer model relative to another computer model." *Id.* *See also* Exs.1022, 1023. The ALJ construed the term "reference point" as "a point used to determine the position of a computer model, or part thereof, relative to another computer model, or part thereof". *Id.* The ALJ's construction is applied below.

B. "region(s)"

In the ITC investigation, Petitioners construed "region(s)" as "portion(s)." Ex.1014, App. A, 11-14. Patent Owner asserted that no construction is necessary but if the ALJ determines that a construction is necessary, the proper construction of "region(s)" is the plain and ordinary meaning which is "area." *Id.* *See also* Exs.1022, 1023. The ALJ construed the term "region(s)" as "area". *Id.* The ALJ's construction is applied below.

C. "matching/match … using the identified reference points"

In the ITC investigation, Petitioners construed "matching/match … using the identified reference points" as "positioning/position … using the identified points on the stable anatomical structures." Ex.1014, App. A, 14-19. Patent Owner asserted that no construction is necessary but if the ALJ determines that a construction is necessary, the proper construction of "matching/match … using the identified reference points" is the plain and ordinary meaning which is "matching the region on the first and second computer models using the identified points to determine the position of a computer model relative to another computer model." *Id.* *See also* Exs.1022, 1023. The ALJ construed the term "matching/match … using the identified reference points" as "using the identified reference points to determine the position of a region of the first computer model relative to the corresponding region of the second computer model". *Id.* The ALJ's construction is applied below.

D. "comprising a portion of the jaw/model other than the teeth"

In the ITC investigation, the ALJ construed the term "comprising a portion of the jaw/model other than the teeth" as "including at least a non-tooth portion of the jaw". Ex.1014, App. A, 19. Petitioners and Patent Owner agreed to this construction in the ITC Investigation. *Id.* The ALJ's construction is applied below.

VII. PETITIONERS HAVE A REASONABLE LIKELIHOOD OF PREVAILING

The challenged claims of the '661 Patent are unpatentable over the prior art.

A. Claims 1-4, 6, 19-22, and 26 Would Have Been Obvious Based on the Combined Disclosures of Ashmore and Jovanovski. [Ground 1]

Section 1 below provides examples of where each element of the challenged claims is found in the prior art. Section 2 below provides an explanation of why the challenged claims as a whole would have been obvious.

1. Reference to Where the Elements of Claims 1-4, 6, 19-22, and 26 Are Found in the Prior Art

The following sections provide reference to where the elements of the challenged claims are found in the prior art, in light of the claim constructions set forth in section VI above.

a. Claim 1 (Element [1.P]): A method for matching computer models of a jaw, the method comprising:

Ashmore discloses the preamble of claim 1.[4] Ex.1005, ¶56.

"A method for matching"

Ashmore discloses a method for matching (*e.g.*, "superimpos[ing]", "best-fit superimposition", "registration", "orient[ing] … into a common frame of reference")

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[4] Petitioners do not concede that any preamble of the challenged claims is limiting.

computer models of a jaw (*e.g.*, "initial (T1) models", "subsequent models", "serial maxillary models"). Ex.1009, 19, 24. Ashmore's technique matches a first (*e.g.*, "initial", "T1") model with a second (*e.g.*, "subsequent", "final") model. *Id.*, 18 ("data were collected from initial and final models"), 19 ("superimpose a patient's subsequent models on the T1 model"), 25. Ashmore's first and subsequent models are a "series of maxillary models" where each model corresponds to a dental cast taken at a different time over the course of patient treatment. *Id.*, 19-20. Ashmore discloses that "[a]fter all casts in a series had been placed in the same coordinate system via superimposition, it was possible to evaluate how the molar positions changed over time." *Id.*, 21. Like Ashmore, the '661 Patent utilizes teeth data obtained from scanning dental casts. Ex.1001, 12:24-28, Fig. 11 (casts 521 are scanned). Ex.1005, ¶57.

Ashmore's superimposing/registering process determines the position of the first computer model relative to the position of the second computer model[5]:

> Spatial data from each subject's initial model were oriented similarly in an anatomically derived coordinate system, and a best-fit

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[5] The term "matching" is construed in the context of Element [1.5]/[19.5]. *See* Section VI.C. The prior art satisfies "matching" in the preamble for at least the same reasons discussed below concerning Element [1.5]/[19.5].

> superimposition of palatal rugae landmarks from subsequent models allowed the measurement of molar movement. [*Id.*, Abstract.]

> …a serial maxillary model superimposition method that permitted a detailed examination of how each person's molars moved during headgear treatment… [*Id.*, 24.]

> …method for superimposing 3-dimensional data obtained from selected landmarks on longitudinally collected dental casts to describe maxillary first molar movement during headgear treatment… [*Id.*, 18.]

> …to orient the initial (Tl) models into a common frame of reference, and then to superimpose a patient's subsequent models on the Tl model by registering unique anatomic landmarks… [*Id.*, 19.]

Thus, Ashmore's superimposing/registering process matches the initial and subsequent computer models. Ex.1005, ¶58.

"computer models of a jaw"

Ashmore's initial and subsequent/final models are "computer" models because the spatial data is 3D digital data, and the models are stored in a computer and manipulated using a software program. Ex.1009, 20 ("The data were stored in the computer", "software program … read the serial port communications from the digitizer and computed the X, Y, Z coordinate locations"). Ex.1005, ¶59.

Ashmore discloses that the computer models are of a jaw. *Id.*, Fig. 1 (depicting a computer model of a jaw oriented in a "common and interpretable spatial frame of reference").

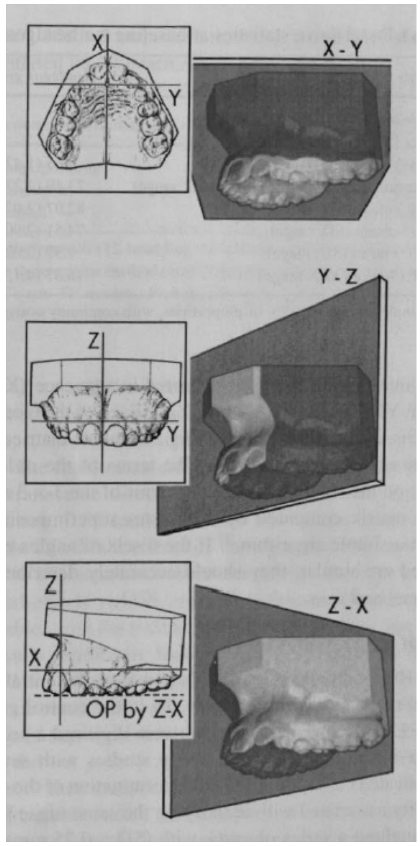

Fig. 1 of Ashmore

Ashmore discloses that the spatial data is of maxillary casts, which are casts of the jaw. *Id.*, 20 ("Spatial data from maxillary casts were collected with a desktop mechanical 3D digitizer", "each subject's series of maxillary models"), 18 ("the maxillary and the mandibular dentitions"); Ex.1015 (defining "maxillary" as "Of or relating to a ***jaw*** or jawbone, esp. the upper one", and "mandible" as "The lower ***jaw*** of a vertebrate animal" (emphases added)). Ashmore's computer models of dental casts include teeth data. Ex.1009, 18. Ex.1005, ¶60.

i. Element [1.1] loading a first computer model of a jaw having teeth in initial positions;

Ashmore alone or in combination with Jovanovski discloses Element [1.1]. Ex.1005, ¶61.

"loading"

Ashmore discloses "loading" a first computer model because Ashmore discloses that the first (*e.g.*, "initial", "T1") computer model is stored in a computer and manipulated via software. Ex.1009, 19-20 ("spatial data" was collected and "stored in the computer by using specialized software", a software program "computed the X, Y, and Z coordinate locations", "each entry was added to a data file by means of a specialized user interface, which facilitated annotation of the captured points."), 23. Ashmore also discloses displaying the models (*e.g.*, Fig. 1) and molar movements (*e.g.*, Figs. 2, 3, 4). A POSITA would have understood that Ashmore's models are "loaded" during Ashmore's data acquisition process (Ex.1009, 19-20), because the models are processed by software, and it is well-known that a data file must be loaded onto a computer in order to be utilized by a computer. *See, e.g.,* Ex.1027, 39:7-43:27 (the program downloads the 3D data file to utilize the file); Ex.1012 at ¶[0120] (data is "loaded into the workstation, and accessed from the treatment planning software"). Ex.1005, ¶62.

<u>Jovanovski</u>

The claimed "loading" does not require displaying/visualizing a computer model. The '661 Patent itself does not require visualization during loading. Ex.1001, Fig. 3, 6:6-17 (visualization is "another option"). Nevertheless, Jovanovski discloses visualizing computer models. Ex.1010, Figs. 15, 18, 19.

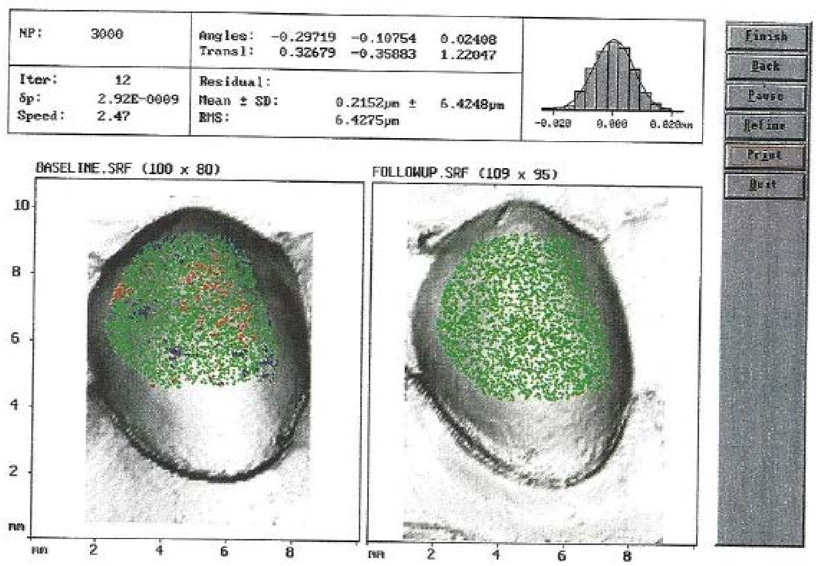

Fig. 19. The main processing phase.

Fig. 19 of Jovanovski

Ex.1005, ¶63.

"first computer model of a jaw having teeth in initial positions"

Ashmore discloses a first computer model of a jaw (*e.g.*, "initial model", "T1") having teeth in initial positions (*e.g.*, teeth in the initial model are in initial positions because they are subsequently moved due to treatment)). Ex.1009, abstract ("best-fit superimposition … from subsequent models allowed the measurement of molar [tooth] movement"), 18-19, ("measure changes in tooth position with serial maxillary models"), 20 ("…to assess molar movement"), Figs. 2-4 (depicting X,Y,Z tooth position changes over time). Ashmore's computer models are of a dental cast of a jaw having teeth. *Id.* at 19, 18, Fig. 1 (depicting teeth); Ex.1015. Like Ashmore, the '661 Patent utilizes teeth data obtained from scanning dental casts. Ex.1001, 12:24-28, Fig. 11 (casts 521 are scanned). Ex.1005, ¶64.

ii. Element [1.2]: loading a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions;

Ashmore alone or in combination with Jovanovski discloses Element [1.2]. Ex.1005, ¶65.

"loading a second computer model of the jaw"

Ashmore discloses "loading" the second computer model as explained above concerning the first computer model of Element [1.1]. Ex.1005, ¶66.

Ashmore discloses a second computer model of the jaw ("subsequent model", "final model", "TF", "T2-T14"). Ex.1009, abstract ("subsequent models"), 22 ("final models"), 19 ("superimpose a patient's subsequent models on the T1 model"), 25 ("Sequence of Serial Maxillary Models (T1-T14)"). Like Ashmore's first computer model, the second computer model is of a jaw having teeth. *Id.* at 19, 18, Fig. 1 (depicting a jaw with teeth). Ex.1005, ¶67.

"positions of at least some of the teeth in the second computer model are different than the initial positions [in the first computer model]"

Ashmore discloses this claim element. Ashmore measures changes in position of teeth in a second computer model (*e.g.*, "subsequent model", "final model", "T2-T14") resulting from treatment, in comparison with teeth positions in the first ("initial") model (as well all models representing dental casts taken at earlier times during treatment). Ex.1009, 21 ("each patient's subsequent models were superimposed on the T1 model"), Figs. 2-4 (depicting x,y,z positional changes). Ashmore's second ("subsequent") models have at least some teeth in different (moved) positions in comparison with a first (any earlier) model because Ashmore discloses that the teeth have moved as a result of treatment. *Id.*, 18 ("3-dimensional analysis of molar movement during headgear treatment"), 19 ("dental movement … to measure changes in tooth position."). Ex.1005, ¶68.

iii. Element [1.3]: identifying at least one reference point on a region of the first computer model, the region comprising a portion of the jaw other than the teeth;

Ashmore discloses Element [1.3]. Ex.1005, ¶69.

"identifying at least one reference point"

Ashmore discloses "identify[ing]" at least one reference point (*e.g.*, "digitized rugae points"; digitized points based on a "minimum of 8 points"; digitized points based on "RR1-4" and "LR1-4") on a region (*e.g.*, "palatal rugae", "medial palatal rugae") of the first computer model, the region comprising a portion of the jaw other than the teeth (*e.g.*, the palatal rugae do not include teeth). Ex.1009, 20 (*e.g.*, "A minimum of 8 points … ***was identified*** that were present on all models in the series") (emphases added)), 19-21, 21 ("palatal rugae points as the registration landmarks"). The '661 Patent is open to using all points on the region or a minimum of 3 points. Ex.1001, Fig. 10A ("n>=3"), 9:35-36 ("for example more than three"). Ex.1005, ¶70.

Ashmore's digitized rugae points satisfy "reference points" under the ALJ's construction. *See* Section VI.A. As explained above, Ashmore's method compares the second computer model (*e.g.*, "subsequent model", "final model", "T2-T14") of the patient's jaw resulting from treatment for moving the teeth, with an "initial" model (or any earlier model) of the jaw to assess teeth movement resulting from the treatment. Ex.1009, 18-21. Specific unique anatomical details are identified on the rugae region of a subject's dental jaw cast, and a minimum of eight (8) points were identified on that region—4 on the left and 4 on the right. *Id.*, 20. Ashmore discloses the following points were digitized, among others:

> **…** RR1-4: a minimum of 4 unique anatomic rugae points on the right side of the palate.
>
> LR1-4: a minimum of 4 unique anatomic rugae points on the left side of the palate**….**

Id., 20. The digitized rugae points are used to determine the position of the first model relative to the second model. *Id.*, 21 ("subsequent models … were superimposed on the T1 model … with palatal rugae points as the registration landmarks."). *See also id.*, 20 ("Points were chosen for specificity of detail and reproducibility throughout the series of models."), 22 ("Comparison of the form of 2 sets of landmarks (such as the digitized rugae points on 2 dental models) is achieved"), 26 ("the best fit of the digitized rugae points can be determined"). Ashmore identifies the digitized corresponding reference points in each of the first and second models in order to perform its matching technique. *Id.*, 21 ("corresponding rugae registration points"). Ex.1005, ¶71.

Further, Ashmore discloses that "specific parts (*e.g.*, medial) of the palatal rugae may be sufficiently stable to serve as an anatomic reference for superimposing serial maxillary models, despite intervening headgear or premolar extraction treatment." Ex.1009, 20; Ex.1015. Thus, Ashmore's digitized rugae points are each a "point used to determine the position of a computer model, or part thereof, relative to another computer model, or part thereof" (ALJ's construction) and "points used to determine the position of a computer model relative to another computer model" (Patent Owner's construction). *See* Section VI.A. Ex.1005, ¶72.

"on a region of the first computer model, the region comprising a portion of the jaw other than the teeth"

Ashmore's "palatal rugae" (*e.g.*, "medial palatal rugae") constitute a region comprising a portion of the jaw other than teeth. Ex.1009, 20. The palatal rugae constitute a region comprising a portion of the jaw other than teeth according to the '661 Patent. Ex.1001, 13:49-52 (an example of the claimed "region comprising a portion of the jaw other than the teeth" is "one or more rugae on a palate of the jaw."). Similarly, the palatal rugae includes "at least a non-tooth portion of the jaw" because the palatal rugae are not teeth. For at least this reason, Ashmore's "palatal rugae" satisfies the claimed "region comprising a portion of the jaw other than the teeth." Ex.1005, ¶73.

Ashmore's palatal rugae (*e.g.*, "medial palatal rugae") satisfy the claimed "region" under the ALJ's and Patent Owner's constructions. *See* Section VI.B. Palatal rugae are an "area". Ashmore's "palatal rugae" constitute an area of the jaw. This is because the palatal rugae do not constitute the entire jaw (*e.g.*, the rugae do not include teeth). Ex.1009, 18-21 (the computer models include molars which are teeth), Fig. 1 (jaw includes teeth). *See also* Ex.1016, 43, Fig. 1. The ALJ stated that the "claimed 'region(s)' cannot consist of entire jaw models." Ex.1014, App. A, 13-14. Ashmore's palatal rugae does not consist of the entire jaw model and thus satisfies "region" under the ALJ's and Patent Owner's constructions.[6] The '661 Patent discloses that rugae constitute an "area". Ex.1001, 2:41-46 ("rugae area"). Ex.1005, ¶74.

Ashmore's palatal rugae is "a portion of the jaw other than the teeth" because the palatal rugae "includ[es] at least a non-tooth portion of the jaw". Ex.1014, App. A, 19. Section VI.D. As shown below, the palatal rugae comprises a portion of the jaw other than the teeth (non-tooth portion):

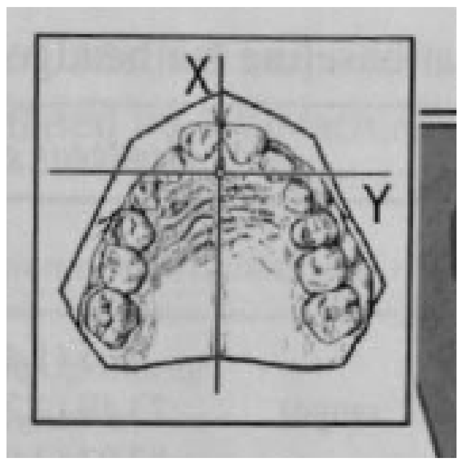

Fig. 1 of Ashmore

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[6] As explained below, the term "region" under the ALJ's construction does not exclude matching additional data in the matching step of Element [1.5].

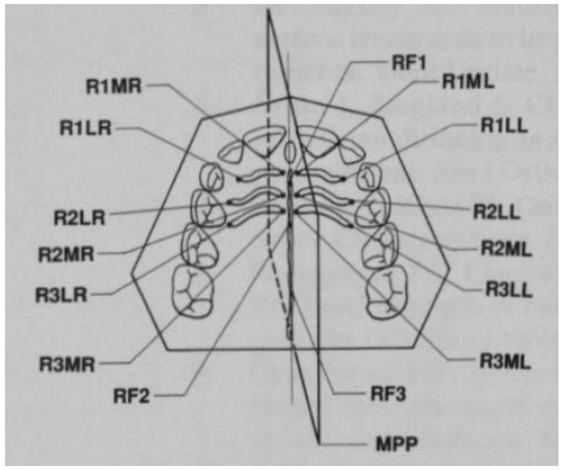

Fig. 1 of Almeida

See also Ex.1009, 18-21; Ex.1016, 43; Exs.1028 (defining "palate" as "The roof of the mouth…"); Ex.1029 (defining "ruga" as "A fold, crease, or wrinkle…"). Ashmore distinguishes the palatal rugae from the dentition (teeth). Ex.1009, 19; Ex.1030. Ex.1005, ¶75.

iv. Element [1.4]: identifying a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model;

Ashmore alone or in combination with Jovanovski discloses Element [1.4]. Ex.1005, ¶76.

Ashmore

Ashmore discloses identifying a corresponding reference point (*e.g.*, "corresponding rugae registration points") on a corresponding region ("corresponding rugae") of the second computer model (*e.g.*, "subsequent models", "T2-T14", "final model") for each point identified on the first model. Ex.1009, 21. Ex.1005, ¶77.

As discussed for Element [1.3], the points initially identified on the rugae region of the first computer model (*e.g.*, "initial model", any earlier model) are the claimed "each point identified on the first model." Ashmore further discloses:

> [E]ach patient's subsequent models were superimposed on the T1 model … ***with palatal rugae points as the registration landmarks***. Digitized data points from subsequent models were translated and rotated to minimize the sum of squared Euclidean distances between ***corresponding rugae registration points***.

Ex.1009, 21 (emphases added). *See also id.*, abstract, 19-22. Ashmore identifies a corresponding reference point "on a corresponding region of the second computer model for each point identified on the first model" because Ashmore's digitized "corresponding rugae registration points" are on the rugae of the second computer model (which represents a corresponding region of the second model) and correspond to corresponding digitized points on the first ("initial" or any earlier) model. *Id.*, 20 ("minimum of 8 points … was identified that were present on all models in the series"), 21 ("patient's subsequent models were superimposed on the T1 model … with palatal rugae points as the registration landmarks"). The digitized rugae registration points of the second model are "reference points" under the ALJ's and Patent Owner's constructions for the reasons discussed for Element [1.3]. Ex.1005, ¶78.

<u>Jovanovski</u>

Like Ashmore, Jovanovski discloses identifying a corresponding reference point on a corresponding region of the second computer model for each point identified on the first computer model. Ex.1010, 96 ("If pairs of corresponding points are identified on two surfaces, then the surfaces can be superposed by finding the rigid motion which brings the second set of points into 'best' correspondence with the first."), 98, 103 ("marking three or more pairs of corresponding points"), 104 ("representative points…in the stable region of the follow-up surface"). Ex.1005, ¶79.

As discussed above, Jovanovski describes two matching steps that each use reference points for superimposition of a first ("baseline") model with a second ("follow-up") model. Ex.1010, 98-105. Jovanovski's first matching step ("landmark-based method") superimposes the baseline and follow-up models using surface landmarks with reference points marked thereon. Ex.1010, 98. These reference points are depicted in FIG. 15 of Jovanovski, which is reproduced below with annotations to identify the reference points using red circles:

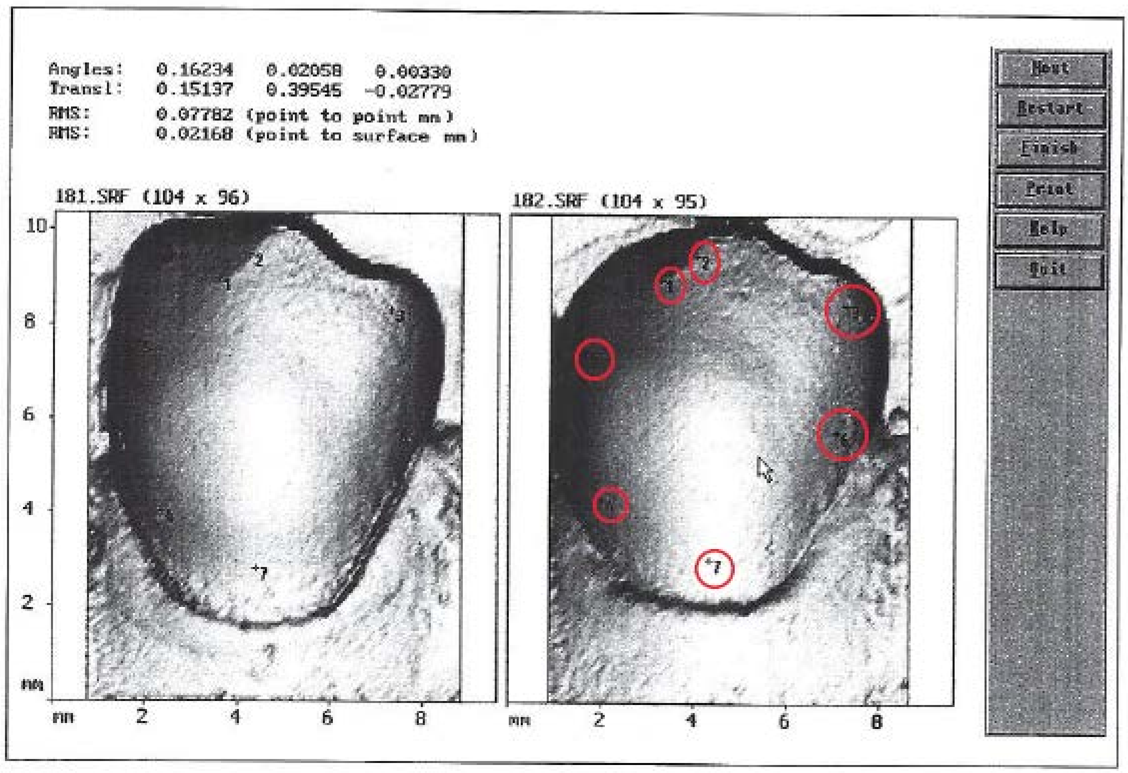

Fig. 15. Interactive identification of corresponding points.

FIG. 15 of Jovanovski (Annotated)

These reference points on Jovanovski's follow-up model are analogous to the reference points on Ashmore's subsequent models (e.g., T2-T14). Ex.1005, ¶80.

v. Element [1.5]: matching the region of the first computer model with the corresponding region of the second computer model, using the identified reference points;

Ashmore discloses Element [1.5]. Ex.1005, ¶81.

"matching"

<u>Ashmore</u>

Ashmore discloses matching the region (*e.g.*, "palatal rugae" area from which the reference points are selected) of the first computer model (*e.g.*, "initial model") with the corresponding region (*e.g.*, corresponding "palatal rugae" area of the second model) of the second computer model (*e.g.*, "subsequent models", "T2-T14"), using the identified reference points (*e.g.*, "corresponding rugae registration points"). Ex.1009, 21, 19 ("unique anatomical landmarks selected on the palatal rugae"). This is because Ashmore discloses that the digitized points of the second model (which include the "corresponding rugae registration points" of the second model) are "superimposed" (and "register[ed]") on the first model (*e.g.*, "initial model"). *Id.* As explained by Ashmore:

> [E]ach subject's subsequent models were superimposed on the T1 model with a least-squares rotational fit (Procrustes) with palatal rugae points as the registration landmarks. ***Digitized data points from subsequent models were translated and rotated to minimize the sum of squared Euclidean distances between corresponding rugae registration points.*** The algorithm used to achieve the rigid transformation was adapted from that described by Rohlf. Only rigid transformations (without scaling) were used ***to achieve the best-fit superimposition***.

Id., 21 (emphases added). Ashmore's best-fit superimposition technique satisfies the ALJ's and Patent Owner's constructions of "matching" because the identified reference points in Ashmore are used to determine the position (*e.g.*, "superimposed", "best-fit superimposition", "register[ed]") of a region (*e.g.*, "palatal rugae" area) of the first computer model relative to the corresponding region (*e.g.*, corresponding "palatal rugae" area) of the second computer model. *Id.*, 22, 26 (emphasis added). Neither the ALJ's nor Patent Owner's construction of matching requires the positioning of the regions or the models. Ex.1014, App. A, 14-19. In fact, the ALJ's construction explicitly distinguishes matching from positioning. *Id.* Thus, Ashmore's superimposing and registering satisfies "matching" because the '661 Patent discloses superimposing the palate rugae regions of the model using rugae registration points. Ex.1001, 5:36-42, 8:52-59, 10:62-11:5. Ex.1005, ¶82.

"the region of the first computer model with the corresponding region of the second computer model"

Ashmore's identified reference points (*e.g.*, "corresponding rugae registration points", "minimum of 8 points … was identified that were present on all models in the series") are selected from palatal rugae areas and thus represent the regions (*e.g.*, palatal rugae areas from which the reference points are selected) of the first and second models. Ex.1009, 20-21. Ashmore's use of corresponding rugae registration points to match (*e.g.*, "superimpose", "register") initial and subsequent regions of the models satisfies the claimed matching because the rugae registration points are being used to determine the positions of the region (*e.g.*, "palatal rugae" area) of the first model (*e.g.*, "T1") relative to the corresponding region (*e.g.*, "palatal rugae" area) of the second model (*e.g.*, "subsequent", "T2-T14"). *Id.* The registration of the rugae reference points is a matching (*i.e.*, determining of position) of the palatal rugae because the identified palatal rugae reference points are being used as "registration landmarks". *Id.*, 21. Ex.1005, ¶83.

Patent Owner may argue that the ALJ's construction of Element [1.5]/[19.5] excludes ***positioning*** an entire model and only allows for positioning a subpart (such as palatal rugae) of the model, thereby excluding Ashmore. This overlooks the ALJ's construction: "using the identified reference points ***to determine the position*** of a region of the first computer model relative to the corresponding region of the second computer model." Ex.1014, App. A, 14-19. The ALJ found that determining the position (*e.g.*, "computation") is related to, yet distinct from, "positioning/repositioning based on that computation". *Id.*, App. A, 18. The ALJ construed Element [1.5]/[19.5] to require determin[ing] the position of a region. The ALJ did not construe such Element to include any requirement concerning positioning a region. The ALJ's statement "matching occurs over corresponding regions of models and not across the rest of the models" (*id.*, App. A, 18) must be read in light of the ALJ's construction that Element [1.5]/[19.5] pertains to "determin[ing] the position", not positioning. Ashmore determines the position of a region of the first computer model relative to the corresponding region of the second computer model. This is because Ashmore recognizes that only points on the stable regions (*e.g.*, palatal rugae) should be used to determine the position of the corresponding regions of the two models. Ex.1009, 19-21. That Ashmore subsequently ***positions*** the entire model based on the ***determination of the position*** (*e.g.*, a transform) of the matched rugae regions does not exclude Ashmore from Element [1.5]/[19.5]. This is because Element [1.5]/[19.5] (again, under the ALJ's construction) is open to positioning an entire model – so long as the determination of the position (*e.g.*, a transform) that is used to position the model is limited to the corresponding regions.[7] This is precisely what Ashmore does by using the palatal rugae region of the models as registration landmarks, as explained above. Ex.1005, ¶84.

Ashmore's palatal rugae area does not consist of the entire jaw model (*e.g.*, it does not have teeth) and thus is an "area" under Patent Owner's and the ALJ's construction. Ex.1009, 20-21, Fig. 1. Ex.1005, ¶85.

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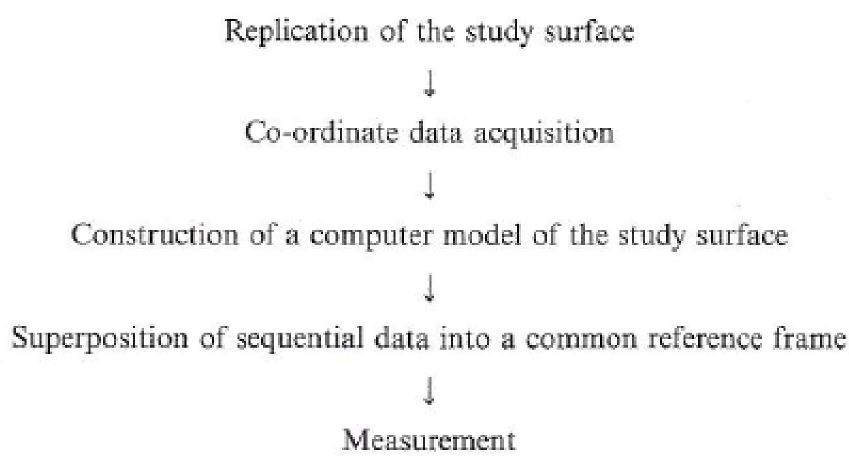
[7] Indeed, the Fig. 10A embodiment of the '661 Patent in block 480 applies the transform to the entire model. Ex.1001, 9:46-48.

Jovanovski

Like Ashmore, Jovanovski discloses Element [1.5]. This similarity supports Petitioners' obviousness rationale discussed below. In this regard, Jovanovski discloses matching a region of a first computer model with the corresponding region of the second computer model, using the identified reference points (*e.g.*, "marking three or more pairs of corresponding points"). Ex.1010, 103. Jovanovski discloses constructing computer models of the study surface ("baseline" and "follow-up" surfaces) and matching (*e.g.*, superposing) such models:



Page 75 of Jovanovski

Id., 75. Ex.1005, ¶86.

Jovanovski discloses that registration of the two computer models is performed in three stages. Ex.1010, 103. The first stage of Jovanovski's registration process is similar to the matching step disclosed by Ashmore. In Jovanovski's first stage, "an ***initial approximation*** of the transformation parameters is obtained by marking three or more pairs of ***corresponding points*** as in the landmark-based method." *Id.*, 103 (emphases added). *See also id.*, 98 ("point-to-point fit is performed"). Jovanovski further discloses that this initial "point-to-point fit" method, which is similar to the matching process described in Ashmore, "is capable of quickly providing an initial approximation which can further be refined by other methods, described next." Ex.1010, 98-99. *See also id.*, 103 ("an initial approximation of the ***transformation*** parameters is obtained by marking three or more pairs of corresponding points" (emphasis added)). Ex.1005, ¶87.

vi. Element [1.6]: matching the first and second computer models as a whole, using the matched regions; and

The combined disclosures of Ashmore and Jovanovski disclose Element [1.6]. Ex.1005, ¶88.

Ashmore discloses Element [1.5] as explained above, which results in "matched regions" of the first and second computer models. The matched regions would have been used in Jovanovski's refining matching step, discussed below. Ex.1005, ¶89.

<u>Jovanovski discloses Element [1.6]</u>

Jovanovski discloses matching the first and second computer models (*e.g.*, "baseline surface" and "follow-up surface", respectively) as a whole (*e.g.*, "the optimal transformation is applied to all the data points of the follow-up surface", "[f]rom these transformed points a new superposed follow-up surface is generated"), using the matched regions. Ex.1010, 103-105. As explained above, Jovanovski discloses a registration process which includes two matching steps: (1) a first, "point-to-point fit" matching step providing an "initial approximation", which is akin to the matching step of Ashmore, and (2) a second matching step that matches the computer models as a whole using matched regions (*e.g.*, the "stable regions") of the first (*e.g.*, "baseline") and second (*e.g.*, "follow-up") models. Ex.1010, 103-105. Ex.1005, ¶90.

Concerning Jovanovski's second matching step, Jovanovski discloses an iterative procedure where the representative points of the second model (*e.g.*, "follow-up surface") are fitted to the corresponding representative points of the first model (*e.g.*, "baseline surface"). Ex.1010, 103-105. Jovanovski discloses that the iterative procedure provides an "optimal transformation" that is "applied to all the data points" of the second model:

> The software … allows the iterative procedure to continue with the new 'refined' set of representative points. ***When the procedure has converged, the optimal transformation is applied to all the data points of the follow-up surface.*** From these transformed points a new, superposed follow-up surface is generated.

Id., 105 (emphasis added). Thus, the second matching step of Jovanovski results (*e.g.*, after convergence) in matching the first and second models as a whole because the optimal transformation is applied to ***all the data points*** of the second model (*e.g.*, "follow-up surface"). Ex.1005, ¶91.

The first matching step of Jovanovski's registration process is similar to Ashmore's matching step. Jovanovski discloses that this first stage provides an "initial approximation" which is "further … refined" in a second stage. Ex.1010, 99. In the second stage, "the operator marks the extent of the stable regions on the follow-up surface by outlining them with the mouse (fig. 18)." *Id.*, 103. Jovanovski discloses that "[o]n completion of the second stage, a set of 3,000 representative points which lie in the ***stable region*** of the follow-up surface is automatically generated." *Id.*, 104 (emphasis added). Because Ashmore discloses using the palatal rugae area (*e.g.*, medial palatal rugae) as a stable region, Ashmore's palatal rugae area is analogous to the stable region selected by the user in Jovanovski. Jovanovski discloses that following the selection of the 3,000 points representing the stable region, "the representative points are fit[t]ed to the baseline surface by the Gauss-Newton method." *Id.* Jovanovski uses the stable regions of the first and second models as a starting point of the second matching step because the representative points were taken from the stable regions. *Id.* Ex.1005, ¶92.

The ALJ construed Element [1.5]/[19.5] but did not construe Element [1.6]/[19.6]. While both Element [1.5]/[19.5] and Element [1.6]/[19.6] contain the term "matching", the ALJ did not provide any explicit construction of the term "matching" independently from its context in Element [1.5]/[19.5]. Concerning the meaning of the term "matching" as generally used in the '661 Patent, the ALJ stated that "'matching' appears to relate to both computation and positioning/repositioning based on that computation." Ex.1014, App. A, 16. Ex.1001, Fig. 10A ("matching two bite0s" in 480 refers to applying the transform, not calculating the transform). Thus, "matching" in Element [1.6]/[19.6] encompasses positioning/repositioning and does not require determination of position (under the ALJ's construction). Ex.1005, ¶93.

vii. Element [1.7]: calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions.

Ashmore alone or in combination with Jovanovski discloses Element [1.7]. Ex.1005, ¶94.

<u>Ashmore</u>

Ashmore discloses calculating positional differences (*e.g.*, "[m]olar rotations were calculated", "it was possible to calculate molar translations and rotations", Figs. 2-4 depicting x,y,z "translational movement for each molar) between the teeth in their initial positions (*e.g.*, in the "initial model", "T1") and the teeth in their positions in the second computer model (*e.g.*, "subsequent models", "T2-T14"), using the matched regions as non-moving reference regions. Ex.1009, 21. Ex.1005, ¶95.

"calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model"

Ashmore's method calculates positional differences between the teeth (*e.g.*, molars) in their initial positions and the teeth (*e.g.*, molars) in their positions in the subsequent models. As explained by Ashmore:

> An important contribution of this study is the development of a serial maxillary model superimposition method that permitted a detailed examination of how each person's molars moved during headgear treatment (Figs 2-5). Accordingly, the method revealed substantial between-subject variation not only in the magnitude of tooth movement, but also in the pattern of movement over time.

Ex.1009, 24-25. *See also id.*, 28 (method provides "accurate measurement of maxillary first-molar translational movement in 3 dimensions for both headgear and untreated groups."). Ex.1005, ¶96.

Ashmore discloses calculating the positional differences (both translational (X,Y,Z) and rotational) of treatment subject molars between a first computer model (T1/initial model) and any one of many second computer models (subsequent model), as explained by Ashmore:

> After all casts in a series had been placed in the same coordinate system via superimposition, it was possible to evaluate how the molar positions changed over time. The 4 points digitized on each molar were averaged

> to create a centroid, which was used to examine translations (anteroposterior, transverse, and vertical movements) along the X, Y, and Z axes for each molar….
>
> Molar rotations were calculated by Procrustes superimposition of the 4 molar points. After the models had been oriented and superimposed, registration of the T-final (TF) molar points onto the T1 molar points resulted in a 3-vector translation and a 3-×-3 rotation matrix that describes molar movement. The translation vector was the same difference in centroid coordinates as described above….

Id. at 21. Ashmore displays the calculated positional differences (*e.g.*, X,Y,Z). *Id.*, Fig. 2.

Id., Fig. 2; *see also id.*, Figs. 3 and 4 (Y and Z axis movement, respectively). This includes a comparison of initial (*e.g.*, T1) and subsequent models (*e.g.*, T2-T14). Ex.1005, ¶97.

"using the matched regions as non-moving reference regions"

Ashmore performs the molar positional difference calculations after matching the rugae regions of the first computer model (*e.g.*, "initial model") and any one of many second computer models (*e.g.*, "subsequent models", "T2-T14") as non-moving reference regions as discussed in detail above with reference to element [1.5], and thus were done "using the matched regions as non-moving reference regions." The palatal rugae disclosed by Ashmore is a non-moving reference region because, as explained above, Ashmore discloses that the palatal rugae is a stable area used as an anatomic reference. Ex.1009, 19, 21. The '661 Patent itself specifies that palatal rugae is an example of a non-moving reference region. Ex.1001, 13:49-52, 16:15-18. *See also id.*, 11:2-4 (palatal rugae are "stable structures"). Ex.1005, ¶98.

Patent Owner may argue that Ashmore does not disclose "use the matched regions as non-moving reference regions." Such argument is untenable. In Ashmore, the calculations are performed subsequent to matching of the rugae regions and rely on such matched regions as stable references, and thus such calculations are performed "using the matched regions as non-moving reference regions." Further, claim 1 uses the term "comprising" which allows for other information and techniques to be "used" when performing the claimed "calculating". The claimed "calculating" does not exclude the use of other information and techniques such as the "X, Y, Z axis" and "Rotational" positional difference calculations in Ashmore. Ex.1005, ¶99.

<u>Jovanovski</u>

Jovanovski also discloses calculating positional differences (*e.g.*, "parameter values obtained at the current iteration", "histogram of the distances", "the magnitude of their change") between surfaces in their initial positions and surfaces in their positions in the second computer model, using the matched regions (*e.g.*, stable regions) as non-moving reference regions:

> the main processing phase is initiated during which the representative points are fit[t]ed to the baseline surface by the Gauss-Newton method. The display (fig. 19) is updated at each iteration to show: (1) the representative points, transformed by the parameter values obtained at the current iteration, overlaid onto the baseline surface: (2) a histogram of the distances (residuals) between the baseline surface and the transformed representative points of the follow-up surface; (3) statistics of the residuals (mean, standard deviation, RMS); (4) the values of the transformation parameters at the current iteration, and (5) the magnitude of their change δ**p** from the previous iteration.

Ex.1010, 104. Jovanovski discloses calculating a "histogram of the distances (residuals) between the baseline surface and the transformed representative points of the follow-up surface." *Id.* This disclosure satisfies the claimed calculating positional differences between the teeth in their initial positions ("baseline surface") and the teeth in their positions in the second computer model ("follow-up surface"). Jovanovski further discloses calculating "statistics of the residuals (mean, standard deviation, RMS)" and "the magnitude of their change δ**p** from the previous iteration." *Id.* These calculations also satisfy the claimed "calculating positional differences." *Id.* The display is updated after "each iteration" including the final iteration where the models are matched as a whole ("optimal transformation is applied to all the data points of the follow-up surface. Since Jovanovski displays positional difference data for all iterations (from initial to final), Jovanovski displays positional differences between the initial positions in the first model and the final positions in the second model. From these transformed points a new, superposed follow-up surface is generated."). *Id.*, 104-105. In Jovanovski, the calculations are performed subsequent to matching of the rugae regions and rely on such matched regions as stable references. Thus, such calculations are performed "using the matched regions as non-moving reference regions." Claim 1 does not exclude the "use" of additional information/techniques when performing the claimed "calculating". Ex.1005, ¶100.

b. Claim 2: The method of claim 1, further comprising: displaying the positional differences between the teeth in the first and second models.

Ashmore and Jovanovski disclose claim 2. Ashmore and Jovanovski disclose claim 1, from which claim 2 depends. *See* Section VII.A.1.a. Ex.1005, ¶101.

Ashmore

Ashmore discloses displaying the positional differences between the teeth in the first and second models. Ex.1009, Figs. 2-4, 23. Ashmore discloses generating graphs with positional differences data. *Id*., Fig. 2.

Ex.1009, Fig. 2. *See also id.*, Figs. 3 and 4 (showing Y and Z axis positional differences, respectively), 24-25 (method shows "how each person's molars moved during headgear treatment"), 23. Ashmore discloses superimposing the initial and subsequent models. Ex.1009, 20-22. With the models superimposed on each other, Ashmore determines positional differences of the teeth as shown in Figs. 2-4. Ex.1005, ¶102.

Jovanovski

As explained regarding Element [1.7], Jovanovski discloses calculating and displaying positional differences between surfaces in their initial positions in the first model and changed positions in the second computer model. Ex.1010, 104. Jovanovski discloses:

> ***The display (fig. 19) is updated at each iteration to show***: (1) the representative points, transformed by the parameter values obtained at the current iteration, overlaid onto the baseline surface: (2) a histogram of the distances (residuals) between the baseline surface and the transformed representative points of the follow-up surface; (3) statistics of the residuals (mean, standard deviation, RMS); (4) the values of the transformation parameters at the current iteration, and (5) the magnitude of their change δ**p** from the previous iteration.

Id. (emphasis added). Fig. 19 of Jovanovski depicts displaying the positional differences between surfaces of the first and second models:

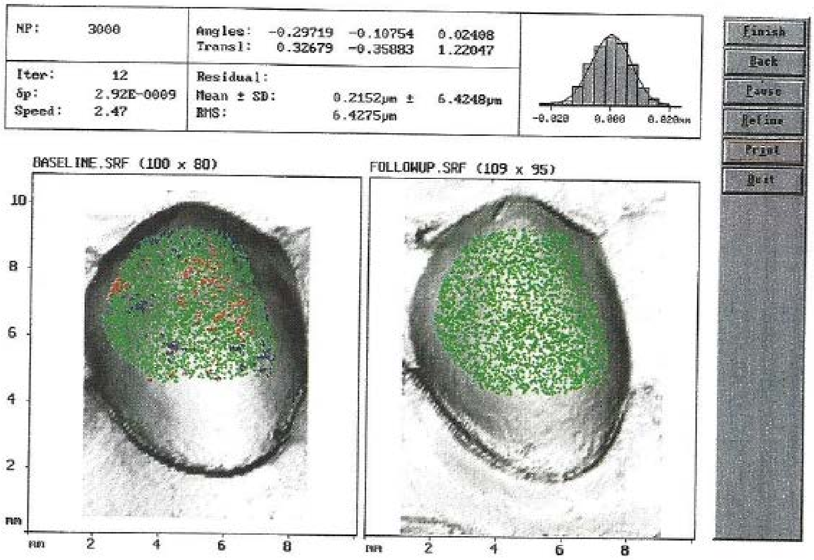


Fig. 19. The main processing phase.

Fig. 19 of Jovanovski

Ex.1005, ¶103.

c. Claim 3: The method of claim 1, wherein matching the region of the first computer model with the corresponding region of the second computer model comprises: placing the first and second computer models in a single coordinate system.

Ashmore and Jovanovski disclose claim 3. Ashmore and Jovanovski disclose claim 1, from which claim 3 depends. *See* Section VII.A.1.a. Ex.1005, ¶104.

Ashmore discloses wherein matching the region of the first (*e.g.*, “initial”) computer model with the corresponding region of the second (*e.g.*, “subsequent”) computer model comprises: placing the first and second computer models in a single coordinate system (*e.g.*, “a common and interpretable spatial coordinate system”). Ex.1009, 20 (“The 3D data from all subjects were oriented in a common and interpretable spatial coordinate system to assess molar movement.”), 21 (“the T1 models of all subjects were oriented in a similarly defined spatial frame of reference…"), 21 ("all casts in a series had been placed in the same coordinate system via superimposition..."). *See also* Ex.1010, abstract ("common reference frame"). Ex.1005, ¶105.

d. Claim 4: The method of claim 1, wherein calculating the positional differences comprises: calculating one or more of intrusion, extrusion, translation, rotation, angulation, or inclination of at least some of the teeth in the second computer model, relative to their initial positions in the first computer model.

Ashmore and Jovanovski disclose claim 4. Ashmore and Jovanovski disclose claim 1, from which claim 4 depends. *See* Section VII.A.1.a. Ex.1005, ¶106.

As discussed above regarding Element [1.7], Ashmore discloses calculating translation (*e.g.*, x,y,z "translational movement") and rotation differences of at least some of the teeth in the second computer model, relative to their initial positions in the first computer model. Ex.1009, 21, Figs. 2-4 (calculating translation movement), 21 ("[m]olar rotations were calculated"). Ex.1005, ¶107.

e. Claim 6: The method of claim 1, wherein the matched region is selected from the group consisting of one or more rugae on a palate of the jaw, gingiva, bone, a restoration and an implant.

Ashmore and Jovanovski disclose claim 6. Ashmore and Jovanovski disclose claim 1, from which claim 6 depends. *See* Section VII.A.1.a. Ex.1005, ¶108.

Ashmore discloses that the matched region is one or more rugae on a palate of the jaw (*e.g.*, "palatal rugae"). Ex.1009, 18 ("a best-fit superimposition of palatal rugae landmarks from subsequent models allowed the measurement of molar movement"), 20 ("specific parts (*e.g.*, medial) of the palatal rugae may be sufficiently stable to serve as an anatomic reference"). Ex.1005, ¶109.

f. Claim 19 (Element [19.P]): A tangible computer readable medium containing code for matching computer models of a jaw, the tangible computer readable medium comprising instructions to:

Ashmore discloses the preamble of claim 19. *See* Section VII.A.1.a. Ex.1005, ¶110.

Ashmore and Jovanovski disclose that the matching processes described therein are conducted using software (*e.g.*, "LabVIEW software program", "Software Implementation") and "data were stored in the computer". Ex.1009, 20, Ex.1010, 75, 90, 93, 103-105. A POSITA would have understood that the code (*e.g.*, "software") for carrying out the processes of Ashmore and Jovanovski would have been stored on a tangible computer readable medium.[8] It was well known that software is contained on a tangible computer readable medium of a computer. Ex.1019, 6:45-58, Ex.1018, 13:22-35. A POSITA would have understood that the computers disclosed by Ashmore and Jovanovski would include such a tangible

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[8] The medium can be "memory and/or storage elements." Ex.1001, 12:45-50.

computer readable medium containing code for performing the disclosed processes. Ex.1005, ¶111.

i. Element [19.1] load a first computer model of a jaw having teeth in initial positions;

Ashmore alone or in combination with Jovanovski discloses Element [1.1]. *See* Section VII.A.1.a.i. Ex.1005, ¶112.

ii. Element [19.2]: load a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions;

Ashmore alone or in combination with Jovanovski discloses Element [1.2]. *See* Section VII.A.1.a.ii. Ex.1005, ¶113.

iii. Element [19.3]: identify at least one reference point on a region of the first computer model, the region comprising a portion of the model other than the teeth;

Ashmore discloses Element [1.3]. *See* Section VII.A.1.a.iii. Ex.1005, ¶114.

iv. Element [19.4]: identify a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model;

Ashmore alone or in combination with Jovanovski discloses Element [1.4]. *See* Section VII.A.1.a.iv. Ex.1005, ¶115.

v. Element [19.5]: march [sic] the region of the first computer model with the corresponding region of the second computer model, using the identified reference points;

Ashmore discloses Element [1.5]. *See* Section VII.A.1.a.v. Ex.1005, ¶116.

vi. Element [19.6]: match the first and second computer models as a whole, using the matched regions; and

The combined disclosures of Ashmore and Jovanovski disclose Element [1.6]. *See* Section VII.A.1.a.vi. Ex.1005, ¶117.

vii. Element [19.7]: calculate positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions.

Ashmore alone or in combination with Jovanovski discloses Element [1.7]. *See* Section VII.A.1.a.vii. Ex.1005, ¶118.

g. Claim 20: The medium of claim 19, further comprising instructions to: display the positional differences between the teeth in the first and second models.

As explained above, Ashmore and Jovanovski disclose claim 19, from which claim 20 depends. Other than the preamble, claim 20 is identical to claim 2. Ashmore and Jovanovski disclose claim 20 for at least the same reasons provided above concerning claim 2. *See* Section VII.A.1.b. Ex.1005, ¶119.

h. Claim 21: The medium of claim 19, further comprising instructions to: place two jaw impressions in a single coordinate system.

As explained above, Ashmore and Jovanovski disclose claim 19, from which claim 21 depends. Like claim 3, claim 21 recites placing two jaw impressions "in a single coordinate system." Ashmore and Jovanovski disclose claim 21 for at least the same reasons provided concerning claim 3. *See* Section VII.A.1.c. Ashmore's computer models are jaw impressions (*e.g.*, "maxillary casts", "maxillary models") as explained above for Element [1.P]. Ex.1009, 20, 18; Ex.1015; Ex.1001, 9:14-17, 9:32-34 ("model" and "impression" used interchangeably to describe Fig. 10A). Ex.1005, ¶120.

i. Claim 22: The medium of claim 19, further comprising instructions to: calculate one or more of intrusion, extrusion, translation, rotation, angulation, or inclination of at least some of the teeth in the second computer model, relative to their initial positions in the first computer model.

As explained above, Ashmore and Jovanovski disclose claim 19, from which claim 22 depends. Other than the preamble, claim 22 is virtually identical to claim 4. Ashmore and Jovanovski disclose claim 22 for at least the same reasons provided above concerning claim 4. *See* Section VII.A.1.d.. Ex.1005, ¶121.

j. Claim 26: The medium of claim 19, wherein the watched [sic] region is selected from the group consisting of one or more rugae on a palate of the jaw, gingiva, bone, a restoration, and an implant.

As explained above, Ashmore and Jovanovski disclose claim 19, from which claim 26 depends. Other than the preamble, claim 26 is virtually identical to claim 6.[9] Ashmore and Jovanovski disclose claim 26 for at least the same reasons provided above concerning claim 6. *See* Section VII.A.1.e. Ex.1005, ¶122.

2. Explanation of Why Claims 1-4, 6, 19-22, and 26 Would Have Been Obvious

The challenged claims would have been obvious over Ashmore in view of Jovanovski. Patent Owner may argue that Ashmore does not disclose: (a) a second matching step of "matching the first and second computer models as a whole, using the matched regions" (Elements [1.6], [19.6]), (b) identifying a reference point on the first and/or second "computer" model because Ashmore discloses identifying points on a physical model (Elements [1.3], [1.4], [19.3], [19.4]), (c) "loading" the first and second computer models (Elements [1.1], [1.2], [19.1], [19.2]), and (d) displaying the positional differences between the teeth in the first and second models (claims 2, 20). Such arguments are untenable. Ex.1005, ¶123.

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[9] The term "watched" in claim 26 is understood as "matched".

Concerning (a), Jovanovski discloses a two-step process for matching initial and subsequent computer models where the second step "refines" an "initial approximation". A POSITA would have had ample reasons to modify Ashmore to use a second matching step to improve accuracy in view of Jovanovski. Concerning (b), Jovanovski discloses there is a limited number of alternative approaches (two) for identifying corresponding points in dental models (*i.e.*, physical and virtual marking), and virtually identifying points improves accuracy/reliability in comparison with physical marking.[10] Concerning (c), loading computer models was well known and a POSITA would have had ample reasons to modify Ashmore to do so. Concerning (d), it was well known and desirable to display positional differences between teeth/surfaces of first and second models to provide the user with such data. These rationales are discussed below. Ex.1005, ¶124.

a. It would have been obvious to modify Ashmore by adding a second matching step in view of Jovanovski (claims 1-4, 6, 19-22, and 26)

Ashmore demonstrates it was well known to match initial and subsequent computer models (and regions thereof) using stable anatomical regions (and points thereof) as a reference (palatal rugae). Jovanovski demonstrates it was well known to use a two-step matching process where the first step provides an "initial

[10] The claims do not exclude physically marking the models, as explained below.

approximation" and the second step provides a "refined" match. Like Ashmore, Jovanovski uses stable regions as a reference in its matching process. Jovanovski discloses that the second, iterative matching step provides a more accurate (*e.g.*, "refined") matching after the first "point-to-point fit" matching which provides an "initial approximation." Ex.1009, 98-99, 102-105. Jovanovski's second, iterative matching step, when adapted for use with Ashmore's computer models, corresponds to Element [1.6]. *See* Section VII.A.1. A POSITA would have had ample reasons to modify Ashmore in view of Jovanovski to employ an initial matching step as an initial approximation (Elements [1.5], [19.5]), and a subsequent matching step for refined matching (Elements [1.6], [19.6]), discussed below.[11] Ex.1005, ¶125.

Both Ashmore and Jovanovski seek accurate matching, and Jovanovski teaches using a second matching step for refining an "initial approximation" matching that is similar to Ashmore's matching

A POSITA would have been motivated to modify Ashmore's method to employ an additional matching step (after Ashmore's matching) where the models are matched as a whole, in view of Jovanovski. This is because a POSITA would have recognized that doing so would improve the accuracy of Ashmore's matching. Ashmore and Jovanovski recognize the desirability of obtaining an accurate

[11] Similarly, Fig. 10A of the '661 Patent provides an initial matching (480) and a subsequent matching (490) "to improve [the] matching result." Ex.1001, 9:32-53.

matching of initial and subsequent models to obtain accurate model comparisons. Ex.1009, 20, 28 (seeking "accurate measurement"); Ex.1010, 98-99 ("this method is capable of quickly providing an initial approximation which can further be refined by other methods, described next."), 103-105, 105 ("The practical application of the shape-based method … has shown that tooth surfaces can generally by superposed to within 6-9 µm RMS/point.").[12] Ex.1005, ¶126.

Jovanovski discloses that the second matching step (shaped based method) results in a more accurate matching of models in comparison with mere "point-to-point fit" matching. Ex.1010, 98-99, 103-105. Indeed, the very purpose of Jovanovski's second matching step is to "refine" the "approximation" obtained from the initial point-to-point fit matching. *Id.* *See also id.*, 99 (first matching step "quickly provid[es] an initial approximation which can further be refined by other methods, described next."), 103 ("First, an initial approximation of the transformation parameters is obtained …"). Thus, a POSITA would have been motivated to modify Ashmore to employ a second matching step in which the first and second computer models are matched as a whole, in order to increase the

[12] While the fit is not perfect due to "the finite accuracy of replication and digitising" (*Id.*, 105, 119), Jovanovski nevertheless teaches its process provides accurate matching.

accuracy of the superimposition of the initial and subsequent models and thereby increase the accuracy of comparisons of oral structures in the models. Ashmore's method would have been modified to incorporate and adapt Jovanovski's second matching step (*i.e.*, "shape-based method") and employ same after Ashmore's matching of the models using rugae reference points, because Jovanovski's matching step is for refining an initial matching similar to Ashmore's matching. Ex.1005, ¶127.

Jovanovski teaches that its second matching step improves the accuracy of matching techniques like the one disclosed by Ashmore. A POSITA would have combined Ashmore with Jovanovski given the similarities of Ashmore's matching step with Jovanovski's "point-to-point fit" matching, with the reasonable expectation that using Jovanovski's matching step after Ashmore's matching would improve matching accuracy. Jovanovski describes performing a "point-to-point fit" in its surface landmark method (first matching step) to approximately superimpose two models. Ex.1010, 98 ("mark points interactively … point-to-point fit"); Fig. 15. *See also id.* 96-98; Ex.1009, 21 (both utilize minimizing the sum of squared distances between corresponding points). This second matching step of Jovanovski, when adapted to matching Ashmore's initial and subsequent models, satisfies the claimed second matching step (Elements [1.6], [19.6]). Ex.1005, ¶128.

Ashmore discloses that the matching process used therein provides accurate results. Ex.1009, 28 ("The method developed for superimposing digital configurations of serial dental models allowed accurate measurement of maxillary first-molar translational movement in 3 dimensions"). Ashmore also suggests improvements to its process. *Id.*, 27-28 (*e.g.*, "Greater statistical emphasis can be placed on rugae points known to be the least susceptible to treatment-induced changes"). Thus, a POSITA would have looked for ways to improve Ashmore.Jovanovski provides one obvious way for improving the accuracy of matching Ashmore's models. For example, applying Jovanovski's second matching step would increase accuracy because using more data points on the stable region would refine the matching. Ex.1005, ¶129.

Both Ashmore and Jovanovski disclose using stable anatomical regions to match initial and subsequent models

Ashmore and Jovanovski are in the same field of endeavor. *See, e.g.,* Ex.1009, title ("3-dimensional analysis" of dental models), abstract; Ex.1010, title, abstract (analysis of 3D dental models). Both Ashmore and Jovanovski seek to compare initial and subsequent dental models to assess changes to the teeth over time. Ex.1009, abstract, 18-21; Ex.1010, abstract, 93-105. Both Ashmore and Jovanovski teach using stable anatomical regions of the models as non-moving reference regions to compare initial and subsequent models. Ex.1009, 19 ("[P]arts (eg, medial) of the palatal rugae may be sufficiently stable to serve as an anatomic reference for superimposing serial maxillary models"); Ex.1010, 102-103 ("there exists a region which remains relatively stable throughout…. [R]egistration … is achieved by restricting the selection of representative points to such stable regions"). Ex.1005, ¶130.

Any argument by Patent Owner that a POSITA would not have looked to Jovanovski to modify Ashmore because of differences between Jovanovski's technique and Ashmore's technique is untenable. This overlooks the close similarities between Ashmore and Jovanovski, *i.e.*, both relate to the same field of endeavor (*e.g.*, dental modeling), address the same general problem in registering models (*e.g.*, calculating changes between initial and subsequent models over time), and provide similar solutions (*e.g.*, using stable regions of the models as non-moving reference regions to compare initial and subsequent models).[13] A POSITA would have recognized that techniques for matching initial and subsequent models for measuring changes due to, *e.g.*, tooth wear, would be applicable to a technique for measuring tooth movement, because both techniques seek to ascertain differences

[13] The '661 patent itself demonstrates that use of stable teeth surfaces is an alternative to stable rugae. Ex.1001, 8:66-9:2 ("teeth can be used for the reference as well.").

between the models.[14] Jovanovski provides techniques for refining matching between models, and a POSITA would have looked to the techniques of Jovanovski to improve the accuracy of the match obtained in Ashmore, as explained above. Ex.1005, ¶131.

A POSITA would have used the rugae area as the stable region when adapting Jovanovski's matching step to Ashmore's initial and subsequent models

As explained above, Ashmore teaches using points selected from the palatal rugae (*e.g.*, medial palatal rugae) as stable anatomical references for superimposing initial and subsequent models. Ex.1009, 20. Jovanovski's second matching step (which when adapted for use in Ashmore's process corresponds to Elements [1.6], [19.6]) uses "representative points" which are on the stable region. Ex.1010, 103-104. A POSITA would have understood that in the obvious combination, the user would have selected the palatal rugae area of Ashmore's subsequent model as the stable region for use in Jovanovski's second matching step. This is because Jovanovski's "baseline" and "follow-up" models are analogous to Ashmore's initial and subsequent models, respectively, and Jovanovski's "stable region" is analogous to Ashmore's rugae area. A POSITA would have understood that a user would select

[14] The '661 Patent itself relates to techniques applicable to both changes in "teeth shapes" and positional differences. Ex.1001, abstract.

the stable region (*e.g.*, palatal rugae area) of Ashmore's subsequent model using any suitable means. For example, Jovanovski discloses that the user selects the "***stable regions*** on the follow-up surface by outlining them with a mouse (fig. 18)." Ex.1010, 103 (emphasis added). Jovanovski discloses that, based on the user's selection of the stable region, "a set of 3,000 representative points which lie in the ***stable region*** of the follow-up surface is automatically generated." *Id.*, 104 (emphasis added). Thus, the user in Jovanovski would select the palatal rugae area (*e.g.*, the medial palatal rugae) as the stable region (*i.e.*, the same region from which reference points are selected in Ashmore) by which the models are further matched as a whole. The purported invention is nothing more than combining known methods, in known ways, to produce a predictable result. Ex.1005, ¶132.

Patent Owner may argue that, in the obvious combination, Jovanovski's second matching step is not performed using the matched regions of Ashmore's matching step. Such an argument is untenable. In the obvious combination, the second matching step (adapted from Jovanovski) would have used the matched regions from the first matching step at least because the matched regions are used as a starting point for the second matching step. The claims do not exclude the use of other data (such as the remainder of the first and second models) in the second matching step. In addition, The Fig.10A embodiment of the '661 Patent (discussed in Section V.A.4.) calls for user input in the second matching step 490. Ex.1001, 9:46-53 ("user can move or rotate the jaw model directly to improve matching result and the matching transform will be updated consequently"). Like the '661 Patent where the second matching of the models as a whole is based on user input, so too is the second matching in the obvious combination. Ex.1005, ¶133.

A POSITA would have had a reasonable expectation of success in incorporating a second matching step in view of Jovanovski after Ashmore's matching step given the similarities between the techniques described in Ashmore and Jovanovski. Ashmore's matching step is akin to Jovanovski's first matching step (*i.e.*, surface landmark method) and Jovanovski explicitly teaches conducting a second matching step (shape-based method) after its first matching step. Ex.1010, 99, 103-105 ("First, an initial approximation of the transformation parameters is obtained by marking three or more pairs of corresponding points as in the landmark-based method"). A POSITA would have reasonably expected that incorporating Jovanovski's second step after Ashmore's matching step would yield a predictable result, *i.e.*, additional matching of the model as a whole using numerous representative points (representative of the matched palatal rugae areas ("regions")) to further refine the matching of the models. Performing an additional matching step to further refine the match would yield predictable results because virtual modeling is a predictable art. Ex.1005, ¶134.

b. It would have been obvious to modify Ashmore to virtually mark reference points on the computer models without physically marking the dental casts, in view of Jovanovski (claims 1-4, 6, 19-22, and 26)

Patent Owner may argue that Ashmore does not disclose identifying a reference point on the first and/or second "computer" model because Ashmore discloses identifying points on a physical model (*e.g.*, by marking the casts with a pencil). Such an argument overlooks the fact that Ashmore discloses that the physically marked points are "digitized," as explained above (Elements [1.3], [1.4], [19.3], [19.4]). Ashmore identifies the digitized corresponding rugae reference points on each of the first and second computer models in order to superimpose the models, as discussed above. Ex.1009, 21 (disclosing comparing "distances between corresponding rugae points" of the computer models). The claims do not exclude physical marking of dental casts. Ex.1005, ¶135.

Furthermore, it would have been obvious to a POSITA at the time of the purported invention to modify Ashmore to virtually mark reference points on the computer models without physically marking the dental casts. Jovanovski discloses "identification of corresponding points" by presenting acquired data on a computer visualization system, *i.e.*, virtually marking corresponding points, as explained above. A POSITA would been motivated to modify Ashmore to virtually mark reference points on the first and second computer models without physically marking the dental casts, because Jovanovski discloses that virtually identifying the corresponding points improves accuracy and/or reliability in comparison with physically marking points. *Id.*, 97-98 (accuracy of external markers was insufficient, external markers "should not be subject to … changes in position"). Ex.1005, ¶136.

Jovanovski identifies two "approaches for identification of corresponding points," *i.e.*, physical ("external") marking and virtual marking:

> In relation to anatomical surfaces (including teeth), there are two approaches to the identification of corresponding points: (a) external markers can be attached to the surface under investigation … or made on the surface itself … , and (b) characteristic points (landmarks) can be identified on the surface anatomy retrospectively by presenting the acquired data on a computer visualisation system.

Ex.1010, 97. Ashmore discloses using both techniques (physical marking the cast, then virtual identifying the points on the first and second computer models). Given the finite number of alternatives (two) taught by Jovanovski, it would have been obvious to modify Ashmore to virtually mark reference points on the computer models, and not physically mark the dental casts. This would have yielded predictable results given that it was well-known that virtually identifying points is an alternative means for identifying corresponding points as taught by Jovanovski. *Id.*, 97. There was a design need and market pressure (improved "accuracy", avoiding any "changes of position" of physical markers) for virtually identifying points. *Id.*, 97-98. Such modification would have yielded predictable results as discussed above and as such, a POSITA would have had a reasonable expectation of success. Ex.1005, ¶137.

c. It would have been obvious to "load" the first and second computer models (claims 1-4, 6, 19-22, and 26)

Ashmore discloses "loading" the computer models (Elements [1.1], [1.2], [19.1], [19.2]). *See* Section VII.A.1. Ex.1005, ¶138.

Patent Owner may argue that Ashmore does not explicitly disclose "loading" a computer model. Assuming (incorrectly) that Ashmore does not disclose "loading" a computer model, it was well known that "loading" data into a computer workstation allows the data to be accessed by software. *See, e.g.*, Ex.1027, 39:7-43:27 (the program downloads the 3D data file to utilize the file); Ex.1012, ¶[0120] (data is "loaded into the workstation, and accessed from the treatment planning software"). Since Ashmore discloses accessing the computer model by software (Ex.1009, 20), it would have been obvious to load the computer model onto a computer to allow software to access the computer model. Loading data files would have yielded predictable results as discussed above and as such, a POSITA would have had a reasonable expectation of success. Ex.1005, ¶139.

The claimed "loading" does not require visualizing a computer model. Ex.1001, Fig. 3, 6:6-17 (visualization is "another option" in the '661 Patent). While "loading" does not require visualization, a POSITA would have understood that visualization satisfies "loading" because the model must to loaded on the computer in order to be visualized. Jovanovski discloses visualizing the baseline computer model (e.g., a first computer model) and positional difference data between iterations. Ex.1010, Figs. 15, 18, 19, 103-105. For the reasons discussed above, the obvious combination of Ashmore and Jovanovski would result in visualizing the computer models, thus satisfying "loading." It would have been obvious to modify Ashmore to visualize its positional difference data, because doing so would aid the user in ascertaining such positional differences as taught by Jovanovski. Ex.1005, ¶140.

d. It would have been obvious to display positional differences between teeth of Ashmore's models in the manner described in Jovanovski (claims 2, 20)

Ashmore discloses the subject matter of claims 2 and 20. *See* Sections VII.A.1.b., VII.A.1.g. Ex.1005, ¶141.

Assuming (incorrectly) that Ashmore does not disclose the subject matter of claims 2 and 20, it would have been obvious to combine Ashmore with Jovanovski to display the positional differences between the teeth in the first and second models. As explained in Sections VII.A.1.b. and VII.A.1.g., Jovanovski demonstrates it was well known to display positional difference data after matching initial and subsequent dental models. Ex.1010, 104 ("The display (fig. 19) is updated at each iteration to show" positional differences), Fig.19. Further, it was well known to display positional differences between the teeth in first and second models and to measure teeth movement using such displaying:

> For example, a point on the tooth in the current model is selected, and the model of the tooth at the original malocclusion is overlaid ***on the screen***. ***The superposition of the two teeth allows the user to view the change in position that has occurred.*** The measurement marker features described earlier allow the user to quantify precisely the amount of movement.

Ex.1012, ¶¶[0143]-[0144] (emphasis added). *See also id.*, ¶¶[0114]-[0116] (describing the measurement marker features). Thus, a POSITA would have been motivated to modify Ashmore to display positional differences between the teeth in the first and second models because: (1) Ashmore already provides such positional difference data (*e.g.*, in Figs. 2-4), (2) Jovanovski and Exhibit 1012 teach that displaying (visualizing) such positional differences was a well known way for a computer system to provide the user with positional difference data, and (3) a POSITA would have desired to view the positional difference data because Ashmore seeks to assess teeth movement as a result of treatment. Ex.1009, abstract. A POSITA would have had a reasonable expectation of success given that displaying data on a computer screen would have yielded predictable results. Ex.1005, ¶142.

Assuming (incorrectly) Ashmore does not disclose calculating positional differences between initial and second positions (Element [1.7]), Jovanovski discloses doing so (Section VII.A.1.a.vii.). As discussed above, a POSITA would have been motivated to display the positional difference information provided in Jovanovski (as adapted to the moved teeth in Ashmore) so that the user would be able to view the status and results of the matching procedure, as taught by Jovanovski. Ex.1005, ¶143.

As such, the combination of Ashmore and Jovanovski renders obvious the challenged claims.

VIII. OTHER CONSIDERATIONS

A. Any Purported Secondary Considerations Evidence Does Not Overcome the Strong Evidence of Obviousness

Petitioners are not aware of any secondary considerations evidence bearing any nexus to the claims. Any secondary considerations evidence Patent Owner may offer in this proceeding would be insufficient to overcome the strong evidence of obviousness.

B. Discretion to Institute

The PTAB should not deny this Petition under § 314(a). The ’661 Patent has not been challenged in any prior AIA trial proceeding. This Petition is not a “follow-on” petition as was the case in *General Plastic*.

Events in the Delaware litigation and ITC investigation do not warrant denial. The IPR statutory framework permits filing within one year of service of a complaint. The Delaware litigation is stayed and trial has not been scheduled.

Exs.1024, 1025. This Petition challenges claims 1-4, 6, 19-22, and 26, whereas only claims 1-2 and 19-20 are at issue in the ITC investigation. Ex.1026, 1. The fact that this Petition challenges a different set of claims than is at issue in the ITC investigation weighs against denial. *See, e.g., 3Shape A/S v. Align Tech., Inc.*, IPR2019-00157, Paper 9 (PTAB Jun. 5, 2019), 38 ("We agree with Petitioner … that differing claim sets is a factor that weighs against exercise of our discretion under § 314(a) to deny institution based on the ITC investigation.").

The ITC cannot resolve a challenge to patent validity because the ITC does not have authority to invalidate a patent. *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996); *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996); *Wirtgen America, Inc. v. Caterpillar Paving Products Inc.*, IPR2018-01201, Paper 13 (PTAB Jan. 8, 2019), 12 ("[T]he ITC does not have authority to invalidate a patent."); *Samsung Elecs. Co., Ltd. v. BiTMICRO LLC*, IPR2018-01545 (PTAB Mar. 7, 2019), 24.

Thus, denying institution due to the Delaware litigation or the ITC investigation does not promote the efficient administration of justice.

Denial under § 325(d) is not warranted. Neither Ashmore nor Jovanovski was considered during prosecution of the '661 Patent, let alone applied in a rejection. There is no indication that the Patent Office previously considered the specific ***combination*** of Ashmore and Jovanovski presented in this Petition.

Denial under § 325(d) is not warranted when considering the six *Becton, Dickinson* factors. Concerning factors (1) and (4), neither reference applied by the examiner (Sachdeva and Snow) was cited as disclosing the use palatal rugae as a stable reference point for comparing initial and subsequent 3D tooth models, as taught by Ashmore. Neither Sachdeva nor Snow was cited as disclosing conducting a second matching step of matching models to refine an initial, approximate match, as taught by Jovanovski. Concerning factor (2), the disclosures of Ashmore and Jovanovski discussed above are not cumulative to Sachdeva and Snow. Concerning factor (3), the examiner neither considered nor applied Ashmore or Jovanovski during prosecution. Concerning factor (5), there is no record that the Examiner substantively evaluated Ashmore and Jovanovski, let alone the combination thereof. Petitioners have shown there is a reasonable likelihood that the challenged claims are unpatentable over Ashmore in view of Jovanovski. Concerning factor (6), Petitioners are unaware of any additional evidence or facts that warrant denial.

IX. CONCLUSION

Petitioners have shown a reasonable likelihood of success. Therefore, this Petition should be granted and the Board should institute trial.

Respectfully submitted,

Date: December 9, 2019

/Todd R. Walters/

Todd R. Walters, Esq.
Registration No. 34,040
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Main Telephone (703) 836-6620
Direct Telephone (703) 838-6556
Main Facsimile (703) 836-2021
todd.walters@bipc.com
Counsel for Petitioners

APPENDIX A - LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1001	U.S. Patent No. 7,156,661, issued on January 2, 2007 to W. Choi *et al.* (“the ’661 Patent”)
1002	File History of U.S. Patent No. 7,156,661
1003	U.S. Patent No. 7,077,647, issued on July 18, 2006 to W. Choi *et al.* (“the ’647 Patent”)
1004	File History of U.S. Patent No. 7,077,647
1005	Declaration of Dr. Eli Saber
1006	*Curriculum Vitae* of Dr. Eli Saber
1007	Declaration of Sylvia D. Hall-Ellis
1008	*Curriculum Vitae* of Sylvia D. Hall-Ellis
1009	Jennifer L. Ashmore *et al.*, “A 3-Dimensional Analysis of Molar Movement During Headgear Treatment,” American Journal of Orthodontics and Dentofacial Orthopedics, Volume 121, Number 1, January 2002, pages 18-29 (“Ashmore”)
1010	V. Jovanovski *et al.*, “Analysis of the Morphology of Oral Structures from 3-D Co-Ordinate Data,” Assessment of Oral Health: Diagnostic Techniques and Validation Criteria, Editor: R.V. Faller, Monographs in Oral Science, Editor: G.M. Whitford, Basel. Karger, 2000, Vol. 17, pp. 73-129 (“Jovanovski”)
1011	P. Commer *et al.*, “Construction and testing of a computer-based intraoral laser scanner for determining tooth positions,” Medical Engineering & Physics 22 (2000), pp. 625-635 (“Commer”)
1012	U.S. Patent Application Publication No. 2002/0010568, published on January 24, 2002 to R. Rubbert *et al.* (“Rubbert ’568”)

EXHIBIT	DESCRIPTION
1013	U.S. Patent No. 6,632,089, issued on October 14, 2003 to R. Rubbert *et al*. (“Rubbert ’089”)
1014	Order No. 36: Construing Certain Terms of the Asserted Claims of the Patents at Issue (*Markman* Claim Construction), Inv. No. 337-TA-1144, *In the Matter of Certain Dental and Orthodontic Scanners and Software*, October 1, 2019
1015	The American Heritage College Dictionary, 3rd Ed., 1997, Houghton Mifflin Company, pp. 823, 839, definitions of “maxillary” and “mandibular”
1016	Marco Almeida *et al*., “Stability of the palatal rugae as landmarks for analysis of dental casts,” The Angle Orthodontist, Vol. 65, No. 1, 1995, pp. 43-48 (“Almeida”)
1017	F. James Rohlf, “Rotational Fit (Procrustes) Methods,” PROCEEDINGS OF MICHIGAN MORPHOMETRICS WORKSHOP, Ann Arbor: University of Michigan Museum of Zoology, p. 227-36 (1990) (“Rohlf”)
1018	U.S. Patent No. 5,564,113 issued on Oct. 8, 1996 to D. Bergen et al. (“Bergen”)
1019	U.S. Patent No. 6,049,743, issued on April 11, 2000 to M. Baba (“Baba”)
1020	Respondent 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.’s Opening Claim Construction Brief, Inv. No. 337-TA-1144, *In the Matter of Certain Dental and Orthodontic Scanners and Software*, June 19, 2019
1021	Respondent 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.’s Rebuttal Claim Construction Brief, Inv. No. 337-TA-1144, *In the Matter of Certain Dental and Orthodontic Scanners and Software*, June 28, 2019
1022	Complainant Align Technology Inc.’s Opening Claim Construction Brief, Inv. No. 337-TA-1144, *In the Matter of Certain Dental and Orthodontic Scanners and Software*, June 19, 2019
1023	Complainant Align Technology Inc.’s Reply Claim Construction Brief, Inv. No. 337-TA-1144, *In the Matter of Certain Dental and Orthodontic Scanners and Software*, June28, 2019

EXHIBIT	DESCRIPTION
1024	Stipulation and [Proposed] Order for Stay in *Align Technology, Inc. v. 3Shape A/S*, Civil Action No. 1:17-cv-01950-LPS-CJB (D. Del.), March 8, 2019
1025	PACER Docket Sheet, *Align v. 3Shape*, Civ. Action No. 1:18-cv-01950 (downloaded on November 25, 2019)
1026	Complainant Align Technology Inc.'s Pre-Hearing Brief [public version], Inv. No. 337-TA-1144, *In the Matter of Certain Dental and Orthodontic Scanners and Software*, dated August 30, 2019
1027	International Publication No. WO 00/19929, published on April 13, 2000 to M. Chishti *et al*. ("Chishti")
1028	The American Heritage College Dictionary, 3rd Ed., 1997, Houghton Mifflin Company, p. 982, definition of "palate"
1029	The American Heritage College Dictionary, 3rd Ed., 1997, Houghton Mifflin Company, p. 1192, definition of "ruga"
1030	The American Heritage College Dictionary, 3rd Ed., 1997, Houghton Mifflin Company, p. 372, definition of "dentition"
1031	International Publication No. WO 01/80761, published on November 1, 2001 to R. Rubbert *et al.*

APPENDIX B - ADDITIONAL REAL PARTIES-IN-INTEREST

Allan Junge Hyldal	Lene Nørgaard
Anders Gaarde	Lise Thorning Christensen
Anders Kjær-Nielsen	Mads Brøkner Christiansen
Anja Engblad	Martin Baltzer
Birk Plönnings	Michael Bing
Bruce Frederic Mendel	Michael Pedersen
Casper Rasmussen	Michael Vinther
Christian Lysholdt Dünweber	Miguel Dovalo
Christian Pejrup	Mikael Toxværd Petersen
Christophe Barthe	Mike van der Poel
David Fischer	Mikkel Ninn-Grønne
Dorota Lebiedowicz	Morten Bonding Granlund
Esben Rosenlund Hansen	Morten Ryde Holm-Hansen
Finn Hansen	Morten Trouplin Nørholm
Hans Laustrup	Nina Lillelund
Henrik Vestermark	Peter Dahl Ejby Jensen
Jan Vittrup Hansen	Rasmus Kjær
Jesper Schou	Remek Nalecz
Jesper Simonsen	Rolf Gunnar Henrik Öjelund
Karl Josef Hollenbeck	Rune Fisker
Kasper Egdø	Simon Fischer
Kasper Kabell Kristensen	Sophie Ellersgaard
Kasper Krogh Hansen	Steen Frost Tofthøj
Klaus Rudbæk Høj	Stefan Elmsted Jensen
Kristian Evers Hansen	Søren Greve Jensen
Kristian Worziger Nielsen	Søren Maagaard Olsen
Kristine Slot	Thomas Clemen Pedersen
Krzysztof Christopher Adamus	Thomas Geoffrey Moon
Lars Christian Lund	Thomas Højgaard Allin
Lars Henrik Jakobsen	Tim Trækjær
Lars Henriksen	Tommy Sanddal Poulsen
Lei Zhang	Ye Jin
	Zhengjie Li

CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that the word count for the foregoing Petition totals 13,504 words in the body of the petition and 396 words in the figures, excluding the parts which are exempted by 37 C.F.R. § 42.24(a)(1).

Date: December 9, 2019

/Todd R. Walters/

Todd R. Walters, Esq.
Registration No. 34,040
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Main Telephone (703) 836-6620
Direct Telephone (703) 838-6556
Main Facsimile (703) 836-2021
todd.walters@bipc.com
Counsel for Petitioners

CERTIFICATE OF FILING AND SERVICE

The undersigned hereby certifies that on this 9th day of December, 2019 a true and correct copy of the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,156,661 B2 UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.** and **EXHIBITS 1001-1031** are being filed via PTAB E2E and served by overnight UPS on the correspondence address of record for **U.S. Patent No. 7,156,661** as follows:

Klein, O'Neill & Singh, LLP (Align Technology)
16755 Von Karman Ave., #275
Irvine, CA 92606

and courtesy copies are being served by overnight UPS to litigation counsel as follows:

John W. Shaw
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
Phone (302) 298-0700

Blair M. Jacobs
PAUL HASTINGS LLP
875 15th Street, N.W.
Washington, DC 20005
Phone (202) 551-1700

Date: December 9, 2019

/Todd R. Walters/
Todd R. Walters, Esq.
Registration No. 34,040
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Main Telephone (703) 836-6620
Direct Telephone (703) 838-6556
Main Facsimile (703) 836-2021
todd.walters@bipc.com
Counsel for Petitioners